Santos

Chemical Risk Assessment Framework

Narrabri Gas Project

EPBC 2014/7376

Date	Rev	Reason For Issue	Author	Checked	Approved
1/4/2022	0	Submission to Department of Agriculture, Water and the Environment	AS	CH	LD

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Table of Contents

Tables:

Appendices:

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) within Santos' Narrabri Gas Project (NGP) Area, in accordance with Commonwealth Approval 2014/7376 (the Approval). The CRAF incorporates best practice risk assessment methodologies 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 Project Area Chemical Risk Assessment Framework (EPBC 2012/6615).

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 completions) to MNES.

The aim of the chemical risk assessment(s) is to also evaluate the potential risks and effects of geogenic chemicals to MNES that may be present in recovered drilling fluids and 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 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 drilling and completion activities.

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**).

1.4 Compliance with EPBC 2014/7376 Conditions

The CRAF has been developed to address the conditions relating to chemicals management in the Approval. **Table 1** identifies the chemicals management conditions and cross-references to where these are addressed in this document.

Table 1: Cross Reference Table Against EPBC 2014/7376 Conditions

EPBC 2014/7376 Conditions	CRAF Section
19. The approval holder must, prior to the commencement of coal seam gas operations, submit to the Minister for written approval a Chemical Risk Assessment Framework (CRAF) that details how the risk of adverse impacts on protected matters posed by chemicals will be assessed and managed for the duration of this approval. The CRAF must include, but is not limited to:	The document (CRAF)
a. Details of how these risks will be assessed consistent with best practice risk assessment methodologies, and how assessment will address:	Section 1.1 Section 2.1
i the process lifecycle for chemicals;	Section 1.3 Appendix 8
ii how risk from geogenic chemicals in recovered drilling fluids will be managed to prevent adverse impacts to protected matters; and	Section 4
iii minimum mitigation and management measures to be undertaken as part of coal seam gas operations	Section 4
b. Details of the criteria by which chemicals will be categorised, based on the properties of each chemical. Criteria must include, but not be limited to:	Section 2 Appendix 1
i combined persistence, bioaccumulative and toxicity assessment;	
ii chemical database of concern assessment; and	
iii specific persistence, bioaccumulative and toxicity assessment.	
These details must be used to determine the risk assessment requirements appropriate to all chemicals in each category. This will include consideration of toxicological profile, qualitative risk assessment, quantitative risk assessment and site-specific information requirements.	
c. Detail a risk assessment process for each chemical to determine risk to protected matters from the chemical's use. This process must:	Section 2 Table 2 Section 4 Appendix 8
i identify the risk assessment requirements based on the chemical's category;	
ii consider the chemical's intended use and function, and an estimation of the quantity of the chemical likely to be used, and at what concentration, in a typical year;	The volume (mass) and concentration of each chemical is implicitly considered within the tiered risk assessment framework, as defined in the CRAF. For Tier 1 chemicals, volume and concentration has no effect on associated risk which is assessed as low (chemicals have no to limited toxicity). For the Tier 2 chemicals, mass and concentration is considered within the qualitative assessment with the low toxicity of the chemicals resulting in no risks at the mass and concentrations utilised for project activities. For Tier 3 and 4 chemicals a quantitative risk assessment is conducted and as part of this process mass and concentration are utilised to define exposure point concentrations that are used within the risk assessment calculations.
iii consider the likely environmental fate of the chemical; and	
iv consider what, if any, mitigation and management measures are needed to prevent adverse impacts to protected matters from that chemical for the duration of this approval.	

EPBC 2014/7376 Conditions	CRAF Section
d. Details of the process by which risk assessments for low risk chemicals will be peer reviewed by an independent chemical risk assessment expert. This process must:	Section 3 Table 3
i consider any checklists completed by the independent chemical risk assessment expert, to demonstrate that risks have been adequately assessed; and	Section 3.1.1 Appendix 11
ii include provision of a signed and dated statement from the independent chemical risk assessment expert confirming that the chemical has been correctly categorised.	Table 3
e. Detail a process for recording each chemical's risk assessment in a register on the approval holder's website and for the provision of each chemical's risk assessment to the Department.	Section 3.2
f. Details of a process to monitor and report on the implementation of any mitigation and management measures undertaken during use and handling of chemicals to demonstrate no adverse impacts to protected matters, including processes to notify the Department if an adverse impact to protected matters is detected.	Section 4
g. Details of the process by which information in the risk assessments will be adaptively used to address any accidental release of a chemical to prevent adverse impacts to protected matters	Section 2 Section 4
20. The approval holder must not commence coal seam gas operations until the CRAF has been approved by the Minister in writing. The approval holder must implement the approved CRAF for the duration of this approval and publish the CRAF on its website within 20 business days of it being approved by the Minister and for the duration of this approval.	
21. The approval holder must not use a low risk chemical until that chemical's risk assessment has been recorded in the register and it has been provided to the Department as required by the approved CRAF.	Table 3 Section 3.1.1
22. The approval holder must not use a high risk chemical until the Minister has approved that chemical's risk assessment in writing and the risk assessment has been recorded in the register as required by the approved CRAF.	Table 3 Section 3.1.2
23. The approval holder must engage a chemical risk assessment expert to peer review all risk assessments at least once every 5 years, commencing from the date of the Minister's approval of the CRAF. The peer review of all risk assessments must be completed before the end of each 5-year anniversary of the Minister's approval of the CRAF. The peer review must include:	Section 3.3
a. an assessment of whether all risk assessments on the register are consistent with current scientific knowledge;	
b. an evaluation of the adequacy of relevant monitoring, mitigation and management measures that have been implemented by the approval holder; and c. an explanation of how the approval holder will address or has addressed any concerns raised by the peer review.	
24. The approval holder must, within 60 business days of the completion of the peer review, submit to the Department a signed statement by the chemical risk assessment expert detailing the findings of the 5-year peer review and evidence of how any concerns raised by the peer review have been addressed	

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 2**).

Table 2: 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 2**:

- 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 during drilling activities or 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 various), 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 NSW *Dangerous Goods (Road and Rail Transport) Act 2008* as well as Santos' traffic management principles identified in Section 4.4.

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 *Narrabri Gas Project Environmental Impact Statement* (EIS) (Santos 2016) are the MNES values for the purpose of this chemical risk assessment.

The 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 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 the with 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 under the NSW development consent (SSD-6456), Environmental Protection Licence (EPL) 20350 and the 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 during drilling activities or 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 NSW development consent (SSD-6456), EPL 20350 and the 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 3** below.

Table 3: Chemical Risk Assessment Review and Approval Requirements

Delivery Scope	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. drilling and completions) 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, in accordance with condition 23 of the Approval. 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, Tier 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 Field Development Protocol

The Field Development Protocol describes the location and selection process for gas field development activities (including wells and linear infrastructure). It takes into account the following constraints:

- maximum ecological disturbance limits by vegetation community and for individual threatened flora
- cultural heritage;
- occupied residences;
- watercourses and riparian buffer widths based on Strahler stream order;
- flooding and geomorphology;
- noise;
- exclusion areas and
- identified sites.

Assessment of fate and transport of constituents in the subsurface, undertaken as part of the EIS, indicates that conservative constituents (soluble and mobile) will sufficiently attenuate in the subsurface such that beyond 90 m there are no potential unacceptable risks associated with potential releases during drilling. As such, production wells will not be installed within 90m of a landholder bore.

For Tier 3 and Tier 4 chemicals, the outcome of the chemical risk assessment (including the outcome of the cumulative assessment) may inform the need for additional mitigation and management controls such as greater offset distances. These additional controls will be identified within the chemical risk assessment documentation and submitted in accordance with the approval process (see Section 3.1.2). These controls will be receptor specific and based on the potential exposure pathway.

4.2 Water Management Plan

Condition B41 of NSW development consent (SSD-6456) requires Santos to develop and implement a Water Management Plan for the Project. Condition 6 of the Approval requires Santos to provide the Department with the approved Water Management Plan within two (2) business days of its approval by the NSW Planning Secretary.

The Water Management Plan, including sub-plans and protocols, contains the existing mitigation and management controls that are in place for chemical constituents associated with produced water and residual drilling materials. These controls are considered sufficient to address the risk of adverse impact to MNES associated with Tier 1 and Tier 2 chemicals.

The following sub-plans and protocols are of relevance to managing risks of adverse impacts to MNES from chemical use during coal seam gas operations (drilling and completions):

- Produced Water Management Plan – details how Santos manages produced water resulting from the operation of its CSG activities in the Narrabri area (during Phase 1 of the Project). This Plan will be updated as required for future phases of the Project.
- Irrigation Management Plan – details how Santos manages the beneficial reuse of treated water for crop irrigation and stock watering, that includes but is not limited to details regarding site selection and assessment; agreements with third parties; baseline soil and groundwater conditions and quality; a protocol for operation of the irrigation management system; and measures to manage any effects on soils structure, erosion, groundwater quality and maintain a water balance.
- Dust Suppression Protocol – details how Santos manages the beneficial reuse of treated water for dust suppression and construction activities including but not limited to details of site selection and assessment; baseline soil and groundwater conditions and quality; a protocol for operation of the dust suppression system; and measures to manage any effects on soils structure, erosion, surface water runoff, groundwater quality and groundwater levels.

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 Water Management Plan, these will be identified within the chemical risk assessment documentation.

Where updates to the Water Management Plan are proposed, Santos will notify the Department of the proposed updates within two (2) business days. Where the NSW Planning Secretary approves a revised version of the Water Management Plan, Santos will provide the approved revised version to the Department in accordance with the Approval. Proposed new management controls will be receptor specific and based on the potential exposure pathway and will include early warning indicators and action triggers, where required. The assessment of the efficacy of each monitoring, mitigation and management control is specified in the Water Management Plan.

4.3 Residual Drilling Materials (RDM) Management Protocol

Well drilling generates drill cuttings, referred to as residual drilling materials (RDM), which are classified as a waste product under the NSW *Protection of the Environment Operations Act 1997*. Santos has developed a sustainable reuse option for rock-based RDM as an alternative to disposing this material at a licenced waste facility. The reuse option involves mechanically applying suitable RDM to the well pad area during rehabilitation once drilling is complete.

A RDM Management Protocol has prepared in accordance with condition B83(h) of NSW development consent (SSD-6456) to describe the management and re-use of RDM. The Protocol:

- identifies RDM that may be used for rehabilitation of well sites to ensure materials are fit for purpose to achieve rehabilitation objectives
- describes RDM sampling, analysis and application methods
- references appropriate rehabilitation monitoring and assessment criteria.

During the drilling process, material brought to surface is stored on the well pad (or adjacent well pad) in stockpiles, skip bins or pits, with appropriate environmental controls in place. Rock-based RDM extracted during drilling of the vertical well section is kept separate to the coal-based drill cuttings which come from the horizontal (on in-seam) component.

Coal-based cuttings are sampled and classified in accordance with the *Waste Classification Guidelines – Part 1: Classifying Waste* (EPA 2014) and disposed of at a suitably licenced waste facility.

Rock-based RDM is permitted to be reused in rehabilitation of sites within the premises under EPL 20350 issued by the NSW Environment Protection Authority.

When drilling is complete, the stored drill materials are mechanically applied to the well pad area using the following approach:

- land application area is identified within the fenced well pad area (as per construction planning); and
- RDM is spread using the selected method to ensure a relatively uniform coverage of the land application areas within the well pad area at an application rate of 100 m^3/ha (with a maximum allowable application rate of 150 m^3/ha).

The lowest practicable application rate would be based on the area available. Any additional cuttings which cannot be applied would be transported to another site within the premises for reuse or to a suitably licensed waste facility for disposal.

The following management controls and monitoring are applied during RDM re-use:

- a buffer/exclusion area of at least 5 m will be established around existing infrastructure and RDM reuse would not occur within this exclusion area;
- the source of RDM and land application extent, volume and rate would be recorded at each reuse site;
- RDM would not be applied to land during or after any rainfall event until surface conditions permit;
- where RDM has been land applied, erosion and sediment controls would be implemented prior to a forecast rainfall event;
- RDM land application areas will be monitored for rehabilitation success and compared against control sites; and
- post application sampling of the RDM land application area will occur within six months of application.

4.4 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 and residual drilling materials.

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.

