Appendix I-1 Chemical Risk Assessment Framework

Chemical Risk Assessment Framework

Fairview Water Release Scheme

EPBC 2021/8914

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1.0 Introduction

1.1 Background

This Chemical Risk Assessment Framework (CRAF) has been developed for the risk assessment of chemicals proposed to be used in coal seam gas operations (drilling and completions, hydraulic fracturing and water treatment) that may be potentially released to surface waters of the Dawson River as part of the Santos Fairview Water Release Scheme (2021/8914). The CRAF incorporates best practice risk assessment methodology for the assessment of the potential impacts of the chemicals proposed to be used in, or arising from, coal seam gas operations on matters of national environmental significance (MNES).

The CRAF aligns with chemical assessment guidance provided by the Australian Industrial Chemicals Introduction Scheme (AICIS) [formerly National Industrial Chemicals Notifications and Assessment Scheme (NICNAS)] and approach used for industrial chemicals. This allows for a defined and streamlined process to:

1. identify low hazard chemicals that can be addressed simply through a hazard assessment process;
2. identify higher hazard chemicals that should be assessed through completion of a quantitative risk assessment
3. identify very high hazard chemicals that should be encouraged not to be used as part of the process;
4. identify very high hazard chemicals that cannot to be used as part of the process; and
5. incorporate the outcomes of the assessment into environmental mitigation and management controls.

The CRAF also aligns with Santos' approved Gas Field Development (GFD) Project Area Chemical Risk Assessment Framework (EPBC 2012/6615). For the purposes of Fairview Water Release Scheme CRAF, drilling and completion, hydraulic fracturing and water treatment chemicals and geogenic constituents are considered to be present in the influent to the facility and potential discharge to the Dawson River.

1.2 Statement of Aim

The aim of the chemical risk assessment(s) is to evaluate the potential risks and effects of chemicals used during coal seam gas operations (defined as drilling and completion, hydraulic fracturing and water treatment) to MNES (including beneficial uses of water) associated with the controlled release of treated water to the Dawson River.

The aim of the chemical risk assessment(s) is to also evaluate the potential risks and effects of geogenic chemicals to MNES within the Dawson River that may be present in produced waters during coal seam gas operations.

1.3 Goal of the Risk Assessment

The goal of the chemical risk assessment is to demonstrate that potential risks to MNES (including beneficial uses) associated with the chemicals used in coal seam gas operations have been eliminated or reduced as much as is reasonably practicable.

This assessment process is designed to align with national guidance and other regulatory frameworks and assesses the full lifecycle of chemicals that are stored, handled, used and/or disposed during or following hydraulic fracturing activities and in the treatment of produced formation water.

Accidental or unintentional release scenarios are not included; however, the outcomes of the assessment are used to inform contingency response actions for these types of releases (**Appendix 10**).

2.0 Chemical Risk Assessment Framework

2.1 Framework Process

The framework is to be adopted for all chemicals used in coal seam gas operations and will involve a two-step process:

- Step 1 – classification of chemicals.
- Step 2 – assessment of chemicals.

Chemicals are to be classified into five Tiers (Tier 1 through 5) based on the following criteria:

- Assessment of whether chemicals are identified on chemical databases used by AICIS as indicators that these chemicals are of concern. These included:
    - European Union Substance of Very High Concern (EU SVHC)
    - US National Toxicology Program (US NTP) Report on Carcinogens
    - International Agency for Research on Cancer (IARC) Monographs
    - European Commission Endocrine Disruptors Strategy - list of Category 1 substances with endocrine disrupting capacity
    - Chemical Substances Control Law of Japan (CSCL) Class I and II Specified Chemical.
    - Polymers identified as of low concern by AICIS
- Completion of a formal persistent, bioaccumulative and toxic (PBT) substances assessment (using environmental reference values contained within the categorisation guidelines) and the factors discussed in the meeting to develop the tiered framework.
- Evaluation of any other concerns associated with persistence in the environment (especially for inorganics) which is not captured in the PBT assessment but may be a consideration in the context of project activities (for example, irrigation of produced water).

The criteria to be used in the chemical category classification within this framework is provided as **Appendix 1**.

A low risk chemical is defined as a chemical that is not identified as a Persistent Bioaccumulative Toxic chemical and is not listed as a chemical of concern on the following databases:

- European Union Substance of Very High Concern (EU SVHC)
- US National Toxicology Program (US NTP) Report on Carcinogens
- International Agency for Research on Cancer (IARC) Monographs
- European Commission Endocrine Disruptors Strategy - list of Category 1 substances with endocrine disrupting capacity
- Chemical Substances Control Law of Japan (CSCL) Class I and II Specified Chemical

A high risk chemical is defined as a chemical that is identified as a Persistent Bioaccumulative Toxic chemical, or a chemical which exhibits toxicity of potential concern, or is listed as a chemical of concern on the following chemical databases:

- European Union Substance of Very High Concern (EU SVHC)
- US National Toxicology Program (US NTP) Report on Carcinogens
- International Agency for Research on Cancer (IARC) Monographs
- European Commission Endocrine Disruptors Strategy - list of Category 1 substances with endocrine disrupting capacity
- Chemical Substances Control Law of Japan (CSCL) Class I and II Specified Chemical

For the purposes of this CRAF, chemicals categorised as Tier 1 or Tier 2 chemicals are designated as ‘low risk’ chemicals. Chemicals categorised as Tier 3, Tier 4 or Tier 5 chemicals are designated as ‘high risk’ chemicals.

Based on the category classification of the chemical (and its potential toxicity, persistence and bioaccumulation potential in the environment), different levels of assessment will be conducted with the most robust assessment conducted on the highest classification (**Table 1**).

Table 1: Risk Assessment Requirements

Tier	Risk Category	Screening Assessment and Categorisation (Appendix 1)	Toxicological Profile (Appendices 2, 3 and 4)	Qualitative Risk Assessment (Appendix 5)	Quantitative Risk Assessment (Appendix 6)	Site Specific Assessment	Prohibited from Use on Project
1	Low Risk	X	X				
2		X	X	X			
3	High Risk	X	X	X	X		
4		X	X	X	X	X	
5		X					X

Consistent with the screening matrix in **Appendix 1** and **Table 1**:

- Tier 1 chemicals, which are effectively low toxicity and therefore low hazard, would be subject to only the screening assessment.
- Tier 2 chemicals, in addition to the screening assessment, will be subjected to a qualitative risk assessment.
- Tier 3 and Tier 4 chemicals will be subject to an additional quantitative risk assessment with Tier 4 chemicals requiring an additional site-specific quantitative risk assessment.

  Site-specific risk assessment for Tier 4 chemicals will require site-specific per use approval by the Minister.

- Tier 5 chemicals will not be used and no further discussion will be provided.

The assessment of geogenic chemicals recovered within produced water will be assessed against risk-based criteria depending on their end fate (i.e. use and/or disposal).

Based on the outcomes of the *National Assessment of the Chemicals used in Coal Seam Gas in Australia* (DoEE 2017), hypothetical accidental releases associated with delivery truck rollovers, including into watercourses, represented the greatest potential risk to MNES. Given the highly regulated nature of transportation of chemicals (at both a Commonwealth and State level), transport related scenarios and assessment will not be incorporated into the risk assessment process.

The movement of chemicals will be performed only by transport contractors with the relevant qualifications and licences required for the movement of each category of goods. Haulage will be performed to the satisfaction of relevant legislative requirements, including but not limited to *Australian Dangerous Goods Code* (NTC 2020) and Queensland *Transport Operations (Road Use Management – Dangerous Goods) Regulation 2008* as well as Santos traffic management principles identified in Section 4.3.

The chemical risk assessment will however be used to inform decisions on a case-by-case basis regarding site assessment, risk management/clean-up and rehabilitation should a transport-related or other accidental release occur in accordance with **Appendix 10**.

2.2 Framework Templates

A template of the Register of Assessed Chemicals, including document control requirements, is provided in **Appendix 2**.

Templates of the toxicological profiles (dossiers) for Tier 1, 2 and 3 chemicals, completed for an example chemical(s), are provided as **Appendices 3**, **4** and **5**, respectively.

Depending on the category of the chemical being assessed (i.e. Tier 1, 2, 3 or 4), the toxicological profiles (dossiers) include chemical identification, physical and chemical properties, environmental fate properties, human health and environmental hazard assessments, derivation of non-cancer and cancer screening levels, a persistent, bioaccumulative and toxic (PBT) assessment, and regulatory status.

An example Tier 2 qualitative risk assessment and Tier 3 quantitative risk assessment is provided as **Appendix 6** and **Appendix 7** respectively.

All future chemical assessments must be conducted using these templates.

2.3 MNES Values and Potential Receptors

This section describes the MNES values and potential receptors subject to the Qualitative and Quantitative Risk Assessment Processes (Tier 2, 3 and 4 chemicals).

For the purposes of the risk assessment, petroleum workers, managed under Australian workplace health and safety legislation, are excluded from assessment.

The project activities, site setting and associated MNES values described in the *Santos Fairview Water Release Scheme* referral (2021/8914) and *Environmental Impact Statement for the Santos GFD Project* (Santos 2014) are the MNES values for the purpose of this chemical risk assessment.

The relevant MNES values listed under the *Environmental Protection and Biodiversity Conservation Act 1999* (EPBC Act) comprise:

- threatened species and ecological communities; and
- water resources.

Consistent with the broad definition of MNES associated with water resources, the potential risks to both the MNES water resources and non-MNES receptors exposed to the water resource must be evaluated. This may include human and livestock through the consumption of water containing chemicals, impacts on crops associated with irrigation of water, and aquatic flora and fauna where a release to waters is authorised. Accidental release scenarios are not to be included; however, the outcomes of the assessment should be used to inform emergency response actions. The chemical risk assessments will be limited to MNES receptors and those non-MNES receptors associated with the MNES water resources.

2.4 Exposure Pathways Subject to the Risk Assessment Process

This section defines the exposure pathways subject to the risk assessment process.

The list of exposure pathways associated with project activities and subject to the risk assessment process is provided in **Appendix 8**. These exposure pathways must be evaluated as part of qualitative assessments (Tier 2) and quantitative risk assessments (Tier 3 and Tier 4). If an exposure pathway is deemed to be not complete for a specific chemical, this must be discussed in the chemical specific risk assessment.

Exposure pathways are categorised as either:

- **Complete exposure** – when a source, a migration pathway, a mechanism for exposure and a potential receptor are present.
- **Incomplete exposure** – when any one or more of the four elements (source, pathway, mechanism and receptor) that make a complete exposure pathway are not present.
- **Insignificant / low probability exposure** – where the potential risks are limited due to attenuation, fate and transport mechanisms, infrequent exposure occurrence, and / or minimal projected chemical concentrations at the point of exposure (i.e. there is no hazard).

For MNES values to be included in the risk assessment process there must be:

- the potential for MNES values to be present (receptor) and an exposure pathway to the chemical additive(s) from an authorised activity, or
- the potential for MNES values to be present (receptor) and an exposure pathway to media (soils or water resources (surface or groundwater)) affected by an authorised activity.

For a non-MNES value(s) to be included in the risk assessment there must be:

- an MNES water resource (surface water and / or groundwater) affected or potentially affected by chemical additive(s) from an authorised gas extraction activity, and
- a complete or potentially complete exposure pathway to the non-MNES receptor.

2.5 Qualitative and Quantitative Risk Assessment

The chemical risk assessment program must be undertaken in accordance with best practice risk assessment methodologies including those contained within the international standards and Australian risk assessment guidance documents (e.g. NEPC 2013; enHealth 2012a,b) referenced in **Appendix 9**. The example qualitative and quantitative risk assessment frameworks provided as **Appendix 6** and **Appendix 7** have been developed in accordance with these standards and guidelines.

The best practice methodologies and guidelines for quantitative risk assessment is the same for both Tier 3 and Tier 4 chemicals. However, the Tier 4 quantitative risk assessment is 'site-specific', requiring more detailed site-specific information to inform use and reuse, as opposed to more generic field level information required for a Tier 3 quantitative risk assessment. The Tier 4 assessment is to be tailored towards discrete use and reuse (e.g. a tailored hydraulic fracturing campaign at discrete well locations, or a discrete (authorised) discharge to a watercourse) rather than field scale application.

Tier 4 quantitative risk assessments are to include a food chain risk assessment to evaluate uptake and accumulation/bioaccumulation within higher trophic organisms, persistence in soil and cumulative impacts; the model to be selected is dependent on the constituent, receptor and media of exposure. The scope of a site-specific risk assessment for a Tier 4 chemical(s) requires assessment and approval by the Department. Tier 4 chemicals require site-specific per use approval by the Minister prior to use.

The data sources for the risk assessment toxicological profiles (dossiers) include the Inventory Multi-Tiered Assessment and Prioritisation (IMAP) framework established by AICIS. The risk assessment toxicological profiles (dossiers) must be prepared in accordance with the Organisation for Economic Cooperation and Development's (OECD's) *Hazard Assessment – Gathering and Evaluating Existing Information and Assessing the Hazards* and *Exposure Assessment – Environmental Fate and Pathways*.

In the assessment of exposure pathways and risks, only authorised operational activities must be considered (i.e. activities that are authorised in the Queensland Environmental Authority and Commonwealth Approval). Where activities are specifically precluded (for example release or disposal of wastes to surface or ground waters are explicitly not authorised) these will not be considered in the risk assessment.

Further the qualitative and quantitative risk assessments must specifically consider management plans developed (as part of Commonwealth and State approvals) which have been developed to avoid, mitigate, manage and monitor potential impacts.

2.6 Geogenic Screening Risk Assessment

The assessment of geogenic chemicals recovered within produced water will be subject to a screening assessment and if required qualitatively assessed against published or derived risk-based criteria depending on their end fate (i.e. use and/or disposal).

The screening assessment must be undertaken in accordance with best practice risk assessment methodologies including those contained within the international standards and Australian risk assessment guidance documents, as provided in **Appendix 9**.

In the assessment of exposure pathways and risks, only authorised operational activities must be considered (i.e. activities that are authorised in the Queensland Environmental Authority and Commonwealth Approval). Accidental release scenarios are not to be included; however, the outcomes of the assessment will be used to inform emergency response actions, as provided in **Appendix 10**.

2.7 Cumulative Risk Assessment

The chemical risk assessment must qualitatively assess the potential for one or more hazards associated with the chemicals used in coal seam gas operations to impact MNES. The assessment must consider the potential causes of cumulative impacts from authorised activities in relation to MNES for Tier 3 and Tier 4 chemicals only (due to their potential persistence and/or potential to bioaccumulate).

3.0 Chemical Risk Assessment Format, Approval Process and Document Control

As noted above, the assessments must be conducted on each chemical in accordance with the respective templates provided (**Appendices 3** to **5** and **6** and **7**).

The requirements for chemical risk assessment review, update, notification and approval are provided in **Table 2** below.

Table 2: Chemical Risk Assessment Review and Approval Requirements

Delivery Scope[1]	Tier			
	1	2	3	4
Complete screening assessment and categorisation and develop a toxicological profile for each chemical.	X	X	X	X
Complete a qualitative risk assessment for the proposed use(s) of the chemical (refer **Appendix 6**).		X		
Appoint an independent chemical risk assessment expert to review the toxicological profile and/or qualitative risk assessment.	X	X		
Notify the Department in writing that a new chemical has been assessed and reviewed, including the assessment outcome and reference to Register of Assessed Chemicals.	X	X		
Negotiate scope of site-specific quantitative risk assessment with the Department.				X
Complete a quantitative risk assessment for the proposed use(s) of the chemical (refer **Appendix 7**).			X	X
Submit toxicological profiles and quantitative risk assessment to Department/Minister approval.			X	X
Update Register of Assessed Chemicals, including document control.	X	X	X	X
Publish the chemical toxicological profile(s) and if applicable qualitative/quantitative risk assessments on the Santos website.	X	X	X	X

3.1 Approval Process

3.1.1 Low Risk Chemicals

Toxicological profiles, risk assessments and a signed and dated statement from the independent chemical risk assessment expert for each low risk chemical (Tier 1 and Tier 2) will be entered into the Register of Assessed Chemicals. This same information will also be provided to the Department. Low risk chemicals must not be used in coal seam gas operations until all of these steps have been undertaken. No further approval is necessary, prior to the use of the chemical in coal seam gas operations.

Compliance checklists and checklists for peer review, provided in **Appendix 11**, define the scope of the review relevant to the level of assessment performed. If any part of the scope is determined to not be applicable, then the reviewer must document this and state the reason as to why it is not applicable.

3.1.2 High Risk Chemicals

Toxicological profiles and respective risk assessments for each high risk chemical (Tier 3 and Tier 4) will be submitted to the Department for review and approval. These will not be reviewed by an independent chemical risk assessment expert. Toxicological profiles and respective risk assessments will be added to the Register of Assessed Chemicals following Department approval. High risk chemicals must not be used in coal seam gas operations until all of these steps have been undertaken and approval has been provided by the Minister.

When the risk assessment for a new chemical identifies the need for additional mitigation and management measures to ensure the potential risks to MNES have been reduced as much as is reasonably practicable the following steps must occur:

- provide a statement with the submitted risk assessment that identifies that additional mitigation and management control(s) is required, including details of the additional controls required and a process to monitor and report on their efficacy;
- following approval of the toxicological profile and respective risk assessment for that chemical, update the relevant approved management plan(s) to include the relevant mitigation and management control(s); and
- submit the relevant approved management plan(s) to the Department where required under the Commonwealth approval conditions.

3.2 Register of Assessed Chemicals

A Register of Assessed Chemicals is to be published and maintained on the Santos website.

The Register of Assessed Chemicals will, for each published chemical, provide a summary of the outcomes of the screening assessment, including the Tier (and Risk Level) categorisation, the activities the chemical has been assessed for (i.e. hydraulic fracturing or water treatment) and the assessed end use /fate of the chemical. The Register for Assessed Chemicals must include the following document control information:

- date of Register of Assessed Chemical publication;
- date of chemical assessment;
- date of independent chemical risk assessment expert review (Tier 1 and 2 chemicals only);
- date of notification to Department (Tier 1 and 2 chemicals)/date of lodgement to Department (Tier 3 and 4 chemicals);
- date of approval from Minister; and
- date of chemical re-evaluation (only if chemical is still in use).

Supporting information (i.e. dossiers, qualitative and quantitative risk assessments) for each assessed chemical is to be made readily accessible via the Register of Assessed Chemicals.

The template for the Register of Assessed Chemicals is in **Appendix 2**.

3.3 Review Process

Tier 1, 2, 3 and 4 risk assessment information for chemicals still in use must be re-evaluated and peer reviewed every five (5) years, commencing from the date of approval of this CRAF. The peer review undertaken by a chemical risk assessment expert, must be completed before the end of each 5-year anniversary of the approval of the CRAF. Peer review is only required for chemicals that are still in use.

A signed statement detailing the findings of the 5-year peer review, including evidence of any concerns raised by the peer review have been addressed, must be submitted to the Department within 60 business days of completion of the peer review.

4.0 Mitigation and Management

Mitigation and management controls are required to be developed and implemented to ensure the potential risks associated with the use of chemicals to MNES have been eliminated or reduced to as low as reasonably practicable.

The risk assessments must consider the management plans developed as part of Commonwealth and State approvals. Unless specifically identified within an assessment, the mitigation and management controls outlined in these management plans are considered adequate for Tier 1 and 2; and Tier 3 chemicals. Where a risk assessment, including a Tier 4 site-specific risk assessment, identifies new or additional mitigation and/or management measures beyond those documented in an existing management plan, the relevant management plan must be updated to include the new mitigation and/or management measures and be submitted to the Department where required under Commonwealth approval conditions.

Key plans integral to the management of the risk of impacts to MNES associated with planning, use and transportation including processes to monitor and review controls are provided in the sections below.

4.1 Environmental Authority

Environmental Authority (EA) EPPG00928713, granted to Santos by the Queensland Department of Environment and Science (DES) for the release of desalinated water to the Dawson River, provides a number of key mitigation and management requirements that must be met before releases are to occur. These include conditions relating to release locations, volumes and water quality objectives (WQOs) for desalinated water.

To ensure the potential for environmental harm is minimised, releases have been designed to ensure WQOs are met within a suitable distance from the release points and that changes to stream hydrological and hydraulic characteristics are negligible. Conditions of the EA to be implemented include:

- monitoring of treated water quality prior to release to ensure compliance with the end of pipe limits;
- discharge to the Dawson River via a pipe outlet into an ephemeral watercourse that flows to the Waterhole;
- monitoring of treated water discharge volumes during releases to ensure compliance with maximum release volumes;
- monitoring of the water chemistry within the receiving environment on a scheduled frequency (i.e. daily, weekly or quarterly) during release; and
- monitoring of other parameters such as aquatic ecology and geomorphology as outlined in Section 4.2 below.

4.2 Receiving Environment Monitoring Program

A crucial requirement of EA EPPG00928713 is the development and implementation of a certified Receiving Environmental Monitoring Program (REMP), the purpose of which is to monitor and record the effects of the release water on the receiving environment whilst it is being discharged, with aim of identifying and describing the extent of any adverse environmental impacts on the receiving waters.

The Dawson River Release Scheme REMP (frc environmental 2021) details a description of the release activities, receiving environment attributes, discussion of the temporal context of the REMP as well as monitoring program design, data analysis and reporting. Monitoring components identified within the REMP include:

- hydrology;
- geomorphology (bed and bank stability);
- water quality;
- sediment quality;

- algae blooms; and
- biology (fish and macroinvertebrates)

Where the outcome(s) of the chemical risk assessment (including the outcome of assessment of cumulative risk) for both low and high risk chemicals inform the need for additional monitoring, mitigation and management controls beyond those already presented in REMP, these will be identified within the chemical risk assessment documentation.

4.3 Traffic Management Principles

The principles behind Santos' road and traffic management are:

- to maintain road-user safety by efficiently planning and optimising traffic movements;
- to mitigate impacts to road-user safety and the environment by ensuring adherence to transport regulations (e.g. dangerous goods code);
- to mitigate impacts on public road infrastructure by using field roads and limiting Santos Project traffic to approved routes;
- to enforce rules on employees and contractors operating in the Narrabri Gas Project area and wider region, including the planning, monitoring and consolidation of vehicle movements.

To achieve these principles the following mitigation and management controls have been developed and implemented:

- Santos implements approved roads/routes for use by both heavy and light vehicles. The approved routes seek to optimise the use of field and public roads to avoid inefficient road movements and unnecessary impacts on the community. Approved route information is communicated through induction training and general communications.
- Implementation of no-go zones for those roads not approved through negotiations with the relevant roads authority for use by Project traffic. No-go zones are also deemed necessary when Project use may adversely impact this road network or there is a potential safety design issue with the road.
- Santos Management Standards require in-vehicle monitoring systems (IVMS) in all vehicles involved in Project development. IVMS functionality also provide pass-through of real-time vehicle location to Santos.
- Where practicable, traffic movements are scheduled to occur during daylight hours.
- Santos project personnel and contractors will adhere to all prescribed heavy vehicle permit conditions and dangerous goods requirements under local, state and Commonwealth Regulations.
- During wet weather events, Santos will liaise with the relevant roads authorities about road restrictions or closures to minimise potential impacts on the road network and the community. In the event of road closures no travel is permitted and work stops unless drivers are advised of an alternative suitable route that has been cleared for use by the relevant road authority together with any specific conditions.
- Additional temporary signage will be deployed in consultation with the relevant roads authorities to ensure that any road limitations are clearly identifiable. Additional signage in road corridors will be requested on roads on an as-need-basis or when a safety issue is to be addressed.
- Movement of dangerous and/or hazardous goods will be performed only by transport contractors with the relevant qualifications and licences required for the movement of each category of goods.

These existing mitigation and management controls are considered sufficient to address the risk of adverse impact to MNES from the transportation of chemical constituents associated with produced water.

Monitoring and reporting on traffic management principles will be undertaken in accordance with Santos Operating Standards and IVMS. If an adverse impact to MNES is detected during the transportation of chemicals, the Department is to be notified in writing within 15 business days of detection. The notification must specify the location, date and time of the adverse impact and include a short description of the adverse impact and the MNES adversely impacted.

5.0 References

American Petroleum Institute (API) 2004, *Risk-based screening levels for the protection of livestock exposed to petroleum hydrocarbons*, Publication number 4733, American Petroleum Institute, Regulatory Analysis and Scientific Affairs Department, Petulma, California, available: https://www.api.org/environment-health-and-safety/environmental-performance/~/~/media/Files/EHS/Environmental_Performance/Final_as_published_4733.ashx (28 March 2022)

ANZG 2018, *Australian and New Zealand Guidelines for Fresh and Marine Water Quality*. Australian and New Zealand Governments and Australian state and territory governments, Canberra, ACT, Australia, available: https://www.waterquality.gov.au/anz-guidelines (28 March 2022)

Australian and New Zealand Environment and Conservation Council (ANZECC) & Agriculture and Resource Management Council of Australia and New Zealand (ARMCANZ) 2000, Australia and *New Zealand Guidelines for Fresh and Marine Water Quality*, available: https://www.waterquality.gov.au/anz-guidelines/resources/previous-guidelines/anzecc-armcanz-2000 (28 March 2022)

Australian Industrial Chemicals Introduction Scheme (AICIS), available: https://www.industrialchemicals.gov.au (28 March 2022)

Chemical Substances Control Law of Japan (CSCL) Class I and II Specified Chemical, available: https://www.nite.go.jp/en/chem/kasinn/lists.html (28 March 2022)

Department of the Environment and Energy (DoEE) 2017 various, *National Assessment of the Chemicals used in Coal Seam Gas in Australia*, available: https://www.awe.gov.au/water/coal-and-coal-seam-gas/national-assessment-chemicals/assessment-reports (28 March 2022)

Department of the Environment and Energy (DoEE) 2017, *Exposure Draft: 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, available: www.environment.gov.au/water/coal-and-coal-seam-gas/national-assessment-chemicals/consultation-risk-assessment-guidance-manual (28 March 2022)

Department of Water Affairs and Forestry 1996, *South African Water Quality Guidelines*, available: https://www.dws.gov.za/Dir_WQM/docs/Pol_saWQguide.zip (28 March 2022)

EnHealth 2012a, *Environmental Health Risk Assessment – Guidelines for assessing human health risks from environmental hazards*, Australian Government Department of Health and Ageing, Commonwealth of Australia, available: https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-publicat-environ.htm (28 March 2022)

EnHealth 2012b *Australian Exposure Factor Guidance*, Australian Government Department of Health and Ageing, Commonwealth of Australia, available: https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-publicat-environ.htm (28 March 2022)

European Commission Endocrine Disruptors Strategy - list of Category 1 substances with endocrine disrupting capacity, available https://ec.europa.eu/environment/chemicals/endocrine/strategy/being_en.htm (28 March 2022)

European Union Substance of Very High Concern (EU SVHC), available: https://echa.europa.eu/home (28 March 2022)

frc environmental 2021, *Dawson River Release Scheme REMP*

International Agency for Research on Cancer (IARC) Monographs, available: https://monographs.iarc.who.int (28 March 2022)

National Environmental Protection Council (NEPC) 2013, *National Environmental Protection (Assessment of Site Contamination) Measure 1999, as amended 2013*, available: http://nepc.gov.au/nepms/assessment-site-contamination (28 March 2022)

National Transport Commission (NTC) 2020, *Australian Code for the Transport of Dangerous Goods by Road & Rail,* Edition 7.7, available: https://www.ntc.gov.au/sites/default/files/assets/files/ADG%20Code%207.7_0.pdf (28 March 2022)

NHMRC, NRMMC 2011, *Australian Drinking Water Guidelines Paper 6 National Water Quality Management Strategy* (updated 2022), National Health and Medical Research Council, National Resource Management Ministerial Council, Commonwealth of Australia, Canberra, available: https://www.nhmrc.gov.au/about-us/publications/australian-drinking-water-guidelines (28 March 2022)

Organisation for Economic Cooperation and Development, *Hazard Assessment – Gathering and Evaluating Existing Information and Assessing the Hazards* and *Exposure Assessment – Environmental Fate and* Pathways, available: http://www.oecd.org/env/ehs/summarytableofavailabletoolsforriskassessment.htm (28 March 2022)

Santos 2014, *Environmental Impact Statement for the Santos GFD Project*, available: https://www.statedevelopment.qld.gov.au/coordinator-general/assessments-and-approvals/coordinated-projects/completed-projects/santos-glng-gas-field-development-project/eis-documents (28 March 2022)

United States Environmental Protection Agency (USEPA) 2006, *EPA Region III Biological Technical Assistance Group (BTAG) Freshwater Screening Benchmarks*, available https://www.epa.gov/risk/freshwater-screening-benchmarks (28 March 2022)

United States Environmental Protection Agency (USEPA) 2009, *National Primary Drinking Water Regulations*, available https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations (28 March 2022)

United States Environmental Protection Agency (USEPA) 2014. EPA-Expo-Box (A Toolbox for Exposure Assessors), available: http://www.epa.gov/expobox (28 March 2022)

United States Environmental Protection Agency (USEPA) 2021, *Regional Screening Levels (RSLs)*, last updated November 2021, available: https://www.epa.gov/risk/regional-screening-levels-rsls-generic-tables (28 March 2022)

United States Environmental Protection Agency (USEPA) 2015, *National Recommended Water Quality Criteria,* available https://www.epa.gov/wqc/national-recommended-water-quality-criteria-tables (28 March 2022)

US NTP (National Toxicology Program) 2021, *Report on Carcinogens, Fifteenth Edition*, Research Triangle Park, NC: U.S. Department of Health and Human Services, Public Health Service. https://ntp.niehs.nih.gov/go/roc15 (31 March 2022)

World Health Organization 2017, *Guidelines for drinking-water quality: fourth edition incorporating the first addendum,* Geneva, available: https://www.who.int/publications/i/item/9789241549950 (28 March 2022)

Appendix 1 – Chemical Category Classification Matrix

Criteria	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5
General PBT Assessment Step					
Combined PBT Assessment Category	Not a PBT	Not a PBT	Not a PBT	Identified as a PBT	N/A
Chemical Databases of Concern Assessment Step					
Listed as a chemical of concern on relevant databases	Not listed as a chemical of potential concern on the following databases: - European Union Substance of Very High Concern (EU SVHC). - US National Toxicology Program (US NTP) Report on Carcinogens - International Agency for Research on Cancer (IARC) Monographs. - European Commission Endocrine Disruptors Strategy - list of Category 1 substances with endocrine disrupting capacity. - Chemical Substances Control Law of Japan (CSCL) Class I and II Specified Chemical.	Not listed as a chemical of potential concern on the following databases: - European Union Substance of Very High Concern (EU SVHC). - US National Toxicology Program (US NTP) Report on Carcinogens - International Agency for Research on Cancer (IARC) Monographs. - European Commission Endocrine Disruptors Strategy - list of Category 1 substances with endocrine disrupting capacity. - Chemical Substances Control Law of Japan (CSCL) Class I and II Specified Chemical.	Listed as a chemical of concern on the following databases: - European Union Substance of Very High Concern (EU SVHC). - US National Toxicology Program (US NTP) Report on Carcinogens - International Agency for Research on Cancer (IARC) Monographs. - European Commission Endocrine Disruptors Strategy - list of Category 1 substances with endocrine disrupting capacity. - Chemical Substances Control Law of Japan (CSCL) Class I and II Specified Chemical.	Listed as a chemical of concern on the following databases: - European Union Substance of Very High Concern (EU SVHC). - US National Toxicology Program (US NTP) Report on Carcinogens - International Agency for Research on Cancer (IARC) Monographs. - European Commission Endocrine Disruptors Strategy - list of Category 1 substances with endocrine disrupting capacity. - Chemical Substances Control Law of Japan (CSCL) Class I and II Specified Chemical.	Chemicals noted in the Rotterdam Accord including: - octabromodiphenyl ether - pentabromodiphenyl ether - perfluorooctane sulfonic acid - perfluorooctane sulfonates - perfluorooctane sulfonamides - perfluorooctane sulfonyls - polybromated biphenyls - short chain chlorinated paraffins - tetramethyl lead - tributyl tin compounds Chemicals restricted in the State of Queensland including: - Benzene* - Toluene* - Ethylbenzene* - m-&p- and o-Xylene*
Identified as Polymer of Low Concern	Yes (no further assessment required)	No	No	No	N/A
Persistence Assessment Step					
Persistence	Not persistent as defined by: Air - Half life < 2 days Water - Half life < 60 days Soil and Sediment - Half life < 6 months	Not persistent as defined by: Air - Half life < 2 days Water - Half life < 60 days Soil and Sediment - Half life < 6 months	Persistent as defined by: Air - Half life ≥ 2 days Water - Half life ≥ 60 days Soil and Sediment - Half life ≥ 6 months	Persistent as defined by: Air - Half life ≥ 2 days Water - Half life ≥ 60 days Soil and Sediment - Half life ≥ 6 months	N/A
Other Persistence Concerns – Chemical identified as potentially accumulating in soil and posing risks	No potential concerns with accumulation in soil and impacts on flora and fauna	No potential concerns with accumulation in soil and impacts on flora and fauna	Potential concerns with accumulation in soils based on ANZECC assessment b (for example metals such as Cd)	Potential concerns with accumulation in soils based on ANZECC assessment b (for example metals such as Cd)	N/A
Bioaccumulative Assessment Step					
Bioaccumulative	Does not Bioaccumulate as defined by: - Aquatic - BAF < 2000 or BCF < 2000 or log K_{ow} < 4.2 (if BAF and BCF are not available) -Terrestrial - log K_{oa} < 6 and log Kow < 2 - Food Chain Bioaccumulation Potential - BMF < 1	Does not Bioaccumulate as defined by: - Aquatic - BAF < 2000 or BCF < 2000 or log K_{ow} < 4.2 (if BAF and BCF are not available) -Terrestrial - log K_{oa} < 6 and log K_{ow} < 2 - Food Chain Bioaccumulation Potential - BMF < 1	Does not Bioaccumulate as defined by: - Aquatic - BAF < 2000 or BCF < 2000 or log K_{ow} < 4.2 (if BAF and BCF are not available) -Terrestrial - log K_{oa} < 6 and log K_{ow} < 2 - Food Chain Bioaccumulation Potential - BMF < 1	Does Bioaccumulate as defined by: - Aquatic - BAF ≥ 2000 or BCF ≥ 2000 or log K_{ow} ≥ 4.2 (if BAF and BCF are not available) -Terrestrial - log K_{oa} ≥ 6 and log K_{ow} ≥ 2 - Food Chain Bioaccumulation Potential - BMF > 1	N/A
Toxicity Assessment Step					
Toxicity	Acute Toxicity: Fish -96h LC50 >10 mg/L Invertebrates - 48h EC50 > 10 mg/L Algae and other aquatic plants - 72 or 96h ErC50 > 10 mg/L	Acute Toxicity: Fish -96h LC50 >1 to < 10 mg/L Invertebrates - 48h EC50 >1 to < 10 mg/L Algae and other aquatic plants - 72 or 96h ErC50 >1 to < 10 mg/L	Acute Toxicity: Fish -96h LC50 ≤ 1 mg/L Invertebrates - 48h EC50 ≤ 1 mg/L Algae and other aquatic plants - 72 or 96h ErC50 ≤ 1 mg/L	Acute Toxicity: Fish -96h LC50 ≤ 1 mg/L Invertebrates - 48h EC50 ≤ 1 mg/L Algae and other aquatic plants - 72 or 96h ErC50 ≤ 1 mg/L	N/A
	Chronic Toxicity: Fish NOEC or ECx >1 mg/L Invertebrates NOEC or ECx > 1 mg/L Algae and other aquatic plants - NOEC or ECx > 1 mg/L	Chronic Toxicity: Fish NOEC or ECx >0.1 to < 1 mg/L Invertebrates NOEC or ECx >0.1 to <1mg/L Algae and other aquatic plants - NOEC or ECx >0.1 to < 1 mg/L	Chronic Toxicity: Fish NOEC or ECx ≤ 0.1 mg/L Invertebrates NOEC or ECx ≤ 0.1mg/L Algae and other aquatic plants - NOEC or ECx ≤ 0.1 mg/L	Chronic Toxicity: Fish NOEC or ECx ≤ 0.1 mg/L Invertebrates NOEC or ECx ≤ 0.1 mg/L Algae and other aquatic plants - NOEC or ECx ≤ 0.1 mg/L	N/A
Risk Assessment Actions Required					
Risk Assessment Action Required	Hazard Assessment only. Do screening only and note it meets the above criteria. Develop toxicological profile	Hazard Assessment and Qualitative Assessment Only. Do screening only and note it meets the above criteria. Develop toxicological profile and PNECs for water and soil and provide qualitative discussion of risk	Quantitative Risk Assessment: Complete PBT, qualitative and quantitative assessment of risk. Quantitative assessment of risk will consider only Tier 3 chemicals in end use determination.	Quantitative Risk Assessment and Full Life Cycle Assessment Need to demonstrate that the chemical cannot be substituted. If retained will need to conduct a full life cycle quantitative risk assessment including food chain risk assessment. Scope to be agreed with Department.	Banned from Use on Project. Would require specific assessment process and require extensive consultation prior to assessment.

Notes:
BAF – bioaccumulation factor
BCF – bioconcentration factor
BMF – biomagnification factor
EC50 – median effective concentration
ErC50 – concentration of test substance which results in a 50 percent reduction in growth rate (ErC50) relative to the control within 72hrs exposure
ECx – concentration of a substance in water or sediment that is estimated to produce an x% change in the response being measured or a certain effect in x% of the test organisms, under specified conditions
K_{oa} *- octanol-air partition coefficient*
K_{ow} *– n-octanol/water partition coefficient*
LC50 – lethal concentration 50%
NOEC – no observed effect concentration
PBT – persistent, bioaccumulative and toxic
PNEC – predicted no-effect concentration
mg/L – milligrams per litre
h – hour
N/A – not applicable
** Above levels prescribed in the Queensland Environment Protection Regulation 1999*

Appendix 2 – Register of Assessed Chemicals (Template)

{Excel Tab 1 – **Document Control**}

Date	**Rev**	**Reason For Issue**
dd/mm/yy	*0*	*Publish Register following CRAF Approval*
dd/mm/yy	*1*	*Addition of “New Chemical A”*

*{Excel Tab 2 – **Register**}*

Chemical Name (incl. dossier hyperlink)	**CAS No.**	**Document Control**					**Screening Assessment**												**Assessed Activity(ies)**			**Assessed Uses(s)**					
							Overall PBT Assessment[2]	**Chemical Databases of Concern Assessment Step**		**Persistence Assessment Step**		**Bioaccumulative Assessment Step**	**Toxicity Assessment Step**			**Tier**[4]	**Risk Level**									
		Chemical Assessment Date	**Independent Peer Reviewer**[1]	**Department Notification Department Date**	**Department Approval Date**	**Chemical Re-evaluation Date**		**Listed as a COC on relevant databases?**	**Identified as Polymer of Low Concern**	**P criteria fulfilled?**	**Other P Concerns**	**B criteria fulfilled?**	**T criteria fulfilled?**	**Acute Toxicity**[3]	**Chronic Toxicity**			**Drilling and Completions**	**Hydraulic Fracturing**	**Water Treatment**	**Residual Drilling Material**	**Irrigation**	**Stock Watering**	**Direct Discharge to Surface Water**	**Dust Suppression/ Construction**	**TBA**
Example Chemical	***1234-12-3***	*dd/mm/yy*	*NA*	*dd/mm/yy*	*dd/mm/yy*	*NA*	*Not a PBT*	*1*	*No*	*Yes*	*No*	*No*	*No*	*1*	*1*	***1***	***Low***	*X*	*X*	*X*	*X*	*X*	*X*	*X*	*X*	

1 – Only required for new Tier 1 and Tier 2 chemicals
2 – PBT Assessment based on PBT Framework (see Table 1); see dossiers for individual chemical PBT information.
3 – Acute and chronic aquatic toxicity evaluated consistent with assessment criteria (see Appendix 1).
4 – See risk dossier for environmental hazard assessment information.

Notes:
CAS No. = chemical abstracts service registry number
COC = chemical of concern
NA = Not Applicable
PBT = Persistent, Bioaccumulative and Toxic
B = bioaccumulative
P = persistent
T = toxic

Appendix 3 – Example Tier 1 Toxicological Profile

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 STABILIZER (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).

Screening Assessment Conclusion – Acrylamide/sodium acrylate copolymer, acrylamide, sodium acrylate polymer and 2-propenoic acid, potassium salt, polymer with 2-propenamide are polymers of low concern. Therefore, these polymers and the other similar polymer in this group are classified as **tier 1** chemicals and require a hazard assessment only.

1. BACKGROUND

Acrylamide/sodium acrylate copolymer is a sodium salt of a polymer consisting of acrylic acid, methacrylic acid or one of their simple esters. Acrylates are a family of polymers which are a type of vinyl polymer. Synthetic chemicals used in the manufacture of plastics, paint formulations and other products. Acrylate copolymer is a general term for copolymers of two or more monomers consisting of acrylic acid, methacrylic acid or one of their simple esters.

Based largely on its high molecular weight, acrylamide/sodium acrylate copolymer are not expected to bioaccumulate or bioconcentrate. It is of low toxicity to environmental receptors and is not expected to degrade substantially under environmental conditions.

2. CHEMICAL NAME AND 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 g/mol (Hamilton *et al.*, 1997).

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[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

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

3. PHYSICO-CHEMICAL PROPERTIES

No information is available.

4. DOMESTIC AND INTERNATIONAL REGULATORY INFORMATION

A review of international and national environmental regulatory information was undertaken (Table 1). This chemical is listed on the Australian Inventory of Chemical Substances – AICS (Inventory). No conditions for its use were identified. No specific environmental regulatory controls or concerns were identified within Australia and internationally for acrylamide/sodium acrylate copolymer.

NICNAS has assessed acrylamide/sodium acrylate copolymer (CAS No. 25085-02-3), acrylamide, sodium acrylate polymer (CAS No. 25987-30-8) and 2-propenoic acid, potassium salt, polymer with 2-propenamide (CAS No. 31212-13-2) in an IMAP Tier 1 assessment and considers each a polymer of low concern[2].

Table 1 Existing International Controls

Convention, Protocol or other international control	Listed Yes or No?
Montreal Protocol	No
Synthetic Greenhouse Gases (SGG)	No
Rotterdam Convention	No
Stockholm Convention	No
REACH (Substances of Very High Concern)	No
United States Endocrine Disrupter Screening Program	No
European Commission Endocrine Disruptors Strategy	No

5. ENVIRONMENTAL FATE SUMMARY

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.

6. ENVIRONMENTAL EFFECTS SUMMARY

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

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[2] https://www.nicnas.gov.au/chemical-information/imap-assessments/how-chemicals-are-assessed/Low-concern-polymers.

weight, it is not expected to be bioavailable. It does not contain any reactive functional groups (*i.e.*, cationic groups).

7. CATEGORISATION AND OTHER CHARACTERISTICS OF CONCERN

A. PBT Categorisation

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2017).

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.

B. Other Characteristics of Concern

No other characteristics of concern were identified for acrylamide/sodium acrylate copolymer.

8. SCREENING ASSESSMENT

Chemical Name	CAS No.	Overall PBT Assessment [1]	Chemical Databases of Concern Assessment Step		Persistence Assessment Step		Bioaccumulative Assessment Step	Toxicity Assessment Step			Risk Assessment Actions Required[3]
			Listed as a COC on relevant databases?	Identified as Polymer of Low Concern	P criteria fulfilled?	Other P Concerns	B criteria fulfilled?	T criteria fulfilled?	Acute Toxicity [2]	Chronic Toxicity[2]	
Acrylamide/sodium acrylate copolymer	25085-02-3	Not a PBT	No	Yes	Yes	No	No	No	1	1	1
2-Propenoic acid, potassium salt, polymer with 2-propenamide	31212-13-2	Not a PBT	No	Yes	Yes	No	No	No	1	1	1
Acrylamide, sodium acrylate polymer	25987-30-8	Not a PBT	No	Yes	Yes	No	No	No	1	1	1
Acrylate Terpolymer	903573-39-7	Not a PBT	No	No	Yes	No	No	No	1	1	1
Silicone based emulsion neutralised polyacrylic based stabiliser	NS	Not a PBT	No	No	Yes	No	No	No	1	1	1

Footnotes:

1 - PBT Assessment based on PBT Framework.

2 - Acute and chronic aquatic toxicity evaluated consistent with assessment criteria (see Framework).

3 – Tier 1 – Hazard Assessment only.

Notes:

NA = not applicable

NS = not supplied

CAS No. = chemical abstracts service number

COC = chemical of concern

PBT = Persistent, Bioaccumulative and Toxic

B = bioaccumulative

P = persistent

T = toxic

9. REFERENCES, ABBREVIATIONS AND ACRONYMS

A. 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. Available: http://www.nepc.gov.au/resource/chemical-risk-assessment-guidance-manuals

European Chemicals Agency (ECHA). (2017). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland. Available: https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

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.

B. Abbreviations and Acronyms

AICS	Australian Inventory of Chemical Substances
CAS No.	Chemical Abstracts Service Number (also referred to as CAS RN)
COC	chemical of concern
DEWHA	Department of the Environment, Water, Heritage and the Arts
ECHA	European Chemicals Agency
EU	European Union
IMAP	Inventory Multi-tiered Assessment and Prioritisation
IUPAC	International Union of Pure and Applied Chemistry
Kl	Klimisch scoring system
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SGG	Synthetic Greenhouse Gases

Appendix 4 – Example Tier 2 Toxicological Profile

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).

Screening Assessment Conclusion – Amine oxides, cocoalkyldimethyl was not identified in chemical databases used by NICNAS as an indicator that the chemical is of concern and is not a PBT substance. Amine oxides, cocoalkyldimethyl was assessed as a tier 2 chemical for acute and chronic toxicity of fish and invertebrates, a tier 3 chemical for acute and chronic toxicity of algae. Based on its potential for rapid degradation in the environment, it is not expected to pose a substantial toxic concern to environmental receptors. Therefore, amine oxides, cocoalkyldimethyl are classified overall as **tier 2** chemicals and require a hazard assessment and qualitative assessment of risk.

1 BACKGROUND

Amine oxides are surfactants commonly used in consumer products such as shampoos, conditioners, detergents, and hard surface cleaners. Alkyl dimethyl amine oxide (chain lengths C10–C16) is the most commercially used amine oxide. They serve as stabilizers, thickeners, emollients, emulsifiers, and conditioners with active concentrations in the range of 0.1–10 percent (%). The remainder (< 5%) is used in personal care, institutional, commercial products and for unique patented uses.

Amine oxides, cocoalkyldimethyl is readily biodegradable. It has a low potential for bioaccumulation and a moderate potential for absorption to soil and sediment.

In general, amine oxides, cocoalkyldimethyl does not exhibit significant acute oral or dermal toxicity. It appears to be a skin and eye irritant but it is not a skin senistiser. It is not a reproductive or developmental toxicant, genotoxic or expected to be a carcinogen. Overall, amine oxides, cocoalkyldimethyl is moderately toxic to aquatic organisms.

2 CHEMICAL NAME AND IDENTIFICATION

Chemical Name: Coco alkyldimethylamine oxides

CAS RN: 61788-90-7

Molecular formula: $CH_3.(CH_2)_R.N(CH_3)_2:O$ where R is 9-17 (UVCB substance)

Molecular weight: Unspecified (UVCB substance)

Synonyms: Cocamine oxide; coco dimethylamine oxide; coconutdimethylamineoxide; N-(cocoalkyl)-dimethylamine oxide; N,N-dimethylcocamino oxide.

3 PHYSICO-CHEMICAL PROPERTIES

Specific physico-chemical properties on amine oxides, cocoalkyldimethyl are unavailable. Therefore, key physical and chemical properties for the surrogate substance Amines, C10-16-Alkyldimethyl, N-oxides, Average Chain Length 12.6* (CAS No. 70592-80-2), are shown in Table 1.

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 (pressure not provided)	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
Water solubility	410 g/L	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.

4 DOMESTIC AND INTERNATIONAL REGULATORY INFORMATION

A review of international and national environmental regulatory information was undertaken (Table 2). This chemical is listed on the Australian Inventory of Chemical Substances – AICS (Inventory). No conditions for its use were identified. No specific environmental regulatory controls or concerns were identified within Australia and internationally for amine oxides, cocoalkyldimethyl.

Table 2 Existing International Controls

Convention, Protocol or other international control	Listed Yes or No?
Montreal Protocol	No
Synthetic Greenhouse Gases (SGG)	No
Rotterdam Convention	No
Stockholm Convention	No
REACH (Substances of Very High Concern)	No
United States Endocrine Disrupter Screening Program	No
European Commission Endocrine Disruptors Strategy	No

5 ENVIRONMENTAL FATE SUMMARY

A. Summary

Amine oxides, cocoalkyldimethyl is readily biodegradable. It has a low potential for bioaccumulation and a moderate potential for absorption to soil and sediment.

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].

If a chemical is found to be inherently biodegradable or 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 amine oxides, cocoalkyldimethyl. Based on read-across from amines, C12-14 (even numbered)-alkyldimethyl, N-oxides (CAS No. 308062-28-4), a normalised organic carbon to water partition coefficient (K_{oc}) value of 1,525 L/kg was identified (ECHA). Based on this estimated value, amine oxides, cocoalkyldimethyl is expected to have low mobility in soil. If released to water, based on the K_{oc} value and its water solubility, it is expected to adsorb to suspended solids and sediment.

D. Bioaccumulation

There are no bioaccumulation studies on amine oxides, cocoalkyldimethyl. Amine oxides, cocoalkyldimethyl is not expected to bioaccumulate based on a log n-octanol/water partition coefficient (K_{ow}) of <2.7 (OECD, 2006).

6 HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

In general, amine oxides, cocoalkyldimethyl does not exhibit significant acute oral or dermal toxicity. It appears to be a skin and eye irritant but it is not a skin senistiser. It is not a reproductive or developmental toxicant, genotoxic or expected to be a carcinogen.

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

Oral

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].

Inhalation

No inhalation studies available.

Dermal

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 senistiser 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 40 and 39 mg/kg BW/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 3.

Table 3 *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).

<u>*In Vivo* Studies</u>

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.

<u>Oral</u>

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].

<u>Dermal</u>

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 based on decreased body weight. The NOAEL for developmental toxicity is > 160 mg/kg-day, the highest dose tested (OECD, 2006) [Kl. score = 1].

K. 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).

Non-Cancer

In a 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

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.

L. Human Health Hazard Assessment of Physico-Chemical Properties

Amine oxides, cocoalkyldimethyl does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

7 ENVIRONMENTAL EFFECTS SUMMARY

A. Summary

Overall, amine oxides, cocoalkyldimethyl is moderately toxic to aquatic organisms. Based on hazard data, freshwater green algae are considered the most sensitive species, for acute and chronic endpoints. Acute toxicity is affected by chain length for fish and invertebrates.

B. Aquatic Toxicity

Acute Studies

Table 4 lists the results of acute aquatic toxicity studies conducted on amine oxides, cocoalkyldimethyl.

Table 4 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].

As noted with acute toxicity, green algae are the most sensitive for chronic endpoints, with a 72-hr EC_{20} value of 0.09 mg/L for *Selenastrum capricornutum*. (The geometric mean of 12 studies for the group was 0.11 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)C50 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 $\text{PNEC}_{\text{water}}$ is 0.009 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, a PNEC_{sed} was calculated using the equilibrium partitioning method. The PNEC_{sed} is 0.21 mg/kg sediment wet weight.

The calculations are as follows:

$\text{PNEC}_{\text{sed}} = (\text{K}_{\text{sed-water}}/\text{BD}_{\text{sed}}) \times 1000 \times \text{PNEC}_{\text{water}}$
$= 30.08/1280 \times 1000 \times 0.009$
$= 0.2115$ mg/kg

Where:
$\text{K}_{\text{sed-water}}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 kg/m^3[default]
$\text{PNEC}_{\text{water}}$ = 0.009 mg/L

$\text{K}_{\text{sed-water}} = 0.8 + [(0.2 \times \text{Kp}_{\text{sed}})/1000 \times \text{BD}_{\text{solid}}]$
$= 0.8 + [(0.2 \times 61)/1000 \times 2400]$
$= 30.08\ \text{m}^3/\text{m}^3$

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

$\text{Kp}_{\text{sed}} = \text{K}_{\text{oc}} \times \text{f}_{\text{oc}}$
$= 1525 \times 0.04$
$= 61$ L/kg

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).
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 0.18 mg/kg soil dry weight.

The calculations are as follows:

$$
\begin{aligned}
PNEC_{soil} &= (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water} \\
&= (30.5/1500) \times 1000 \times 0.009 \\
&= 0.18 \text{ mg/kg dw}
\end{aligned}
$$

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

$$
\begin{aligned}
Kp_{soil} &= K_{oc} \times f_{oc} \\
&= 1525 \times 0.02 \\
&= 30.5 \ m^3/m^3
\end{aligned}
$$

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).
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

8 CATEGORISATION AND OTHER CHARACTERISTICS OF CONCERN

A. PBT Categorisation

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2017).

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. Thus, amino oxides, cocoalkyldimethyl meets the screening criteria for toxicity.

The overall conclusion is that amine oxides, cocoalkyldimethyl is not a PBT substance.

B. Other Characteristics of Concern

No other characteristics of concern were identified for amine oxide cocoalkyldimethyl.

9 SCREENING ASSESSMENT

Chemical Name	CAS No.	Overall PBT Assessment [1]	Chemical Databases of Concern Assessment Step		Persistence Assessment Step		Bioaccumulative Assessment Step	Toxicity Assessment Step			Risk Assessment Actions Required[3]
			Listed as a COC on relevant databases?	Identified as Polymer of Low Concern	P criteria fulfilled?	Other P Concerns	B criteria fulfilled?	T criteria fulfilled?	Acute Toxicity [2]	Chronic Toxicity[2]	
Amine oxides cocoalkyldimethyl	61788-90-7	Not a PBT	No	No	No	No	No	Yes	2 (fish, inv) 3 (algae)	2 (fish, inv) 3 (algae)	2

Footnotes:

1 - PBT Assessment based on PBT Framework.

2 - Acute and chronic aquatic toxicity evaluated consistent with assessment criteria (see Framework).

3 - Tier 2 - Hazard Assessment and Qualitative Assessment Only. Develop toxicological profile and PNECs for water and soil and provide qualitative discussion of risk.

Notes:

CAS No. = chemical abstracts service number

COC = chemical of concern

PBT = Persistent, Bioaccumulative and Toxic

B = bioaccumulative

P = persistent

T = toxic

10 REFERENCES, ABBREVIATIONS AND ACRONYMS

A. 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. Updated March 2021. Available: https://www.nhmrc.gov.au/about-us/publications/australian-drinking-water-guidelines

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. Available: http://www.nepc.gov.au/resource/chemical-risk-assessment-guidance-manuals

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. Available: www.environment.gov.au/water/coal-and-coal-seam-gas/national-assessment-chemicals/consultation-risk-assessment-guidance-manual

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. Available: https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-publicat-environ.htm

European Chemicals Agency [ECHA] (2017). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland. Available: https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

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: 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: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

B. Abbreviations and Acronyms

°C	degrees Celsius
ADWG	Australian Drinking Water Guidelines
AICS	Australian Inventory of Chemical Substances
CAS No.	Chemical Abstracts Service Number (also referred to as CAS RN)
COC	chemical of concern
DEWHA	Department of the Environment, Water, Heritage and the Arts
EC_{50}	median effective concentration
ECHA	European Chemicals Agency
EU	European Union
HHRA	enHealth Human Risk Assessment
IUPAC	International Union of Pure and Applied Chemistry
kg	kilograms
kg/m^3	kilograms per cubic metre
Kl	Klimisch scoring system
kPa	kilopascal
L	litre
L/kg	litres per kilogram
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOAEL	lowest observed adverse effect level
m^3	cubic metre
mg/kg	milligrams per kilogram
mg/L	milligrams per litre
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No Effect Concentration

ppm	parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RfD	Reference Dose
SGG	Synthetic Greenhouse Gases
SIDS	Screening Information Dataset
TG	Test Guideline
USEPA	United States Environmental Protection Agency

Appendix 5 – Example Tier 3 Toxicological Profile

ALUMINIUM HYDROXYCHLORIDE

This dossier on aluminium hydroxychloride presents the most critical studies pertinent to the risk assessment of aluminium hydroxychloride in water treatment systems. 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).

Screening Assessment Conclusion – Aluminium hydroxychloride was not identified in chemical databases used by NICNAS as an indicator that the chemical is of concern and is not a PBT substance. However, aluminium hydroxychloride was assessed as a tier 3 chemical for acute toxicity and as a tier 3 chemical for chronic toxicity. Therefore, aluminium hydroxychloride is classified overall as a **tier 3** chemical and requires a quantitative risk assessment for end uses.

1 BACKGROUND

Aluminium hydroxychloride is very soluble in water and will dissociate to form aluminium hydroxide species and chloride ions. Biodegradation is not applicable to Aluminium hydroxychloride. The Aluminium hydroxide hydrolysis products will adsorb to colloidal matter. Aluminium hydroxychloride is not expected to bioaccumulate in aquatic organisms. Aluminium hydroxychloride has low acute toxicity by the oral and dermal routes. It is non-irritating to the skin and slightly irritating to the eyes. It is not a skin sensitiser. No systemic, reproductive, or developmental toxicity was seen in rats at oral doses up to 1,000 mg/kg-day Aluminium hydroxychloride in a combined repeated dose toxicity and reproductive/developmental toxicity screening (OECD 422) study. Aluminium hydroxychloride is not genotoxic. The Australian drinking water guideline (ADWG) values for aluminium (acid-soluble) is 0.2 mg/L based on aesthetics. ADWG has concluded that there is insufficient data to set a guidance value based on health considerations. The ANZECC water quality guideline (2000) used acute and chronic laboratory toxicity data for the derivation of trigger values for aluminium, which are 55 µg/L at pH >6.5 and 0.8 µg/L at pH of <6.5.