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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 2000 (ANZG 2018) assessment (for example metals such as Cd)	Potential concerns with accumulation in soils based on ANZECC 2000 (ANZG 2018) assessment (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 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 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)					
								Chemical Databases of Concern Assessment Step		Persistence Assessment Step		Bioaccumulative Assessment Step	Toxicity Assessment Step			Tier									
		Chemical Assessment Date	Independent Peer Reviewer[1]	Department Notification Department Date	Department Approval Date	Chemical Re-evaluation Date	Overall PBT Assessment[1]	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	(incl. RA hyperlink)	Risk Level	Drilling and Completions	Hydraulic Fracturing	Water Treatment	Residual Drilling Material	Irrigation	Stock Watering	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 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).

[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

[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

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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
KI	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 ≤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).

In Vivo Studies

In a dominant lethal test, male mice were given in their drinking water 0, 10, 100, or 1,000 mg/kg 1-dodecanamine, N,N-dimethyl-, N-oxide (CAS No. 1643-20-5). There was no evidence of a mutagenic effect (OECD, 2006) [Kl. score = 2].

H. Carcinogenicity

No carcinogenicity studies are available on amine oxides, cocoalkyldimethyl.

Oral

Male and female rats were given in their diet 0, 0.1, 0.1, or 0.2% C10-16 alkyldimethyl, N-oxides (CAS No. 70592-80-2) for 104 weeks. The estimated daily intakes were: 0, 4.24, 42.3, or 87.4 mg/kg-day for males; and 0, 5.23, 52.6, or 107 mg/kg-day for females. The incidence of tumors was similar between treated and control animals (OECD, 2006) [Kl. score = 1].

Dermal

Male and female ICR Swiss mice received dermal applications of an aqueous solution of C10-16 alkyldimethyl, N-oxides (CAS No. 70592-80-2) 3 times/week for 104 weeks. The average daily dose was 0, 1.1, 2.8, or 5.6 mg/kg-day. The high-dose mice showed microscopic signs of skin irritation. There was no evidence of skin tumors at any dose level (OECD, 2006) [Kl. score = 2].

I. Reproductive Toxicity

A two-generation reproductive toxicity study has been conducted in CD rats on 1-dodecanamine, N,N-dimethyl-, N-oxide (CAS No. 1643-20-5). The dietary levels were 0, 750, 1,500, and 3,000 ppm for 6.5 weeks, and 0, 188, 375, and 750 ppm for the remainder of the study. The dietary levels were reduced because of the reduced body weight gain in the mid- and high-dose groups. There were slight reductions in body weight gain of both the parental animals and offspring, but mating performance and fertility were unaffected by treatment in either generation. Macroscopic and microscopic pathologic examinations showed no differences between treated and control groups. The NOAEL for reproductive and developmental toxicity is 750 ppm, which corresponded to 40 mg/kg-day (OECD, 2006) [Kl. score = 1].

J. Developmental Toxicity

Pregnant female CD rats were dosed by oral gavage with 0, 50, 100, or 200 mg/kg 1-dodecanamine, N,N-dimethyl-, N-oxide (CAS No. 1643-20-5) on GD 7 to 17. One-half of the females/group were sacrificed on GD 20, and the other half were allowed to deliver; the pups were weaned at PND 25 and the F_1 animals were paired at 10 weeks of age. Body weights and water consumption were lower (<10%) in the 200 mg/kg group. Mean fetal weights were lower and associated with slight retardation of fetal ossification in the 200 mg/kg group that were sacrificed in GD 20. However, pup survival and pup growth were unaffected in the offspring of the 200 mg/kg group that were allowed to deliver. The subsequent growth, mating performance, and fertility of the F_1 animals were similar between treated and control groups; F_1 females from the 200 mg/kg F_0 group had slightly elevated fetal and placental weights. There were no macroscopic changes seen in the F_1 animals at terminal necropsy that were considered to be treatment-related. The NOAEL for maternal and developmental toxicity is 100 mg/kg-day (OECD, 2006) [Kl. score = 1] suggesting that observations of developmental toxicity are related to maternal effects.

Pregnant female SD rats were dosed by oral gavage with 0, 25, 100, or 200 mg/kg C10-16 alkyldimethyl, N-oxides (CAS No. 70592-80-2) on GD 6-19. There was one death in the 200 mg/kg group. The $\geq$100 mg/kg groups had reduced body weight gain and relative feed consumption. In the 200 mg/kg group, early resorptions were increased, and liver litter sizes and fetal body weights were decreased. The reduced fetal body weights were associated with fetal variations consisting of delays in skeletal ossifications. The 100 mg/kg group also showed some delays in ossification. There was no indication of fetal malformations at any dose level. The NOAEL for maternal and developmental toxicity is 25 mg/kg-day (OECD, 2006) [Kl. score = 2] suggesting that observations of developmental toxicity are related to maternal effects.

Pregnant female New Zealand rabbits were dosed by oral gavage with 0, 40, 80, or 160 mg/kg 1-dodecanamine, N,N-dimethyl-, N-oxide (CAS No. 1643-20-5) on GD 6-18. Three of the 80 mg/kg and three of the 160 mg/kg dams died or were killed in extremis; these deaths were not considered to be treatment-related. Body weight gain was reduced in all treated groups, although 40 mg/kg dams achieved similar body weights to controls at study termination. Feed consumption was reduced compared to the pre-treatment period during the second half of the treatment period in the 40 and 80 mg/kg animals and for the entire treatment period in the 160 mg/kg animals. Water consumption was also decreased in all treated groups. There was no indication of developmental toxicity. The NOAEL for maternal toxicity was considered to be > 160 mg/kg-day 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 $PNEC_{water}$ 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:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= 30.08/1280 \times 1000 \times 0.009$
$= 0.2115$ mg/kg

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

$K_{sed\text{-}water} = 0.8 + [(0.2 \times Kp_{sed})/1000 \times BD_{solid}]$
$= 0.8 + [(0.2 \times 61)/1000 \times 2400]$
$= 30.08\ m^3/m^3$

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

$Kp_{sed} = K_{oc} \times f_{oc}$
$= 1525 \times 0.04$
$= 61$ 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:

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

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]

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

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

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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
KI	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 andre*i 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

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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
KI	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

CTAC

In accordance with the 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 characterized 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.

The qualitative assessment of risk evaluates exposure to the vendor chemical that may occur during activities that do not intentionally result in a release to the environment, but where a potential release may occur. For this evaluation, these potential releases primarily are focused on the vendor chemical transported to the well pad site or water management facility (WMF), chemicals utilised in drilling fluid systems that may impact groundwater, residual chemicals that may be present in hydraulic flowback and workover fluids and chemicals and chemicals and residues of chemicals that may be present in water undergoing treatment or beneficially re-used.

Potentially complete exposure pathways (in that a source, a migration pathway, a mechanism for exposure, and a potential receptor are present) are 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,
- Australia SafeWork Place and Santos Occupational Safety Guidance used to minimise human health exposure.

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

1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (CTAC) is a component in a product used in the KCl/Polymer Stuck Pipe Mud system. The secondary mud system is used to free stuck pipes and, as a secondary mud, will only be used as required. As a result, these secondary muds are considered insignificant relative to the primary muds due to the considerably reduced volume used (<0.1%) as compared to the other muds.

The purpose and maximum quantity (i.e., in all muds) for this chemical is summarised in **Table 1**. A safety data sheet (SDS) for the drilling fluid product is included as **Attachment 1**.

Table 1 Drilling Fluid Chemicals

Chemical Name	CAS No.	Use	Quantity[1]
1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (CTAC)	4080-31-3-9	Biocide	NA

[1] Based on maximum of combined muds assessed.
CAS No = Chemical Abstracts Service Number
NA = quantity used varies with severity of loss

CTAC is an active ingredient in several biocide products. One of these products, DOWICIL 75, is stabilised with sodium bicarbonate (CAS No. 144-55-8). Sodium bicarbonate at ≤ 39% is added to stabilize the active ingredient and in solution will dissociate to the sodium cation and bicarbonate anion. No adverse effects are associated with sodium bicarbonate (see dossier in **Appendix A**). Other substances include the following impurities: 1,3-dichloropropene (CAS No. 542-75-6) at <0.25%, dichloromethane (CAS No. 75-09-2) at <0.1%, and hexamethylenetramine (CAS No. 100-97-0) at <5%. These impurities are at *de minimus* levels and for purposes of this assessment are not further evaluated.

The assessment of toxicity of this chemical was used to evaluate human health exposure scenarios and is presented in **Attachment 2**. There are no carcinogenicity studies on CTAC; 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)
1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (CTAC) (4080-31-3)	90-day rat dietary	Liver	15	1,000	0.015	0.05

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 2** 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. 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 toxicological 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 were developed to assess aquatic receptors, and PNECs for soil were developed for terrestrial receptors.

Table 3 present the chemical, the endpoint, no observable effects 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 2** for the development of PNECs, or the rational for PNECs that do not have a calculated PNEC.

Table 3 PNECs Water – Tier 2 Chemicals

Constituents	Endpoint	EC_{50} or NOEC (mg/L)	Assessment Factor	$PNEC_{water}$ (mg/L)
1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (CTAC) (4080-31-3)	Acute Algae	1.5	1,000	0.0015

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.

Table 4 PNECs Sediment – Tier 2 Chemicals

Constituents	Endpoint	EC_{50} or NOEC (mg/kg wet wt)	Assessment Factor	$PNEC_{sed}$ (mg/kg wet wt)
1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (CTAC) (4080-31-3)	[a]	-	-	0.0081

[a]Calculated using equilibrium partitioning method.
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 2** for information on the development of PNECs listed above.

Table 5 PNECs Soil – Tier 2 Chemicals

Constituents	Endpoint	EC_{50} or NOEC (mg/kg dry wt)	Assessment Factor	$PNEC_{soil}$ (mg/kg dry wt)
1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (CTAC) (4080-31-3)	[a]	-	-	0.0064

[a]Calculated using equilibrium partitioning method
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 2** for information on the development of PNECs listed above.

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

General Overview

CTAC is a quaternary ammonium salt. CTAC can be present as a cis- and trans-isomer, depending on the biocide formulation. The molecular structure of CTAC is presented in **Figure 1**.

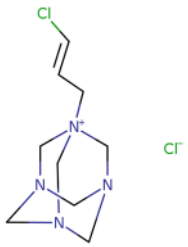

Figure 1 Molecular Structure of CTAC[1]

CTAC is expected to be readily biodegradable, and is not expected to bioaccumulate. It has a medium potential for adsorption to soil or sediments.

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

Human Health Hazards

The acute toxicity of CTAC is low-to-moderate by the oral route and low by the dermal route. It is slightly irritating to the skin and eyes; prolonged or repeated contact may cause skin irritation. Skin sensitisation studies on the cis isomer of CTAC have indicated mixed results.

Repeated dose toxicity studies by the oral route have shown the liver to be a target organ; studies conducted by the dermal route showed only irritation at the site of contact and no systemic toxicity. Relatively high oral doses of products containing CTAC have caused birth defects in animal studies;

[1] Source https://chem.nlm.nih.gov/chemidplus/rn/4080-31-3

studies conducted by the dermal route have shown no developmental effects. The genotoxicity studies are generally negative. Given the findings from the repeated dose toxicity and genotoxicity studies, there is a low concern for carcinogenicity.

Based on a review of repeated dose and developmental toxicity studies, a TRV was derived for CTAC. The drinking water guideline value derived using the non-carcinogenic oral RfD is 0.05 milligrams per litre (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 2**.

The lifecycle of chemicals, including CTAC, used during the drilling and completion of wells includes the following general categories: transportation of chemicals; drilling, stimulation and completion operations; and, treatment, recycling, disposal and beneficial reuse. Without management controls in place, there is the potential for human receptors to be exposed to drilling fluid chemicals that contain CTAC during drilling and completion operations and management of drilling fluids and cuttings. Based on an assessment of land use and an understanding of the project description provided in the Environmental Impact Statement (EIS) (URS, 2014) and the CRAF developed for the GFD Project Area, potential human receptors include:

1. Workers at the well lease involved with blending, storage, transfer, reuse, recovery and recycling of drilling fluids and cuttings; recycling, reuse or disposal of recovered materials including beneficial reuse activities such as land applications of drilling materials and dust suppression; and, mitigating releases at the well lease or along the transport or conveyance routes.
2. Agricultural workers or residents in irrigation areas.
3. Landholders that have access to the water supply from a bore hydraulically downgradient of the well lease.