2 CHEMICAL NAME AND IDENTIFICATION

Chemical Name (IUPAC): Aluminium(3+) ion dichloride hydroxide

CAS RN: 1327-41-9

Molecular formula: General formula $Al(OH)_x(Cl)_{(3-x)}$, with x ranging from >0 to 2.3 and typically being >0.5.

Molecular weight: variable

Synonyms: Aluminium hydroxychloride; polyaluminium chloride; aluminium chloride, basic; aluminium(3+) ion dichloride hydroxide

3 PHYSICO-CHEMICAL PROPERTIES

Key physical and chemical properties for the substance are shown in Table 1.

Table 1 Overview of the Physico-chemical Properties of Aluminium Hydroxychloride (as Aqueous Solution)

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Clear yellow liquid.	1	ECHA
Melting Point	<-90°C	1	ECHA
Boiling Point	70 – 170°C*	1	ECHA
Density	1.36 g/cm^3	1	ECHA
Partition Coefficient (log K_{ow})	Not applicable	-	-
Water Solubility	>1,000 g/L @ 20°C (pH of sample was 2.4)	1	ECHA
Flash Point	No flash point was observed.	1	ECHA
Auto flammability	Not auto-ignitable	1	ECHA

*Assigned to boiling of water in the test sample.

4 DOMESTIC AND INTERNATIONAL REGULATORY INFORMATION

A review of international and national environmental regulatory information was undertaken (Table 2). This chemical is listed on the Australian Inventory of Chemical Substances – AICS (Inventory). No conditions for its use were identified. No specific environmental regulatory controls or concerns were identified within Australia and internationally for aluminium hydroxychloride.

Table 2 Existing International Controls

Convention, Protocol or other international control	Listed Yes or No?
Montreal Protocol	No
Synthetic Greenhouse Gases (SGG)	No
Rotterdam Convention	No
Stockholm Convention	No
REACH (Substances of Very High Concern)	No
United States Endocrine Disrupter Screening Program	No
European Commission Endocrine Disruptors Strategy	No

5 ENVIRONMENTAL FATE SUMMARY

Aluminium hydroxychloride is highly soluble and dissociates rapidly in aqueous solution. It is not expected to bioaccumulate and as an inorganic substance does not biodegrade. Further environmental fate details are provided below.

A. Summary

Aluminium hydroxychloride is very soluble in water and will dissociate to form aluminium hydroxide species and chloride ions. Biodegradation is not applicable to aluminium hydroxychloride. The aluminium hydroxide hydrolysis products will adsorb to colloidal matter. Aluminium hydroxychloride is not expected to bioaccumulate in aquatic organisms.

B. Biodegradation

Biodegradation testing is not relevant for this substance as it is inorganic in nature and expected to dissociate in the environment.

C. Bioaccumulation

Fish accumulate aluminium in and on the gill, and it has been suggested that the rate of transfer of aluminium into the body is either slow or negligible under natural environmental conditions (Spry and Wiener, 1991). The initial uptake of aluminium by fish occurs mainly on the gill mucous layer (Wilkinson and Campbell, 1993); both mucus and bound aluminium may be rapidly eliminated following exposure. Roy (1999) calculated the BCFs in fish to range from 400 to 1,365 L/kg.

The BCF for *Daphnia magna* varied from 10,000 L/kg at pH 6.5 to 0 at pH 4.5, based on the results of Havas (1985). Most of the metal appears to be adsorbed to external surfaces and is not internalised (Havas, 1985; Frick and Hermann, 1990).

The accumulation of aluminium by the algae *Chlorella pyrenoidosa* increased with the concentration of inorganic monomeric aluminium (Parent and Campbell, 1994). A comparison of assays performed at different pH values but the same concentration of aluminium showed suppression of that aluminium accumulation at low pH.

6 HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Aluminium hydroxychloride has low acute toxicity by the oral, dermal and inhalation routes. It is non-irritating to the skin, but severely irritating to the eyes. It is not a skin sensitiser. No systemic, reproductive or developmental toxicity was seen in rats at oral doses up to 1,000 mg/kg-day aluminium hydroxychloride in a combined repeated dose toxicity and reproductive/developmental toxicity screening (OECD 422) study. Aluminium hydroxychloride is not genotoxic.

B. Acute Toxicity

The oral LD_{50} of aluminium hydroxychloride in rats is >2,000 mg/kg (ECHA). [Kl. score = 2]

The 4-hour LC_{50} in rats is >5 mg/L as aerosol (ECHA). [Kl. score = 2]

The dermal LD_{50} of aluminium hydroxychloride in rats is >2,000 mg/kg (ECHA). [Kl. score = 2]

C. Irritation

Application of 0.5 mL of aluminium hydroxychloride to the skin of rabbits for 4 hours under semi-occlusive conditions was not irritating. The mean of the 24, 48 and 72 hour scores were zero for both erythema and edema (ECHA). [Kl. score = 1]

Instillation of 0.1 mL of aluminium hydroxychloride (low basicity) to the eyes of rabbits was severely irritating/corrosive. The mean of the 24, 48 and 72 hour scores were: 1.45 for corneal opacity; 0.89 for iridial lesions; 2.67 for conjunctival redness; and 2.55 for chemosis. The effects were not completely reversible within 21 days. One animal was killed due to the severity of the eye effects (ECHA). [Kl. score = 2]

D. Sensitisation

Aluminium hydrochloride was not a skin sensitiser in a guinea pig maximisation test using the Magnusson and Kligman method (ECHA). [Kl. score = 2]

E. Repeated Dose Toxicity

Oral

Aluminium hydroxychloride was tested in a combined repeated dose toxicity and reproductive/developmental screening toxicity (OECD 422) study. Male and female Wistar rats were dosed by oral gavage with 0, 40, 200, or 1,000 mg/kg aluminium hydroxychloride; these doses correspond to 0, 3.6, 18 or 90 mg/kg-day aluminium. There were no effects in the females at any dose level. In males, there were effects indicative of stomach irritation at the high-dose; no other effects were noted. The NOAEL for systemic effects in this study is 1,000 mg/kg-day, the highest dose tested. The NOAEL for localised effects (site-of-contact) is 200 mg/kg-day (ECHA). [Kl. score = 2]

Inhalation

No adequate studies are available.

Dermal

No studies are available.

F. Genotoxicity

The *in vitro* genotoxicity studies on aluminium hydroxychloride are presented in Table 3.

In Vitro Studies

Table 3 *In Vitro* Genotoxicity Studies on Aluminium Hydroxychloride

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
Micronucleus (peripheral human lymphocytes)	-	-	1	ECHA

*+, positive; -, negative

In Vivo Studies

No studies are available on aluminium hydroxychloride.

G. Carcinogenicity

No studies are available.

H. Reproductive/Developmental Toxicity

Aluminium hydroxychloride was tested in a combined repeated dose toxicity and reproductive/developmental screening toxicity (OECD 422) study. Male and female Wistar rats were dosed by oral gavage with 0, 40, 200 or 1,000 mg/kg aluminium hydroxychloride; these doses correspond to 0, 3.6, 18 or 90 mg/kg-day aluminium. There was no reproductive or developmental toxicity at any dose level. The NOAELs for reproductive and developmental toxicity is 1,000 mg/kg-day, the highest dose tested (ECHA). [Kl. score = 1]

I. Derivation of Toxicological Reference and Drinking Water Guidance Values

Toxicological reference values were not derived for aluminium hydroxychloride.

The Australian drinking water guideline values for aluminium (acid-soluble) is 0.2 mg/L based on aesthetics. ADWG has concluded that there is insufficient data to set a guidance value based on health considerations (ADWG, 2011).

The Australian drinking water guidance value for chloride is 250 mg/L based on aesthetics (ADWG, 2011).

J. Human Health Hazard Assessment Of Physico-Chemical Properties

Aluminium hydroxychloride does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

7 ENVIRONMENTAL EFFECTS SUMMARY

A. Summary

Acute toxicity values for a variety of organisms are provided below and have, where possible, been converted to equivalence of aluminium. In general, acute toxicity values are pH dependent and range from LC_{50} of less than 1 mg/L to greater than 100 mg/L. Values used by ANZECC to derive water quality guidelines range from less than 1 to over 100 mg/L. Only acute values were used by ANZECC to derive the water quality trigger value of 55 µg/L for aluminium at pH >6.5.

B. Aquatic Toxicity

Acute Studies on Aluminium Polychlorohydrate

The 96-hr LC_{50} for aluminium polychlorohydrate in *Danio rerio* was determined to be 142 mg/L nominal. For dissolved aluminium, the 96-hr LC_{50} was 0.58 mg/L. A very steep concentration-effect relationship was observed for the test substance; this was due to the increase in solubility of aluminium as a result of the drop in pH from the increasing concentration of the test substance (ECHA). [Kl. score = 2]

The 96-hr LC_{50} for aluminium polychlorohydrate in *Danio rerio* was determined to be 186 mg/L nominal. For dissolved aluminium, the 96-hr LC_{50} was 1.39 mg/L, corresponding to 16.9 mg/L Total Al (measured values). A very steep concentration-effect relationship was observed for the test substance; this was due to the increase in solubility of aluminium as a result of the drop in pH from the increasing concentration of the test substance. Theoretically, 186 mg/L of aluminium polychlorohydrate reduced the pH of reconstituted water to a level which enabled 1.4 mg Al/L to be dissolved. (ECHA). [Kl. score = 2]

The 96-hr EC_{50} and NOEC for aluminium polychlorohydrate in *Danio rerio* were determined to be >0.357 mg/L measured as dissolved Al (equivalent to 91.5 Total Al). The NOEC was >1,000 mg/L nominal, which is equivalent to 91.5 mL Total Al. In this study, the pH of the test media was maintained at 7.5 (ECHA). [Kl. score = 1]

The 48-hr EC_{50} for aluminium polychlorohydrate in *Daphnia magna* is 98 mg/L nominal and 7.8 mg/L measured (ECHA) [Kl. score = 2]. Another study reported 48-hr EC_{50} values for aluminium chlorohydrate of 38 mg/L nominal and 3.45 mg/L measured (ECHA) [Kl. score = 2].

The 72-hr EC_{50} for growth rate in *Pseudokidrchneriella subcapitata* was 14 mg/L nominal, which was equivalent to 0.644 mg/L as Total Al. The average measured concentrations of dissolved Al were 0.24 mg/L at a pH between 7.1 and 8.4. The EC_{10} for growth rate was 0.14 mg/L as Total Al and 0.051 mg/L based on measured Al. The NOEC for growth inhibition was nominally 1.0 mg/L (0.046 mg/l based on Total Al) and <0.02 mg/L when based on measured Al (ECHA). [Kl. score = 1]

Data used by ANZECC for Aluminium water quality guideline

In developing a water quality guideline for aluminium (ANZECC & ARMCANZ, 2000), ANZECC separated the screened freshwater toxicity data into those conducted at pH >6.5 and those at pH <6.5. These data are summarised below (it should be noted that only the acute toxicity data was used to derive a water quality guideline).

Freshwater pH >6.5:

Fish

The 48-96 hour LC_{50} values for 5 species were 600 to 106,000 µg/L (the lowest value was for *Salmo salar*). The chronic 8- to 28-day NOEC equivalents[1] from seven species were 34-7,100 µg/L. The lowest measured chronic value was an 8-day LC_{50} for *Micropterus* species of 170 µg/L.

Amphibian

The 96-hour LC_{50} values for *Bufo americanus* were 860-1,660 µg/L. The chronic 8-day LC_{50} for *Bufo americanus* was 2,280 µg/L.

Crustacean

The 48-hour LC_{50} values for one species were 2,300-36,900 µg/L. The chronic 7- to 28-day NOECs were 136-1,720 µg/L.

Algae

The 96-hour EC_{50} values were 460-570 µg/L based on population growth. The NOECs for two species were 800-2,000 µg/L.

Freshwater pH<6.5 (all between pH 4.5 and 6.0):

Fish

The 24-96-hour LC_{50} values for two species were 15-4,200 µg/L (the lowest value was for *Salmo trutta*). The 21- to 42-day LC_{50} values were 15-105 µg/L.

Amphibian

The 96- to 120-day LC_{50} values were 540-2,670 µg/L; the absolute range was 400-5,200 µg/L.

Algae

The NOEC from one species was 2,000 µg/L based on growth.

[1] Chronic toxicity values were a mixture of LC/EC_{50} LOEC, MATC, and NOEC values; where stated, these were converted to NOEC equivalents.

C. Terrestrial Toxicity

A study equivalent to the earthworm acute toxicity (OECD TG 207) test was conducted on sulfuric acid, aluminium salt (3:2), octadecahydrate (CAS No. 7784-31-8). The 14-day LC_{50} to earthworm *Eisenia andrei* is 316 mg/kg soil dry weight (van Gestel and Hoogerwerf, 2001; ECHA). [Kl. score = 2]

D. Calculation of PNEC

The ANZECC and ARMCANZ water quality guideline (2000) used acute and chronic laboratory toxicity data for the derivation of trigger values for aluminium. The guideline for freshwater is: “A freshwater moderate reliability trigger value of 55 µg/L for aluminium at pH >6.5 using the statistical distribution method (Burr distribution as modified by SCIRO, Section 8.3.3.3) with 95% protection and an ACR of 8.2.”

“A freshwater low-reliability trigger value of 0.8 µg/L was derived for aluminium at pH of <6.5 using an AF of 20 (essential element) on the low pH trout figure.”

“The low-reliability figures should only be used as indicative interim working levels.”

PNEC sediment

No experimental toxicity data on sediment organisms are available. Octanol/water partition coefficient (K_{ow}) and organic carbon-water partition coefficient (K_{oc}) parameters do not readily apply to inorganics, such as aluminium hydroxychloride. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sed}$. Based on its properties, no adsorption of aluminium hydroxychloride 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. The environmental distribution of aluminium hydroxychloride is dominated by its water solubility. Sorption of aluminium hydroxychloride 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 aluminium hydroxychloride. Thus, the equilibrium partitioning methods cannot be used to calculate the $PNEC_{soil}$. Based on its properties, aluminium hydroxychloride is not expected to significantly adsorb to soil, and the assessment of this compartment will be covered by the aquatic assessment.

8 CATEGORISATION AND OTHER CHARACTERISTICS OF CONCERN

A. PBT Categorisation

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2017).

Aluminium hydroxychloride is an inorganic compound that dissociates in water to form chloride ions and various species of aluminium hydroxide hydrolysis. Biodegradation is not applicable to aluminium hydroxychloride. Both chloride ions and aluminium hydroxide ionic species can be found naturally in the environment. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to this inorganic compound.

Fish accumulate aluminium in and on the gill, and it has been suggested that the rate of transfer of aluminium into the body is either slow or negligible under natural environmental conditions. Chloride ions are essential to all living organisms, and their intracellular, and extracellular concentrations are actively regulated. Thus, aluminium hydroxychloride and its dissociated ions are not expected to meet the criteria for bioaccumulation.

The lowest chronic NOEC value in fish for aluminium is <0.1 mg/L; thus, the dissolved aluminium from aluminium hydroxychloride meets the screening criteria for toxicity.

The overall conclusion is that aluminium hydroxychloride is not a PBT substance.

B. Other Characteristics of Concern

Only tier 3 chemicals which trigger persistence and bioacummulative thresholds are considered to be chemicals with a potential for cumulative impacts. As noted in the prior section, aluminium hydroxychloride does not meet the criteria for persistence or bioaccumulation.

No other characteristics of concern were identified for aluminium hydroxychloride.

9 SCREENING ASSESSMENT

Chemical Name	CAS No.	Overall PBT Assessment [1]	Chemical Databases of Concern Assessment Step		Persistence Assessment Step		Bioaccumulative Assessment Step	Toxicity Assessment Step			Risk Assessment Actions Required[3]
			Listed as a COC on relevant databases?	Identified as Polymer of Low Concern	P criteria fulfilled?	Other P Concerns	B criteria fulfilled?	T criteria fulfilled?	Acute Toxicity [2]	Chronic Toxicity[2]	
Aluminium Hydroxychloride	1327-41-9	Not a PBT	No	No	NA	No	No	Yes	3	3	3

Footnotes:

1 - PBT Assessment based on PBT Framework.

2 - Acute and chronic aquatic toxicity evaluated consistent with assessment criteria (see Framework).

3 - Tier 3 - Quantitative Risk Assessment: Complete PBT, qualitative and quantitative assessment of risk.

Notes:

CAS No. = chemical abstracts service number

COC = chemical of concern

NA = not applicable

PBT = Persistent, Bioaccumulative and Toxic

B = bioaccumulative

P = persistent

T = toxic

10 REFERENCES, ABBREVIATIONS AND ACRONYMS

A. 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. Updated February 2016. Available: https://www.nhmrc.gov.au/about-us/publications/australian-drinking-water-guidelines

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. Available: https://www.waterquality.gov.au/anz-guidelines/resources/previous-guidelines/anzecc-armcanz-2000

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. Available: http://www.nepc.gov.au/resource/chemical-risk-assessment-guidance-manuals

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

European Chemicals Agency [ECHA]. (2017). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland. Available: https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

Frick, K.G., and Herrmann J. (1990). Aluminium accumulation in a lotic mayfly at low pH — a laboratory study. Ecotoxicol. Environ. Safety 19: 81–88.

Havas, M. (1985). Aluminium bioaccumulation and toxicity to *Daphnia magna* in soft water at low pH. Can. J. Fish. Aquat. Sci. 42: 1741–1748.

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.

Magnusson B. and Kligman A.M. (1969). The identification of contact allergens by animal assay. The guinea pig maximisation test. Journal of Investigative Dermatology., 52, 268.

Parent, L., and Campbell, P.G.C. (1994). Aluminium bioavailability to the green alga *Chlorella pyrenoidosa* in acidified synthetic soft water. Environ. Toxicol. Chem. 13: 587–598.

Roy R. (1999). The chemistry, bioaccumulation and toxicity of aluminium in the aquatic environment for the PSL2 assessment of aluminium salts. Report prepared by Fisheries and Oceans Canada for Environment Canada. Montreal (QC): Environment Canada. 110 pp. Unpublished report.

Spry, D.J., and Wiener, J.G. (1991). Metal bioavailability and toxicity to fish in low-alkalinity lakes — a critical review. Environ. Pollut. 71: 243–304.

van Gestel, C.A.M., and Hoogerwerf, G. (2001). Influence of soil pH on the toxicity of aluminium for Eisenia Andrei (Oligochaeta: Lumbricidae) in an artificial soil substrate. Pedobiologia 45: 385-395).

Wilkinson, K.J., and Campbell, P.G.C. (1993). Aluminium bioconcentration at the gill surface of juvenile Atlantic salmon in acidic media. Environ. Toxicol. Chem. 12: 2083–2095.

B. Abbreviations and Acronyms

°C	degrees Celsius
ADWG	Australian Drinking Water Guidelines
AICS	Australian Inventory of Chemical Substances
ANZECC	Australian and New Zealand Environment and Conservation Council
ARMCANZ	Agriculture and Resource Management Council of Australia and New Zealand
BCF	bioconcentration factor
CAS No.	Chemical Abstracts Service Number (also referred to as CAS RN)
COC	chemical of concern
DEWHA	Department of the Environment, Water, Heritage and the Arts
EC_{50}	median effective concentration
ECHA	European Chemicals Agency
EU	European Union
g/cm^3	grams per cubic centimetre
g/L	grams per litre
IUPAC	International Union of Pure and Applied Chemistry
Kl	Klimisch scoring system
kPa	kilopascal
L/kg	litres per kilogram
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOEC	lowest observed effective concentration
MATC	maximum acceptable toxicant concentration
mg/kg	milligrams per kilogram

mg/L	milligrams per litre
mL	millilitre
NICNAS	The National Industrial Chemicals Notification and Assessment Scheme
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SGG	Synthetic Greenhouse Gases
UVCB	Unknown or Variable Composition, Complex Reaction Products and Biological Materials
μg/L	micrograms per litre

Appendix 6 – Example Tier 2 Qualitative Risk Assessment

Qualitative Tier 2 Assessment

Ammonium Hydroxide

In accordance with the Dawson River Release (DRR) Chemical Risk Assessment Framework (CRAF), chemicals assigned a Tier 2 designation require a hazard assessment and qualitative assessment of risk.

Consistent with National Industrial Chemicals Notification and Assessment Scheme (NICNAS), the human health hazards for each chemical are characterised by analysing the toxicokinetics (the absorption, distribution, metabolism and excretion of the chemical in humans or laboratory animals), acute toxicity, irritation and corrosivity, repeat dose toxicity, genotoxicity, carcinogenicity, reproductive toxicity, and other health effects. The environmental hazards for each chemical are characterised by analysing the environmental fate properties (such as mobility, persistence, bioavailability and bioaccumulation), acute toxicity and chronic toxicity. In support of the hazard assessment, a risk assessment dossier is prepared for each of the chemicals included in the assessment.

Potentially complete exposure pathways (in that a source, a migration pathway, a mechanism for exposure, and a potential receptor are present) are qualitatively assessed herein 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 are evaluated. Key controls limiting the potential for exposure include:

- Engineering controls (including fencing and secondary containment);
- Storage (drums, totes and storage tanks) constructed in accordance with Australian standards and managed and monitored in accordance with regulatory requirements;
- Maintenance of access control restrictions during site activities that will preclude access by the public, livestock and large native fauna; and,
- Safe Work Australia and Santos Occupational Safety Guidance used to minimise human health exposure.

This qualitative assessment provides information to be used as a complement to the risk assessment dossier to provide a summary of human and ecological hazards that may occur from exposure to the chemical. Where a potential hazard exists, additional information is provided in the risk assessment dossiers and safety data sheets (SDSs) and are available to emergency responders, health and safety managers, and environmental hazard clean-up teams.

As a result, the assessment for this Tier 2 chemical includes the following components: completing the screening; developing a risk assessment dossier and Predicted No Effect Concentrations (PNECs) for water and soil; and, providing a qualitative discussion of risk. Each of these components is detailed within this memorandum.

Background

Santos has been releasing treated water to the Dawson River since 2015. The Dawson River Release Scheme[1] is located in the southeast region of the Fairview Arcadia Project Area (FAPA) (within the hub compressor station four (HCS4) gathering network). Coal seam water produced in the HCS4 gathering network is collected and is treated at Reverse Osmosis Plant 2 (ROP2) with the treated permeate stored within a permeate pond prior to release to the Dawson River. The outfall location is located within a tributary gully of the Dawson River, which joins the Dawson River midway between "Dawson's Bend" and Yebna Crossing.

The permeate pond is connected to the outfall location by a 5.3 kilometre (km) pipeline constructed across farmland with the released water flowing down a 2.9 km tributary gully before discharging to the Waterbody (nominal capacity 500 megalitre [ML]) and then flowing 1.8 km before joining the Dawson River at its downstream confluence.

ROP 2 at FAPA is a reverse osmosis plant with a specification designed to produce high quality water for the intended release of treated coal seam water to the Dawson River. The process removes the suspended and dissolved solids through a set of six processes to produce high quality treated water. These include coagulation/clarification, oxidation, filtration, softening, reverse osmosis, and finally adjustment of sodium adsorption ratio (SAR).

Ammonia (CAS No. 7664-41-7) dissolves readily in water to form the solution described as ammonium hydroxide (CAS No. 1336-21-6). Ammonium Hydroxide is a component in the Water Management Facility (WMF) product used as a disinfectant during oily water treatment. Process and usage information for this chemical is included in **Attachment 1** and summarised in **Table 1**.

Table 1 Water Management Facility Chemicals

Chemical Name	CAS No.	Use	Approximate Quantity Stored On-Site (plant available storage)
Ammonium hydroxide Water	1336-21-6 7732-18-5	Disinfectant	2 x 1000 L (IBC)

CAS No = Chemical Abstracts Service Number
IBC = intermediate bulk container
L = litre

The assessment of toxicity of this chemical was used to develop initial screening criteria for human health exposure scenarios and is presented in the risk assessment dossier provided in **Attachment 2**. Since an Australian Drinking Water Guideline (ADWG) Value is available for ammonia (see **Table 2**), toxicological reference values (TRVs) were not derived for the chemical. A detailed discussion of the drinking water guideline values is presented in the risk assessment dossier provided in **Attachment 2**.

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[1] Santos obtained an amendment to the Fairview Arcadia Project Area (FAPA) Environmental Authority (EA) (EPPG00928713) on 31st May 2013 to authorise the release of desalinated produced water from the Fairview reverse osmosis plant (ROP) 2 to the Dawson River – the Dawson River Release Scheme (DRRS).

Table 2 Australian Drinking Water Screening Values

Constituent (CAS No.)	Drinking Water Screening Guideline	Drinking Water Screening Value
Ammonia (7664-41-7)	Ammonia	0.5 mg/L (aesthetics)

CAS No = Chemical Abstracts Service Number mg/L = milligram per litre

For ecological receptors, the assessment utilises the information presented in the dossiers on the relative toxicity of the aquatic and terrestrial flora and fauna to the chemical. This assessment focuses on the aquatic invertebrate and fish species within the surface water resources, and the soil flora and fauna associated with releases to the soil.

The determination of TRVs was conducted according to the PNEC guidance in the *Environmental Risk Assessment Guidance Manual for Industrial Chemicals* prepared by the Australian Environmental Agency (AEA, 2009). PNECs for freshwater and sediment were developed to assess aquatic receptors, and PNECs for soil were developed for terrestrial receptors.

Table 3 present the chemical, the endpoint, no observed effect concentration (NOEC) (mg/L), assessment factor, and the aquatic PNEC (mg/L). A PNEC for soil was not calculated for the chemical. Refer to **Attachment 2** regarding the development of PNECs, or the rational for PNECs that do not have a calculated PNEC.

Table 3 PNECs Water – Tier 2

Constituents	Endpoint	EC_{50} or NOEC (mg/L)	Assessment Factor	$PNEC_{water}$ (mg/L)
Ammonia (7664-41-7)	-	-	-	0.9[a]

[a] $PNEC_{water}$ for ammonia is the ANZG Water Quality Guideline – Freshwater Trigger Value for total ammonia-N.
EC_{50} = effects concentration – 50%
mg/L = milligram per litre
NOEC = no observable effects concentration
PNEC = predicted no effect concentration
Refer to **Attachment 2** for information on the development of PNECs listed above.

A detailed assessment of the potential risks posed by this Tier 2 chemical is provided in the following sections.

General Overview

The molecular structure of ammonium hydroxide is presented in **Figure 1** below.

$$NH_4^+ \quad OH^-$$

Figure 1 Molecular Structure of Ammonium Hydroxide[2]

Ammonium hydroxide is a solution of ammonia in water. The term 'ammonia' refers to two chemical species of ammonia that are in equilibrium in water: the un-ionised ammonia, NH_3, and the ionised ammonium ion, NH_4^+. The proportion of the two chemical forms in water varies with the physico-chemical properties of the water, particularly pH and temperature. Under environmental conditions (pH 5-8), the predominant form will be the ammonium ion (NH_4^+). As a result, hereafter within this assessment, the term ammonia refers to ammonium hydroxide, ammonia or the ammonia/ammonium ion.

Ammonia is rapidly converted to nitrate by nitrification under aerobic conditions in the aquatic environment. Ammonia is part of the nitrogen cycle. Biodegradation is not applicable to ammonia. Ammonia is easily mineralised to the nitrite ion (NO_2^-) by numerous species of bacteria. Ammonia is not expected to bioaccumulate in the environment because of its dissociation to the ammonium ion and because it is part of the nitrogen cycles in air, soil and water. Ammonia has a low potential to adsorb to soil and sediment.

The Persistent, Bioaccumulative and Toxic (PBT) assessment for ammonia is included in the dossier provided in **Attachment 2**. Based on physico-chemical properties and screening data detailed below, the overall conclusion was that the chemical is not a PBT substance.

Human Health Hazards

Ammonia has a moderate acute toxicity by the inhalation route. Depending on the concentration, solutions of ammonia 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 ammonia can cause respiratory irritation.

No systemic, reproductive or developmental toxicity was seen in rats at oral doses up to 1,500 milligrams per kilogram-day (mg/kg-day) diammonium phosphate in a combined repeated dose toxicity and reproductive/developmental toxicity screening (OECD 422) study. Ammonia is not genotoxic.

TRVs were not derived for ammonia. The ADWG value for ammonia is 0.5 milligrams per litre (mg/L) based on aesthetics (see **Table 2**). A detailed discussion f the drinking water guideline values is presented in **Attachment 2**.

Based on the treatment process described in **Attachment 1**, residual ammonia would be present in treated water (permeate) but is not directed to the brine pond. Managed release of treated water to

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[2] Source https://chem.nlm.nih.gov/chemidplus/rn/startswith/1336-21-6

the Dawson River would have the potential to affect surface water within the river. As the Dawson River meanders through large areas that are uncontrolled, exposures could potentially occur to downstream agricultural workers and residents.