In terms of risks associated with transport of chemicals and wastes, this risk is considered to be managed to a level as low as reasonably practicable. This is because the potential for a release is controlled through implementation of traffic management principles including use of designated trucking routes, vehicle signage, vehicle management systems (to manage speed and driving behaviour/habits) and, in the unlikely event of a vehicular accident, implementation of incident and spill response procedures. Given the highly regulated nature of transportation of chemicals (at both a Commonwealth and State level), transport-related scenarios are not evaluated further in this assessment. However, the outcome of the assessment should be used to inform emergency response actions.

Exposure of workers to drilling fluid chemicals is possible via inadvertent spills and leaks, during the recycling and beneficial reuse of recovered materials (e.g., drilling fluids and cuttings), and during application of the recovered material to land. However, chemical exposures to workers are controlled through engineering, management controls and personal protective equipment, which are focused on elimination and mitigation of the potential for dermal contact and potential for incidental ingestion. In addition, Australia SafeWork Place and Santos Occupational Safety Guidance are used to minimise human health exposure. As a result, petroleum workers, are also excluded from assessment. No potentially complete exposure pathways were identified.

The management of chemicals and wastes will be conducted at the well lease using drums, totes and engineered tanks designed to contain the fluids. In the unlikely event of a release to ground, the potential for exposures (other than workers) is limited. The well pad sites are fenced and access is controlled, which limits access to the public. If drilling fluid chemicals are spilled to ground then

investigation, remediation and rehabilitation activities would be implemented to address soil impacts.

On-lease storage may utilise tanks, pits or turkey nests and there is the possibility that a containment failure could result in the release of the materials to the well lease and the surrounding environment. Releases on the well pad would be of limited volumes, and, as such, these products would not be anticipated to migrate a significant distance off lease to the surrounding environment, including proximal water bodies.

The potential for a significant drilling fluid loss during drilling is rare, particularly given the volumes used and the management controls in place during drilling. Where lost circulation is identified during drilling, a lost circulation fluid (i.e. cellulose) is used to plug the interval and prevent further loss of fluids. Despite the limited potential for large scale losses during drilling, EHS Support (2015) completed modelling of how a conservative tracer or highly soluble organic constituents could migrate in the subsurface to assess the potential effects of potential loss of drilling muds on groundwater systems. The BIOSCREEN model was utilized to facilitate assessment of organic constituent mobility with and without biodecay. The modelling indicated that the potential for impact on ground water quality is limited even under a worst-case scenario utilising conservative assumptions.

Exposure of potential receptors (other than workers) is also possible to residual chemicals in areas adjacent to a well lease that have been used for the application of materials for beneficial reuse. The primary land use within the development area is agricultural (grazing on improved or unimproved pastures), and it is sparsely populated. There may be potential for human receptors such as residents and agricultural workers to be exposed to residual chemicals in recovered materials via direct contact (ingestion and dermal) and inhalation pathways. Relative potential exposure to agricultural workers/residents is considered low due to the remote location of the well leases and the sparse population. In addition, activities are undertaken in operational and controlled areas of the well lease.

However, Environmental Authority (EA) or Beneficial Use Approval conditions regulate project reuse. A plan for the beneficial reuse of materials has been developed by a Suitably Qualified Person (SQP) in accordance with the EA conditions which require materials of a certain quality and controls the maximum volumes that can be applied to land. In addition, the application techniques and location of application are controlled with specific monitoring required. Irrigation areas are designed to manage the risk of pooling and runoff with a general deficit irrigation strategy employed; and, are fitted with monitoring bores to manage the risk of vertical and horizontal migration. Additional details regarding mitigation and management controls are discussed in the CRAF.

As a result, potential exposures during the drilling process are low due to the employment of mechanical equipment/processes, engineering controls (including secondary containment) and other mitigation and management strategies. Similarly, there is a low potential for human receptors exposed to surface water bodies that may receive runoff from beneficial reuse applications. Finally, the probability of any surface related discharge infiltrating subsurface soils and migrating to groundwater is very low.

Environmental Hazards

In standard aquatic toxicity tests, CTAC is a high acute toxicity concern to algae, but moderately toxic to fish and invertebrates. To birds, it is practically non-toxic on an acute basis and slightly to non-toxic on a subacute dietary basis. CTAC is readily biodegradable and therefore is not persistent in the environment. It does not bioaccumulate.

PNECs for CTAC are provided in **Tables 3 – 5**. Experimental toxicity data on water organisms was available for three trophic levels to calculate PNECs in water. There are no toxicity data for sediment-dwelling organisms or soil organisms. Therefore, PNECs for sediment and soil were calculated using the equilibrium partitioning method. PNEC calculations and assumptions are detailed in the dossier provided in **Attachment 2**.

During the drilling process, there is the potential for environmental receptors to be exposed to drilling fluid chemicals that contain CTAC. Pipelines (where treated water is conveyed) can transect sensitive ecological areas (including Matters of National Environmental Significance [MNES]). There is the concern of wildlife (terrestrial and aquatic receptors) and livestock in the vicinity of the well leases to have adverse effects from potential exposures. Potential environmental receptors include:

1. Wildlife and livestock accessing the well lease and areas adjacent to the well lease, including surface water features, that have received runoff from an accidental release during drilling and completion operations or loss of containment.
2. Wildlife and livestock accessing areas of the well lease where materials have been applied, as well as accessing stored materials in pits and turkey nests.
3. Aquatic flora and fauna within a proximal surface water body that has received runoff from an accidental release during drilling and completion operations or loss of containment, or from beneficial use applications.
4. Wildlife, including livestock, that have access to the water supply from a bore hydraulically downgradient of the well lease.

The potential for exposure of sensitive receptors (including MNES) is considered low. The drilling and completion activities occur over a short duration and are conducted in controlled/operational areas within a perimeter fence. Further, the activity level, noise, etc. will be a disincentive for wildlife and livestock to access the lease through gaps in the fencing or unsecured gates.

Based on the engineering and management controls described in the previous section (Human Health Hazards), there is a low potential for ecological receptors exposed to surface water bodies that may receive runoff from an accidental release. There is also concern that recovered material applied to the land surface could migrate to groundwater or surface water, and therefore result in adverse effects to the environment (e.g., uptake by aquatic receptors). Due to EA conditions regulating land application techniques, the remote nature of the well leases, vertical separation of groundwater and distances to watercourses, the ephemeral nature of the watercourses and the physical and chemical properties of the residual chemicals post treatment or beneficial reuse, these potential exposures are low.

References

Australian Environmental Agency (AEA). (2009). Environmental Risk Assessment Guidance Manual for Industrial Chemicals, Commonwealth of Australia.

EHS Support. (2015). Santos GLNG Upstream Hydraulic Fracturing Risk Assessment Compendium of Assessed Fluid Systems. Revision 1. 23 November 2015.

URS. (2014). Santos GLNG Project: Gas Field Development Project Environmental Impact Statement. Available online at: http://www.santosglng.com/environment-and-water/gas-field-development-project-eis.aspx

Attachment 1 Safety Data Sheet

SAFETY DATA SHEET

THE DOW CHEMICAL COMPANY

Product name: DOWICIL™ 75 Preservative

Issue Date: 03/05/2015
Print Date: 05/18/2015

THE DOW CHEMICAL COMPANY encourages and expects you to read and understand the entire (M)SDS, as there is important information throughout the document. We expect you to follow the precautions identified in this document unless your use conditions would necessitate other appropriate methods or actions.

1. IDENTIFICATION

Product name: DOWICIL™ 75 Preservative

Recommended use of the chemical and restrictions on use
Identified uses: For biocidal applications. For industrial use.

COMPANY IDENTIFICATION
THE DOW CHEMICAL COMPANY
2030 WILLARD H DOW CENTER
MIDLAND MI 48674-0000
UNITED STATES

Customer Information Number: 800-258-2436
SDSQuestion@dow.com

EMERGENCY TELEPHONE NUMBER
24-Hour Emergency Contact: 800-424-9300
Local Emergency Contact: 800-424-9300

2. HAZARDS IDENTIFICATION

Hazard classification
This material is hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29CFR 1910.1200.
Flammable solids - Category 2
Combustible dust
Acute toxicity - Category 4 - Oral
Skin sensitisation - Category 1

Label elements
Hazard pictograms

Signal word: **WARNING!**

Hazards
Flammable solid.
May form combustible dust concentrations in air
Harmful if swallowed.
May cause an allergic skin reaction.

Precautionary statements

Prevention
Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
Ground/bond container and receiving equipment.
Use explosion-proof electrical/ ventilating/ lighting/ equipment.
Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
Wash skin thoroughly after handling.
Do not eat, drink or smoke when using this product.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/ eye protection/ face protection.

Response
IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth.
IF ON SKIN: Wash with plenty of soap and water.
If skin irritation or rash occurs: Get medical advice/ attention.
Wash contaminated clothing before reuse.
In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish.

Disposal
Dispose of contents/ container to an approved waste disposal plant.

Other hazards
no data available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical nature: Biocidal product
This product is a mixture.

Component	CASRN	Concentration
3,5,7-Triaza-1-azoniatricyclo[3.3.1.13,7]decane,1-(3-chloro-2-propenyl)- , chloride (CTAC)	4080-31-3	64.0%

Hexamethylenetetramine	100-97-0	<= 5.0 %
1,3-Dichloropropene	542-75-6	<= 0.25 %
Dichloromethane (methylene chloride)	75-09-2	< 0.1 %
Sodium bicarbonate	144-55-8	<= 39.0 %

4. FIRST AID MEASURES

Description of first aid measures
General advice: First Aid responders should pay attention to self-protection and use the recommended protective clothing (chemical resistant gloves, splash protection). If potential for exposure exists refer to Section 8 for specific personal protective equipment.

Inhalation: Move person to fresh air. If person is not breathing, call an emergency responder or ambulance, then give artificial respiration; if by mouth to mouth use rescuer protection (pocket mask etc). Call a poison control center or doctor for treatment advice.

Skin contact: Take off contaminated clothing. Wash skin with soap and plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. Wash clothing before reuse. Shoes and other leather items which cannot be decontaminated should be disposed of properly.

Eye contact: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes. Call a poison control center or doctor for treatment advice. Get medical attention immediately.

Ingestion: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Never give anything by mouth to an unconscious person. If swallowed, DO NOT induce vomiting.

Most important symptoms and effects, both acute and delayed: Aside from the information found under Description of first aid measures (above) and Indication of immediate medical attention and special treatment needed (below), any additional important symptoms and effects are described in Section 11: Toxicology Information.

Indication of any immediate medical attention and special treatment needed
Notes to physician: No specific antidote. Treatment of exposure should be directed at the control of symptoms and the clinical condition of the patient. Have the Safety Data Sheet, and if available, the product container or label with you when calling a poison control center or doctor, or going for treatment.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water. Dry chemical fire extinguishers. Carbon dioxide fire extinguishers.

Unsuitable extinguishing media: no data available

Special hazards arising from the substance or mixture
Hazardous combustion products: During a fire, smoke may contain the original material in addition to combustion products of varying composition which may be toxic and/or irritating. Combustion products may include and are not limited to: Nitrogen oxides. Hydrogen chloride. Carbon monoxide. Carbon dioxide. Ammonia. Amines.

Unusual Fire and Explosion Hazards: Container may rupture from gas generation in a fire situation. Do not permit dust to accumulate. When suspended in air dust can pose an explosion hazard. Minimize ignition sources. If dust layers are exposed to elevated temperatures, spontaneous combustion may occur. Pneumatic conveying and other mechanical handling operations can generate combustible dust. To reduce the potential for dust explosions, electrically bond and ground equipment and do not permit dust to accumulate. Dust can be ignited by static discharge.

Advice for firefighters
Fire Fighting Procedures: Keep people away. Isolate fire and deny unnecessary entry. Soak thoroughly with water to cool and prevent re-ignition. Use water spray to cool fire exposed containers and fire affected zone until fire is out and danger of reignition has passed. If product becomes contaminated with water, monitor product for heat generation and/or decomposition. Fight fire from protected location or safe distance. Consider the use of unmanned hose holders or monitor nozzles. Immediately withdraw all personnel from the area in case of rising sound from venting safety device or discoloration of the container. Hand held dry chemical or carbon dioxide extinguishers may be used for small fires. Dust explosion hazard may result from forceful application of fire extinguishing agents. Move container from fire area if this is possible without hazard.

Special protective equipment for firefighters: Wear positive-pressure self-contained breathing apparatus (SCBA) and protective fire fighting clothing (includes fire fighting helmet, coat, trousers, boots, and gloves). If protective equipment is not available or not used, fight fire from a protected location or safe distance.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Isolate area. Refer to section 7, Handling, for additional precautionary measures. Keep unnecessary and unprotected personnel from entering the area. Spilled material may cause a slipping hazard. Use appropriate safety equipment. For additional information, refer to Section 8, Exposure Controls and Personal Protection.

Environmental precautions: Prevent from entering into soil, ditches, sewers, waterways and/or groundwater. See Section 12, Ecological Information.

Methods and materials for containment and cleaning up: Contain spilled material if possible. Sweep up. Collect in suitable and properly labeled containers. See Section 13, Disposal Considerations, for additional information.

7. HANDLING AND STORAGE

Precautions for safe handling: Keep out of reach of children. Keep away from heat, sparks and flame. Avoid contact with eyes. Do not swallow. Wash thoroughly after handling. No smoking, open flames or sources of ignition in handling and storage area. Electrically ground and bond all equipment. Good housekeeping and controlling of dusts are necessary for safe handling of product. See Section 8, EXPOSURE CONTROLS AND PERSONAL PROTECTION.

Aqueous solutions containing this product can generate formaldehyde. Additional information on this and other products we offer may be obtained by contacting us. Ask for a product information brochure or data on how to access our website.

Conditions for safe storage: Protect from atmospheric moisture. Store in a dry place. Avoid moisture. Do not store in: Aluminum.

Storage stability
Shelf life: Use within 24 Month
Storage temperature: <= 60 °C (<= 140 °F)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters
Exposure limits are listed below, if they exist.

Component	Regulation	Type of listing	Value/Notation
1,3-Dichloropropene	ACGIH	TWA	1 ppm
	ACGIH	TWA	Absorbed via skin
Dichloromethane (methylene chloride)	ACGIH	TWA	50 ppm
	ACGIH	TWA	BEI
	OSHA Z-2		
	OSHA CARC	PEL	25 ppm
	OSHA CARC	STEL	125 ppm
	OSHA Z-1		
Sodium bicarbonate	Dow IHG	TWA	10 mg/m3

Exposure controls
Engineering controls: Use local exhaust ventilation, or other engineering controls to maintain airborne levels below exposure limit requirements or guidelines. If there are no applicable exposure limit requirements or guidelines, general ventilation should be sufficient for most operations. Local exhaust ventilation may be necessary for some operations.

Individual protection measures

Eye/face protection: Use safety glasses (with side shields).

Skin protection

Hand protection: Use gloves chemically resistant to this material. Examples of preferred glove barrier materials include: Neoprene. Polyvinyl chloride ("PVC" or "vinyl"). Nitrile/butadiene rubber ("nitrile" or "NBR"). NOTICE: The selection of a specific glove for a particular application and duration of use in a workplace should also take into account all relevant workplace factors such as, but not limited to: Other chemicals which may be handled, physical requirements (cut/puncture protection, dexterity, thermal protection), potential body reactions to glove materials, as well as the instructions/specifications provided by the glove supplier.

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

Respiratory protection: Respiratory protection should be worn when there is a potential to exceed the exposure limit requirements or guidelines. If there are no applicable exposure limit requirements or guidelines, wear respiratory protection when adverse effects, such as respiratory irritation or discomfort have been experienced, or where indicated by your risk assessment process. For most conditions, no respiratory protection should be needed; however, in dusty atmospheres, use an approved particulate respirator.
The following should be effective types of air-purifying respirators: Particulate filter.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	
Physical state	Powder
Color	Off-white
Odor	Amine.
Odor Threshold	No test data available
pH	8.1 *Measured*
Melting point/range	145.7 °C (294.3 °F) *EC Method A1* Decomposes at 145.7° C.
Freezing point	Not applicable
Boiling point (760 mmHg)	Not applicable
Flash point	**closed cup** Not applicable
Evaporation Rate (Butyl Acetate = 1)	No test data available
Flammability (solid, gas)	May form combustible dust concentrations in air
Lower explosion limit	Not applicable
Upper explosion limit	Not applicable
Vapor Pressure	0.00107 Pa at 25 °C (77 °F) *Estimated.*
Relative Vapor Density (air = 1)	No test data available
Relative Density (water = 1)	Not applicable
Water solubility	> 70 % at 25 °C (77 °F) *EC Method A6*
Partition coefficient: n-octanol/water	log Pow: 0.3 *Measured*
Auto-ignition temperature	> 400 °C (> 752 °F) *EC Method A16*
Decomposition temperature	145.7 °C (294.3 °F) *Literature*
Kinematic Viscosity	Not applicable
Explosive properties	no data available
Oxidizing properties	no data available
Bulk density	0.83 g/cm3 *CIPAC MT 33*
Molecular weight	251.2 g/mol *Literature*
Percent volatility	no data available

NOTE: The physical data presented above are typical values and should not be construed as a specification.

10. STABILITY AND REACTIVITY

Reactivity: no data available

Chemical stability: Stable under recommended storage conditions. See Storage, Section 7. Unstable at elevated temperatures.

Possibility of hazardous reactions: Polymerization will not occur.

Conditions to avoid: Avoid temperatures above 80°C (176°F) Active ingredient decomposes at elevated temperatures. Generation of gas during decomposition can cause pressure in closed systems. Avoid static discharge. Avoid moisture. Water contamination may cause heat generation and decomposition.

Incompatible materials: Avoid contact with oxidizing materials. Avoid contact with: Strong acids. Avoid contact with metals such as: Aluminum.

Hazardous decomposition products: Decomposition products depend upon temperature, air supply and the presence of other materials. Decomposition products can include and are not limited to: Chlorinated hydrocarbons. Carbon dioxide. Ammonia. Amines. Hydrogen chloride. Trimethylamine. Gases are released during decomposition.

11. TOXICOLOGICAL INFORMATION

Toxicological information on this product or its components appear in this section when such data is available.

Acute toxicity

Acute oral toxicity
Low toxicity if swallowed. Small amounts swallowed incidentally as a result of normal handling operations are not likely to cause injury; however, swallowing larger amounts may cause injury.

LD50, Rat, 1,000 mg/kg

Acute dermal toxicity
Prolonged skin contact is unlikely to result in absorption of harmful amounts.

LD50, Rabbit, > 5,000 mg/kg

Acute inhalation toxicity
No adverse effects are anticipated from single exposure to dust. For respiratory irritation and narcotic effects: No relevant data found.

LC50, Rat, 4 Hour, dust/mist, > 5.2 mg/l No deaths occurred at this concentration.

Skin corrosion/irritation
Brief contact may cause slight skin irritation with local redness.
May cause more severe response if skin is abraded (scratched or cut).
May cause more severe response if skin is damp.

Serious eye damage/eye irritation
May cause slight eye irritation.

Sensitization
For the minor component(s):
Skin contact may cause an allergic skin reaction in a small proportion of individuals.
As product:
Did not cause allergic skin reactions when tested in guinea pigs.

For respiratory sensitization:
No relevant data found.

Specific Target Organ Systemic Toxicity (Single Exposure)
Evaluation of available data suggests that this material is not an STOT-SE toxicant.

Specific Target Organ Systemic Toxicity (Repeated Exposure)
The data presented are for the following material:
CTAC
In animals, effects have been reported on the following organs after ingestion:
Liver.
High doses of sodium bicarbonate caused bladder effects in rats; however, repeated ingestion of sodium bicarbonate by humans has not resulted in known significant adverse effects.

Carcinogenicity
Methylene chloride has been shown to increase the incidence of malignant tumors in mice and benign tumors in rats. Other animal studies on methylene chloride alone, as well as several human epidemiology studies, failed to show a tumorigenic response. Methylene chloride is not believed to pose a measurable carcinogenic risk to humans when handled as recommended. Studies have shown that tumors observed in mice are unique to that species.

1,3-Dichloropropene. Has been shown to cause cancer in laboratory animals by the oral route. Inhalation exposure resulted in an increase in the normal occurrence of benign lung tumors in male mice.

Teratogenicity
CTAC has caused birth defects in rats administered relatively high oral doses; no defects were observed at lower doses. CTAC did not cause birth defects or any other effects on the fetus when relatively high doses were administered dermally, the most likely route of exposure. The data presented are for the following material: Methylene chloride. Has been toxic to the fetus in laboratory animals at doses toxic to the mother.

Reproductive toxicity
Contains component(s) which did not interfere with reproduction in animal studies.

Mutagenicity
For the major component(s): In vitro genetic toxicity studies were predominantly negative. Animal genetic toxicity studies were negative.

Aspiration Hazard
Based on physical properties, not likely to be an aspiration hazard.

Carcinogenicity

Component	List	Classification
1,3-Dichloropropene	IARC	Group 2B: Possibly carcinogenic to humans
	US NTP	Reasonably anticipated to be a human carcinogen
	ACGIH	A3: Confirmed animal carcinogen with unknown relevance to humans.
Dichloromethane (methylene chloride)	IARC	Group 2B: Possibly carcinogenic to humans
	US NTP	Reasonably anticipated to be a human carcinogen
	OSHA CARC	OSHA specifically regulated carcinogen
	ACGIH	A3: Confirmed animal carcinogen with unknown relevance to humans.

12. ECOLOGICAL INFORMATION

Ecotoxicological information on this product or its components appear in this section when such data is available.

Toxicity

Acute toxicity to fish
Material is moderately toxic to aquatic organisms on an acute basis (LC50/EC50 between 1 and 10 mg/L in the most sensitive species tested).

LC50, Lepomis macrochirus (Bluegill sunfish), 96 Hour, 66 mg/l

LC50, Oncorhynchus mykiss (rainbow trout), 96 Hour, 64 mg/l

Acute toxicity to aquatic invertebrates
EC50, Daphnia magna (Water flea), 48 Hour, 25.8 mg/l

LC50, copepod Acartia tonsa, 14.1 mg/l

LC50, grass shrimp (Palaemonetes pugio), > 128 mg/l

LC50, pink shrimp (Penaeus duorarum), 182 mg/l

Acute toxicity to algae/aquatic plants
ErC50, Pseudokirchneriella subcapitata (green algae), 96 Hour, Growth rate inhibition, 1.5 mg/l, OECD Test Guideline 201 or Equivalent

NOEC, Pseudokirchneriella subcapitata (green algae), 96 Hour, Growth rate inhibition, 0.243 mg/l, OECD Test Guideline 201 or Equivalent

Toxicity to bacteria
EC50, activated sludge, 1,504 mg/l

Toxicity to Above Ground Organisms
Material is slightly toxic to birds on a dietary basis (LC50 between 1001 and 5000 ppm).
Material is practically non-toxic to birds on an acute basis (LD50 > 2000 mg/kg).

oral LD50, Anas platyrhynchos (Mallard duck), > 2,510 mg/kg

dietary LC50, Colinus virginianus (Bobwhite quail), 3,223 ppm

dietary LC50, Anas platyrhynchos (Mallard duck), > 5,620 ppm

Persistence and degradability

Biodegradability: Material is readily biodegradable. Passes OECD test(s) for ready biodegradability.
10-day Window: Pass
Biodegradation: 75 %
Exposure time: 28 d
Method: OECD Test Guideline 301A or Equivalent
10-day Window: Not applicable
Biodegradation: 83 - 90 %
Exposure time: 28 d
Method: OECD Test Guideline 306 or Equivalent

Bioaccumulative potential

Bioaccumulation: Bioconcentration potential is low (BCF < 100 or Log Pow < 3).
Partition coefficient: n-octanol/water(log Pow): 0.3 Measured

Mobility in soil

Potential for mobility in soil is medium (Koc between 150 and 500).
Partition coefficient(Koc): 320 Estimated.

13. DISPOSAL CONSIDERATIONS

Disposal methods: DO NOT DUMP INTO ANY SEWERS, ON THE GROUND, OR INTO ANY BODY OF WATER. All disposal practices must be in compliance with all Federal, State/Provincial and local laws and regulations. Regulations may vary in different locations. Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator. AS YOUR SUPPLIER, WE HAVE NO CONTROL OVER THE MANAGEMENT PRACTICES OR MANUFACTURING PROCESSES OF PARTIES HANDLING OR USING THIS MATERIAL. THE INFORMATION PRESENTED HERE PERTAINS ONLY TO THE PRODUCT AS SHIPPED IN ITS INTENDED CONDITION AS DESCRIBED IN MSDS SECTION: Composition Information. FOR UNUSED & UNCONTAMINATED PRODUCT, the preferred option is to contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. The preferred option in other jurisdictions is to contact the regulatory authority for this product for guidance.

Treatment and disposal methods of used packaging: Do not dump into any sewers, on the ground, or into any body of water.