However, there is low potential for human receptors to be exposed to ammonia in Dawson River discharge. Currently, there is no irrigation in the immediate vicinity of the Waterbody, with the closest irrigation being approximately 5km to the west. There is a water supply scheme in the Dawson River that supplies irrigators but this is located 250 km downstream, with a search of the Department of Natural Resources, Mines and Energy (DNRME) now Department of Resources (DoR), data base indicating that the nearest licensed surface water take for irrigation is 71 km downstream noting this licence provides authority to extract from an ‘Unnamed tributary of the Dawson River’, not the Dawson River. The nearest surface water domestic water supply entitlement is 244 km downstream (AECOM, 2019).

Environmental Hazards

In standard aquatic toxicity tests, ammonia is moderately toxic to a variety of aquatic and terrestrial organisms on both an acute and chronic basis. In general, the effect concentration is on the order of a low to mid part per million range. The chronic no observable effect concentrations (NOECs) reported in ANZG (2018) for ammonia for aquatic species are greater than 1 mg/L, except for a mollusc found in New Zealand. It is unknown whether a similar sensitive species is found in Australia.

Ammonia is part of the nitrogen cycle. Biodegradation is not applicable to ammonia or the ammonium ion. Ammonia is also not expected to bioaccumulate in the environment because of its dissociation to the ammonium ion.

The ANZG (2018) for ammonia in freshwaters is: “A freshwater high reliability trigger value of 900 µg/L TOTAL ammonia-N was calculated at pH 8.0 [emphasis added] using the statistical distribution method with 95% protection. This translates to about 900 µg/L un-ionised ammonia-N at 20°C.” Considering the land uses adjacent to the Dawson River include light to moderate grazing, and there is some development upstream of the Horseshoe Lakes, adoption of the 95% species protection criteria is considered appropriate (AECOM, 2019).

No experimental toxicity data on sediment or soil organisms are available. Octanol/water partition coefficient (K_{ow}) and organic carbon-water partition coefficient (K_{oc}) parameters do not readily apply to inorganics, such as ammonia or the ammonium ion. Thus, the equilibrium partitioning method cannot be used to calculate PNECs for soil or sediment. Based on its properties, ammonia and the ammonium ion are not expected to significantly adsorb to soil, and the assessment of this compartment will be covered by the aquatic assessment.

As described in the previous section (Human Health Hazards), managed release of treated water to the Dawson River would have the potential to affect surface water within the river. As released treated water would become part of the regional surface water resource (i.e., Dawson River water quality and flow), ecological resources (livestock and native flora and fauna) are potential receptors. Specifically, potential receptors include:

- Aquatic ecological receptors within Dawson River downstream of the release point
- Livestock and wildlife that may access Dawson River surface water

Stock access to large portions of the Waterbody is permitted and has been observed. The banks of the Waterbody are severely degraded and lack riparian vegetation due to cattle access/activity. Similarly, cattle access the Dawson River for water at numerous places within and downstream of the receiving environment (frc environmental, 2021).

There is limited extraction of water for general farm supply downstream of the release location to the Dawson River. There is one licensed surface water take for agriculture within the extent of the release location area. Santos is in regular direct communication with the landholder and is not aware of any abstraction being undertaken under this licence to date. In addition, the nearest downstream agricultural area is located approximately 7 km downstream of the release location to the Dawson River.

Biological monitoring has identified the presence of Matters of National Environmental Significance (MNES) receptor white-throated snapping turtle (*Elseya albagula*) in two upstream locations (at site DRR2 on Hutton Creek and at site DRR1 on Dawson River). The presence of MNES receptor Fitzroy River Turtle (*Rheodytes leukops*) has not been identified.

The potential for exposure of sensitive receptors, including MNES, is low. Released treated water mixes with surface water in a manner that is protective of aquatic receptors within the Dawson River (AECOM, 2019). Treated water releases from the permeate ponds are less than 18 megalitre (ML)/day with Santos undertaking periodic releases. Releases are currently dictated by treated effluent production rates. Perennial base flow in the Dawson River downstream of Dawson's Bend at the Dawson River discharge point has been assessed as 21 ML/day. Baseflow in the Dawson River is associated with spring discharges.

Further, estimated permeate concentrations in released treated water (0.0175 mg/L, refer **Attachment 2**) are less than the ANZG freshwater quality guideline value of 0.9 mg/L.

References

AECOM. 2019. Revised Boron Site-Specific Water Quality Criterion – Dawson River Release Scheme. Letter from B. Goldsworthy and N. Lee to A. Lavery. 12 July 2019..

Australian Environmental Agency (AEA). (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia. Available: http://www.nepc.gov.au/resource/chemical-risk-assessment-guidance-manuals

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. Updated March 2021. Available: https://www.nhmrc.gov.au/about-us/publications/australian-drinking-water-guidelines

Australian and New Zealand Guidelines (ANZG). (2018). Australian and New Zealand Guidelines for Fresh and Marine Water Quality. Australian and New Zealand Governments and Australian state and territory governments, Canberra, ACT, Australia. Available: https://www.waterquality.gov.au/anz-guidelines.

frc environmental. 2021. Santos GLNG Dawson River Watercourse Releases: Receiving Environment Monitoring Program. April 2021.

Attachment 1 Vendor WMF Chemicals and Exposure Point Concentration

Attachment 1
Summary of Exposure Point Concentration Development
(Water Treatment Chemicals)

Product Name	Chemical Name	CAS Number	%	Proper Shipping Name	Supplier	Area	Transport		Onsite Storage		Operation		Annual Usage (ROP volumes based on peak rate of 10ML/d)	Purpose / Function
							mass/volume	concentration	mass/volume	concentration	mass/volume	concentration		
Ammonium Hydroxide 10-35%	Ammonium Hydroxide	1336-21-6	10-35%	Ammonia Aqueous Solution	REDOX	Reverse Osmosis Plant	1000L (IBC)	20%	2 x 1000L (IBC)	20%	2 mg/L (AVG)	20%	7300L	used to form monochloramine / disinfectant
	Water	7732-18-5	65-90%											

AVG = average
CAS = Chemical Abstracts Service
COPC = constituent of potential concern
IBC = intermediate bulk container
L = litres
mg/kg = milligrams per kilogram
mg/L = milligrams per litre
ML/d = millilitre per day
NA = not applicable
ROP = reverse osmosis process

Attachment 1
Summary of Exposure Point Concentration Development
(Water Treatment Chemicals)

Product Name	Chemical Name	CAS Number	Fate	Permeate Concentration		Brine Concentration	
				(mg/L)	Permeate notes	(mg/L)	Brine Notes
Ammonium Hydroxide 10-35%	Ammonium Hydroxide	1336-21-6	Unreacted / residual ammonia to Desalinated Water Balance Pond	0.0175	Will stay as ammonia or ammonium (NH_4^+) and approximately 50:50. Therefore, residual ammonia = 2 mg/L * 35%*0.5 = 0.35 mg/L. At a rejection efficiency of 95%, the estimated concentration of ammonia in the permeate is 0.0175 mg/L.	NA	Not directed to brine pond
	Water	7732-18-5		NA		NA	

AVG = average
CAS = Chemical Abstracts Service
COPC = constituent of potential concern
IBC = intermediate bulk container
L = litres
mg/kg = milligrams per kilogram
mg/L = milligrams per litre
ML/d = millilitre per day
NA = not applicable
ROP = reverse osmosis process

Attachment 2 Risk Assessment Dossier

AMMONIA (CAS NO. 7664-41-7)
AMMONIUM HYDROXIDE (CAS NO. 1336-21-6)

This dossier on ammonia and ammonium hydroxide presents the most critical studies pertinent to the risk assessment of ammonia and ammonium hydroxide in their use in water treatment systems. 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) and the OECD-SIDS category for ammonia (OECD, 2007). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

Screening Assessment Conclusion – Ammonia and ammonium hydroxide were not identified in chemical databases used by NICNAS as an indicator that the chemicals are of concern and are not a PBT substance. Ammonia and ammonium hydroxide was assessed as tier 2 chemicals for acute and chronic toxicity. Therefore, ammonia and ammonium hydroxide are classified overall as **tier 2** chemicals and require a hazard assessment and qualitative assessment of risk.

1 BACKGROUND

Ammonia (CAS No. 7664-41-7) dissolves readily in water to form the solution described as ammonium hydroxide (CAS No. 1336-21-6). In water, ammonia is in equilibrium with the ammonium ion (NH_4^+), depending on the pH. Under environmental conditions (pH 5-8), the predominant form will be the ammonium ion (NH_4^+).

Ammonia or ammonium ion is rapidly converted to nitrate by nitrification under aerobic conditions in the aquatic environment. Ammonia is part of the nitrogen cycle. Biodegradation is not applicable to ammonia or the ammonium ion. Ammonia (or the ammonium ion) is easily mineralised to the nitrite ion (NO_2^-) by numerous species of bacteria. Ammonia is not expected to bioaccumulate in the environment because of its dissociation to the ammonium ion and because it is part of the nitrogen cycles in air, soil and water. Ammonia and the ammonium ion have a low potential to adsorb to soil and sediment.

The acute toxicity of ammonia is moderate by the inhalation route. Depending on the concentration, solutions of ammonia 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 ammonia can cause respiratory irritation. No target organ effects were seen in rats given ammonia by oral gavage or in feed for up to two years. Ammonia is not genotoxic. There were no increases in tumours when rats were fed ammonia in their diet for two years. A reproductive and developmental screening toxicity (OECD 422) study showed no reproductive or developmental effects in rats when given oral gavage doses of an aqueous solution of ammonia.

Ammonia is acutely toxic to aquatic life. The ANZG guidelines for fresh and marine water quality (ANZG, 2018) has a freshwaters trigger value of 900 µg/L TOTAL ammonia-N at pH 8.0.

2 CHEMICAL NAME AND IDENTIFICATION

Chemical Name (IUPAC): Ammonia
CAS RN: 7664-41-7
Molecular formula: NH_3
Molecular weight: 17 g/mol

Synonyms: Ammonia, ammonia gas, ammonia anhydrous, liquid ammonia

Chemical Name (IUPAC): Ammonium Hydroxide
CAS RN: 1336-21-6
Molecular formula: H_5NO or NH_4OH
Molecular weight: 35.05 g/mol

Synonyms: Ammonia, aqueous solution; aqua ammonia; ammonia, monohydrate; ammonia liquor; ammonia water

3 PHYSICO-CHEMICAL PROPERTIES

Key physical and chemical properties for the substances are shown in Tables 1 and 2.

Table 1 Overview of the Physico-chemical Properties of Ammonia

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colourless gas	2	ECHA
Melting Point	-77.7°C @ 101.3 kPa	2	ECHA
Boiling Point	-33.15°C @ 101.3 kPa	2	ECHA
Vapour Pressure	861,100 Pa @ 20°C	2	ECHA
Partition Coefficient (log K_{ow})	0.23 @ 20 °C	-	ECHA
Water Solubility	482 g/L @ 25°C	2	ECHA
Dissociation constant (pKa)	9.25@ 25°C	2	ECHA

Table 2 Overview of the Physico-chemical Properties of Ammonium Hydroxide

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colourless aqueous solution	-	PubChem
Melting Point	-77°C @ 101.3 kPa	2	OECD, 2007
Boiling Point	-36°C, pressure not specified	4	OECD, 2007
Vapour Pressure	287,800 Pa @ 20°C	2	OECD, 2007
Partition Coefficient (log K_{ow})	Not applicable	-	OECD, 2007
Water Solubility	Miscible	2	OECD, 2007
Dissociation constant (pKa)	10.6-11.6 @ 25°C	2	OECD, 2007

4 DOMESTIC AND INTERNATIONAL REGULATORY INFORMATION

A review of international and national environmental regulatory information was undertaken (Table 3). This chemical is listed on the Australian Inventory of Chemical Substances – AICS (Inventory). No conditions for its use were identified. No other specific environmental regulatory controls or concerns were identified within Australia and internationally for ammonia.

NICNAS has assessed ammonium hydroxide in an IMAP Tier 1 assessment and concluded that it poses no unreasonable risk to the environment. It is a reactive substance which rapidly converts into species of low ecotoxicological concern. This chemical, and its degradant species, are not expected to pose an unreasonable risk to the environment provided that ANZECC water quality guidelines for physical and chemical stressors are not exceeded[1].

Table 3 Existing International Controls

Convention, Protocol or other international control	Listed Yes or No?
Montreal Protocol	No
Synthetic Greenhouse Gases (SGG)	No
Rotterdam Convention	No
Stockholm Convention	No
REACH (Substances of Very High Concern)	No
United States Endocrine Disrupter Screening Program	No
European Commission Endocrine Disruptors Strategy	No

5 ENVIRONMENTAL FATE SUMMARY

Ammonium hydroxide is a solution of ammonia in water. The term 'ammonia' refers to two chemical species of ammonia that are in equilibrium in water: the un-ionised ammonia, NH_3, and the ionised ammonium ion, NH_4^+. The proportion of the two chemical forms in water varies with the physico-chemical properties of the water, particularly pH and temperature.

The following equilibria occurs at ambient environmental conditions:

$NH^+ + H_2O \leftrightarrow NH_3 + H^+$
$NH_3 + H_2O \leftrightarrow NH_4^+ + OH^-$

Under environmental conditions (pH 5-8), the predominant form will be the ammonium ion (NH_4^+). As pH decreases, the concentration of the ammonium ion will increase, while the un-ionised ammonia concentration will decrease.

Ammonia is volatile and once exposed to open air, liquid ammonia quickly turns into a gas and forms ammonia gas. Ammonia is a colourless gas at room temperature and pressure. Gas-phase ammonia

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[1] https://www.industrialchemicals.gov.au/chemical-information/search-assessments?assessmentcasnumber=1336-21-6

will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals and nitrate radicals (PubChem).

Ammonia is very soluble in water, the solubility being around 482 g/L at 25°C. Ammonia or ammonium ion is rapidly converted to nitrate by nitrification under aerobic conditions in the aquatic environment (OECD, 2007). Ammonia is part of the nitrogen cycle. Biodegradation is not applicable to ammonia or the ammonium ion. Ammonia (or the ammonium ion) is easily mineralised to the nitrite ion (NO_2^-) by numerous species of bacteria (OECD, 2007).

Ammonia is not expected to bioaccumulate in the environment because of its dissociation to the ammonium ion and because it is part of the nitrogen cycles in air, soil and water. Ammonia and the ammonium ion have a low potential to adsorb to soil and sediment.

6 HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The acute toxicity of ammonia is moderate by the inhalation route. Depending on the concentration, solutions of ammonia 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 ammonia can cause respiratory irritation. No target organ effects were seen in rats given ammonia by oral gavage or in feed for up to two years. Ammonia is not genotoxic. There were no increases in tumours when rats were fed ammonia in their diet for two years. A reproductive and developmental screening toxicity (OECD 422) study showed no reproductive or developmental effects in rats when given oral gavage doses of an aqueous solution of ammonia.

B. Acute Toxicity

The oral LD_{50} of aqueous ammonia (as ammonium hydroxide) in rats is 350 mg/kg (Smyth et al., 1941). [Kl. score = 2]

The 1-hour LC_{50} values of ammonia in rats are 9,850 mg/m^3 for males and 13,770 mg/m^3 for females (Appelman et al., 1982). [Kl. score = 2]

C. Irritation

Application of a 12% aqueous solution of ammonia (as ammonium hydroxide) to the skin of rabbits for four hours under occlusive conditions was corrosive. A 10% aqueous solution was not corrosive under similar conditions (ECHA). [Kl. score = 2]

No eye irritation studies are available.

D. Sensitisation

No studies are available.

E. Repeated Dose Toxicity

Oral

In a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD 422), male and female Crj: CD(SD) male and female rats were dosed by oral gavage with 0, 250, 750 or 1,500 mg/kg diammonium phosphate. The exposure period for the toxicity subgroup was 35 days. There was no treatment-related deaths and no clinical signs of toxicity. The 1,500 mg/kg males had reduced (22% of controls) body weight gain and feed consumption. Activated partial thromboplastin time was reduced in the 750 and 1,500 mg/kg males. In males: elevated alkaline phosphatase (750 and 1,500 mg/kg; 132% and 131% of controls); reduced glucose and phosphorus levels (1,500 mg/kg; 79% and 82% of controls); reduced total protein (750 and 1,500 mg/kg; 93% and 91% of controls); slightly elevated albumin/globulin ratio (1,500 mg/kg; 117% of controls). In females: decreased phosphorus levels (1,500 mg/kg; 81% of controls). No details were given as to whether these values were within normal range. The functional observation battery (FOB) and motor activity results showed no treatment-related effects. Relative kidney and liver weights were increased in the 1,500 mg/kg females compared to controls. Reddening of the extremities were seen in all dose groups during the first week of the study but were reduced as the study progressed. Histopathologic examination showed submucosal inflammation of the stomach at all dose levels, which was not statistically significant at 250 mg/kg-day. Given the lack of histopathological findings (excluding the irritation effect seen in stomach), the serum chemistry changes do not seem indicative of an adverse effect. The NOAEL for this study is 750 mg/kg-day (ECHA). [Kl. score = 1]

Male and female F344 rats were fed in their diet 0, 0.1, 0.6 or 3% ammonium sulfate for 52 weeks. The estimated daily intakes were: 0, 42, 256 and 1,527 mg/kg-day for the males; and 0, 48, 284 and 1,490 mg/kg-day for the females. There was a significant increase in kidney and/or liver weights in the 3% dietary group. No effects were noted for survival, body weights, hematology, serum chemistry, or histopathology. The kidney and liver weight changes do not appear to be an adverse effect because of no corresponding serum chemistry and/or histopathological changes in these organs. The NOAEL for this study is 3% in the diet, corresponding to 1,527 and 1,490 mg/kg-day for males and females, respectively (Ota et al., 2006). [Kl. score = 2]

Male and female F344 rats were fed in their diet 0, 1.5 or 3% ammonium sulfate for 104 weeks. The estimated daily intakes were: 0, 564 and 1,288 mg/kg-day for the males; and 0, 650 and 1,371 mg/kg-day for the females. Body weights and feed consumptions were similar across all groups. There was an increased incidence of chronic nephropathy in the male rats, which was statistically significant only in the 1.5% dietary group (Ota et al., 2006). [Kl. score = 2]

Inhalation

The study of ammonia exposure in workers in a soda ash plant with support from three studies in urea fertilizer plants was identified as the principal study for the derivation of an inhalation reference concentration (RfC). Respiratory effects, characterized as increased respiratory symptoms based on self-report (including cough, wheezing, and other asthma-related symptoms) and decreased lung function in workers exposed to ammonia, were selected as the critical effect. An RfC of 0.5 mg/m^3 was calculated (USEPA, 2016).

Additional information can be found in USEPA's Integrated Risk Information System (IRIS) assessment for ammonia available on-line at: https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=422

Dermal

No studies are available.

F. Genotoxicity

Table 4 lists the *in vitro* genotoxicity studies on ammonia and ammonium sulfate.

In Vitro Studies

Table 4 *In Vitro* Genotoxicity Studies on Ammonia and Ammonium Sulfate

Test System	Test Substance	Results*		Klimisch Score	Reference
		-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* and *E. coli* strains)	Anhydrous ammonia	-	-	2	ECHA
Bacterial reverse mutation (*S. typhimurium* strains)	Ammonium sulfate	-	-	1	ECHA

*+, positive

In Vivo Studies

Male ddY mice were given a single intraperitoneal injection of 0, 62.5, 125, 250 or 500 mg/kg ammonium chloride. There were no increases in the frequency of micronucleated erythrocytes at any dose level (Hayashi et al., 1988).

Male ddY mice were given intraperitoneal injections of 0, 31.3, 62.6, 125 or 250 mg/kg ammonium chloride on four consecutive days. There were no treatment-related increases in the frequency of micronucleated erythrocytes at any dose level (Hayashi et al., 1988).

G. Carcinogenicity

Male and female F344 rats were fed in their diet 0, 1.5 or 3% ammonium sulfate for 104 weeks. The estimated daily intakes were 0, 564 and 1,288 mg/kg-day for the males; and 0, 650 and 1,371 mg/kg-day for the females. Body weights and feed consumptions were similar across all groups. The tumour incidences were similar between the treated and control groups (Ota et al., 2006). [Kl. score = 2]

H. Reproductive/Developmental Toxicity

In a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD 422), male and female Crj: CD(SD) male and female rats were dosed by oral gavage with 0, 250, 750 or 1,500 mg/kg diammonium phosphate. The males and females were treated for 28 and 53 days, respectively. There were no reproductive or developmental toxicity at any dose level. The NOAEL for reproductive and developmental toxicity is 1,500 mg/kg-day (ECHA). [Kl. score = 1]

I. Derivation of Toxicological Reference and Drinking Water Guidance Values

Non-Cancer

An oral reference dose was not derived for ammonia.

The Australian drinking water guideline value for ammonia (0.5 mg/L, aesthetics) may be applicable (ADWG, 2021).

Cancer

A two-year rat dietary study on ammonium sulfate showed no carcinogenic effects. Thus, a cancer reference value was not derived.

J. Human Health Hazard Assessment of Physico-Chemical Properties

Ammonia is a flammable gas.

It does not exhibit the following physico-chemical properties:

- Explosivity
- Oxidising potential

7 ENVIRONMENTAL EFFECTS SUMMARY

A. Summary

Ammonia is moderately toxic to a variety of aquatic and terrestrial organisms. In general the effect concentration is on the order of a low to mid part per million range. Specific data are discussed below.

B. Aquatic Toxicity

ANZG developed a water quality guideline for ammonia (ANZG, 2018). The term 'ammonia' refers to both the un-ionised ammonia (NH_3) and the ionised ammonium ion (NH_4^+). The proportion of the chemical forms in water varies with the physico-chemical properties of the water, particularly pH and temperature. The concentrations of ammonia are usually expressed as either total ammonia (the sum of NH_3 and NH_4^+) which takes into account the total amount as NH_3 or N, or as concentration of the un-ionised NH_3. The concentrations can be given as component of N (e.g., NH_3-N) or total ammonia-N.

The values given below from ANZG (2018) are geometric means of species data taken from all screened data that concurrently measured pH and temperature. Figures were adjusted to a standard pH of 8.0 and calculated in terms of total ammonia-N.

Freshwater fish

The 24 – 96 hour LC_{50} values for 15 species were 3,944 to 169,873 μg/L (an anomalous figure of 72 μg/L was extracted from AQUIRE database [1994]). The 6- to 28-d chronic NOEC and EC_{20} (growth and survival) for 9 species were 1,350 to 19,720 μg/L.

Freshwater crustacean

The 24 – 96 hour LC_{50} values for 10 species are 7,754 to 108,500 μg/L. The cladoceran *Simocephalus vetulus* was the most sensitive (24-hour EC and LC_{50} values were approximately 1,580 μg/L), and the amphipod *Crangonyx pseudogracilis* was the least sensitive. The 7-day to 10-week chronic NOEC and EC_{20} values (reproduction) for 4 species are 1,450 to 19,770 μg/L.

Freshwater insects

The 24 – 96 hour LC_{50} values for eight species are 15,091 to 282,400 μg/L. The 29-day chronic NOEC (reproduction) for two species are 1,790 to 4,400 μg/L.

Freshwater molluscs

The acute toxicity for seven species were 12,588 to 74,623 μg/L. The chronic 42- to 60-day NOEC and EC_{20} (reproduction and survival) for two species are 540 to 2,620 μg/L. The most sensitive species under chronic exposure was the New Zealand species *Sphaerium novaezelandiae* with NOEC (60-day mortality and reproduction) of 540 μg/L total ammonia-N.

Freshwater annelid

The 24 – 96 hour LC_{50} values for two species are 20,071 to 79,788 μg/L.

Freshwater rotifer

The 24-hour LC_{50} for *Brachionus rubens* is 1,300 μg/L.

Freshwater Platyhelminthes

The 24 – 96 LC_{50} value for *Polycelus tenuis* is 37,634 μg/L.

C. Terrestrial Toxicity

At 2.1 to 28 mg/m^3, ammonia gas may damage foliage of plants within four hours; damage may occur within 4 to 8 minutes at air concentrations of 175 to 700 mg/m^3 (WHO, 1986; OECD, 2007). Application of ammonium sulfate to soil inhibited onion growth at 399 mg N/kg soil (OECD, 2007).

Frog species *Pseudacris regilla* and *Rana aurora* exposed to ammonium sulfate in the water for 10 days showed no adverse effects at 17.4 to 82.7 mg NH_3-N/L (OECD, 2007). Larvae of the salamander *Ambystoma gracile* showed no effects after 10 days of exposure to 81.5 mg NH_3-N/L (OECD, 2007).

D. Calculation of PNEC

PNEC water

The ANZG water quality guideline (2018) for ammonia in freshwaters is: "A freshwater high reliability trigger value of 900 μg/L TOTAL ammonia-N was calculated at pH 8.0 [emphasis added] using the statistical distribution method with 95% protection. This translates to about 900 μg/L un-ionised ammonia-N at 20°C." See Appendix for information regarding how the guideline figure changes at different pH values.

PNEC sediment

No experimental toxicity data on sediment organisms are available. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as ammonia and the ammonium ion. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sed}$. Based on its properties, no adsorption of ammonia or the ammonium ion 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. The environmental distribution of ammonia is dominated by its water solubility. Sorption of ammonia and the ammonium ion 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 ammonia or the ammonium ion. Thus, the equilibrium partitioning methods cannot be used to calculate the $PNEC_{soil}$. Based on its properties, ammonia and the ammonium ion are not expected to significantly adsorb to soil, and the assessment of this compartment will be covered by the aquatic assessment.

8 CATEGORISATION AND OTHER CHARACTERISTICS OF CONCERN

A. PBT Categorisation

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 hydroxide is a solution of ammonia in water. In water, ammonia is in equilibrium with the ammonium ion (NH_4^+), depending on the pH. Under environmental conditions (pH 5-8), the predominant form will be the ammonium ion (NH_4^+). Ammonia or ammonium ion is rapidly converted to nitrate by nitrification under aerobic conditions in the aquatic environment. Ammonia is part of the nitrogen cycle. Biodegradation is not applicable to ammonia or the ammonium ion. Ammonia (or the ammonium ion) is easily mineralised to the nitrite ion (NO_2^-) by numerous species of bacteria. Therefore, ammonia does not meet the criteria for persistence.

Ammonia is not expected to bioaccumulate in the environment because of its dissociation to the ammonium ion and because it is part of the nitrogen cycles in air, soil and water. Thus, ammonia does not meet the criteria for bioaccumulation.

The chronic NOECs reported in ANZG (2018) for ammonia for aquatic species are greater than 0.1 mg/L, except for a mollusc found in New Zealand. It is unknown whether a similar sensitive species is found in Australia. For the purposes of this risk assessment, the chronic NOECs for ammonia will be considered to be greater than 0.1 mg/L. Acute aquatic toxicity values were greater than 1 mg/L. Thus, ammonia does not meet the screening criteria for toxicity.

The overall conclusion is that ammonia and ammonium hydroxide are not PBT substances.

B. Other Characteristics of Concern

No other characteristics of concern were identified for ammonia or ammonium hydroxide.

9 SCREENING ASSESSMENT

Chemical Name	CAS No.	Overall PBT Assessment [1]	Chemical Databases of Concern Assessment Step		Persistence Assessment Step		Bioaccumulative Assessment Step	Toxicity Assessment Step			Risk Assessment Actions Required[3]
			Listed as a COC on relevant databases?	Identified as Polymer of Low Concern	P criteria fulfilled?	Other P Concerns	B criteria fulfilled?	T criteria fulfilled?	Acute Toxicity [2]	Chronic Toxicity[2]	
Ammonia	7664-41-7	Not a PBT	No	No	NA	No	No	No	2	2	2
Ammonium Hydroxide	1336-21-6	Not a PBT	No	No	NA	No	No	No	2	2	2

Footnotes:

1 - PBT Assessment based on PBT Framework.

2 - Acute and chronic aquatic toxicity evaluated consistent with assessment criteria (see Framework).

3 - Tier 2 - Hazard Assessment and Qualitative Assessment Only. Develop toxicological profile and PNECs for water and soil and provide qualitative discussion of risk.

Notes:

NA = not applicable

PBT = Persistent, Bioaccumulative and Toxic

B = bioaccumulative

P = persistent

T = toxic

10 REFERENCES, ABBREVIATIONS AND ACRONYMS

A. 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 (2018). Australian and New Zealand Guidelines for Fresh and Marine Water Quality. Australian and New Zealand Governments and Australian state and territory governments, Canberra, ACT, Australia. https://www.waterquality.gov.au/anz-guidelines.

Appelman, L.M., Ten Berge, W.F., and Reuzel, P.G.J. (1982). Acute inhalation toxicity study of ammonia in rats with variable exposure periods. Am. Ind. Hyg. Assoc. J. 43: 662-665.

AQUIRE. AQUIRE (AQUatic toxicity Information REtrieval) United States Environmental Protection Agency (US EPA), Mid-Continent Ecology Division, Duluth, MN (MED-Duluth).

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.

Hayashi, M., Kishi, M., Sofuni, T., and Ishidate, M., Jr. (1988). Micronucleus tests in mice on 39 food additives and eight miscellaneous chemicals. Food. Chem. Toxicol. 26: 487-500.

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. (2007). OECD-SIDS Initial Assessment Report (SIAR) for the Ammonia Category. Available at: https://hpvchemicals.oecd.org/UI/SIDS_Details.aspx?id=02CDBB42-D1AF-4EA5-8527-7318F39AB60A.

Ota, Y., Hasumura, M., Okamura, M., Takahashi, A., Ueda, M., Onodera, H., Imai, T., Mitsumori, K., and Hirose, M. (2006). Chronic toxicity and carcinogenicity of dietary administered ammonium sulfate in F344 rats. Food Chem. Toxicol. 44: 17-27.

PubChem. National Institutes of Health. National Library of Medicine National Center for Biotechnology Information. https://pubchem.ncbi.nlm.nih.gov/

Smyth, H.F., Seaton, J., and Fischer, L. (1941). The single dose toxicity of some glycols and derivates. J. Ind. Hyg. Toxicol. 23: 259.

United States Environmental Protection Agency [USEPA]. 2016. Toxicological Review of Ammonia Noncancer Inhalation: Executive Summary [CASRN 7664-41-7]. Integrated Risk Information System, National Center for Environmental Assessment, Office of Research and Development. EPA/635/R-16/163Fc. September 2016.

WHO. (1986). Ammonia. Environmental Health Criteria 54, International Programme on Chemical Safety, World Health Organization. Available at: http://www.inchem.org/documents/ehc/ehc/ehc54.htm.

B. Abbreviations and Acronyms

^{o}C	degrees Celsius
AICS	Australian Inventory of Chemical Substances
ANZG	Australian and New Zealand Guidelines
AQUIRE	Aquatic Toxicity Information Retrieval
atm-m^{3}mol	atmosphere meter cubed mole
COC	constituent of concern
DEWHA	Department of the Environment, Water, Heritage and the Arts
EC	effective concentration
ECHA	European Chemicals Agency
EU	European Union
FOB	functional observation battery
g/L	grams per litre
hPa	hectopascal
IRIS	Integrated Risk Information System
IUPAC	International Union of Pure and Applied Chemistry
Kl	Klimisch scoring system
LC	lethal concentration
mg/kg	milligrams per kilogram
mg/m^3	milligrams per cubic metre
NICNAS	The National Industrial Chemicals Notification and Assessment Scheme
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration

OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SGG	Synthetic Greenhouse Gases
SIDS	screening information data set
USEPA	United States Environmental Protection Agency
WHO	World Health Organization
μg/L	micrograms per litre

Appendix

Freshwater trigger values as total ammonia-N in µg/L at different pH (temperature is not taken into consideration). Taken from Table 8.3.7 (ANZG, 2018).

pH	**Freshwater Trigger value (mg/L as total ammonia-N)**	**pH**	**Freshwater Trigger value (mg/L as total ammonia-N)**
6.0	2570	7.6	1470
6.1	2555	7.7	1320
6.2	2540	7.8	1180
6.3	2520	7.9	1030
6.4	2490	8.0	900
6.5	2460	8.1	780
6.6	2430	8.2	660
6.7	2380	8.2	560
6.8	2330	8.4	480
6.9	2260	8.4	400
7.0	2180	8.6	340
7.1	2090	8.7	290
7.2	1990	8.8	240
7.3	1880	8.9	210
7.4	1750	9.0	180
7.5	1610	-	-

Appendix 7 – Example Tier 3 Quantitative Risk Assessment

Qualitative and Quantitative Tier 3 Assessment

Mixture of 5-Chloro-2-Methyl-2H-Isothiazol-3-One and 2-Methyl-2H-Isothiazol-3-One (3:1)

In accordance with the Dawson River Release (DRR) Chemical Risk Assessment Framework (CRAF), the assessment for this Tier 3 chemical includes the following components: completing the screening; developing a risk assessment dossier and Predicted No-Effects Concentrations (PNECs) for water and soil; and completing a qualitative and quantitative assessment of risk. Each of these components is detailed within this attachment.

Background

Santos has been releasing treated water to the Dawson River since 2015. The Dawson River Release Scheme[1] is located in the southeast region of the Fairview Arcadia Project Area (FAPA) (within the hub compressor station four (HCS4) gathering network). Coal seam water produced in the HCS4 gathering network is collected and is treated at Reverse Osmosis Plant 2 (ROP2) with the treated permeate stored within a permeate pond prior to release to the Dawson River. The outfall location is located within a tributary gully of the Dawson River, which joins the Dawson River midway between "Dawson's Bend" and Yebna Crossing.

The permeate pond is connected to the outfall location by a 5.3-kilometre (km) pipeline constructed across farmland with the released water flowing down a 2.9 km tributary gully before discharging to the Waterbody (nominal capacity 500 megalitre [ML]) and then flowing 1.8 km before joining the Dawson River at its downstream confluence.

ROP 2 at FAPA is a reverse osmosis plant with a specification designed to produce high quality water for the intended release of treated coal seam water to the Dawson River. The process removes the suspended and dissolved solids through a set of six processes to produce high quality treated water. These include coagulation/clarification, oxidation, filtration, softening, reverse osmosis, and finally adjustment of sodium adsorption ratio (SAR).

The mixture of 5-chloro-2-methyl-2h-isothiazolol-3-one (CMIT) and 2-methyl-2h-isothiazol-3-one (MIT) (3:1) is a component in hydraulic fracturing fluid systems used in stimulation activities. Hydraulic fracturing fluid systems comprise water and chemical additives (including a proppant) blended at the surface of the well lease and injected down the cased well to improve formation permeability, enhancing the gas flow towards the well. The chemical additives are also used to assist well completion by preparing the well or maintain the gas flow to the well (i.e., prevent the swelling of clays within the target hydrocarbon formation).

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[1] Santos obtained an amendment to the Fairview Arcadia Project Area (FAPA) Environmental Authority (EA) (EPPG00928713) on 31st May 2013 to authorise the release of desalinated produced water from the Fairview reverse osmosis plant (ROP) 2 to the Dawson River – the Dawson River Release Scheme (DRRS).

The purpose and maximum quantity for this chemical in the total fluid system is summarised in **Table 1**.

Table 1 Hydraulic Fracturing Chemicals

Chemical Name	CAS No.	Use	Quantity[1]
Mixture of 5-chloro-2-methyl-2h-isothiazolol-3-one (CMIT) and 2-methyl-2h-isothiazol-3-one (MIT)	55965-84-9	bactericide	0.00054%

[1] Volume Percent in Treatment (%)
CAS No = Chemical Abstracts Service Number

The assessment of toxicity of this chemical was used to evaluate human health exposure scenarios and is presented in the risk assessment dossier provided in **Attachment 1**. CMIT/MIT is not a carcinogen, and, as a result, only a non-carcinogenic oral reference dose (RfD) was calculated. A detailed discussion of the derivation of the oral RfD and drinking water guideline values is presented in the attachment. **Table 2** provides a summary of the derivation.

Table 2 Oral Reference Doses and Derived Drinking Water Guidelines

Constituent (CAS No.)	Study	Critical Effect/ Target Organ(s)	NOAEL (mg/kg-day)	Uncertainty Factors	Oral Reference Dose (mg/kg-day)	Drinking Water Guideline (mg/L)
Mixture of 5-chloro-2-methyl-2h-isothiazolol-3-one (CMIT) and 2-methyl-2h-isothiazol-3-one (MIT) (55965-84-9)	2-year rat drinking water	Gastric irritation of the stomach	17	100	0.17	0.60

CAS = Chemical Abstracts Service
mg/kg-day = milligram per kilogram-day
mg/L = milligram per litre
NOAEL = No observed adverse effect level
Refer to **Attachment 1** for information on the key studies selected for oral reference dose and drinking water level development.

For ecological receptors, the assessment utilises the information presented in the dossiers on the relative toxicity of the aquatic and terrestrial flora and fauna to the chemical. The qualitative assessment focuses on the aquatic invertebrate and fish species within the surface water resources, and the soil flora and fauna associated with releases to the soil. The quantitative assessment includes evaluating the potential risks to these same aquatic and soil ecological receptors, in addition to higher trophic level organisms such as livestock and terrestrial wildlife.

The determination of toxicity reference values (TRVs) was conducted according to the PNEC guidance in the *Environmental Risk Assessment Guidance Manual for Industrial Chemicals* prepared by the Australian Environmental Agency (AEA, 2009). PNECs for freshwater and sediment are developed to assess aquatic receptors, and PNECs for soil are developed for terrestrial receptors.

Table 3 presents the chemical, endpoint, no observed effect concentration (NOEC) (milligrams per litre [mg/L]), assessment factor, and the aquatic PNEC (mg/L). PNECs for sediment and soil are detailed in **Tables 4** and **5,** respectively. Refer to **Attachment 1** for the development of PNECs, or the rational for PNECs that do not have a calculated PNEC.

Table 3 PNECs Water – Tier 3 Chemicals

Constituents	Endpoint	EC_{50} or NOEC (mg/L)	Assessment Factor	$PNEC_{water}$ (mg/L)
Mixture of 5-chloro-2-methyl-2h-isothiazolol-3-one (CMIT) and 2-methyl-2h-isothiazol-3-one (MIT) (55965-84-9)	Chronic Algae	0.0014	10	0.00014

EC_{50} = effects concentration – 50%
mg/L = milligram per litre
NOEC = no observable effects concentration
PNEC = predicted no effect concentration
Refer to **Attachment 1** for information on the development of PNECs listed above.

Table 4 PNECs Sediment – Tier 3 Chemicals

Constituents	Endpoint	EC_{50} or NOEC (mg/kg wet wt)	Assessment Factor	$PNEC_{sed}$ (mg/kg wet wt)
Mixture of 5-chloro-2-methyl-2h-isothiazolol-3-one (CMIT) and 2-methyl-2h-isothiazol-3-one (MIT) (55965-84-9)	Chronic Oligochaete	0.27	50	0.0054

EC_{50} = effects concentration – 50%
mg/kg wet wt = milligram per kilogram wet weight
NOEC = no observable effects concentration
PNEC = predicted no effect concentration
Refer to **Attachment 1** for information on the development of PNECs listed above.

Table 5 PNECs Soil – Tier 3 Chemicals

Constituents	Endpoint	EC_{50} or NOEC (mg/kg dry wt)	Assessment Factor	$PNEC_{soil}$ (mg/kg dry wt)
Mixture of 5-chloro-2-methyl-2h-isothiazolol-3-one (CMIT) and 2-methyl-2h-isothiazol-3-one (MIT) (55965-84-9)	Soil Microorganisms	1	50	0.02

EC_{50} = effects concentration – 50%
mg/kg dry wt = milligram per kilogram dry weight
NOEC = no observable effects concentration
PNEC = predicted no effect concentration
Refer to **Attachment 1** for information on the development of PNECs listed above.

A detailed assessment of the potential risks posed by this Tier 3 chemical is provided in the following sections.

General Overview

Methylisothiazolinones are made industrially by oxidative cyclisation of the linear organic di-sulfide, N,N'-dimethyl-3,3'-dithiodipropionamide (CAS RN 999-72-4), in a process that uses chlorine as the oxidant. This manufacturing process inevitably produces a mixture of MIT and CMIT, as well as a small amount of the dichloro derivative (DCMIT; CAS RN 26542-23-4). These mixtures are generally not separated into their constituent chemicals and CMIT is not commercially available except as a mixture with MIT (NICNAS, 2020).

The mixture of CMIT and MIT is a powerful biocide and preservative and has a role as an antifouling biocide, an antimicrobial agent, and an antifungal agent. MIT and CMIT use is reported across a wide range of both consumer product uses (e.g. cosmetics, personal care products, baby wipes, automotive and marine sealants and waxes) and industrial uses (e.g. biocides in industrial circulating cooling water systems, preservatives in papermaking, leather treatment and cutting fluids) and are active pharmaceutical ingredients in biological products and prescription medicines (NICNAS, 2000). The molecular structure of the mixture of CMIT and MIT is presented in **Figure 1**.

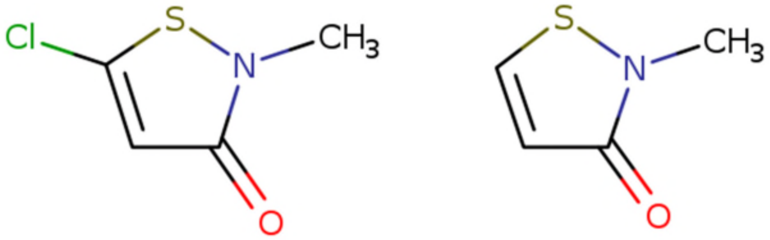

Figure 1 **Molecular Structure of 5-chloro-2-methyl-2h-isothiazolol-3-one (CMIT) with 2-methyl-2h-isothiazol-3-one (MIT)**[2]

Combined formulations of CMIT and MIT are marketed under several trade names, such as Kathon™ 886 and ACTICIDE LG. Magnesium nitrate and magnesium chloride are present in the commercial CMIT/MIT mixture as an inert ingredient and impurity, respectively. The amount of these two salts vary depending on the formulation (EU SCCS, 2009).

The mixture of CMIT and MIT is readily soluble in water and is stable up to pH 9 where extensive degradation is observed. It is susceptible to photodegradation. The mixture of CMIT and MIT is biodegradable at expected environmental exposure concentrations and would also be removed by common biological wastewater treatment facilities. The mixture is not expected to bioaccumulate and has a low potential to adsorb to soil.

The PBT assessment for the mixture of CMIT and MIT is included in the dossier provided in **Attachment 1**. Based on physico-chemical properties and screening data detailed below, the overall conclusion was that CMIT/MIT is not a PBT substance.

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[2] Source https://chem.nlm.nih.gov/chemidview/image/55965-84-9?size=3

Human Health Hazards

The acute toxicity of CMIT/MIT is moderate to highly toxic by the oral, inhalation and dermal routes. It is corrosive to the skin and eye and is expected to be a skin sensitiser according to a local lymph node assay.

Repeated exposures to rats by the oral, dermal, or inhalation routes have shown no systemic toxicity; however, evidence of localised irritation (site-of-contact) was observed by all routes of exposure. CMIT/MIT may exhibit weak genotoxic effects in some *in vitro* tests, whereas the *in vivo* studies consistently show no genotoxic activity. It has no reported reproductive or developmental effects; and, is not considered carcinogenic.

A 2-year rat drinking water study has been conducted on a product containing the mixture of CMIT and MIT. The no observed adverse effects level (NOAEL) from this study is 17 milligrams per kilogram-day (mg/kg-day) based on gastric irritation of the stomach. The NOAEL was used to derive the oral RfD and the drinking water guidance value (0.60 mg/L) (see **Table 2**). Description of the oral RFD and calculation of the drinking water guideline value is included in the dossier provided in **Attachment 1**.

CMIT/MIT may be present in treated water (permeate). Managed release of treated water to the Dawson River would have the potential to affect surface water within the river. As the Dawson River meanders through large areas that are uncontrolled, exposures could potentially occur to downstream agricultural workers and residents.

There is low potential for human receptors to be exposed to CMIT/MIT in Dawson River discharge. The combination of mixing/dilution, storage (and associated biodecay) prior to treatment, treatment and retention (and associated biodecay) following treatment are all key components that will reduce the potential risk to potential receptors from discharges to surface water. For example, the concentration of stimulation fluid chemicals in flowback water would be diluted by at least 90% in the water feed pond due to the aggregation of produced water from other wells within one pond. During water treatment, concentrations would be further reduced by efficiencies of the reverse osmosis system. In addition, in the presence of sunlight, CMIT/MIT is susceptible to rapid photodegradation with a half-life of 117 hours, and it is considered rapidly biodegradable in an aerobic aquatic environment with a half-life of 17.3 hours for CMIT and 9.1 hours for MIT in the water/sediment system. Therefore, the biocide is not expected to be a significant risk driver.

Finally, there are no public access points to Dawson River within 1.4 km downstream of the most downstream release location, and while there may be some fishing by local landowners in this reach, other forms of secondary recreation are unlikely. Currently, there is no irrigation in the immediate vicinity of the Waterbody, with the closest irrigation being approximately 5km to the west. There is a water supply scheme in the Dawson River that supplies irrigators but this is located 250 km downstream, with a search of the Department of Natural Resources, Mines and Energy (DNRME) now Department of Resources (DoR), data base indicating that the nearest licensed surface water take for irrigation is 71 km downstream noting this licence provides authority to extract from an ‘Unnamed tributary of the Dawson River’, not the Dawson River. The nearest surface water domestic water supply entitlement is 244 km downstream (AECOM, 2019).

Environmental Hazards

The mixture of CMIT and MIT exhibits significant acute and chronic aquatic toxicity. The mixture is also toxic to sediment dwelling organisms but less toxic to terrestrial receptors. Under expected environmental conditions, the mixture is readily biodegradable and is not expected to bioaccumulate.

PNECs for the mixture of CMIT and MIT are provided in **Tables 3 – 5**. Toxicity data on water, sediment and soil-dwelling organisms was available to calculate PNECs. Experimental results were available for three trophic levels for water and soil organisms. Experimental results were available for one sediment-dwelling organism. PNEC calculations and assumptions are included in the dossier provided in **Attachment 1**.

As described in the previous section (Human Health Hazards), managed release of treated water to the Dawson River would have the potential to affect surface water within the river. As released treated water would become part of the regional surface water resource (i.e., Dawson River water quality and flow), ecological resources (livestock and native flora and fauna) are potential receptors. Specifically, potential receptors include:

1. Aquatic ecological receptors within Dawson River downstream of the release point
2. Livestock and wildlife that may access Dawson River surface water

Stock access to large portions of the Waterbody is permitted and has been observed. The banks of the Waterbody are severely degraded and lack riparian vegetation due to cattle access/activity. Similarly, cattle access the Dawson River for water at numerous places within and downstream of the receiving environment (frc environmental, 2021).

There is limited extraction of water for general farm supply downstream of the release location to the Dawson River. There is one licensed surface water take for agriculture within the extent of the release location area. Santos is in regular direct communication with the landholder and is not aware of any abstraction being undertaken under this licence to date. In addition, the nearest downstream agricultural area is located approximately 7 km downstream of the release location to the Dawson River.

Biological monitoring has identified the presence of Matters of National Environmental Significance (MNES) receptor white-throated snapping turtle (*Elseya albagula*) in two upstream locations (at site DRR2 on Hutton Creek and at site DRR1 on Dawson River). The presence of MNES receptor Fitzroy River Turtle (*Rheodytes leukops*) has not been identified.

The potential for exposure of sensitive receptors, including MNES, is low. Released produced water mixes with surface water in a manner that is protective of aquatic receptors within the Dawson River (AECOM, 2019). Treated water releases from the permeate ponds are less than 18 megalitre (ML)/day with Santos undertaking periodic releases. Releases are currently dictated by treated effluent production rates. Perennial base flow in the Dawson River downstream of Dawson's Bend at the Dawson River discharge point has been assessed as 21 ML/day. Baseflow in the Dawson River is associated with spring discharges.

Risk Characterisation

The purpose of the risk characterisation portion of the assessment is to provide a conservative estimate of the potential risk resulting from exposure to the mixture of CMIT and MIT that may occur during hydraulic fracturing and work over activities. The risk characterisation evaluates the toxicity of this chemical and characterises the risk of the chemical assessed for specific exposure pathways identified in the previous sections.

A two-stage process is employed during risk characterization. First, risk ratios are developed for the chemical for potentially complete exposure pathways associated with applicable release scenarios. The risk ratio is calculated by dividing the EPC by the applicable risk-based screening level (drinking water level or PNECs for aquatic and terrestrial receptors). If the ratio of exceedance of screening levels is less than 1.0, then there are no anticipated adverse effects associated with the exposure scenario evaluated and no additional risk / hazard reduction measures are required. There should be no need for further management controls on the chemical additional to those already in place (DoEE, 2017).

If the ratio is greater than 1.0, then further quantitative analysis is conducted. Consistent with the assessment framework, quantitative assessment of risk will consider only Tier 3 chemicals in end use determination.

Exposure Point Concentration Calculations

A quantitative mass balance calculation was undertaken to estimate the potential concentrations of stimulation chemicals containing CMIT/MIT within diluted produced water. For the mass balance calculation, vendor disclosure forms were used to determine the percentage of CMIT/MIT in the pre-injection fluid. **Table 6** presents the estimated pre-injection fluid concentration.

Table 6 Mass Balance Estimates for CMIT/MIT

Chemical Name	CAS No.	Estimated Pre-injection fluid concentration (mg/L)[1]
Mixture of 5-chloro-2-methyl-2h-isothiazolol-3-one (CMIT) and 2-methyl-2h-isothiazol-3-one (MIT)	55965-84-9	0.054

1 – Based on volumes provided in Table 1
CAS No = Chemical Abstracts Service Number
mg/L = milligram per litre

The mass balance of CMIT/MIT was then used to estimate potential EPCs for the evaluation of releases of treated water to the Dawson River. The potential EPCs have been conservatively estimated.

First, an estimated chemical concentration in the produced water from a recently hydraulically fractured well was calculated assuming 20% of the mass returned in the flowback water to the surface at a point in time and was conservatively diluted with 150% of the injected volume of return water. The water from recently hydraulic fractured wells (10% of volume) was diluted in the Water Management Facility (WMF) water feed pond influent by wells that did not contain detectable concentrations of these constituents. This EPC was then adjusted based on biodegradation rates to calculate the theoretical EPCs for two exposure time periods (0 and 30 days) which represent no storage/no degradation (Day 0) and a bounding estimate which considers degradation during storage at the WMF. The biodegradation information was obtained from the OECD ready tests (OECD, 1992) that were developed as a first-tier testing scheme to provide preliminary screening of organic chemicals. The ready tests are stringent screening tests that are conducted under aerobic conditions in which a high concentration of the test substance is used, and biodegradation is measured by non-specific parameters including dissolved organic carbon, biochemical oxygen demand and carbon dioxide production. **Attachment 2, Table 1** includes the environmental fate information that was used to assess biodegradation of the chemical.

The concentrations in the water feed pond were then further reduced by a factor of 99% to account for efficiencies in the WMF system.

Finally, a dilution factor of 50 was assumed to account for dilution into the receiving water body. This factor was based on the approved mixing zone described in the Santos 2013 report *Dawson River Release Scheme – Environmental Authority Amendment Application –Supporting Information*. This dilution factor is far less than the dilution that would occur (>1,500 fold) based on a maximum release rate of 18 ML/day and a Dawson River average low flow of 28,000 ML/day.

These estimated surface water EPCs were used to derive EPCs for sediment using the equilibrium partitioning method. **Attachment 2, Table 1** includes the equation and environmental fate information used to derive the sediment EPC.

Release Scenario Assessment

There is no potentially complete exposure pathway to sources of drinking water; however, as a conservative measure, the theoretical concentrations for the release scenarios were compared to human health toxicity-based screening levels to screen for potential effects as a result of a release to surface water used as a drinking water source. The results of this comparison, including the ratio of exceedance of screening levels, is presented in **Attachment 2, Table 2**. As detailed in the table, the risk ratio did not exceed the target level of 1 for any of the scenarios.

Theoretical concentrations were also compared to the PNEC for aquatic receptors. **Attachment 2, Table 3** presents the results of this comparison, including the ratio of exceedance of screening levels. Similar to above, risk ratios did not exceed the target level of 1.

The primary land use within the development area is agricultural (grazing on improved or unimproved pastures), and it is sparsely populated. To further evaluate potential risks to non-MNES receptors (mammals and avian), additional quantitative analysis of the managed releases to Dawson River was conducted.

Terrestrial receptors evaluated for exposure to Dawson River discharge include domesticated livestock, large mammalian wildlife and small mammalian wildlife. Beef cattle were used to evaluate domesticated livestock, kangaroos were evaluated for large mammalian wildlife, and dingos were evaluated for small mammalian wildlife. The cattle egret was selected to evaluate avian exposures. Exposure assumptions, TRVs and total intake calculations are detailed in **Attachment 2, Tables 4, 5, 6 and 7**. **Attachment 2, Table 4** presents the calculated risk estimates for the kangaroo. **Attachment 2, Table 5** presents the calculated risk estimates for the dingo. **Attachment 2, Table 6** presents the calculated risk estimates for the cattle. **Attachment 2, Table 7** presents the calculated risk estimates for the cattle egret. As indicated in the tables, the calculated HQ for CMIT/MIT did not exceed the risk threshold level of 1 for any of the scenarios evaluated.

Cumulative Impacts

The potential for cumulative impacts associated with chemicals used during stimulation activities is limited. Residual chemicals may be entrained within produced water and subsequently transported for water treatment at a WMF. However, these chemicals are removed by the treatment systems; and, therefore, no additional risk is provided during managed releases to Dawson River. Likewise, the presence of water treatment chemicals at the point of produced water storage or during managed releases to the Dawson River also poses no significant increase in risk.

Tier 3 chemicals which trigger persistence and bioacummulative thresholds are considered to be chemicals with a potential for cumulative impacts. As noted earlier and discussed in detail in the dossier (**Attachment 1**), CMIT/MIT does meet the criteria for persistence or bioaccumulation. Further, estimated concentrations in surface water and sediment were less than PNECs. Thus, there is negligible incremental risk posed by the use of this Tier 3 chemical and the existing management and monitoring controls are appropriate to ensure that the risk to MNES (and non MNES) receptors remains low.

Uncertainty Analysis

The procedures and assumptions used to assess potential human health and ecological risks in this Tier 3 assessment are subject to a wide variety of uncertainties. However, the presence of uncertainty is inherent in the risk assessment process, from the sampling and analysis of the chemical in environmental media to the assessment of exposure and toxicity, and risk characterisation. Accordingly, it is important to note that the risks presented within this Tier 3 assessment are based on numerous conservative assumptions in order to be protective of human health and the environment, and to ensure that the risks presented herein are more likely to be overestimated rather than underestimated.

The discussion detailed in **Table 7** below provides an evaluation of uncertainty for this Tier 3 assessment, including elements previously discussed within this assessment.

Table 7 Evaluation of Uncertainty – CMIT/MIT

Risk Characterisation Component	Description of Uncertainty	Magnitude of Uncertainty	Effect on Risk Assessment
Hazard Assessment –COPC concentrations	The concentrations of COPCs in residual stimulation fluids were estimated based on previous operations and may not accurately estimate the concentrations of COPCs in the future. Detailed discussions with Santos occurred to identify a conservative estimate of the COPC; however, there is the potential that the empirical concentrations would differ than those presented in the risk assessment.	Low	This assumption may overestimate or underestimate the calculated risks to receptors, dependent on-site-specific conditions.
Exposure Assessment	The use of the food consumption relationship with body weight for mammalian and avian receptors.	Low to Medium	Low to medium potential to underestimate or overestimate risk

Risk Characterisation Component	Description of Uncertainty	Magnitude of Uncertainty	Effect on Risk Assessment
Toxicity Assessment	The use of toxicity values in a risk assessment is based on extrapolations from animal data, adjust factors for inherent uncertainty in the toxicological estimate and use of surrogate toxicity criteria	Low	Low potential to underestimate risk
Toxicity Assessment	The use of lowest observed adverse effect level (LOAEL)/NOAEL for calculation of the TRVs	Low to Medium	Low to medium potential to underestimate or overestimate risk
Toxicity Assessment	The use of the allometric scaling method to estimate the population-level effects on wildlife based on individual level of exposures.	Low to Medium	Low to medium potential to underestimate or overestimate risk

References

AECOM. 2019. Revised Boron Site-Specific Water Quality Criterion – Dawson River Release Scheme. Letter from B. Goldsworthy and N. Lee to A. Lavery. 12 July 2019..

Australian Environmental Agency (AEA). (2009). Environmental Risk Assessment Guidance Manual for Industrial Chemicals, Commonwealth of Australia. Available: http://www.nepc.gov.au/resource/chemical-risk-assessment-guidance-manuals

Department of the Environment and Energy (DoEE). (2017). Exposure draft: Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction. Commonwealth of Australia, Available: http://www.environment.gov.au/water/coal-and-coal-seam-gas/national-assessment-chemicals/consultation-risk-assessment-guidance-manual

EU Scientific Committee on Consumer Safety [EU SCCS]. (2009). Opinion on the mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one [3:1], Colipa No P56, Scientific Committee on Consumer Safety, SCCS/1238/09. Available: https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_009.pdf

frc environmental. 2021. Santos GLNG Dawson River Watercourse Releases: Receiving Environment Monitoring Program. April 2021.

NICNAS. (2020). Methylisothiazolinone preservatives and industrial biocides: Environmental tier II assessment. 16 June 2020. Available: https://www.industrialchemicals.gov.au/sites/default/files/Methylisothiazolinone%20preservatives%20and%20industrial%20biocides_%20Environment%20tier%20II%20assessment.pdf

OECD. (1992). Test No. 301: Ready Biodegradability. (Biodégradabilité Facile.) Paris: OECD Publishing.

Santos, 2013. Dawson River Release Scheme – Environmental Authority Amendment Application – Supporting Information. May 2013.

Attachment 1 Risk Assessment Dossier

MIXTURE OF 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE AND 2-METHYL-2H-ISOTHIAZOL-3-ONE (3:1)
(CAS NO. 55965-84-9)

This dossier on the mixture of 5-chloro-2-methyl-2h-isothiazolol-3-one (CMIT) and 2-methyl-2h-isothiazol-3-one (MIT) (3:1) presents the most critical studies pertinent to the risk assessment of the mixture in coal seam gas applications. 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).