14. TRANSPORT INFORMATION

DOT

Not regulated for transport

Classification for SEA transport (IMO-IMDG):

Not regulated for transport

Transport in bulk according to Annex I or II of MARPOL 73/78 and the IBC or IGC Code	Consult IMO regulations before transporting ocean bulk

Classification for AIR transport (IATA/ICAO):

Not regulated for transport

This information is not intended to convey all specific regulatory or operational requirements/information relating to this product. Transportation classifications may vary by container volume and may be influenced by regional or country variations in regulations. Additional transportation system information can be obtained through an authorized sales or customer service representative. It is the responsibility of the transporting organization to follow all applicable laws, regulations and rules relating to the transportation of the material.

15. REGULATORY INFORMATION

OSHA Hazard Communication Standard
This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Superfund Amendments and Reauthorization Act of 1986 Title III (Emergency Planning and Community Right-to-Know Act of 1986) Sections 311 and 312
Acute Health Hazard
Chronic Health Hazard

Superfund Amendments and Reauthorization Act of 1986 Title III (Emergency Planning and Community Right-to-Know Act of 1986) Section 313

Components	**CASRN**
3,5,7-Triaza-1-azoniatricyclo[3.3.1.13,7]decane,1-(3-chloro-2-propenyl)- , chloride (CTAC)	4080-31-3
Dichloromethane (methylene chloride)	75-09-2
1,3-Dichloropropene	542-75-6

Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) Section 103

Components	**CASRN**	**RQ**
1,3-Dichloropropene	542-75-6	100 lbs RQ

Pennsylvania Worker and Community Right-To-Know Act:
The following chemicals are listed because of the additional requirements of Pennsylvania law:

Components	**CASRN**
Dichloromethane (methylene chloride)	75-09-2
1,3-Dichloropropene	542-75-6

California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986)
WARNING: This product contains a chemical(s) known to the State of California to cause cancer.

Components	**CASRN**
Dichloromethane (methylene chloride)	75-09-2
1,3-Dichloropropene	542-75-6

California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986)
This product (when prepared in aqueous formulations) contains a chemical known to the State of California to cause cancer.

United States TSCA Inventory (TSCA)
This product contains chemical substance(s) exempt from U.S. EPA TSCA Inventory requirements. It is regulated as a pesticide subject to Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requirements.

Federal Insecticide, Fungicide and Rodenticide Act
EPA Registration Number: 464-403
This chemical is a pesticide product registered by the Environmental Protection Agency and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets, and for workplace labels of non-pesticide chemicals. Following is the hazard information as required on the pesticide label:

CAUTION

Harmful if swallowed.
This pesticide is toxic to fish and aquatic invertebrates.

16. OTHER INFORMATION

Revision
Identification Number: 101201642 / A001 / Issue Date: 03/05/2015 / Version: 10.0
Most recent revision(s) are noted by the bold, double bars in left-hand margin throughout this document.

Legend

Absorbed via skin	Absorbed via skin
ACGIH	USA. ACGIH Threshold Limit Values (TLV)
BEI	Biological Exposure Indices
Dow IHG	Dow Industrial Hygiene Guideline
OSHA CARC	OSHA Specifically Regulated Chemicals/Carcinogens

OSHA Z-1	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA Z-2	USA. Occupational Exposure Limits (OSHA) - Table Z-2
PEL	Permissible exposure limit (PEL)
STEL	Excursion limit
TWA	8-hour, time-weighted average

Information Source and References
This SDS is prepared by Product Regulatory Services and Hazard Communications Groups from information supplied by internal references within our company.

THE DOW CHEMICAL COMPANY urges each customer or recipient of this (M)SDS to study it carefully and consult appropriate expertise, as necessary or appropriate, to become aware of and understand the data contained in this (M)SDS and any hazards associated with the product. The information herein is provided in good faith and believed to be accurate as of the effective date shown above. However, no warranty, express or implied, is given. Regulatory requirements are subject to change and may differ between various locations. It is the buyer's/user's responsibility to ensure that his activities comply with all federal, state, provincial or local laws. The information presented here pertains only to the product as shipped. Since conditions for use of the product are not under the control of the manufacturer, it is the buyer's/user's duty to determine the conditions necessary for the safe use of this product. Due to the proliferation of sources for information such as manufacturer-specific (M)SDSs, we are not and cannot be responsible for (M)SDSs obtained from any source other than ourselves. If you have obtained an (M)SDS from another source or if you are not sure that the (M)SDS you have is current, please contact us for the most current version.

Attachment 2 Risk Assessment Dossier

1-(3-CHLOROALLYL)-3,5,7-TRIAZA-1-AZONIAADAMANTANE CHLORIDE (CTAC)

This dossier on 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (CTAC) presents the most critical studies pertinent to the risk assessment of CTAC in its use in drilling muds. It does not represent an exhaustive or critical review of all available data. Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

Screening Assessment Conclusion – CTAC is an active ingredient in several biocide products. One of these products, DOWICIL 75, contains CTAC (64%) (CAS 4080-31-3) along with sodium bicarbonate (<39%) (CAS 144-55-8), methenamine (<5%) (CAS 100-97-0), 1,3-dichloropropene (<0.25%) (CAS 542-75-6) and methylene chloride (<0.1%) (CAS 75-09-2). For the purposes of this dossier, methenamine, 1,3-dichloropropene and methylene chloride occur at *de minimus* levels and do not warrant further hazard assessment. A standalone dossier has been developed for sodium bicarbonate wherein it is classified as a Tier 1 chemical. CTAC was not identified in chemical databases used by NICNAS as an indicator that the chemical is of concern and is not a PBT substance. CTAC was assessed as a tier 2 chemical for acute toxicity. No chronic toxicity data were available to categorize the substance. Therefore, CTAC is classified overall as a **tier 2** chemical and requires a hazard assessment and qualitative assessment of risk.

1 BACKGROUND

CTAC is readily biodegradable, and is not expected to bioaccumulate. It has a medium potential for adsorption to soil or sediments. The acute toxicity of CTAC is low-to-moderate by the oral route and low by the dermal route. It is slightly irritating to the skin and eyes; prolonged or repeated contact may cause skin irritation. Although the Dowicil products have tested negative for skin sensitisation in animals and humans, Dowicil 75 contains hexamethylenetetramine, which is a skin sensitiser. Repeated dose toxicity studies by the oral route have shown the liver to be a target organ; studies conducted by the dermal route showed only irritation at the site of contact and no systemic toxicity. The genotoxicity studies are generally negative. Dowicil 75 contains traces of impurities (methylene chloride and 1,3-dichloropropene) known to cause cancer in animal studies. Given the findings from the repeated dose toxicity and genotoxicity studies, there is a low concern for carcinogenicity for CTAC. Relatively high oral doses of Dowicil products containing the same active ingredient as Dowicil 75 (CTAC) have caused birth defects in animal studies; studies conducted by the dermal route have shown no developmental effects. CTAC is of high acute toxicity concern to algae, but moderately toxic to fish and invertebrates. To birds, it is practically non-toxic on an acute basis and slightly to non-toxic on a subacute dietary basis.

2 CHEMICAL NAME AND IDENTIFICATION

Chemical Name (IUPAC): 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride
CAS RN: 4080-31-3
Molecular formula: $C_9H_{16}N_4Cl_2$
Molecular weight: 251.2 g/mol

Synonyms: Methenamine 3-chlorallylochloride; hexamethylenetetramine chloroallyl chloride; 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride; 3,5,7-triaza-1-azoniatricyclo[3.3.1.13,]decane, 1-(3-chloro-2-propenyl)-chloride; CTAC, DOWICIL™ 75; quaternium-15; CTAC

The active ingredient of DOWICIL 75 is 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (CTAC), and it is stabilised with sodium bicarbonate. The composition of the product is shown below in Table 1. Sodium bicarbonate at ≤ 39% is added to stabilize the active ingredient and in solution will dissociate to the sodium cation and bicarbonate anion. No adverse effects are associated with sodium bicarbonate. The other substances are at *de minimus* levels and for purposes of this dossier are not further evaluated.

Table 1 Composition of Dowicil 75 (Dow, 2014)

Component	CAS Number	Composition
CTAC	4080-31-3	64.0%
Sodium bicarbonate	144-55-8	≤39.0%
Methenamine	100-97-0	<5%
1,3-Dichloropropene	542-75-6	≤0.25%
Methylene chloride	75-09-2	<0.1%

There are three Dowicil products: Dowicil 75, Dowicil 150 and Dowicil 200. CTAC is the active ingredient in all three products. CTAC can be present, however, as a cis- and trans-isomer. Dowicil 75 contain both isomers in roughly equal amounts; whereas, Dowicil 150 and 200 contain the cis-isomer (SCCS, 2011). As the CTAC comprises by far the largest percentage of Dowicil 75 components, the following dossier will focus on testing that has been conducted either on the Dowicil 75 product or CTAC.

3 PHYSICO-CHEMICAL PROPERTIES

Key physical and chemical properties for the substance are shown in Table 2.

Table 2 Overview of the Physico-chemical Properties of CTAC

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Powder, with a slight amine-like odour	-	USEPA, 1995
Melting Point	178-210°C	-	USEPA, 1995
Density	400 kg/m^3	-	USEPA, 1995
Vapor Pressure	<1.3 x 10^{-5} Pa @ 25°C	-	USEPA, 1995
Partition Coefficient (log K_{ow})	-0.1 (measured) 0.3 (measured)	-	USEPA, 1995 Dow, 2013
Water Solubility	> 100 g/L @ 25°C	-	PubChem

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 specific environmental regulatory controls or concerns were identified within Australia and internationally for CTAC.

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

A. Summary

CTAC is readily biodegradable, and is not expected to bioaccumulate. It has a medium potential for adsorption to soil or sediments.

B. Partitioning

CTAC is 97.8% ionized in moist soil, indicating that this compound will exist almost entirely in cation form in the environment and cations generally adsorb more strongly to soils containing organic carbon and clay than their neutral counterparts. Because of these cations, volatilization in moist soil surfaces and in water is not expected to be an important fate process (PubChem).

The aqueous hydrolysis half-lives of CTAC (58 ppm concentration, 25 °C) were reported as 1.1, 2.7, and 2.2 days at pH 5, 7, and 9, respectively (PubChem).

C. Biodegradation

Dowicil 75 is readily biodegradable. In an OECD 301A test, there was 75% degradation after 28 days (Dow, 2013). In an OECD 306 test, there was 83-90% degradation after 28 days (Dow, 2013).

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

D. Environmental Distribution

No experimental data are available for CTAC. The estimated soil K_{oc} is 320 (Dow, 2013) which indicates a moderate potential for sorption. If released to soil, based on this K_{oc} value along with its ionization properties, CTAC is expected to be moderately mobile.

E. Bioaccumulation

Bioconcentration of CTAC in aquatic organisms is not expected to occur based on a measured log K_{ow} of -0.1 (USEPA, 1995).

6 HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The acute toxicity of CTAC is low-to-moderate by the oral route and low by the dermal route. It is slightly irritating to the skin and eyes; prolonged or repeated contact may cause skin irritation. Although the Dowicil products have tested negative for skin sensitisation in animals and humans, Dowicil 75 contains hexamethylenetetramine which is a skin sensitiser. Repeated dose toxicity studies by the oral route have shown the liver to be a target organ; studies conducted by the dermal route showed only irritation at the site of contact and no systemic toxicity. The genotoxicity studies are generally negative. Dowicil 75 contains traces of impurities (methylene chloride and 1,3-dichloropropene) known to cause cancer in animal studies. Given the findings from the repeated dose toxicity and genotoxicity studies, there is a low concern for carcinogenicity for CTAC. Relatively high oral doses of Dowicil products containing the same active ingredient as Dowicil 75 (CTAC) have caused birth defects in animal studies; studies conducted by the dermal route have shown no developmental effects.

B. Acute Toxicity

The oral LD_{50} for Dowicil 75 in rats is 1,000 to 2,000 mg/kg; and the dermal LD_{50} in rabbits is >5,000 mg/kg (Dow, 2013).

C. Irritation

The Dowicil 200 (cis-CTAC) is slightly irritating to the skin and eyes of rabbits (SCCS, 2011). However, prolonged or repeated skin contact may cause irritation (see Section E).

D. Sensitisation

Dowicil 200 (cis-CTAC) was not considered to be a skin sensitiser in a guinea pig maximisation test. The induction and challenge doses were a 10% solution in Dowanol DPM/Tween 80 (9:1) (SCCS, 2011).