Screening Assessment Conclusion – CMIT and MIT were not identified in chemical databases used by NICNAS as an indicator that the chemicals are of concern and are not PBT substances. The mixture of CMIT and MIT were assessed as tier 3 chemicals for acute and chronic aquatic toxicity. Therefore, CMIT/MIT are classified overall as **tier 3** chemicals and require a quantitative risk assessment for end uses.

1 BACKGROUND

The methylisothiazolinones in this assessment belong to a larger group of preservatives and industrial biocides which all have an isothiazolinone heterocyclic ring system. CMIT is the monochloro derivative of parent chemical MIT.

Methylisothiazolinones are made industrially by oxidative cyclisation of the linear organic di-sulfide, N,N′-dimethyl-3,3′-dithiodipropionamide (CAS RN 999-72-4), in a process that uses chlorine as the oxidant. This manufacturing process inevitably produces a mixture of MIT and CMIT, as well as a small amount of the dichloro derivative (DCMIT; CAS RN 26542-23-4). These mixtures are generally not separated into their constituent chemicals and CMIT is not commercially available except as a mixture with MIT (NICNAS, 2020).

The mixture of CMIT and MIT is biodegradable at expected environmental exposure concentrations and would also be removed by common biological wastewater treatment facilities. The mixture is not expected to bioaccumulate, and has a low potential to adsorb to soil.

The acute toxicity of CMIT/MIT is moderate to highly toxic by the oral, inhalation and dermal routes. It is corrosive to the skin and eye and is expected to be a skin sensitiser according to a local lymph node assay. Repeated exposures to rats by the oral, dermal, or inhalation routes have shown no systemic toxicity; however, evidence of localised irritation (site-of-contact) was observed by all routes of exposure. CMIT/MIT may exhibit weak genotoxic effects in some *in vitro* tests, whereas the *in vivo* studies consistently show no genotoxic activity. It has no reported reproductive or developmental effects; and, is not considered carcinogenic.

The mixture of CMIT and MIT exhibits significant acute and chronic aquatic toxicity. The mixture is also toxic to sediment dwelling organisms but less toxic to terrestrial receptors.

2 CHEMICAL NAME AND IDENTIFICATION

Chemical Name (IUPAC): Reaction mass of 2-methyl-2H-isothiazol-3-one and 5-chloro-2-methyl-2H-isothiazol-3-one

CAS RN: 55965-84-9

Molecular formula: C_4H_5NOS. C_4H_4ClNOS

Molecular weight: 264.8 g/mol

Synonyms: Bio-Perge; Isothiazolinone chloride; 5-Chloro-2-methyl-4-isothiazolin-3-one -2-methyl-4-isothiazolin-3-one mixture; 3(2H)-Isothiazolone, 5-chloro-2-methyl-, mixt. with 2-methyl -3 (2H) -isothiazolone

3 PHYSICO-CHEMICAL PROPERTIES

Key physical and chemical properties for these substances are shown in Table 1.

Table 1 Overview of the Physico-chemical Properties of Mixture of CMIT and MIT (3:1)

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Solid, pale yellow to yellow	1	ECHA
Melting Point	22.2°C at 101.3 kPa	1	ECHA
Boiling Point	100.1°C at 101.3 kPa	1	ECHA
Density	1,256 kg/m^3 @ 20°C	1	ECHA
Partition Coefficient (log K_{ow})	0.75 @ 27°C	1	ECHA
Water Solubility	3,000 g/L @ 20°C	1	ECHA
Vapour Pressure	2.2 Pa @ 20°C	1	ECHA

Combined formulations of CMIT and MIT are marketed under several trade names, such as Kathon CG, Kathon 886, Kathon 886 WT, Kathon™ 886, ACTICIDE LG, ACTICIDE 14 L, ACTICIDE 14P, Microcare IT, Microcare ITL, etc. (EU SCCS, 2009). Initially, all formulations were prepared as a mixture of two individual active ingredients CMIT and MIT and salts. However, Kathon™ 886 biocide is now defined as a combination of the two active ingredients produced by an integrated production process, resulting in an approximate total of 14% active ingredients, 16% magnesium nitrate, 10% magnesium chloride and 62% water. There is no indication as to when this change was made in the manufacturing process (EU SCCS, 2009).

As such, magnesium nitrate and magnesium chloride are present in the commercial CMIT/MIT mixture as an inert ingredient and impurity, respectively. The amount of these two salts vary depending on the source (EU SCCS, 2009).

4 DOMESTIC AND INTERNATIONAL REGULATORY INFORMATION

A review of international and national environmental regulatory information was undertaken (Table 2). This chemical is listed on the Australian Inventory of Chemical Substances – AICS (Inventory). No conditions for its use were identified. No specific environmental regulatory controls or concerns were identified within Australia and internationally for the mixture of CMIT and MIT.

Table 2 Existing International Controls

Convention, Protocol or other international control	Listed Yes or No?
Montreal Protocol	No
Synthetic Greenhouse Gases (SGG)	No
Rotterdam Convention	No
Stockholm Convention	No
REACH (Substances of Very High Concern)	No
United States Endocrine Disrupter Screening Program	No
European Commission Endocrine Disruptors Strategy	No

5 ENVIRONMENTAL FATE SUMMARY

A. Summary

The mixture of CMIT and MIT is biodegradable at expected environmental exposure concentrations, is not expected to bioaccumulate, and has a low potential to adsorb to soil.

B. Partitioning

The mixture of CMIT and MIT is readily soluble in water. Given low Henry's Law constants for MIT and CMIT (0.005 Pa-m^3/mol and 0.0036 Pa-m^3/mol, respectively), these chemicals are considered slightly volatile from water and moist soil. The mixture is also expected to volatilise from dry soil surfaces based upon its vapour pressure.

Based on hydrolysis measurements made using OECD Guideline 111, CMIT/MIT was stable (<10% degradation) at pH 4 and 7. At pH 9 extensive degradation of CIT/MIT was observed. The rate constant was found to be 0.0283 per day and the DT50 and DT90 to be 24.5 days and 81 days, respectively (ECHA). [Kl. Score = 1].

In the presence of sunlight, CMIT/MIT is susceptible to rapid photodegradation with DT50 and DT90 values of 117 and 389 hours, respectively. (ECHA). [Kl. Score = 1].

C. Biodegradation

The biodegradation of the test substance, a 14% aqueous solution of 3 parts 5 -Chloro-2 -methyl-2H-isothiazol-3 -one and 1 part 2 -Methyl-2H-isothiazol-3 -one (cited as ACTICIDE® 14 in the study report), was investigated in a closed-bottle seawater test according to OECD guideline 306. The test substance was incubated with natural seawater over a period of 28 days under aerobic conditions, and oxygen content was determined by means of an oxygen electrode after 0, 5, 15 and 28 days.

ACTICIDE® 14 can be considered inhibitory to bacteria in the seawater sample. Due to inhibition of bacteria, the biodegradability of ACTICIDE® 14 could not be established in this test (ECHA). [Kl. Score = 1].

Biodegradation studies on CMIT and MIT separately have also been conducted. In these studies, CMIT is classified as being readily biodegradable, failing the 10 -day window and MIT is classified as being not readily biodegradable according to the criteria of the test, although significant biodegradation occurred (ECHA).

An OECD Guideline 301 B (Ready Biodegradability: CO2 Evolution Test) was performed on MIT. 50% of the test substance biodegraded within 29 days. Although extensive metabolism occurs over the 29-day interval, the test material does not meet the requirements for readily biodegradable but can be considered ultimately biodegradable. [Kl Score=1](ECHA). The same test with CMIT showed up to 62% of the test substance biodegraded within the same time frame of 29 days. [Kl Score=1](ECHA). The rate of biodegradation in these tests does not satisfy the OECD criterion for readily biodegradability (60% in a 10-day window), but the results do show that these chemicals are biodegradable at more realistic environmental exposure concentrations (NICNAS, 2020).

The primary aerobic biodegradability of MIT has been examined in a river sediment-water system by use of a 14C-labelled model compound. During the 7-day experiment 14C-labelled MIT was rapidly metabolized as only 12.6% of the initial MIT was present after 24 hours of incubation at 25C. The calculated half-life for the parent compound was 9.1 hours (Reynolds, 1994a). The primary biodegradability of CMIT has been examined with the same type of sediment and water as described for MIT. The 14C-labelled CMIT was rapidly metabolized as only 30% of the initial CMI remained after 24 hours of incubation at 25°C. The calculated half-life for the intact CMIT was 17.3 hours (Reynolds, 1994b).

In soil, CMIT and MIT are rapidly biodegradable with reported half-lives of 10.4 hours and 6.5 hours, respectively (ECHA). [Kl. Score = 1].

If a chemical is found to be readily or inherently biodegradable, it is categorised as Not Persistent since its half-life is substantially less than 60 days (DoEE, 2017).

D. Environmental Distribution

An OECD Guideline 106 (Adsorption - Desorption Using a Batch Equilibrium Method) was conducted on the CMIT/MIT mixture. The adsorption/desorption characteristics of [14C]-CMIT/MIT were studied in two UK sewage sludges; Basildon (pH 6.6, 29.3% organic carbon) and Chelmsford (pH 6.7, 23.7% organic carbon) and three UK soils, Farditch silt loam (pH 5.5, 4.19% organic carbon), Longwoods sandy loam (pH 7.1, 1.62% organic carbon) and Kenslow loam (pH 4.9, 3.88% organic carbon) using the batch equilibrium method. The Kfoc values obtained ranged from 34 to 54 mL/g (mean of 44 mL/g). The Freundlich exponents (1/n) ranged from 0.564 to 0.778, indicating a non-linear relationship between adsorption and concentration with a higher degree of adsorption to soil at lower concentrations. The determined Kfoc values indicated that CMIT/MIT can be classified as being of intermediate to high mobility in soil. [Kl Score=1](ECHA).

Soil adsorption coefficients (K_{oc}) for MIT (log K_{oc} = 1.08) and CMIT (log K_{oc} – 1.28) indicate both chemicals will have very high mobility in soil (NICNAS, 2020). Likewise, if released to water, based on their high solubility, they are not expected to adsorb to suspended solids or sediments.

E. Bioaccumulation

Bioaccumulation studies are not available for the CMIT/MIT mixture. Individually, MIT and CMIT are not expected to bioaccumulate. Studies of the bioconcentration of MIT and CMIT in bluegill sunfish (Lepomis macrochirus) at an exposure concentration of 0.12 mg/L showed bioconcentration factors (BCF) in this species of 2.3 and 114 L/kg respectively (Madsen, et al., 2001).

The low bioconcentration potential, hydrophilicity, and the reactivity of both chemicals with biomolecules indicate that they will not biomagnify in aquatic or terrestrial food webs (NICNAS, 2020).

6 HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The acute toxicity of CMIT/MIT is moderate to highly toxic by the oral, inhalation and dermal routes. It is corrosive to the skin and eye and is expected to be a skin sensitiser according to a local lymph node assay. Repeated exposures to rats by the oral, dermal, or inhalation routes have shown no systemic toxicity; however, evidence of localised irritation (site-of-contact) was observed by all routes of exposure. CMIT/MIT may exhibit weak genotoxic effects in some *in vitro* tests, whereas the *in vivo* studies consistently show no genotoxic activity. It has no reported reproductive or developmental effects; and, is not considered carcinogenic.

B. Toxicokinetics and Metabolism

Rats were given by gavage a single dose of 3.75 milligrams per kilogram body weight (mg/kg bw), 11.25 mg/kg bw or 22.5 mg/kg bw radiolabeled CMIT. CMIT was rapidly and extensively excreted in the urine and faeces following oral administration. A majority of the radioactivity was excreted from the rats in 24 hour (77-87%). Renal and fecal routes of elimination were equally important. Tissues contained 0.93-1.44% (female and male, respectively) of dosed radioactivity in the low dose group and 3.94-4.72% (female and male, respectively) in the high dose group. The highest amount of radioactivity was found in blood, particularly in red blood cells (0.67-1.09% of the dose in the low dose group, and 3.41-4.11% in the high dose group), followed by muscle (0.15%) in low dose group, and by muscle and liver (0.25%) in high dose group. Gender differences in excretion appeared to be minimal. CMIT was extensively metabolized. Approximately twenty-nine radioactive components were observed in urine and faeces samples from the HPLC radio profiling. Among these N-methyl malonamic acid was detected as the major component in the urine (15.35-18.19%). 3 -mercapturic acid conjugate of 3 -sulfinyl-N-methyl-propionamide was detected as the major component in the feces (up to 32.54%). All other metabolites accounted for less than 5% of the dose. Metabolites are thought to result from reduction and oxidation reactions involving phase I enzymes followed by conjugation to glutathione, giving rise to conjugates to glutathione or to mercapturic acid. (ECHA). [Kl. Score = 1].

C. Acute Toxicity

Oral

An acute oral toxicity study was conducted in 1977 before implementation of the GLP. Groups of CD rats were administered orally via gavage Kathon 886 at 221, 313, 442, 625 or 883 mg/kg b.w. Clinical signs were observed in all dose levels of this study. Under the conditions of the study, the acute oral LD_{50} in male rats is based on the lowest value, 457 mg/kg Kathon 886 corresponding to 64 mg/kg active ingredient (a.i.) (pure CMIT/MIT). (ECHA). [Kl Score = 2].

Inhalation

An acute inhalation toxicity study was conducted in accordance with GLP and as per OECD 403 guideline. Groups of male and female CD (BR) rats were exposed to an aerosol of Kathon 886 via nose only at concentrations of 0.19, 0.32, 0.50, 1.26, 2.24, and 3.02 mg test material/L. Signs of respiratory irritation, including gasping, rales, hyperpnea, dyspnea and vocalization, were seen in some animals in all groups immediately post-exposure. The number of animals showing these signs and the severity of the respiratory irritation correlated with the concentration of the test material to which the animals were exposed in the report. The signs of respiratory irritation disappeared in all surviving animals, taking from two to twelve days. Under the conditions of the study, a combined male and female LC_{50} value of 0.33 mg a.i per litre of air was determined (ECHA). [Kl Score = 1].

Dermal

An acute dermal toxicity study was conducted in 1976 before implementation of the GLP. Male albino rabbits were exposed dermally to Kathon 886 at 313, 625, 1250 and 2500 mg/kg under occlusive conditions. Skin irritation consisted of severe erythema and edema followed by eschar formation. LD_{50} was determined to be 660 mg Kathon^{TM} 886/kg bw with 95% confidence limits of 370 and 1210 mg/kg. This corresponds to LD_{50} = 87.12 mg/kg a.i. (pure CMIT/MIT). (ECHA). [Kl Score = 2].

D. Irritation

Skin

Two OECD 404 guideline compliant studies are provided indicating CMIT/MIT is corrosive to the skin.

A skin irritation/corrosion study was conducted according to OECD Guideline 404. As part of the study, white rabbits under semiocclusive conditions were exposed to the test substance for 1 or 4 hours. A severe edema (score = 4) was observed in five animals and one animal had a moderate edema (score = 3) one hour after patch removal. This edema was raised more than 2 mm and extended beyond the area of exposure. By day 3, this irritation reversed such that only 3 animals had a slight edema. There was total recovery after 8 days. One animal had a well-defined erythema with slight eschar formations. A reversal was observed after 72 h with total recovery after 11 days. Under the conditions of the study, the material was classified as corrosive to skin following a 1-hour or 4-hour exposure period, but the effects were fully reversible [Kl. Score = 2](ECHA).

A second skin irritation/corrosion study was also conducted according to the OECD Guideline 404. In the study, the irritating or corrosive potential of a 13.9 % aqueous solution of a 3:1 mixture of 5 -chloro-2 -methyl-2H-isothiazol-3 -one and 2 -methyl-2H-isothiazol-3 -one in water (named ACTICIDE 14 in this study report) was evaluated. One male New Zealand White rabbit was treated by on the exposed skin with 0.5 ml of the test item for 4 hours. The test substance was removed, and the treated skin was observed for abnormalities, their severity and eventual reversibility. Findings were scored according to the system proposed by Draize. Severe erythema and edema were observed shortly after treatment. While erythema was not reversible, edema was not observed after day 7. (ECHA). [Kl. Score = 1].

Eye

An in vivo eye irritation study indicated that Kathon™ 886 produces severe lesion to the eyes of rabbit which were not reversible. Kathon™ 886 should be considered as corrosive to the eyes of rabbits. (ECHA). [Kl. Score = 2].

E. Sensitisation

A local lymph node assay (LLNA) study in CBA/J mice was conducted in compliance with the proposed Local Lymph Node Assay protocol prepared by the Interagency Coordinating Committee for Validation of Alternative Methods (ICCVAM) Immunotoxicology Working Group (IWG): National Institutes of Health Publication N°: 99-449, Appendix J, 1999. Groups of mice were exposed to Kathon 886 at nominal concentrations of 0, 30, 50, 70, 90, 360, 1000 ppm a.i. in 4:1 acetone/olive oil and evaluated for skin sensitisation reactions. All concentrations evaluated produced a stimulation index greater than or equal to 3. The results of the study indicate that the test material CMIT/MIT exhibits a statistically significant, generally dose-related potential to induce contact hypersensitivity in mice. [Kl Score=1] (ECHA).

The potential of a 14% aqueous solution of 3 parts 5 -chloro-2 -methyl-2H-isothiazol-3 -one and 1 part 2 -methyl-2H-isothiazol-3 -one (ACTICIDE 14) to cause skin sensitisation was investigated in a Guinea Pig Maximisation Test according to OECD guideline 406. Male and female Dunkin-Hartley guinea pigs were treated with the test substance by intradermal injection (mixed with Freud`s complete Adjuvant) and 6 days later by cutaneous application under occlusive dressing for 48 hours (induction). Two weeks later, animals were treated with the test substance by cutaneous application for 24 hours at a site different from the first application sites (challenge). After another week, animals of the low-dose group were treated with the test substance by dermal application at a lower dose (rechallenge). Slight to moderate erythema were observed after intradermal induction, and local irritation after cutaneous induction. At challenge, all substance-induced animals and half of the control animals presented signs of severe skin reactions. Therefore, animals of the low dose group and a new control group were re-challenged one week later with 100 -1000 -fold less substance by dermal route. In the rechallenge, only animals treated with the high concentration (0.025% ACTICIDE 14) responded positive (4 of ten animals), while animals treated with factor ten lower amounts and the control animals showed no signs of toxicity. [Kl Score = 1](ECHA).

F. Repeated Dose Toxicity

Oral

CMIT/MIT was tested in several oral repeated dose toxicity studies in rabbits, rats and dogs for 4 weeks and 3 months.

The toxic potential of a 13.9 % aqueous solution of a 3:1 mixture of 5 -chloro-2 -methyl-2H-isothiazol-3 -one and 2 -methyl-2H-isothiazol-3 -one in water (ACTICIDE 14) was evaluated in a 90-day repeated dose dietary toxicity study in non-rodents according to OECD guideline 409. Male and female beagle dogs were treated with the test item by dietary administration over a period of 90 days. The animals were observed for clinical signs, alterations in body weight and food consumption throughout the study period. At selected timepoints before and during the study, blood was collected for haematology and clinical chemistry. At the end of the treatment period, the animals were sacrificed and subjected to detailed macroscopic and microscopic pathological examination.

A dose-dependent loss of bodyweight and reduction in food consumption was observed, while all other observed alterations/abnormalities could not be related to treatment and were considered incidental. The applied doses could analytically not be verified, and thus the exposure doses of the test animals were calculated from the worst-case recovered values.

The observed effects on body weight gain were only seen at the two highest doses and were probably the result of the poor palatability of the diet rather than any toxic properties of ACTICIDE 14. Thus, it was concluded that there was no evidence of organ or systemic toxicity when ACTICIDE 14 was offered in the diet at an analysed dose level up to 555 ppm (nominal concentration 750 ppm) which is equivalent to 22 mg ai/kg body weight/day (30 mg ai/kg body weight/day) to the laboratory beagle for up to 13 weeks. A No Observed Adverse Effect Level (NOAEL) of 22 mg/kg bw/day was established. (ECHA). [Kl. Score = 1].

In a repeated dose 90-day oral toxicity study in rodents, no systemic toxic effects and no adverse effects on the histopathology of any tissues/organs distant from the site of dosing (drinking water) was observed. A NOAEL of 250 ppm ai in water (16.3 mg a.i./kg/day in males and 24.7 mg a.i./kg/day in females) was established. (ECHA). [Kl. Score = 1].

In another oral toxicity study, administration of Kathon™ biocide to male and female rats in the drinking water for 24 months at concentrations up to and including 300 ppm a.i. showed no effects on the type or incidence of neoplasms in any group. No systemic effects were observed. Treatment-related morphologic changes were observed only in the stomach of both sexes in mid and high dose groups. Gastric irritation was the primary effect observed. No adverse effects on the histopathology of any tissues/organs distant from the site of dosing. Based on the study findings, a NOAEL of 300 ppm was established (17.2 mg a.i./kg bw/day in males and 25.7 mg a.i./kg bw/day in females). (ECHA). [Kl. Score = 1].

Inhalation

In a 90-day sub-chronic inhalation study, conducted in accordance with GLP and as per OECD 403 guideline, groups of male and female CD (SD) BR rats were exposed to an aerosol of Kathon 886 via nose only at concentrations of 0.34, 1.15 and 2.64 mg/m^3. There were no systemic effects in this study. Rats at the highest dose (2.64 mg/m^3) exhibited very mild, low grade respiratory irritation. No adverse effects on the histopathology of any tissues/organs distant from the site of dosing. A NOAEL of 0.34 mg/m^3 was established. (ECHA). [Kl. Score = 1].

Dermal

The toxic potential of a 13.9 % aqueous solution of a 3:1 mixture of 5 -chloro-2 -methyl-2H-isothiazol-3 -one and 2 -methyl-2H-isothiazol-3 -one in water (ACTICID 14) was evaluated in a 90-day repeated dose dermal toxicity study in rats according to EPA OPP 82 -3 guideline. Male and female Sprague-Dawley rats were treated with the test item on exposed skin daily for 6 hours over a period of 90 days. The test article was kept in place and prevented from oral ingestion by means of a semi-occlusive dressing for exposure and remainders of the test item were then removed with water. The animals were observed for mortality, clinical signs, body weight gain and food consumption. At the end of the treatment period, blood and urine were collected for haematology and clinical chemistry. The animals were subjected to detailed macroscopic and microscopic pathological evaluation, including scoring of observed skin abnormalities.

Mortalities observed in two control animals and one high-dose male are considered to be incidental and not related to the application of the test material. Treatment with the test article ACTICIDE 14 applied dermally to intact skin produced skin reactions (slight to moderate erythema and desquamation, slight edema and atonia as well as eschar formation) with dose-dependent grades of severity. Females appeared to be more sensitive than males. There were no other effects at the end of the treatment period that could be attributed to the test substance. A NOAEL for systemic toxicity was established as 2.625 mg a.i. /kg bw/day. A NOAEL for local irritation was established as 0.105 mg a.i./kg bw/day in males. No NOAEL for local irritation was established for female rats. (ECHA). [Kl. Score = 1].

A 90-day subchronic dermal toxicity study was conducted in White New Zealand Rabbits. Doses of 100, 200 and 400 ppm of Kathon 886 were applied 5 days per week for a minimum total of 65 applications. Slight to severe erythema and slight edema were noted in a dose-related manner (0.1 mg/kg/day and above). There were no systemic effects in this study. No adverse effects on the histopathology of any tissues/organs distant from the site of dosing. A NOAEL of 400 ppm a.i. based on skin irritation (0.4 mg/kg bw/day) was established. (ECHA). [Kl. Score = 2].

G. Genotoxicity

In Vitro Studies

Several in vitro studies of genotoxicity were performed with CMIT/MIT. Positive results were observed in three Ames assays and in three tests in mammalian cells (one chromosomal aberration test and two mouse lymphoma assays), with or without S9 activation. (ECHA).[Kl. Score =1 or Kl. Score =2]. In contrast, CMIT/MIT was not mutagenic in primary culture of rat hepatocytes [Unscheduled DNA Synthesis (UDS)] and in a mouse cell transformation test.(ECHA) [Kl. Score =1 or Kl. Score = 2].

In Vivo Studies

CMIT/MIT was tested in one in vivo chromosomal aberration assay in mice (bone marrow) and one micronucleus test in mice (bone marrow). Negative results were observed in these in vivo studies. (ECHA). [Kl. Score = 1].

In the absence of genotoxicity, additional tests were carried out in tissue other than bone marrow. Two UDS assays in rats confirmed the absence of genotoxicity of CMIT/MIT when tested in vivo. (ECHA). [Kl. Score = 1].

H. Carcinogenicity

Oral

An OECD Guideline 453 (Combined Chronic Toxicity / Carcinogenicity Studies) on male and female Crl:CD BR rats was performed. Administration of the substance to male and female rats in the drinking water for 24 months at concentrations up to and including 300 ppm a.i. (17.2 mg a.i./kg of body weight/day in males and 25.7 mg a.i./kg of body weight/day in females) showed no effects on the type or incidence of neoplasms in any group.

No treatment-related signs of toxicity were seen at 30 ppm a.i.(2.0 mg a.i./kg of body weight/day in males and 3.1 mg a.i./kg of body weight/day in females), the No-Observed Effect Level (NOEL) in this study [Kl Score = 1](ECHA).

Dermal

The mouse skin painting carcinogenicity study was initiated prior to the adoption of carcinogenicity study guidelines. However, the principles of OECD Guideline 451, in general, were followed. Kathon™CG, when applied dermally to the closely clipped skin on the backs of male CD-1 mice at a concentration of 400 ppm active substance and at a dose of 25 microliters (µL) 3 times per week for 30 months, showed no local or systemic tumorigenic potential. No adverse effects were seen on the histopathology of any tissues/organs distant from the site of dosing. (ECHA). [Kl. Score = 2].

I. Reproductive/Developmental Toxicity

An OECD Guideline 416 (Two-Generation Reproduction Toxicity Study) was performed on male and female Sprague-Dawley rats exposed to Kathon™ 886F biocide in the drinking water. No treatment-related deaths or clinical signs of systemic toxicity in either sex up to and including 300 ppm. No treatment-related effects on body weights up to and including 100 ppm in males and females and 300 ppm in females. In 300 ppm males, a treatment-related decrease (5 %) in mean body weight was seen during weeks 1 through 6 of treatment. No treatment-related effects on premating feed consumption in either sex at any dose level. Treatment-related and concentration-dependent decreases in water consumption were noted in all-Kathon™ exposed groups in both the P1 and P2 animals through most of the premating, gestation and lactation periods. No treatment-related effects on any endpoint of mating or fertility in either generation at any dose level. No treatment related effects on sperm motility, testicular sperm count or caudal epididymal reserves of P1 and P2 males at any dose level. Treatment-related microscopic findings were limited to the stomach of male and female parental animals at 100 and/or 300 ppm. These changes included an increased incidence of focal superficial erosions of the glandular mucosa, edema and inflammation of the submucosa of the glandular and nonglandular areas, and hyperplasia and hyperkeratosis of the nonglandular stomach. Based on these findings, a NOAEL for parental animal toxicity of 30 ppm (2.8-4.4 mg/kg/day in the P1 animals and 4.3-5.5 mg/kg/day in the P2 animals) was established. The reproductive and developmental NOEL was 300 ppm (22.7-28.0 mg/kg/day in the P1 animals and 35.7-39.1 mg/kg/day in the P2 animals).(ECHA). [Kl. score = 1]

An OECD Guideline 415 (One-Generation Reproduction Toxicity Study) was performed on male and female Sprague-Dawley rats exposed to Kathon™ 886F biocide in the drinking water. Kathon™ 886 NAR has no adverse effects on the reproductive capability of male or female rats and no effect on fetal health or survival to day 21 at concentrations up to and including 225 ppm in the drinking water. These values correspond to a dose level of 16.3 mg/kg/day in males and 24.7 mg/kg/day in females. (ECHA). [Kl. score = 1]

The potential of a 14% aqueous solution of 3 parts 5 -chloro- 2 -methyl-2H-isothiazol-3 -one (CMIT) and 1 part 2 -methyl-2H-isothiazol-3 -one (MIT) (ACTICIDE 14) to induce teratogenic effects in rats was evaluated in a Prenatal Developmental Toxicity Study (according to guideline EPA OPP 83 -3). Pregnant female Sprague-Dawley rats were treated with the test substance by oral gavage during the period of organogenesis (days 6 -15 post coitum). Animals were observed for mortality, signs of toxicity, food consumption and body weight gain during the treatment and a post-exposure period of 5 days. At day 20 of gestation, animals were sacrificed and examined for macroscopic pathological abnormalities. Uterine contents were examined for signs abnormal pregnancy courses, and fetuses were examined for external, visceral and skeletal abnormalities.

Treatment with the test article resulted in maternal toxicity with clearly distinguished dose-dependent grades of severity (clinical signs, moderately reduced body weight gain, slightly reduced food consumption). In spite of the observed adverse maternal effects, treatment with the test article did not have any influence on the embryonic and fetal development, as there was no embryotoxicity and no teratogenicity detected in any of the dose groups. (ECHA). [Kl. Score = 1].

An equivalent OECD Guideline 414 (Prenatal Developmental Toxicity Study) was performed on male and female Sprague-Dawley rats exposed to Kathon™ 886F biocide administered orally by gavage. No developmental effects were observed. Kathon™ 886 is non-teratogenic to the rat when administered at dosages of 100 mg/kg/day (15 mg ai/kg bw/day) during organogenesis. (ECHA). [Kl. Score = 1].

An OECD Guideline 414 (Prenatal Developmental Toxicity Study) was performed on pregnant New Zealand white rabbits exposed to Kathon™ 886 MW Biocide administered orally by gavage. No treatment-related deaths were observed at doses of 0, 0.5, 2 or 8 mg a.i./kg. At 20 mg a.i./kg, 16/16 animals were sacrificed moribund on or before day 15 G. Based on the results of this study, a maternal NOEL of 2 mg a.i./kg and an embryo-fetal NOEL of 8 mg a.i./kg was established. No treatment related increases were detected in the type or incidence of external, visceral or skeletal malformations, variations due to retarded development or in the total of these two categories combined. (ECHA). [Kl. Score = 1].

J. Derivation of Toxicological Reference and Drinking Water Guidance Values

Toxicological reference values were derived for the mixture of CMIT and MIT using methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011) as shown below.

Non-Cancer

A two-year drinking water study has been conducted in rats with a CMIT/MIT mixture (14.2% a.i.; 10.13% CMI/3.85% MI). No systemic toxicity was observed at doses up to 300 ppm a.i., although there was gastric irritation of the stomach at doses of 100 and 300 ppm a.i. The NOAEL for systemic toxicity in this study is 300 ppm (corresponding to 17.2 mg a.i./kg bw/day in males and 25.7 mg a.i./kg bw/day in females). The lowest NOAEL from this study (17 mg/kg bw/day) 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) = 1
UF_D (database uncertainty) = 1

Oral RfD = 17.2/(10 x 10 x 1 x 1 x 1) = 17.2/100 = <u>0.17 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 = (0.17 x 70 x 0.1)/2 = <u>0.60 mg/L</u>

<u>Cancer</u>

The mixture of CMIT and MIT was not carcinogenic to rats in a two-year dietary study. Thus, a cancer reference value was not derived.

K. Human Health Hazard Assessment of Physico-Chemical Properties

CMIT/MIT does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

7 ENVIRONMENTAL EFFECTS SUMMARY

A. Summary

The mixture of CMIT and MIT exhibits significant acute and chronic aquatic toxicity. The mixture is also toxic to sediment dwelling organisms but less toxic to terrestrial receptors.

B. Aquatic Toxicity

<u>Acute Studies</u>

Table 3 lists the results of acute aquatic toxicity studies conducted on the mixture of CMIT and MIT.

Table 3 Acute Aquatic Toxicity Studies on CMIT/MIT

Test Species	Endpoint	Results (mg/L)	Klimisch Score	Reference
Rainbow Trout (*Oncorhynchus mykiss*)	96-hour LC_{50}	0.19	1	ECHA
Water Flea *(Daphnia magna)*	48-hour EC_{50}	0.16	1	ECHA
Skeletonema costatum	72-hour EC_{50} growth rate	0.0063	1	ECHA
Selenastrum capricornutum	72-hour EC_{50} growth rate	0.0273	1	ECHA

Chronic Studies for MIT/CMIT

Table 4 lists the results of chronic aquatic toxicity studies conducted on the mixture of CMIT and MIT.

Table 4 Chronic Aquatic Toxicity Studies on CMIT/MIT

Test Species	Endpoint	Results (mg/L)	Klimisch Score	Reference
Rainbow Trout (*Oncorhynchus mykiss*)	38-day NOEC	0.02	1	ECHA
Water Flea *(Daphnia magna)*	21-day NOEC	0.10	1	ECHA
Skeletonema costatum	72-hour NOEC	0.0014	1	ECHA

C. Sediment Toxicity

The 28-day no observed effect concentration (NOEC) for Oligochaete (*Lumbriculus variegatus*) is 0.27 mg/kg dry weight based on survival (ECHA) [Kl. score = 2].

The 28-day no observed effect concentration (NOEC) for the midge *Chironomus riparius* is 3.65 mg/kg dry weight based on survival (ECHA) [Kl. score = 1].

D. Terrestrial Toxicity

An OECD Guideline 208 (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test) was conducted on CMIT/MIT. No apparent signs of treatment-related phytotoxicity was observed to any of the three species tested (Trifolium pratense, Oryza sativa and Brassica napus). A 21-day NOEC of 1000 mg/kg soil dw, the highest concentration tested, was derived from the study results (ECHA). [Kl. Score = 1].

Effects on soil microflora carbon respiration transformation (OECD Guideline 217) and effects on nitrogen transformation activity of soil microorganisms (OECD Guideline 216) was also studied. Greater than 50 % respiration rate inhibition was demonstrated at test concentrations of 50, 100 and 500 mg CMIT/MIT per kg dry weight soil. A 28-day NOEC value of 1 mg/kg soil dw (based on respiration rate) was determined. (ECHA) [Kl. Score = 1]. CMIT/MIT inhibited the nitrogen transformation process in active soil within the range of concentrations evaluated. A 28-day NOEC value of 10 mg/kg soil dw (based on nitrate formation rate) was determined. (ECHA) [Kl. Score = 1]..

An acute toxicity test with the earthworm *Eisenia fetida* under static conditions in artificial soil was performed with ACTICIDE® 14 (14.3% aqueous solution of CIT and MIT (3:1)) according to OECD Guideline 207 and ISO 11 268-1. Five concentrations were tested ranging from 100 to 1000 mg ACTICIDE® 14/kg dry soil (nominal). ACTICIDE® 14 caused clear sub-lethal but only moderate lethal effects in earthworms. A NOEC of 100 mg/kg dry soil (=14.3 mg a.i./kg dry soil) due to reduced mobility of the worms and a 14-day LC_{50} of >1000 mg/kg dry soil (>143 mg a.i./kg dry soil) was determined. (ECHA). [Kl. Score = 1].

Results from toxicity studies on mallard duck (*Anas platyrhynchos*) and bobwhite quail (*Colinus virginianus*) demonstrate that C(M)IT/MIT exhibits slight to moderate toxicity to birds. The 21-day oral LD_{50} for bobwhite quail is 64.5 mg/kg bw. The short-term (8-day) dietary LC_{50} for mallard duck is 945 mg/kg and bobwhite quail is 3532 mg/kg (ECHA). [Kl. Score = 1].

E. Calculation of PNEC

The PNEC calculations for CMIT/MIT 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 (0.19 mg/L), invertebrates (0.16 mg/L) and algae (0.0063 mg/L). Results from chronic studies are also available for all three trophic levels, with the lowest NOEC value being 0.0014 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 0.0014 mg/L for algae. The $PNEC_{water}$ for CMIT/MIT is 0.00014 mg/L.

PNEC sediment

Experimental results are available for two sediment dwelling organisms. The lowest NOEC was observed in a chronic sediment-spiked test with Oligochaete, the 28-day NOEC was 0.27 mg/kg dw. Using an assessment factor of 50, the $PNEC_{sediment}$ was determined to 0.0054 mg/kg dw.

PNEC soil

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for earthworms (>1000 mg/kg dw). Long-term studies have also been conducted on plants and soil microorganisms. On the basis that the data consists of acute tests from one trophic level and long-term tests from two trophic levels, an assessment factor of 50 has been applied to the lowest reported NOEC value of 1 mg/kg dw for soil microorganisms. The $PNEC_{soil}$ is 0.02 mg/kg dw.

8 CATEGORISATION AND OTHER CHARACTERISTICS OF CONCERN

A. PBT Categorisation

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2017).

The biodegradability of the mixture of CMIT and MIT could not be established. Biodegradation studies on CMIT and MIT separately have been conducted. An OECD Guideline 301 B (Ready Biodegradability: CO2 Evolution Test) was performed. 50% of the MIT biodegraded within 29 days. While the substance does not qualify as readily biodegradable, the data suggest it is ultimately biodegradable. The same test with CMIT showed up to 62% of the test substance biodegraded within the same time frame of 29 days. [Kl Score=1](ECHA). The rate of biodegradation in these tests does not satisfy the OECD criterion for readily biodegradability (60% in a 10-day window), but the results do show that these chemicals are biodegradable at more realistic environmental exposure concentrations. Thus, CMIT/MIT do not meet the criteria for persistence.

Bioaccumulation studies are not available for the CMIT/MIT mixture. Individually, the experimental BCF for CMIT is 67-114 in bluefish sunfish, and the BCF for MIT was determined to be 2.3. Thus, CMIT/MIT do not meet the criteria for bioaccumulation.

The chronic toxicity data on the mixture of CMIT and MIT has a NOEC < 0.1 mg/L.. The lowest acute LC_{50} value for the mixture are < 1 mg/L. Therefore, CMIT/MIT meets the criteria for toxicity.

The overall conclusion is that the mixture of CMIT/MIT is not a PBT substance.

B. Other Characteristics of Concern

Only tier 3 chemicals which trigger persistence and bioaccumulative thresholds are considered to be chemicals with a potential for cumulative impacts. As noted in the prior section, both CMIT/MIT mixture do not meet the criteria for persistence or bioaccumulation.

No other characteristics of concern were identified for the mixture of CMIT and MIT.

9 SCREENING ASSESSMENT

Chemical Name	CAS No.	Overall PBT Assessment [1]	Chemical Databases of Concern Assessment Step		Persistence Assessment Step		Bioaccumulative Assessment Step	Toxicity Assessment Step			Risk Assessment Actions Required[3]
			Listed as a COC on relevant databases?	Identified as Polymer of Low Concern	P criteria fulfilled?	Other P Concerns	B criteria fulfilled?	T criteria fulfilled?	Acute Toxicity [2]	Chronic Toxicity[2]	
Mixture of 5-chloro-2-methyl-2h-isothiazolol-3-one (CMIT) and 2-methyl-2h-isothiazol-3-one (MIT)	55965-84-9	Not a PBT	No	No	No	No	No	Yes	3	3	3

Footnotes:

1 - PBT Assessment based on PBT Framework.

2 - Acute and chronic aquatic toxicity evaluated consistent with assessment criteria (see Framework).

3 - Tier 3 - Quantitative Risk Assessment: Complete PBT, qualitative and quantitative assessment of risk.

Notes:

CAS No. = chemical abstracts service number

COC = chemical of concern

PBT = Persistent, Bioaccumulative and Toxic

B = bioaccumulative

P = persistent

T = toxic

10 REFERENCES, ABBREVIATIONS AND ACRONYMS

A. 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. Updated March 2021. Available: https://www.nhmrc.gov.au/about-us/publications/australian-drinking-water-guidelines

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. Available: http://www.nepc.gov.au/resource/chemical-risk-assessment-guidance-manuals

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. Available: www.environment.gov.au/water/coal-and-coal-seam-gas/national-assessment-chemicals/consultation-risk-assessment-guidance-manual

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

enHealth. 2012. Environmental health risk assessment: Guidelines for assessing human health risks from environmental hazards. Available: https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-publicat-environ.htm

European Chemicals Agency [ECHA]. (2017). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland. Available: https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

EU Scientific Committee on Consumer Safety [EU SCCS]. (2009). Opinion on the mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one [3:1], Colipa No P56, Scientific Committee on Consumer Safety, SCCS/1238/09. Available: https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_009.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.

NICNAS. (2020). Methylisothiazolinone preservatives and industrial biocides: Environmental tier II assessment. 16 June 2020. Available: https://www.industrialchemicals.gov.au/sites/default/files/Methylisothiazolinone%20preservatives%20and%20industrial%20biocides_%20Environment%20tier%20II%20assessment.pdf

Reynolds, J.L. (1994a). Aerobic aquatic metabolism of 14C-RH-573. Rohm and Haas Technical Report No. 34-94-122. XenoBiotic Laboratories, Inc., Plainsboro, NJ. United States.

Reynolds, J.L. (1994b). Aerobic aquatic metabolism of 14C-RH-651. Rohm and Haas Technical Report No. 34-94-64. XenoBiotic Laboratories, Inc., Plainsboro, NJ. United States.

B. Abbreviations and Acronyms

°C	degrees Celsius
µg/L	micrograms per litre
a.i.	active ingredient
ADWG	Australian Drinking Water Guidelines
AICS	Australian Inventory of Chemical Substances
bw	body weight
CAS No.	Chemical Abstracts Service Number (also referred to as CAS RN)
CFR	Code of Federal Regulations
COC	chemical of concern
DEWHA	Department of the Environment, Water, Heritage and the Arts
EC_{50}	median effective concentration
ECHA	European Chemicals Agency
EU	European Union
g/L	grams per litre
GLP	Good Laboratory Practice
IUPAC	International Union of Pure and Applied Chemistry
kg/m^3	kilogram per cubic metre
Kl	Klimisch scoring system
K_{ow}	n-octanol/water partition coefficient
kPa	kilopascal
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LLNA	local lymph node assay
LOAEL	lowest observed adverse effect concentration
LOEC	lowest observed effect concentration
mg/kg	milligrams per kilogram
mg/L	milligrams per litre
NICNAS	The National Industrial Chemicals Notification and Assessment Scheme

NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OECD	Organisation for Economic Co-operation and Development
Pa	Pascal
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No Effect Concentration
ppm	parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RfD	reference dose
SGG	Synthetic Greenhouse Gases
UDS	Unscheduled DNA Synthesis
USEPA	United States Environmental Protection Agency

Attachment 2 Risk Characterisation Tables

Attachment 2, Table 1
Summary of Exposure Point Concentrations

Chemical	CAS No.	Estimated concentration in pre-injection fluid systems (mg/L)	Half-Life (days)	Estimated Flowback Concentration (mg/L)[1]	Estimated Concentration in Combined Balance Water Feed Pond to WMF (mg/L)[2]		Estimated Concentration in Permeate after 99% treatment efficiency by RO plant (mg/L)[3]		Estimated Concentration in Dawson River (Treated Water Release) (mg/L)[4]		Estimated Concentration in Dawson River Sediment (mg/kg)[4]	
					Temporal Scenario (days)		Temporal Scenario (days)		Temporal Scenario (days)		Temporal Scenario (days)	
					0	30	0	30	0	30	0	30
Mixture of 5-chloro-2-methyl-2h-isothiazolol-3-one (CMIT) and 2-methyl-2h-isothiazol-3-one (MIT)	55965-84-9	5.40E-02	7.21E-01	7.20E-03	7.20E-04	2.13E-16	7.20E-06	2.13E-18	1.44E-07	4.27E-20	9.01E-08	2.67E-20

Notes:
mg/L = milligrams per liter
CAS = Chemical Abstracts Service
NA = not applicable
RO = reverse osmosis
WMF = Water Management Facility

1) Estimated flowback concentration in pond influent (150% of injected fluid volume) per coal seam per 20% of mass returned calculated using equation: Pond Influent = FBconcentration (mg/L)/ FB dilution 150% x percent mass returned (mg/L)
2) Estimated flowback concentration was multiplied by a factor of 10% to account for dilution in the water feed pond (90:1) due to the aggregation of produced water from other wells which were not recently hydraulically fractured into the same pond.
3) Concentrations in the water feed pond were further reduced by a factor of 99% to account for efficiencies in the WMF system.
4) A dilution factor of 50 was assumed within the approved mixing zone.
5) EPC_{sed} = ($K_{sed\text{-}water}$/BD_{sed}) x 1000 x EPC_{water}
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 kg/m^3[default]
$PNEC_{water}$ = treated water EPC
$K_{sed\text{-}water}$ = 0.8 + [(0.2 x Kp_{sed})/1000 x BD_{solid}]
And:
Kp_{sed} = solid-water partition coefficient (L/kg)
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 kg/m^3[default]
Kp_{sed} = K_{oc} x f_{oc}
Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg), chemical-specific value found in dossier provided in Attachment 1.
f_{oc} = fraction of organic carbon in sediment = 0.04 [default].

Attachment 2, Table 2
Comparison of Theoretical Concentrations of COPCs to Drinking Water Guidelines

Permeate Pond								
Chemical	**CAS No.**	**Estimated Concentration in Permeate after 99% treatment efficiency by RO plant (mg/L)[1]**		**Estimated Concentration in Dawson River (Treated Water Release) (mg/L)[1]**		**Drinking Water Screening Level (mg/L)**	**Ratio of COPC Concentrations and Screening Criteria (Ratio greater than one = unacceptable potential risk)**	
		Temporal Scenario (days)		**Temporal Scenario (days)**			**Temporal Scenario (days)**	
		0	**30**	**0**	**30**		**0**	**30**
Mixture of 5-chloro-2-methyl-2h-isothiazolol-3-one (CMIT) and 2-methyl-2h-isothiazol-3-one (MIT)	55965-84-9	7.20E-06	2.13E-18	1.44E-07	4.27E-20	6.00E-01	2.4E-07	7.1E-20

Notes:
mg/L = milligrams per liter
CAS = Chemical Abstracts Service
NA = not applicable
RO = reverse osmosis
WMF = Water Management Facility

1) Estimated concentrations derived in Table 1.

Attachment 2, Table 3
Comparison of Theoretical Concentrations of COPCs to PNECs (Water and Sediment)

Permeate Pond												
Chemical	**CAS No.**	**Estimated Concentration in Permeate after 99% treatment efficiency by RO plant (mg/L)[1]**		**Estimated Concentration in Dawson River (Treated Water Release) (mg/L)[1]**		**PNEC aquatic (mg/L)**	**Ratio of COPC Concentrations and Screening Criteria (Ratio greater than one = unacceptable potential risk)**		**Estimated Concentration in Dawson River Sediment (mg/kg)[1]**		**PNEC sediment (mg/kg)**	**Ratio of COPC Concentrations and Screening Criteria (Ratio greater than one = unacceptable potential risk)**	
		Temporal Scenario (days)		**Temporal Scenario (days)**			**Temporal Scenario (days)**		**Temporal Scenario (days)**			**Temporal Scenario (days)**	
		0	**30**	**0**	**30**		**0**	**30**	**0**	**30**		**0**	**30**
Mixture of 5-chloro-2-methyl-2h-isothiazolol-3-one (CMIT) and 2-methyl-2h-isothiazol-3-one (MIT)	55965-84-9	7.20E-06	2.13E-18	1.44E-07	4.27E-20	1.40E-04	1.0E-03	3.0E-16	9.01E-08	2.67E-20	5.40E-03	1.7E-05	4.9E-18

Notes:
mg/L = milligrams per liter
CAS = Chemical Abstracts Service
NA = not applicable
PNEC = predicted no effects concentration
RO = reverse osmosis
WMF = Water Management Facility

1) Estimated concentrations derived in Table 1.

Attachment 2, Table 4
Risk Estimates for Cattle Egret - Dawson River Release

Constituent Name	CAS No.	Mammal NOAELt	Mammal NOAEL Test Animal		Avian NOAELt [1]	Avian NOAEL Test Animal		Avian Receptor Cattle Egret	
			Animal	**Body Weight (kg)**		**Animal**	**Body Weight (kg)**	**Body Weight (kg)**	**Derived TRV**
Mixture of 5-chloro-2-methyl-2h-isothiazolol-3-one (CMIT) and 2-methyl-2h-isothiazol-3-one (MIT)	55965-84-9	1.70E+01	Rat	3.50E-01	2.06E+00	Mallard Duck	1.58E+00	3.90E-01	1.7E+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.

$$Derived\ TRV = NOAEL_{test} * \left(\frac{Body\ Weighttest}{Body\ Weightreceptor}\right)^{(1/4)}$$

Exposure Route	Parameter Code	Parameter Definition	Units (a)	Parameter Value	Source (b)
Ingestion	IR	Ingestion rate	l/day	0.03	(c)
	EF	Exposure frequency	day/yr	7	BPJ
	ED	Exposure duration	yr	1	BPJ
	BW	Body weight	kg	0.39	Siegfried, 1969
	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
- W.R. Siegfried (1969) Energy Metabolism of the Cattle Egret, ZoologicaAfricana, 4:2, 265-273, DOI: 10.1080/00445096.1969.11447375

c/ 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)$^{0.67}$

Constituent Name	CAS No.	EPC [1] Day 0	EPC [1] Day 30	Toxicity	Total Intake (mg/kg/day)	Hazard Quotient	Total Intake (mg/kg/day)	Hazard Quotient
		CW (mg/l)	**CW (mg/l)**	**TRVs**	**Day 0**	**Ingestion**	**Day 30**	**Ingestion**
Mixture of 5-chloro-2-methyl-2h-isothiazolol-3-one (CMIT) and 2-methyl-2h-isothiazol-3-one (MIT)	55965-84-9	1.4E-07	4.3E-20	1.7E+01	2.1E-10	1.3E-11	6.3E-23	3.8E-24

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 estimated concentration in Dawson River in Table 1 for Day 0 and Day 30

$$Total\ Intake = \frac{EPC\ \times IR\ \times EF\ \times ED}{BW\ \times ED\ x\ 365\ ^{days}/_{year}}$$

$$Hazard\ Quotient = \frac{Total\ Intake\ \left(\frac{mg}{kg - day}\right)}{TRV\ \left(\frac{mg}{kg - day}\right)}$$

Attachment 2, Table 5
Risk Estimates for Kangaroo - Dawson River Release

Constituent Name	CAS No.	Mammal NOAELt	Mammal NOAEL Test Animal		Mammal Kangaroo	
			Animal	Body Weight (kg)	Body Weight (kg)	Derived TRV
Mixture of 5-chloro-2-methyl-2h-isothiazolol-3-one (CMIT) and 2-methyl-2h-isothiazol-3-one (MIT)	55965-84-9	1.70E+01	Rat	3.50E-01	2.50E+01	2.83E-02

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.

$$Derived\ TRV = NOAEL_{test} * \left(\frac{Body\ Weighttest}{Body\ Weightreceptor}\right)^{\left(1/4\right)}$$

Exposure Route	Parameter Code	Parameter Definition	Units (a)	Parameter Value	Source (b)
Ingestion	IR	Ingestion rate	l/day	3	Fleming, 2001
	EF	Exposure frequency	day/yr	7	BPJ
	ED	Exposure duration	yr	1	BPJ
	BW	Body weight	kg	25	Fleming, 2001
	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
Fleming, 2001
Fleming, Peter; Laurie Corbett, Robert Harden, Peter Thomson (2001). Managing the Impacts of Dingoes and Other Wild Dogs. Commonwealth of Australia: Bureau of Rural Sciences.

Constituent Name	CAS No.	EPC[1] Day 0	EPC[1] Day 30	Toxicity	Total Intake (mg/kg/day)	Hazard Quotient	Total Intake (mg/kg/day)	Hazard Quotient
		CW (mg/l)	CW (mg/l)	TRVs	Day 0	Ingestion	Day 30	Ingestion
Mixture of 5-chloro-2-methyl-2h-isothiazolol-3-one (CMIT) and 2-methyl-2h-isothiazol-3-one (MIT)	55965-84-9	1.4E-07	4.3E-20	2.8E-02	3.3E-10	1.2E-08	9.8E-23	3.5E-21

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 estimated concentration in Dawson River in Table 1 for Day 0 and Day 30

$$Total\ Intake = \frac{EPC\ \times IR\ \times EF\ \times ED}{BW\ \times ED\ x\ 365\ {}^{days}/_{year}}$$

$$Hazard\ Quotient = \frac{Total\ Intake\ \left(\frac{mg}{kg-day}\right)}{TRV\ \left(\frac{mg}{kg-day}\right)}$$

Attachment 2, Table 6
Risk Estimates for Dingo - Dawson River Release

Constituent Name	CAS No.	Mammal NOAELt	Mammal NOAEL		Mammal	
			Test Animal		Dingo	
			Animal	Body Weight (kg)	Body Weight (kg)	Derived TRV
Mixture of 5-chloro-2-methyl-2h-isothiazolol-3-one (CMIT) and 2-methyl-2h-isothiazol-3-one (MIT)	55965-84-9	1.70E+01	Rat	3.50E-01	1.30E+01	2.83E-02

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.

$$Derived\ TRV = NOAEL_{test} * \left(\frac{Body\ Weighttest}{Body\ Weightreceptor}\right)^{(1/4)}$$

Exposure Route	Parameter Code	Parameter Definition	Units (a)	Parameter Value	Source (b)
Ingestion	IR	Ingestion rate	l/day	0.75	Dawson, 1995
	EF	Exposure frequency	day/yr	7	BPJ
	ED	Exposure duration	yr	1	BPJ
	BW	Body weight	kg	13	Dawson, 1995
	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
Dawson, 1995
Dawson, Terence J. (1995). Kangaroos: Biology of the Largest Marsupials. Cornell University Press, Ithaca, New York. Second printing: 1998. ISBN 0-8014-8262-3.

Constituent Name	CAS No.	EPC[1] Day 0	EPC[1] Day 30	Toxicity	Total Intake (mg/kg/day)	Hazard Quotient	Total Intake (mg/kg/day)	Hazard Quotient
		CW (mg/l)	CW (mg/l)	TRVs	Day 0	Ingestion	Day 30	Ingestion
Mixture of 5-chloro-2-methyl-2h-isothiazolol-3-one (CMIT) and 2-methyl-2h-isothiazol-3-one (MIT)	55965-84-9	1.4E-07	4.3E-20	2.8E-02	1.6E-10	5.6E-09	4.7E-23	1.7E-21

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 estimated concentration in Dawson River in Table 1 for Day 0 and Day 30

$$Total\ Intake = \frac{EPC\ \times IR\ \times EF\ \times ED}{BW\ \times ED\ x\ 365\ {days}/{year}}$$

$$Hazard\ Quotient = \frac{Total\ Intake\ \left(\frac{mg}{kg - day}\right)}{TRV\ \left(\frac{mg}{kg - day}\right)}$$

Attachment 2, Table 7
Risk Estimates for Cattle - Dawson River Release

Constituent Name	CAS No.	Mammal NOAELt	Mammal NOAEL		Mammal	
			Test Animal		Cattle	
			Animal	Body Weight (kg)	Body Weight (kg)	Derived TRV
Mixture of 5-chloro-2-methyl-2h-isothiazolol-3-one (CMIT) and 2-methyl-2h-isothiazol-3-one (MIT)	55965-84-9	1.70E+01	Rat	3.50E-01	4.54E+02	2.83E+00

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.

$$Derived\ TRV = NOAEL_{test} * \left(\frac{Body\ Weighttest}{Body\ Weightreceptor}\right)^{\left(1/4\right)}$$

Exposure Route	Parameter Code	Parameter Definition	Units (a)	Parameter Value	Source (b)
Ingestion	IR	Ingestion rate	l/day	86	API, 2004
	EF	Exposure frequency	day/yr	7	BPJ
	ED	Exposure duration	yr	1	BPJ
	BW	Body weight	kg	454	API, 2004
	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
API, 2004
API. (2004). Risk-Based Screening Levels for the Protection of Livestock Exposed to Petroleum Hydrocarbons, Regulatory Analysis and Scientific Affairs No. 4733 July 2004.