The Dowicil 200 (cis-CTAC), which was 0.6% in petrolatum, did not induce allergic contact dermatitis in a human repeat insult patch test (HRIPT) (SCCS, 2011). However, in another HRIPT, Dowicil 200 at 1% was considered to be a potential skin sensitiser. There are a number of published studies on the human patch test results for Quaternium-15; these have been reviewed by De Groot et al. (2010).

The Dowicil products contain the impurity hexamethylenetetramine (CAS No. 100-97-0), which is a known skin sensitiser.

E. Repeated Dose Toxicity

Oral

Male and female Sprague Dawley (SD) rats were given in their diet 0, 7.5, 15, 30 or 60 mg/kg Dowicil 100 (cis-/trans-CTAC, 91% purity) for 90 days. There were significantly decreased body weights (up to 20%) and a corresponding decrease in feed consumption in all dose groups (both sexes). Brain weights relative to body weights were significantly increased in all dose groups (both sexes); testis weights relative to body weights were significantly increased in male of all dose groups. Relative liver weights to body weights were increased in the 60 mg/kg animals (both sexes). In the 60 mg/kg males, serum urea nitrogen levels were significantly higher and alkaline phosphatase levels were significantly lower. SGPT levels were significantly lower in the ≥15 mg/kg males. Hepatocellular swelling was seen in some 60 mg/kg males. The NOAEL for this study is considered to be 15 mg/kg-day (SCCS, 2011). [Kl. score = 2]

Inhalation

No studies are available.

Dermal

A modified OECD 422 study was conducted on a cis-/trans-CTAC product (30.9% cis, 32.0% trans). Male and female Crl:CD(SD) rats were given dermal applications of 0, 75, 225 or 750 mg/kg (dose levels have been corrected for purity of cis-/trans-CTAC) for 6 hours/day. Males were dosed for 10 weeks, starting with a 4-week pre-mating period. Females were dosed from 4 weeks prior to mating until the end of lactation. The F_1 offspring were dosed for one week following weaning. The 750 mg/kg group was terminated early on day 17 of the study due to the severity of the skin lesions. There were no treatment-related clinical signs. The 225 mg/kg animals had scaling, erythema, and edema of the skin; these effects were minor in the 75 mg/kg animals. Female final body weights were significantly lower (8.1%) in the 225 mg/kg females; the 225 mg/kg males had lower (5.8%) final body weights that were not statistically significant. The 225 mg/kg males and females had significantly lower feed consumption; for the females, it was significantly reduced throughout the pre-mating period. Haematological parameters were similar between treated and control groups. There was a dose-related change in triglyceride levels, with statistical significance in the 225 mg/kg males. Chloroallylamine, the metabolite of CTAC, was found in the urine of treated rats. Histopathological effects in the parental animals were limited to skin lesions in two 225 mg/kg females. The NOAEL for parental toxicity is 75 mg/kg-day (SCCS, 2011). [Kl. score = 1]

Male and female New Zealand White rabbits were given dermal applications of 0, 50, 200 or 1,000 mg/kg Dowicil 100 (cis-/trans-CTAC; two batches of 94.85% and 90.2% purity) 6 hours/day, 5 days/week for 91 days. There were signs of irritation at the test site, which ranged from slight to severe erythema, edema and scaling, slight fissuring, scabbing and scarring, mainly limited to areas of abrasion from clipping. The onset and degree of skin changes were dose-related. Haematological parameters in treated males were similar to the controls; however, there was an increase in white blood cell count and platelets in the 1,000 mg/kg females. There were no treatment-related changes

in the clinical chemistry. Gross pathological findings and histopathology were limited to the skin at the site of application. The NOAEL for systemic toxicity is 1,000 mg/kg-day (SCCS, 2011).

Male and female mice were given dermal applications of 0, 100, 400 or 1,200 mg/kg Dowicil 100 (cis-/trans-CTAC, 91.3% purity) 6 hours/day for 90 days. There was no indication of systemic toxicity. The NOAEL for systemic toxicity is 1,200 mg/kg-day (SCCS, 2011).

F. Genotoxicity

In Vitro Studies

The results of the *in vitro* genotoxicity studies on CTAC are presented below in Table 4.

Table 4 *In Vitro* Genotoxicity Studies on CTAC

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Mammalian cell gene mutation (CHO cells/HGPRT)	-	+	-	USEPA, 1995; SCCS, 2011
Unscheduled DNA synthesis (rat hepatocytes)	NA	-	-	USEPA, 1995

*+, positive; -, negative; NA, not applicable.

In Vivo Studies

CTAC was negative in mouse micronucleus test. No details were given (USEPA, 1995). Dowicil 200 (cis-CTAC) did not induce micronuclei in the bone marrow cells of male CD-1 mice given up to 2,000 mg/kg as a single oral dose on two consecutive days (SCCS, 2011). Dowicil 150 (cis-CTAC) did not induce unscheduled DNA synthesis (UDS) in male F344 rats given 750 or 1,500 mg/kg as a single oral gavage dose (SCCS, 2011).

G. Carcinogenicity

No studies are available.

H. Reproductive Toxicity

Oral Studies

No studies are available.

Dermal Studies

A modified OECD 22 study was conducted on a cis-/trans-CTAC product (30.9% cis, 32.0% trans). Male and female Crl:CD(SD) Sprague Dawley rats were given dermal applications of 0, 75, 225 or 750 mg/kg (dose levels have been corrected for purity of cis-/trans-CTAC) for 6 hours/day. Males were dosed for 10 weeks, starting with a 4-week pre-mating period. Females were dosed from 4 weeks prior to mating and until the end of lactation. The F_1 offspring were dosed for one week following weaning. The 750 mg/kg group was terminated early on day 17 of the study due to the severity of

the skin lesions. Parental toxicity for this study is described above in the Repeated Dose Toxicity section. Reproductive indices, pup survival and sex ratio were similar across all groups. The 225 mg/kg male and female pup weights tended to decrease (7.5-14.7%) relative to controls throughout the lactation period. On PND 21, the mean female pup weights were statistically significantly lower than the controls. There were no treatment-related clinical signs in the F_1 weanlings, and dermal effects were seen in only one 225 mg/kg male (slight scaling on test days 5 to 7). Body weights of the 225 mg/kg male F_1 offspring were significantly lower than control on test days 4 and 7; the 225 mg/kg female F_1 offspring had lower body weights, but were not statistically significantly different from controls. Feed consumption was significantly lower in the 225 mg/kg males. The NOAEL for reproductive toxicity is 750 mg/kg-day. The NOAEL for post-natal toxicity is 75 mg/kg-day (SCCS, 2011). [Kl. score = 1]

I. Developmental Toxicity

Oral Studies

Pregnant female New Zealand White rabbits were dosed by oral gavage with 0, 2.5, 8 or 25 mg/kg cis-/trans-CTAC product (31.3% cis, 32.5% trans) on gestational days 7-27. Body weight gain and feed consumption were decreased throughout the entire dosing period in the 25 mg/kg does. Foetal body weights and mean gravid uterine weights were also lower in the 25 mg/kg group. The NOAEL for maternal and developmental toxicity is 8 mg/kg-day (SCCS, 2011). [Kl. score = 2]

Pregnant female F344 rats were dosed by oral gavage with 0, 5, 25 or 75 mg/kg Dowicil 200 (cis-CTAC) on gestational days 6 through 15. Body weight and body weight gain were significantly lower in the 75 mg/kg dams. Absolute and relative liver weights were also increased in the 75 mg/kg dams. The 25 mg/kg dams had significantly lower body weights during the first three days of dosing. Food consumption was significantly lower in the 75 mg/kg dams; water consumption was also significantly lower. Feed consumption was also significantly lower in the 25 mg/kg dams during GD 9 through 14. The incidence of resorptions was significantly increased in the 75 mg/kg group, and there was a significant decrease in foetal body weights. The incidence of total major malformation of foetuses was significantly higher in the $\geq$25 mg/kg groups. The majority of the malformed foetuses exhibited anomalies of the eye, microphthalmia or anophthalmia. The NOAEL for maternal and developmental toxicity is 5 mg/kg-day (SCCS, 2011). [Kl. score = 1]

In a repeat study done 23 years later, pregnant female F344 rats were dosed by oral gavage with 0, 25 or 75 mg/kg Dowicil 200 (cis-CTAC) during gestational days 6 through 15. The dams showed similar toxicity as in the previous developmental study on cis-CTAC: decreases in maternal body weight, body weight gains and feed consumption. Foetal body weights were also decreased in the 75 mg/kg dose group. The incidence of microphthalmia and/or anophthalmia was similar to the historical control incidence for F344 rats, and was considerably lower than the incidence of eye defects in the first study. There was no dose-response relationship with respect to these malformations. The study authors concluded that the known propensity of F344 rats for foetal eye defects suggests that the original study findings were likely related to a spontaneously occurring genetic cluster effect, rather than a specific consequence of Dowicil 200 exposure.

Dermal Studies

Pregnant female F344 rats were given dermal applications of 0, 250 or 500 mg/kg CTAC on gestational days 6 to 15. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 500 mg/kg-day (USEPA, 1995).

J. Derivation of Toxicological Reference and Drinking Water Guidance Values

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

Non-Cancer

Oral

A 90-day rat dietary study is available on former product Dowicil 100, which can be used to read-across to Dowicil 75 (SCCS, 2011). Both products contain a mixture of cis- and trans-isomer of CTAC. The NOAEL for this study is 15 mg/kg-day, which will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

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

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

Oral RfD = 15/(10 x 10 x 1 x 10 x 1) = 15/1000 = 0.015 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 = (0.015 x 70 x 0.1)/2 = 0.05 mg/L

K. Cancer

There are no carcinogenicity studies on the Dowicil products containing either cis-CTAC or cis-/trans-CTAC. Therefore, no cancer reference value was derived.

It should be noted that methylene chloride and 1,3-dichlorpropene are impurities of Dowicil 75. Both substances have been shown to be carcinogenic in laboratory animals.

L. Human Health Hazard Assessment of Physico-Chemical Properties

CTAC does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

7 ENVIRONMENTAL EFFECTS SUMMARY

A. Summary

CTAC is of high acute toxicity concern to algae, but moderately toxic to fish and invertebrates. To birds, it is practically non-toxic on an acute basis and slightly to non-toxic on a subacute dietary basis.

B. Aquatic Toxicity

Acute Studies

Table 5 lists the results of acute aquatic toxicity studies conducted on CTAC.

Table 5 Acute Aquatic Toxicity Studies on CTAC

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Bluegill	96-h LC_{50}	59	-	ECOTOX
Bluegill	96-h LC_{50}	>148	-	ECOTOX
Fathead minnow	96-h LC_{50}	29	-	ECOTOX
Fathead minnow	96-h LC_{50}	34	-	ECOTOX
Sheepshead minnow	96-h LC_{50}	>122	-	ECOTOX
Rainbow trout	96-h LC_{50}	20.5	-	ECOTOX
Rainbow trout	96-h LC_{50}	>144	-	ECOTOX
Daphnia magna	48-h EC_{50}	27	-	ECOTOX
Daphnia magna	48-h EC_{50}	40	-	ECOTOX

Pseudokrichneriella subcaptitata	EC_{50} NOEC	1.5 (growth rate) 0.243	-	Dow, 2013

Chronic Studies

No studies are available.

C. Terrestrial Toxicity

Avian Species

The oral acute LD_{50} of CTAC to mallard ducks is >2,510 mg/kg (USEPA, 1995). The dietary subacute LC_{50} to bobwhite quail and mallard ducks are 3,223 and >5,620 ppm, respectively (USEPA, 1995).

D. Calculation of PNEC

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

PNEC water

Experimental results are available for three trophic levels. The acute EC_{50} values are available for fish (20.5 mg/L), *Daphnia* (27 mg/L), and algae (1.5 mg/L). On the basis that the data consists of short-term results from three trophic levels, an assessment factor of 1,000 has been applied to the lowest reported EC_{50} value of 1.5 mg/L for algae. The $PNEC_{water}$ is 0.0015 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 0.0081 mg/kg sediment wet weight.