Constituent Name	CAS No.	EPC[1] Day 0	EPC[1] Day 30	Toxicity	Total Intake (mg/kg/day)	Hazard Quotient	Total Intake (mg/kg/day)	Hazard Quotient
		CW (mg/l)	CW (mg/l)	TRVs	Day 0	Ingestion	Day 30	Ingestion
Mixture of 5-chloro-2-methyl-2h-isothiazolol-3-one (CMIT) and 2-methyl-2h-isothiazol-3-one (MIT)	55965-84-9	1.4E-07	4.3E-20	2.8E+00	5.2E-10	1.8E-10	1.5E-22	5.5E-23

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 estimated concentration in Dawson River in Table 1 for Day 0 and Day 30

$$Total\ Intake = \frac{EPC\ \times IR\ \times EF\ \times ED}{BW\ \times ED\ x\ 365\ {days}/{year}}$$

$$Hazard\ Quotient = \frac{Total\ Intake\ \left(\frac{mg}{kg - day}\right)}{TRV\ \left(\frac{mg}{kg - day}\right)}$$

Appendix 8 – Exposure Pathways

	Lifecycle Primary Source	Potential Residual Drilling and Completion, Hydraulic Fracturing and Water Management Facility Chemical Exposure
	Modes of Exposure	**Release of Desalinated Water**
Affected Media/ Environment	**Stored Fluids/Produced Water**	No
	Soils	No
	Surface Water	Yes
	Groundwater	No
Stored Fluids/Produced Water		
Human Receptors	Worker	-
Ecological Receptors	Terrestrial flora	-
	Terrestrial fauna	-
	Aquatic flora	-
	Aquatic fauna	-
Soils		
Human Receptors	Worker	-
	Agricultural Worker or Resident	-
Ecological Receptors	Terrestrial flora	-
	Terrestrial fauna	-
	Aquatic flora	-
	Aquatic fauna	-
Surface Water		
Human Receptors	Worker	NA
	Agricultural Worker or Resident	I/LP
Ecological Receptors	Terrestrial flora	C
	Terrestrial fauna	C
	Aquatic flora	C
	Aquatic fauna	C
Groundwater		
Human Receptors	Worker	-
	Agricultural Worker or Resident	-
Ecological Receptors	Terrestrial flora	-
	Terrestrial fauna	-
	Aquatic flora	-
	Aquatic fauna	-

Notes:

C	*Complete exposure pathway*
IC	*Incomplete exposure pathway*
I/LP	*Insignificant / Low Probability Exposure Pathway*
NA	*Not a Matter of National Environmental Significance (MNES)*

Appendix 9 – Summary of Best Practice Methodologies

Best Practice Risk Assessment Methodology – Chemical Additives

The approval defines “best practice risk assessment methodology” as follows:

- A chemical risk assessment in accordance with best practice national or international standards and guidelines may be based on the following:
    - United States Environmental Protection Agency (USEPA) (2014). EPA-Expo-Box (A Toolbox for Exposure Assessors), available at http://www.epa.gov/expobox
    - Organisation for Economic Co-operation and Development (OECD) (2014). The OECD Environmental Risk Assessment Toolkit: Tools for Environmental Risk Assessment and Management, available at https://www.oecd.org/env/ehs/risk-assessment/environmental-risk-assessment-toolkit.htm
    - The most recently published and approved guideline recommended by the Minister
- In addition, the chemical risk assessment must be based following best practice guidance:
    - Department of the Environment and Energy (DoEE) (2017). Exposure Draft: Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction (CSG Risk Assessment Guidance Manual). Commonwealth of Australia, available at www.environment.gov.au/water/coal-and-coal-seam-gas/national-assessment-chemicals/consultation-risk-assessment-guidance-manual
    - The National Environment Protection (Assessment of Site Contamination) Measure (NEPM) 1999 as amended 2013 (NEPC, 2013); specifically, Volume 5: Schedule B4 Guideline on Site-Specific Health Risk Assessment
    - Environmental health risk assessment: Guidelines for assessing human health risks from environmental hazards, enHealth Subcommittee (enHealth) of the Australian Health Protection Principal Committee, Canberra, Australia, 2012a
    - Australian exposure factor guidance, enHealth Subcommittee (enHealth) of the Australian Health Protection Principal Committee, Canberra, Australia, 2012b

USEPA’s EXPOsure toolBOX (EPA-Expo-Box) has been referenced as a framework that should be leveraged in the chemical risk assessment. EPA-Expo-Box was developed by USEPA Office of Research and Development, as a compendium of exposure assessment tools that links to exposure assessment guidance, databases, models, key references and related resources. The toolbox provides a variety of exposure assessment resources organized into six Tool Sets, each containing a series of modules as shown in the table below:

Table 8-1: Document Revision and Approval Requirements

Approach	Media	Routes
• Direct Measurement (Point-of-Contact) • Indirect Estimation (Scenario Evaluation) • Exposure Reconstruction (Biomonitoring and Reverse Dosimetry)	• Air • Water and Sediment • Soil and Dust • Food • Aquatic Biota • Consumer Products	• Inhalation • Ingestion • Dermal
Tiers and Types	**Life Stages and Population**	**Chemical Classes**
• Screening-Level and Refined • Deterministic and Probabilistic • Aggregate and Cumulative	• General Population • Residential Consumer • Occupational Workers • Life stages • Highly Exposed	• Pesticides • Other Organics • Inorganics and Fibres • Nanomaterials

For example, the inhalation module under the route tool set provides the following:

- Method used in the dose-response
- Calculations for exposure concentrations and potential dose
- Estimating media-specific concentrations
- Exposure scenarios and potential receptors
- Exposure factors
- Guidance and references.

OECD Environmental Risk Assessment Toolkit provides access to practical tools on environmental risk assessment of chemicals. It describes the general work-flow of environmental risk assessment and provides examples of risk assessment. The toolkit also provides links to relevant tools developed by OECD and member countries that can be used in each step of the work-flow. The examples provide a roadmap of the process, showing the steps involved in each case and the tools that were used.

The OECD general risk assessment process for environmental risk assessment includes four steps: hazard identification, hazard characterisation, exposure assessment, and risk characterization. summarises the available tools for the risk assessment process.

Table 8-2: Summary of Available Tools for Risk Assessment

Categories		Links to Available Materials	Explanation
Hazard Assessment	Gathering existing information	OECD Existing Chemicals database	OECD-wide agreed hazard assessments elaborated in the OECD Co-operative Chemicals Assessment Programme
		eChemPortal	Global Portal to Information on Chemical Substances
		Manual for the Assessment of Chemicals (Chapter 2)	A set of guidance documents for (initial) risk assessment developed for the OECD Co-operative Chemicals Assessment Programme. See chapter 2 for gathering data
	Evaluating existing information	Manual for the Assessment of Chemicals (Chapter 3)	See chapter 3.1 for determining the quality of existing data
	Generating new data	Test guidelines	Test methods for assessing (hazard) properties of chemicals
		The OECD (Q)SAR Project	Guidance and tools for filling data gaps by non-testing methods.
	Assessing the hazards	Manual for the Assessment of Chemicals (Chapter 4) & (Chapter 5)	Chapter 4 provides guidance assessing the hazards of chemical substances to man and the environment Chapter 5 provides guidance on elaborating a hazard assessment report.
		Series on Testing and Assessment	Guidance documents and reports related to assessment of several inherent effects

Categories		Links to Available Materials	Explanation
Exposure Assessment	General guidance for exposure assessment	Environmental Exposure Assessment Strategies for Existing Industrial Chemicals in Member Countries	An overview of the approaches on environmental exposure assessment used in the late 1990s by OECD member countries
		Manual for the Assessment of Chemicals (Chapter 6)	Guidance on reporting exposure information (Section 6.2) and on initial exposure assessment. (Sections 6.3 and 6.4)
	Measuring or estimating releases to the environment	Emission Scenario Documents	Estimating emission of chemicals in specific industry and use categories
		Global Portal to PRTR Information (PRTR net)	A gateway and databases of global information on Pollutant Release and Transfer Registers (PRTRs)
		Resource Centre for PRTR Release Estimation Techniques	
		Centre for PRTR Data	
	Environmental fate and pathways	Test guidelines	Test methods for assessing (hazard) properties of chemicals
		The OECD (Q)SAR Project	Guidance and tools for filling data gaps by non-testing methods.
		Pov and LRTP Screening Tool	A tool for screening overall persistence and long-range transport potential of chemicals
		Guidance Document on the Use of Multimedia Models for Estimating Overall Environmental Persistence and Long-range Transport	Guidance on the models estimating Pov and LRTP
		EPISuite™	The EPI (Estimation Programs Interface) Suite™ is a Windows®-based suite of physical/chemical property and environmental fate estimation programs developed by the USEPA's Office of Pollution Prevention Toxics and Syracuse Research Corporation (SRC).
	Measuring or estimating concentrations in the environment	Report on improving the use of monitoring data	The workshop report on the use of monitoring data in exposure assessment
		Available tools and models for exposure assessment	A list of tools and models developed and used in OECD member countries for different tiers of exposure assessment.
Other Relevant Materials/		New Chemical Assessment Comparisons and Implications for Work Sharing	Comparison of risk assessment of new chemicals.

Categories	Links to Available Materials	Explanation
Risk Assessment of Specific Chemicals	Policy Dialogue on Exposure Assessment	Comparison of approaches to exposure assessment in OECD member countries
	Pesticide Testing and Assessment	Guidance documents etc. on hazard and exposure assessment of pesticides and biocides respectively.
	Biocides	

The *CSG Risk Assessment Guidance Manual* (DoEE 2017) references the USEPA and OECD toolboxes in developing their chemical risk assessment framework and their tools to guide best practice for human health and environmental risk assessment. These toolboxes are all based on the principles contained within USEPA's risk assessment guidelines. As a toolbox, not all of the tools are to be utilized, rather only those tools that are appropriate to the chemical, its functional toxicity, and the exposure pathway being used for assessment should be used. As with all risk assessment methods, a hierarchy is applied in the use and assessment of data on exposure point concentrations and toxicity, with direct measurements and toxicity values provided by epidemiological studies providing the least uncertainty in the risk assessment process.

Best Practice Risk Assessment Methodology – Geogenic Chemicals

The assessment of geogenic chemicals recovered within produced water will be subject to a screening assessment and if required qualitatively assessed against published or derived risk-based criteria depending on their end fate (i.e. use and/or disposal).

For produced water, potentially applicable criteria may include:

- Human Health:
    - National Water Quality Management Strategy Australian Drinking Water Guidelines (2022)
    - WHO Drinking-water Quality, Fourth Edition (2017)
    - USEPA Regional Screening Levels (RSLs) Resident Tapwater (November 2022 update) (2022)
    - USEPA Maximum Contaminant Levels (MCLs, 2009)
- Environmental and Ecological:
    - Australian and New Zealand Guidelines for Fresh and Marine Water Quality (ANZG 2018)
    - Risk-Based Screening Levels for the Protection of Livestock Exposed to Petroleum Hydrocarbons, Publication Number 4733 (API 2004)
    - Republic of South Africa South African Water Quality Guidelines (1996)
    - USEPA National Recommended Water Quality Criteria (2015)
    - USEPA Region 3 Biological Technical Assistance Group Freshwater Screening Benchmarks (2006).

Appendix 10 – Contingency Response Actions

Contingency Response Actions for Chemicals used in Coal Seam Gas Extraction

Gas Field Development Project, including Fairview Water Release Scheme

Introduction

This document provides an overview of management practices in place within Santos to minimise the risk of potential harm to Matters of National Environmental Significant (MNES) from an accidental spill or release of chemicals used in the extraction of coal seam gas.

The potential for harm and any responding actions necessary to manage the risk of harm will also be informed by the outputs of the Chemical Risk Assessment(s).

This document provides a framework for Santos to:

- Inform response to a spill or accidental release;
- Communicate with the appropriate parties in the event of a spill or accidental release;
- Inform environmental management and / or remedial actions necessary; and
- Inform monitoring and reporting

Scope and Response Process Overview

Scope

This document addresses all spills and accidental releases for the chemicals used for the extraction of coal seam gas to the environment. It does not include spills or releases that occur within operational or construction areas or other chemical substances.

Spill or accidental release scenarios could include (but not limited to):

- Transport truck rollover
- Overflow, over topping or failure of storages such ponds and tanks
- Failure of transfer pipelines, hoses or associated connections
- Uncontrolled releases from irrigation areas

Response Process Overview

To align with overarching emergency response actions for the GLNG and Gas Field Development Projects, a copy of the standard response procedure for a chemical spill or accidental release is provided as Attachment 1.

To respond to a spill or accidental release and in accordance with Santos escalation procedures, a combination of on-site field resources, regional operations resources and other company resources will be utilised. Contractors will be utilised as needed to implement management and / or remedial actions and monitoring.

Response actions as provided in the following section.

Response Actions

These actions will be executed with the aim to:

- Reduce the threat to human life or injury
- Protect and manage the risk of harm to the environment (including MNES), and
- Preserve infrastructure, product, and equipment.

General Response Actions

1. **Evacuate** (all non-essential personnel at the location)
2. **Eliminate** (sources of ignition, sparks, etc.)
3. **Stop and Coordinate** (stop source of the incident (e.g. spill) and coordinate shut down of relevant equipment, if possible)
4. **Notify** (internal and external notifications)
    (a) All emergency environmental incidents must be reported to the Santos Duty Manager upon discovery, and
    (b) Conduct regulatory or emergency services report, as required
5. **Identify** (material (if unknown) and identify PPE, hazards, and response procedures using SDSs)
6. **Contain / Isolate** (contain released material / incident using emergency response equipment and/or set up perimeter to isolate area)
7. **Stabilise and Neutralise** (neutralise / stabilise spilt material (where relevant), use absorbents to stabilise released materials etc)
8. **Clean up** (remove released materials, spill response materials, and affected clean-up media etc.)
9. **Evaluate** (based on the outcomes of the Chemical Risk Assessment)
10. **Document**
11. **Monitor and Manage and / or Remediate** (as necessary based on the outcomes of step 9 and outcomes of monitoring), and
12. **Report.**

Accidental Releases to Land

Utilising the steps described above, actions associated with a release to land are focused on stopping and containing the release, thereby preventing further migration and the risk of receptor exposure.

Following containment, and based on the outcomes of the Chemical Risk Assessment in relation to the potential risk to MNES, soil will either be:

- Left in-situ – only where there is no risk of adverse impact to MNES (i.e. concentrations are non-hazardous and / or do not persist at hazardous concentrations, and / or there is no exposure pathway to MNES
- Excavated and disposed (in accordance with regulatory requirements) and / or remedial action applied to treat the soil
- Sampled and analysed to inform whether residues within soils need to be excavated and disposed, or managed in-situ.

Post excavation or implementation of management actions, validation monitoring (sampling) may be necessary to confirm that that sufficient residue has been removed or, to confirm that management actions have been successful in managing the risk of adverse impact to MNES. Conversely monitoring may demonstrate that an unacceptable risk remains and that further excavation or management actions would be required to manage that risk. Validation monitoring and remedial actions would be repeated until it has been demonstrated that the risk of adverse impact to MNES has been managed.

Accidental Releases to Water

Where releases occur to water the nature of the response actions are focused on containment of the release and then the associated impacted water to the extent feasible. This can involve a range of activities dependent on the nature of the resource involving establishment of temporary earthen dams, containment booms or sorbent booms.

Consistent with the hierarchy described above stopping further migration to water and limiting the extent of migration downstream is the primary focus of initial activities.

Remediation activities will focus on removal of the chemical released and may involve a combination of pumping and removal of impacted water and/or treatment in place (for example aeration for organic volatile compounds).

Communication

Internal Communication

Emergency incidents will initially be notified internally to facilitate resourcing and effective response actions. This may involve co-ordination with emergency services (fire, police, ambulance) as necessary. Further, all emergency environmental incidents will be recorded in the Incident Management System (IMS) as soon as possible.

Regulatory Notifications

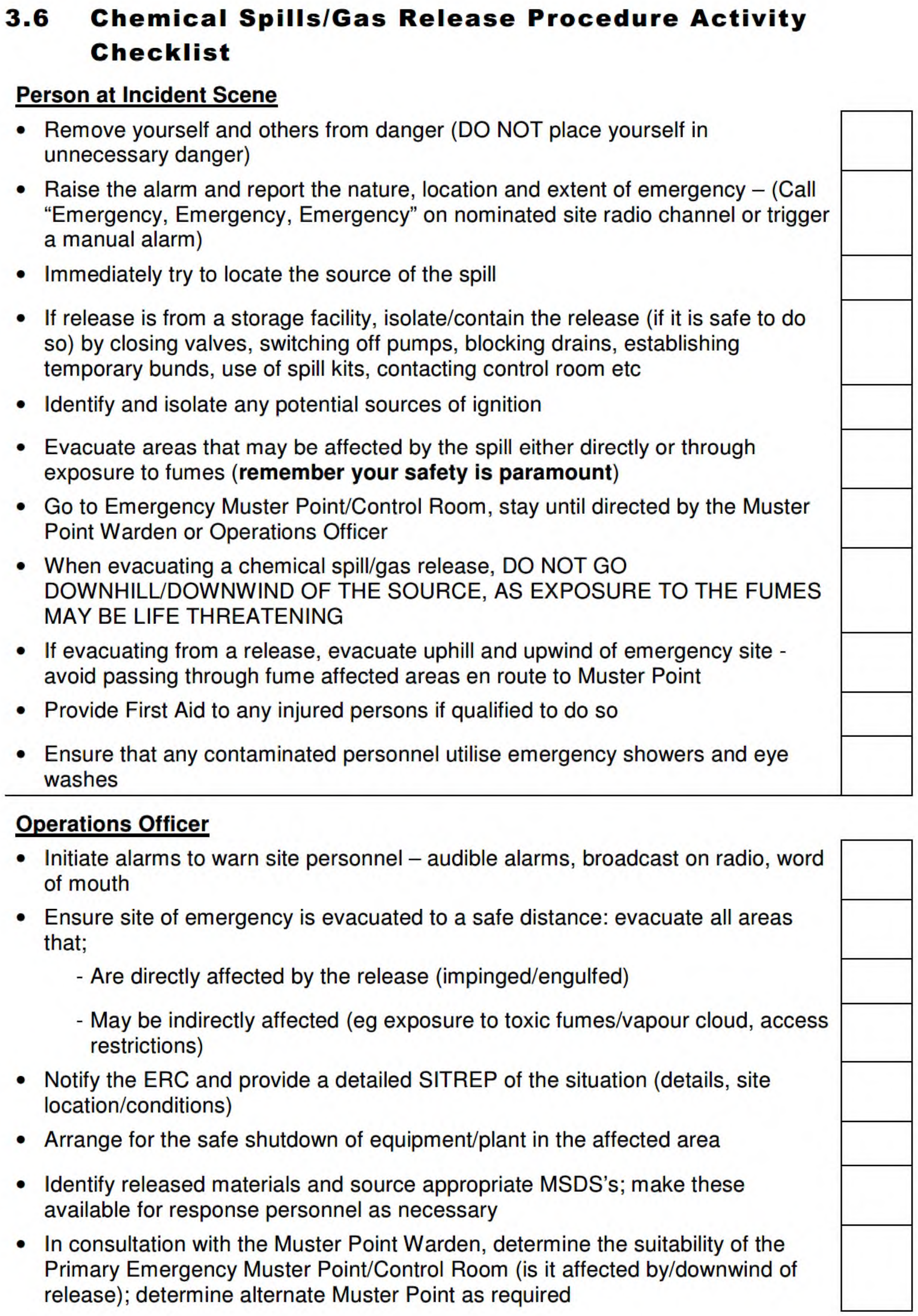
Notification will be made to the Department of Agriculture, Water and the Environment in accordance with the relevant approval requirements.

Incident investigation

All incidents will be investigated to determine the casual factors and associated underlying root causes.

Attachment 1

Santos Standard - Chemical Spill Checklist



3.6 Chemical Spills/Gas Release Procedure Activity Checklist

Person at Incident Scene

- Remove yourself and others from danger (DO NOT place yourself in unnecessary danger) ☐
- Raise the alarm and report the nature, location and extent of emergency – (Call “Emergency, Emergency, Emergency” on nominated site radio channel or trigger a manual alarm) ☐
- Immediately try to locate the source of the spill ☐
- If release is from a storage facility, isolate/contain the release (if it is safe to do so) by closing valves, switching off pumps, blocking drains, establishing temporary bunds, use of spill kits, contacting control room etc ☐
- Identify and isolate any potential sources of ignition ☐
- Evacuate areas that may be affected by the spill either directly or through exposure to fumes (**remember your safety is paramount**) ☐
- Go to Emergency Muster Point/Control Room, stay until directed by the Muster Point Warden or Operations Officer ☐
- When evacuating a chemical spill/gas release, DO NOT GO DOWNHILL/DOWNWIND OF THE SOURCE, AS EXPOSURE TO THE FUMES MAY BE LIFE THREATENING ☐
- If evacuating from a release, evacuate uphill and upwind of emergency site - avoid passing through fume affected areas en route to Muster Point ☐
- Provide First Aid to any injured persons if qualified to do so ☐
- Ensure that any contaminated personnel utilise emergency showers and eye washes ☐

Operations Officer

- Initiate alarms to warn site personnel – audible alarms, broadcast on radio, word of mouth ☐
- Ensure site of emergency is evacuated to a safe distance: evacuate all areas that; ☐
    - Are directly affected by the release (impinged/engulfed) ☐
    - May be indirectly affected (eg exposure to toxic fumes/vapour cloud, access restrictions) ☐
- Notify the ERC and provide a detailed SITREP of the situation (details, site location/conditions) ☐
- Arrange for the safe shutdown of equipment/plant in the affected area ☐
- Identify released materials and source appropriate MSDS’s; make these available for response personnel as necessary ☐
- In consultation with the Muster Point Warden, determine the suitability of the Primary Emergency Muster Point/Control Room (is it affected by/downwind of release); determine alternate Muster Point as required ☐

- For an offsite spill/release, ensure that the ERC has all information required to carry out appropriate notification of government departments, Police etc ☐
- Relay all environmental information to the ERC and EOC and ensure that appropriate environmental/governmental agencies are notified ☐
- Determine containment/decontamination requirements (in consultation with ERT or specialists – onsite or offsite) and source equipment from offsite as required – confer with EOC ☐
- Continue to provide SITREPS to the ERC and ERT - develop ongoing response strategy in consultation with them ☐
- When developing response strategies, consider; ☐
    - Advice from Environmental Department
    - Physical response constraints (weather, wind direction/strength, release location)
    - Review available MSDSs
    - PPE/response equipment availability
    - Exposures of site personnel (injuries/trapped personnel)
- Ensure that appropriate toxic/chemical exposure monitoring is conducted during response to limit responders exposure to within acceptable levels (refer MSDS's) ☐
- Ensure external emergency services have been contacted ☐
- If spill/release escalates or creates secondary hazards to personnel (eg escalation, exposure to spill/release), consider further/more extensive evacuations (or relocation of evacuated personnel) ☐
- Arrange for barricading of affected area until remediation is complete/atmosphere is clear ☐
- When considering the impacts of the release, take into the account any potential for contamination of site water supplies – provide alternate drinking water supply if required ☐
- Try to minimise the impact of the spill by implementing the three C's rule: ☐
    - CEASE flow of release into the surrounding area
    - CONTAIN the spillage
    - CLEAN-UP spill
- Review the need for any off site expertise or equipment to control/contain the spill/release and communicate requirements to the ERC and EOC ☐
- Establish Control Zones ☐
- Assist with investigation and review of the procedures/actions taken ☐

Appendix 11 – Peer Review Checklists

Note: The following checklists for Tier 3 and Tier 4 will inform and guide the review of a submitted chemical risk assessment for a high risk chemical. It is noted that all listed aspects within the respective checklists may or may not be completed, as this will depend on the level and nature of assessment for each chemical. The checklists do not constrain the Minister in their approval of a chemical risk assessment.

Chemical			
Dossier Review Checklist			**Comments (if applicable)**
Dossier Section	**Check if**		
	Yes	**No**	
All Chemicals (Tier 1, 2, 3 and 4)			
Has the substance been correctly identified?			
Have physical/chemical properties been documented?			
Was the chemical listed on any data bases indicating chemical of concern?			
Environmental Hazard Assessment Complete?			
Aquatic acute toxicity			
Aquatic chronic toxicity			
Terrestrial acute toxicity			
Terrestrial chronic toxicity			
Environmental Fate Assessment Complete?			
Biodegradation			
Environmental distribution			
Bioaccumulation			
PBT Assessment Complete?			
Persistent			
Bioaccumulative			
Toxic			
Categorisation Correct?			
Tier 1			
Tier 2			
Tier 3			
Tier 4			
Additional Requirements for Tier 2, 3 and 4 Chemicals			
Human Health Hazard Assessment Complete?			
Acute toxicity			
Irritation/Corrosion			
Skin			
Eye			
Sensitisation			
Genotoxicity			
in vitro			
in vivo			
Carcinogenicity			
Repeated dose toxicity			
Reproductive toxicity			
Developmental toxicity			
PNEC Development Complete?			
Water			
Soil			
Additional Requirement for Tier 3 and 4 Chemicals			
Has an assessment of cumulative impact(s) been completed?			

Note: The following checklists for Tier 3 and Tier 4 will inform and guide the review of a submitted chemical risk assessment for a high risk chemical. It is noted that all listed aspects within the respective checklists may or may not be completed, as this will depend on the level and nature of assessment for each chemical. The checklists do not constrain the Minister in their approval of a chemical risk assessment.

Chemical			
Qualitative Assessment Review Checklist			**Comments (if applicable)**
Assessment Section	**Check if**		
	Yes	**No**	
All Chemicals (Tier 2, 3 and 4)			
Problem Formulation and Issue Identification			
Bounds of the assessment defined (Tier 2, 3 or 4 components listed)?			
Process and usage information provided for the chemical?			
SDS attached?			
Dossier attached?			
Relevant soil and water guidelines detailed?			
Hazard Assessment			
Physical and chemical properties summarized?			
PBT assessment findings described?			
Human Health Hazard Assessment			
Human toxicity endpoints described?			
Risk-based criteria for qualitatively assessing human health exposure defined?			
Potential receptors and potentially complete exposure pathways identified for assessed uses?			
Potential for exposure assessed in context of site setting and management protocols?			
Key controls limiting potential for exposure detailed?			
Environmental Hazard Assessment			
Aquatic and terrestrial toxicity endpoints described?			
Environmental fate properties which impact potential for toxicity evaluated?			
Risk-based criteria for qualitatively assessing ecological exposure defined?			
Potential receptors and potentially complete exposure pathways identified for assessed uses?			
Potential for exposure assessed in context of site setting and management protocols?			
Key controls limiting potential for exposure detailed?			
Risk Communication and Management			
Key plans and/or systems applicable to the management and mitigation of risks associated with chemical usage identified?			

Note: The following checklists for Tier 3 and Tier 4 will inform and guide the review of a submitted chemical risk assessment for a high risk chemical. It is noted that all listed aspects within the respective checklists may or may not be completed, as this will depend on the level and nature of assessment for each chemical. The checklists do not constrain the Minister in their approval of a chemical risk assessment.

Chemical	
Quantitative Assessment Review Checklist	**Comments (if applicable)**
Assessment Section	
All Chemicals (Tier 3)	
Problem Formulation and Issue Identification	
Bounds of the assessment defined (Tier 3 components listed)?	
Process and usage information provided for the chemical?	
SDS attached?	
Dossier attached?	
Relevant soil and water guidelines detailed?	
Hazard Assessment	
Physical and chemical properties summarized?	
PBT assessment findings described?	
Safety/Uncertainty Factors considered?	
Human Health Hazard Assessment	
Human toxicity endpoints described?	
Risk-based criteria for qualitatively assessing human health exposure defined?	
Potential receptors and potentially complete exposure pathways identified for assessed uses?	
Potential for exposure assessed in context of site setting and management protocols?	
Key controls limiting potential for exposure detailed?	
Environmental Hazard Assessment	
Aquatic and terrestrial toxicity endpoints described?	
Environmental fate properties which impact potential for toxicity evaluated?	
Risk-based criteria for qualitatively assessing ecological exposure defined?	
Potential receptors and potentially complete exposure pathways identified for assessed uses?	
Potential for exposure assessed in context of site setting and management protocols?	
Key controls limiting potential for exposure detailed?	
Exposure Assessment	
Mass balance calculations conducted to identify the amount of the chemical used in the process?	
Exposure point concentrations calculated for each applicable release scenario?	
Risk Characterisation	
Potential risks for complete exposure pathways assessed for MNES and non-MNES receptors?	
Risk ratios developed for potentially complete exposure pathways associated with applicable release scenarios?	
Based on the magnitude and severity of the potential exposure, additional quantitative assessment provided relevant to end use?	
Cumulative impact(s) assessed?	
Uncertainty analysis complete?	
Risk Communication and Management	
Key plans and/or systems applicable to the management and mitigation of risks associated with chemical usage identified?	

Note: The following checklists for Tier 3 and Tier 4 will inform and guide the review of a submitted chemical risk assessment for a high risk chemical. It is noted that all listed aspects within the respective checklists may or may not be completed, as this will depend on the level and nature of assessment for each chemical. The checklists do not constrain the Minister in their approval of a chemical risk assessment.

Chemical	
Quantitative Assessment Review Checklist	**Comments (if applicable)**
Assessment Section	
All Chemicals (Tier 4)	
Problem Formulation and Issue Identification	
Bounds of the assessment defined (Tier 4 components listed)?	
Process and usage information provided for the chemical?	
SDS attached?	
Dossier attached?	
Relevant soil and water guidelines detailed?	
Hazard Assessment	
Physical and chemical properties summarized?	
PBT assessment findings described?	
Chemical substitution discussed?	
Safety/Uncertainty Factors considered?	
Human Health Hazard Assessment	
Human toxicity endpoints described?	
Risk-based criteria for qualitatively assessing human health exposure defined?	
Potential receptors and potentially complete exposure pathways identified for assessed uses?	
Potential for exposure assessed in context of site setting and management protocols?	
Key controls limiting potential for exposure detailed?	
Environmental Hazard Assessment	
Aquatic and terrestrial toxicity endpoints described?	
Environmental fate properties which impact potential for toxicity evaluated?	
Risk-based criteria for qualitatively assessing ecological exposure defined?	
Potential receptors and potentially complete exposure pathways identified for assessed uses?	
Potential for exposure assessed in context of site setting and management protocols?	
Key controls limiting potential for exposure detailed?	
Exposure Assessment	
Mass balance calculations conducted to identify the amount of the chemical used in the process?	
Exposure point concentrations calculated for each applicable release scenario?	
Risk Characterisation	
Potential risks for complete exposure pathways assessed for MNES and non-MNES receptors?	
Risk ratios developed for potentially complete exposure pathways associated with applicable release scenarios?	
Full life cycle quantitative risk assessment conducted, including food chain risk assessment?	
Cumulative impact(s) assessed?	
Uncertainty analysis complete?	
Risk Communication and Management	
Key plans and/or systems applicable to the management and mitigation of risks associated with chemical usage identified?	