The calculations are as follows:

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

$= (6.94/1280) \times 1000 \times 0.0015$

$= 0.0081$ mg/kg

Where:

$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)

BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]

$PNEC_{water}$ = predicted no effect concentration in water

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

$= 0.8 + [0.2 \times 12.8/1000 \times 2400]$

$= 6.94\ m^3/m^3$

Where:

Kp_{sed} = solid-water partition coefficient (L/kg)

BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$
= 320 x 0.04
= 12.8 L/kg

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for CTAC is estimated to be 320 L/kg.
f_{oc} = fraction of organic carbon in sediment = 0.04 [default]

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.0064 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
= (6.4/1500) x 1000 x 0.0015
= 0.0064 mg/kg

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]
$PNEC_{water}$ = predicted no effect concentration in water

$Kp_{soil} = K_{oc} \times f_{oc}$
= 320 x 0.02
= 6.4 m^3/m^3

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for CTAC is estimated to be 320 L/kg.
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, 2008).

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

Based on a measured log K_{ow} of -0.1, CTAC does not meet the screening criteria for bioaccumulation.

The 96-h NOEC from an algal study on CTAC is >0.1 mg/L. The acute EC_{50} values for CTAC are >1 mg/L in fish, invertebrates and algae. Thus, CTAC does not meet the screening criteria for toxicity.

The overall conclusion is that CTAC is not a PBT substance.

B. Other Characteristics of Concern

No other characteristics of concern were identified for CTAC.

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]	
CTAC (64%)	4080-31-3	No	No	No	No	No	No	No	2	No data	2
Sodium bicarbonate (<39%)[4]	144-55-8	No	No	No	No	No	No	No	1	No data	1
Methenamine (<5%)[5]	100-97-0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
1,3-Dichloropropene (<0.25%) [5]	542-75-6	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Methylene chloride (<0.1%) [5]	75-09-2	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

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.

4 – Refer to sodium bicarbonate dossier

5 – De minimus level: no further assessment warranted.

Notes:

NA = not applicable

PBT = Persistent, Bioaccumulative and Toxic

B = bioaccumulative

P = persistent

T = toxic

10 REFERENCES, ABBREVIATIONS AND ACRONYMS

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B. Abbreviations and Acronyms

°C	degrees Celsius
AICS	Australian Inventory of Chemical Substances
CHO	Chinese hamster ovary
COC	constituent of concern
CTAC	1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride
DEWHA	Department of the Environment, Water, Heritage and the Arts
EC	effective concentration
ECHA	European Chemicals Agency
EU	European Union
g/cm^3	grams per cubic centimetre
GD	Gestation day
HGPRT	hypoxanthine-guanine phosphoribosyltransferase
HRIPT	human repeat insult patch test
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
kg/m^3	kilogram per cubic metre
KI	Klimisch scoring system
kPa	kilopascal
L	litre
LC	lethal concentration
LD	lethal dose
LOAEL	lowest observed adverse effect level
m^3	cubic metre
mg/kg	milligrams per kilogram
mg/L	milligrams per litre
mm	millimetre
NICNAS	The National Industrial Chemicals Notification and Assessment Scheme

NOAEL	no observed adverse effect level
NOEC	no observed effective concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative and Toxic
PND	post natal day
PNEC	Predicted No Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RfD	reference dose
SD	Sprague Dawley
SGG	Synthetic Greenhouse Gases
SGPT	Serum glutamic pyruvic transaminase
UDS	unscheduled DNA synthesis

Appendix 7 – Example Tier 3 Quantitative Risk Assessment

Qualitative and Quantitative Tier 3 Assessment

Dazomet

In accordance with the 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

Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione (dazomet) is a component in a drilling fluid product (DEXTRID® LTE) used as a fluid loss additive in the following fluid systems:

- KCl/Polymer Mud System
- Inhibitive Mud System
- Inhibited Star Shield Mud System
- KCl/Polymer Mud - Stuck Pipe Mud System
- LCM Pill 1 Mud
- LCM Pill 2 Mud
- LCM Pill 3 Mud

The first two fluid systems (muds) are the primary systems to be used as drilling fluids. The Inhibited Star Shield mud system is used as a preventative wellbore shielding additive during drilling operations for the production of coal seam gas. The loss control muds (LCMs) are used to plug fractures and are considered secondary muds and will only be used as required. Likewise, the KCl/Polymer Stuck Pipe Mud system is used to free stuck pipes and is also considered a secondary mud that will only be used as required. These secondary muds are considered insignificant relative to the primary muds due to the considerably reduced volume used as compared to the other muds.

The purpose and maximum quantity (i.e., in all muds) for this chemical is summarised in **Table 1**. A safety data sheet (SDS) for the drilling fluid product is included as **Attachment 1**.

Table 1 Drilling Fluid Chemicals

Chemical Name	CAS No.	Use	Quantity[1]
Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione (Dazomet)	533-74-4	Fluid loss stabiliser	1.33 mL/L
Methylisothiocyanate (MITC)	556-61-6	NA	0 mL/L

[1] Based on maximum of combined muds assessed
CAS No = Chemical Abstracts Service Number
L = litre
mL = millilitre

Methylisothiocyanate (MITC) is not a chemical additive; however, dazomet breaks down through hydrolysis to MITC relatively rapidly. Therefore, MITC was also included in this assessment for the residual drilling fluids.

The assessment of toxicity of these chemicals was used to evaluate human health exposure scenarios and is presented in **Attachment 2**. Neither chemical is a carcinogen, and, as a result, only non-carcinogenic oral reference doses (RfDs) were derived. 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)
Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione (Dazomet) (533-74-4)	2-year rat dietary	Liver and RBC toxicity	1	100	0.01	0.04
Methylisothiocyanate (MITC) (556-61-6)	2-year rat drinking water	Decreased water consumption, body weights	0.5	100	0.005	0.018

CAS = Chemical Abstracts Service
mg/kg-day = milligram per kilogram-day
mg/L = milligram per litre
NOAEL = No observed adverse effect level
RBC = Red blood cell
Refer to **Attachment 2** 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 toxicological 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 effects concentration (NOEC) (milligrams per litre [mg/L]), assessment factor, and the aquatic PNEC (mg/L). The PNEC for soil is detailed in **Table 4**. Refer to **Attachment 2** 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)
Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione (Dazomet) (533-74-4)	Acute fish	0.16	1,000	0.00016
Methylisothiocyanate (MITC) (556-61-6)	Chronic fish	0.004	50	0.0008

EC_{50} = effects concentration – 50%
mg/L = milligram per litre
NOEC = no observed effects concentration
PNEC = predicted no effect concentration
Refer to **Attachment 2** for information on the development of PNECs listed above.

Table 4 PNECs Soil – Tier 3 Chemicals

Constituents	Endpoint	EC_{50} or NOEC (mg/kg dry wt)	Assessment Factor	$PNEC_{soil}$ (mg/kg dry wt)
Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione (Dazomet) (533-74-4)	Acute earthworm	4	1,000	0.004
Methylisothiocyanate (MITC) (556-61-6)	Acute earthworm	2.79	1,000	0.00279

EC_{50} = effects concentration – 50%
mg/kg dry wt = milligram per kilogram dry weight
NOEC = no observed 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 risks posed by this Tier 3 chemical is provided in the following sections.

General Overview

Dazomet is a colourless solid that is rapidly hydrolysed to MITC. The molecular structure of dazomet is presented in **Figure 1**. The molecular structure of MITC is presented in **Figure 2**.

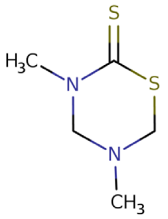

Figure 1 Molecular Structure of Dazomet[1]

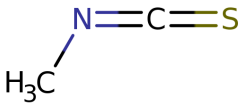

Figure 2 Molecular Structure of MITC[2]

Dazomet is rapidly hydrolysed to MITC (half-life of 5 hours at 25 degrees Celsius [°C], pH = 7). It is not readily biodegradable, but it is inherently biodegradable. In biologically active soils, it is degraded to MITC with a half-life of 7-12 hours at 20°C. Dazomet does not adsorb substantially to soil and is rapidly degraded under the conditions of the tests. MITC adsorbs little to soil and is degraded with a half-life of 5-14 days at 20°C. Dazomet is not likely to volatilise due to its very low vapour pressure; however, MITC, with a vapour pressure of 2,500 Pascals (Pa), will rapidly evaporate. Both dazomet and MITC have a low potential to bioaccumulate.

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

Human Health Hazards

Dazomet is moderately acutely toxic by the oral route but exhibits low acute toxicity by the dermal and inhalation routes. It is not irritating to the skin and eyes, and it is not a skin sensitiser when tested on guinea pigs. MITC is highly acutely toxic by the oral and inhalation routes. By the dermal route, a wide range has been reported for rodents and rabbits that range from highly toxic to low toxicity. MITC is severely irritating to the skin and eyes, and it is a skin sensitiser.

[1] Source https://chem.nlm.nih.gov/chemidplus/rn/533-74-4

[2] Source https://chem.nlm.nih.gov/chemidplus/rn/556-61-6

Repeated oral exposures to dazomet have shown the liver and red blood cell (RBC) toxicity in rats, mice and dogs. There was no toxicity in rats exposed by inhalation for 21-days, nor was there any indication of systemic toxicity in rabbits when dazomet was applied to the skin for 21 days. Dazomet was weakly genotoxic in some *in vitro* assays, but was not genotoxic in the *in vivo* tests. Dazomet is not a reproductive toxicant; developmental toxicity can occur at maternally toxic doses, but there is no teratogenicity. Dazomet is not a carcinogen.

The nasal cavity is a target organ for repeated inhalation exposures to MITC. In oral studies, repeated exposures have resulted in systemic toxicity with no clear target organ effects. MITC is not genotoxic. MITC is not a reproductive toxicant; developmental toxicity can occur at maternally toxic doses, but there is no teratogenicity. An increased incidence of mammary gland tumours (fibroadenomas) in female rats was reported in the two-year drinking water study. The increase was marginally statistically significant in the highest dose tested (50 parts per million [ppm]). MITC was not carcinogenic in mice when given in drinking water for two years.

Based on a review of repeated dose and developmental toxicity studies, toxicological reference values were derived for dazomet and MITC. The drinking water guideline value derived using the non-carcinogenic oral RfD is 0.04 mg/L and 0.018 mg/L for dazomet and MITC, respectively.

Without management controls in place, there is the potential for human receptors to be exposed to drilling fluid chemicals that contain dazomet (and MITC by hydrolysis) during drilling and completion operations and management of drilling fluids and cuttings. Based on an assessment of land use and an understanding of the project description provided in the Environmental Impact Statement (EIS) (URS, 2014) and the CRAF conceptual exposure model (CEM), potential human receptors include:

1. Workers at the well lease involved with blending, storage, transfer, reuse, recovery and recycling of drilling fluids and cuttings; recycling, reuse or disposal of recovered materials including beneficial reuse activities such as land applications of drilling materials and dust suppression; and, mitigating releases at the well lease or along the transport or conveyance routes.
2. Agricultural workers or residents in irrigation areas.
3. Landholders that have access to the water supply from a bore hydraulically downgradient of the well lease.

In terms of risks associated with transport of chemicals and wastes, this risk is considered to be managed to a level as low as reasonably practicable. This is because the potential for a release is controlled through implementation of a traffic management principles including use of designated trucking routes, vehicle signage, vehicle management systems (to manage speed and driving behaviour/habits) and in the unlikely event of a vehicular accident, implementation of incident and spill response procedures. Given the highly regulated nature of transportation of chemicals (at both a Commonwealth and State level), transport-related scenarios are not evaluated further in this assessment. However, the outcome of the assessment should be used to inform emergency response actions.

Exposure of workers to drilling fluid chemicals is possible via inadvertent spills and leaks, during the recycling and beneficial reuse of recovered materials (e.g., drilling fluids and cuttings), and during application of the recovered material to land. However, chemical exposures to workers are controlled through engineering, management controls and personal protective equipment, which are focused on elimination and mitigation of the potential for dermal contact and potential for incidental ingestion. In addition, Australia SafeWork Place and Santos Occupational Safety Guidance

are used to minimise human health exposure. As a result, petroleum workers, are also excluded from assessment.

The management of chemicals and wastes will be conducted at the well lease using drums, totes and engineered tanks designed to contain the fluids. In the unlikely event of a release to ground, the potential for exposures (other than workers) is limited. The well pad sites are fenced and access is controlled, which limits access to the public. If drilling fluid chemicals are spilled to ground then investigation, remediation and rehabilitation activities would be implemented to address soil impacts.

On-lease storage may utilise tanks, pits or turkey nests and there is the possibility that a containment failure could result in the release of the materials to the well lease and the surrounding environment. Releases on the well pad would be of limited volumes and, as such, these products would not be anticipated to migrate a significant distance off lease to the surrounding environment, including proximal water bodies.

Exposure of potential receptors (other than workers) is also possible to residual chemicals in areas adjacent to a well lease that have been used for the application of materials for beneficial reuse. However, Environmental Authority (EA) or Beneficial Use Approval conditions regulate project reuse. A plan for the beneficial reuse of materials has been developed by a Suitably Qualified Person (SQP) in accordance with the EA conditions which require materials of a certain quality and controls the maximum volumes that can be applied to land. In addition, the application techniques and location of application are controlled with specific monitoring required. Irrigation areas are designed to manage the risk of pooling and runoff with a general deficit irrigation strategy employed; and, are fitted with monitoring bores to manage the risk of vertical and horizontal migration.

As a result, potential exposures during the drilling process are low due to the employment of mechanical equipment/processes, engineering controls (including secondary containment) and other mitigation and management strategies. Similarly, there is a low potential for human receptors exposed to residual chemicals in areas adjacent to a well lease that have been used for the application of materials for beneficial reuse and to surface water bodies that may receive runoff from beneficial reuse applications. Finally, the probability of any surface related discharge infiltrating subsurface soils and migrating to groundwater is very low.

Environmental Hazards

Dazomet exhibits high acute toxicity to aquatic organism, particularly to fish (96-hour LC_{50} = 0.16 mg/L [LC; lethal concentration]). This effect, however, is unlikely to be attributed only to dazomet since dazomet is rapidly degraded to MITC in water. MITC exhibits a higher acute toxicity to fish compared to dazomet (96-hour LC_{50} = 0.053 mg/L). Both dazomet and MITC show moderate toxicity to earthworms.

There is rapid degradation of dazomet by hydrolysis in the aquatic environment and soil. Conversely, MITC does not degrade in freshwater by hydrolysis and it is also not readily biodegradable. However, it is expected to be removed rapidly from water by volatilisation. In soil, the degradation half-life is 5-13 days (<6 months). MITC also disappears rapidly in sediment: < 2 % can be found in sediment after 14 days (EU, 2010). Therefore, neither chemical is persistent in the environment. Both chemicals have a low potential for bioaccumulation.

Experimental toxicity data on water organisms was available for three trophic levels to calculate PNECs in water. Experimental toxicity data on soil organisms was available for one trophic level to calculate PNECs in soil. However, there are no toxicity data for sediment-dwelling organisms. Therefore, PNECs for sediment were calculated using the equilibrium partitioning method.

During the drilling process, there is the potential for environmental receptors to be exposed to drilling fluid chemicals that contain dazomet (and by hydrolysis, MITC). Pipelines (where treated water is conveyed) can transect sensitive ecological areas (including Matters of National Environmental Significance [MNES]). There is the concern of wildlife (terrestrial and aquatic receptors) and livestock in the vicinity of the well leases to have adverse effects from potential exposures. Potential environmental receptors include:

1. Wildlife and livestock accessing the well lease and areas adjacent to a well lease, including surface water features, that have received runoff from an accidental release during drilling and completion operations or loss of containment.
2. Wildlife and livestock accessing areas of the well lease where materials have been applied as well as accessing stored materials in pits and turkey nests.
3. Aquatic flora and fauna within a proximal surface water body that has received runoff from an accidental release during drilling and completion operations or loss of containment, or from beneficial reuse applications.
4. Wildlife, including livestock, that have access to the water supply from a bore hydraulically downgradient of the well lease.

The potential for exposure of sensitive receptors (including MNES) is considered low. The drilling and completion activities occur over a short duration and are conducted in controlled/operational areas within a perimeter fence. Further, the activity level, noise, etc. will be a disincentive for wildlife and livestock to access the lease through gaps in the fencing or unsecured gates.

Based on the engineering and management controls described in the previous section (Human Health Hazards), there is a low potential for ecological receptors exposed to surface water bodies that may receive runoff from an accidental release. There is also concern that recovered material applied to the land surface could migrate to groundwater or surface water, and therefore result in adverse effects to the environment (e.g., uptake by aquatic receptors). Due to EA conditions regulating land application techniques, the remote nature of the well leases, vertical separation of groundwater and distances to watercourses, the ephemeral nature of the watercourses and the physical and chemical properties of the residual chemicals post treatment or beneficial reuse, these potential exposures are low.

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 dazomet and MITC that may occur during activities associated with drilling and completion operations and management of drilling fluids and cuttings. These exposures may include operational activities where planned direct releases to the environment may occur (e.g., land application). The risk characterisation evaluates the toxicity of these chemicals and characterises the risk of the chemicals 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 exposure point concentration (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. No 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 identify the amount of dazomet in the primary drilling fluid systems. As the specific drilling fluid formulation to be used at an individual well lease will be adapted / determined based on specific geology encountered during drilling, the maximum concentration for dazomet in the mud systems was used to calculate a mass in the liquids for a composite of the mud systems. This composite mud approach was used to conservatively estimate the concentration of exposure; therefore, to assess all possible scenarios.

For the mass balance calculation, 100% of the mass of chemicals in the liquids was conservatively assumed to be partitioned into the dry solids (accounting for the additional mass of native silts and clays introduced into the fluid during drilling – a conversion) by applying a factor of 0.6 to the estimated fluid mass to calculate a solids estimated concentration. MITC is not a chemical additive; however, dazomet breaks down through hydrolysis to MITC relatively rapidly. Therefore, an estimate was calculated for MITC in solids. **Table 5** presents the calculated chemical additive concentrations of the drilling fluids.

Table 5 Mass Balance Estimates for Dazomet and MITC

Chemical Name	CAS No.	Water Maximum Estimated Concentration (mg/L)	Solids Maximum Estimated Concentration (mg/kg)
Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione (Dazomet)	533-74-4	51	0
Methylisothiocyanate (MITC)	556-61-6	0	30.6

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

The mass balance of the chemicals was then used to estimate the potential EPCs within the aqueous phase of residual drilling materials. It is anticipated that the solid materials may be stockpiled and allowed to dry (potentially one week) prior to land application. Therefore, the EPCs of dazomet and MITC within the drilling fluids will decrease, where applicable, to account for the biodegradation and photolytic degradation of the chemical over time. 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 3, Table 1** includes the

environmental fate information that was used to assess biodegradation of the chemical, and that was applied at the time periods of 0, 3 and 7 days from initial recovery. The time periods of 0, 3 and 7 days were based on the length of drilling operations that would generate dazomet in the drilling fluids systems that may result in exposure. It is not expected that drilling operations would last longer than 7 days.

As detailed in **Attachment 3, Table 1**, the initial EPC (i.e., day 0) for MITC was assumed to be 0 mg/L in the spent drilling fluids because it is a degradation chemical. However, based on the half-life (five hours) of dazomet, an EPC for MITC was calculated by assuming complete hydrolysis of dazomet to MITC. The EPC for MITC for day 3 and day 7 was calculated based on a ratio of residual dazomet to generated MITC. For the application of the spent drilling muds to the well lease, the ratio of dazomet to MITC would result in an MITC concentration representative of complete hydrolysis. Therefore, dazomet is assumed to not be present as a constituent of potential concern (COPC) in the spent muds.

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 three exposure scenarios (0, 3 and 7 days) were compared to human health toxicity-based screening levels to screen for potential effects as a result of a release from the well lease that may migrate to groundwater used as a drinking water source. The results of this comparison, including the ratio of exceedance of screening levels, is presented in **Attachment 3, Table 2**. As detailed in the table, dazomet exceeded the screening levels in day 0 and MITC exceeded the screening levels for days 3 and 7.

The potential for MITC to migrate from the well lease to a landowner bore was evaluated in a detailed fate and transport model (EHS Support, 2015). As detailed in the model, the chemical is unlikely to migrate to a potable water source due to the chemical and physical properties of the additive, the geology of the project area and distances to water bores. In the evaluation, the modelled concentration has been compared to general screening criteria for the most sensitive beneficial uses. However as noted above, this beneficial use is unlikely to be realised, with stock watering and irrigation the most likely uses of water. The constituent does not limit the use of groundwater for irrigation and, given the larger mass of cattle, is unlikely to pose a risk to livestock. Rapid degradation of this organic compound will not result in it persisting within groundwater.

To screen for a potential release of drilling fluids to surface water, the theoretical concentrations of the three exposure scenarios were also compared to the PNEC for aquatic receptors. **Attachment 3, Table 3** presents the results of this comparison, including the ratio of exceedance of screening levels. Dazomet or MITC exceeded the screening levels for each exposure scenario on days 0, 3 and 7. Based on the screening, there is a potential for adverse impacts to surface water resources and associated aquatic flora and fauna from a potential release of residual drilling fluids. Based on the environmental fate of dazomet along with the engineering and management controls previously described, the potential for exposure is low. Dazomet is rapidly hydrolysed to MITC (half-life of 5 hours), and MITC has a high volatility in water. Therefore, MITC will likely evaporate in the water phase during a release, and therefore, will not be a risk driver. As a result, further quantitative evaluation of this exposure scenario was not conducted.

There is also the potential for exposure of receptors to MITC in residual drilling materials prior to or during application of the material to land. To evaluate the potential exposure of the receptors to residual drilling material, two scenarios were considered: a conservative scenario that addressed the

full concentration of the COPC in the residual drilling materials and a post-application scenario that considered the resultant concentrations on the well lease after utilising mix bury cover (MBC) or land application beneficial reuse techniques. To estimate the resultant concentration of the chemical post management (treatment), an MBC scenario was used where the residual drilling materials were mixed and covered with *in situ* soils at a rate of 20 cubic metres (m^3) within 1 hectare (10,000 square metres [m^2]) x 10 centimetres (cm) (0.01 metre [m]), resulting in a management (treatment) factor of 0.02. **Attachment 3, Table 4** presents the theoretical estimates of the residual MITC concentrations.

The theoretical concentrations were compared to PNECs for solids for ecological receptors and are presented in **Attachment 3, Table 5**. The ratio of exceedance of screening levels to the untreated and treated concentrations are also presented in the table. The ratio of estimated concentrations in both untreated and treated soils to PNECs for soil exceeded the threshold of 10. MITC is a hydrolysis product of dazomet, and due to its high volatility in water, MITC will likely evaporate in the aqueous phase during application to the soil and not persist. However, to further evaluate potential risks to non-MNES receptors (mammals and avian) receptors, additional quantitative analysis of the potential exposure pathway was conducted.

The Northern Quoll and Cattle Egret were selected as ecological endpoints for potential exposure to COPCs in soils on the well lease (residual drilling fluid COPCs with soils). Exposure assumptions, TRVs and total intake calculations are detailed in **Attachment 3, Tables 6 and 7**.

Attachment 3, Table 6 presents the calculated risk estimates for the Northern Quoll. As indicated in the table, the calculated hazard quotient (HQ) for MITC did not exceed the risk threshold level of 1 for either scenario (untreated or treated).

Attachment 3, Table 7 presents the calculated risk estimates for the Cattle Egret. As indicated in the table, the calculated HQ for MITC exceeded the risk threshold in the untreated scenario (unmixed cuttings) but did not exceed the risk threshold for treated scenario (mixed cuttings).

As detailed in the attachment, the exposure assumptions for Cattle Egret dietary intake assume consumption of earthworms as 50% of their food intake, which is not their typical dietary prey selection. In addition, surface exposure of the earthworms to the drill cuttings assumes no mix, turn and bury management, which results in an approximately 50% reduction in COPC concentration due to mixing with clean soil. As a result, no management controls are considered to be required as it is unlikely that >50% of their dietary requirements are sourced from earthworms, with the risk reduced even lower as it is extremely unlikely that >50% of their diet is sources from only the areas subject to land application activities.

The primary land use within the development area is agricultural (grazing on improved or unimproved pastures), and it is sparsely populated. However, as noted earlier, there may be potential for human receptors such as residents and agricultural workers to be exposed to chemicals in recovered materials during beneficial reuse applications. Relative potential exposure to agricultural workers or trespassers is considered low due to the remote location of the well leases and the sparse population. In addition, activities are undertaken in operational and controlled areas of the well lease. There are no risk-based screening levels (RBSLs) to evaluate potential exposures of agricultural workers or residents to COPCs in residual drilling materials. Therefore, to further evaluate potential direct contact risks to these receptors, additional quantitative analysis was conducted.

For potential human health exposure scenarios, exposure assumptions are detailed in **Attachment 3, Table 8**. As detailed in the table, the resident exposure pathway assumes that a child/adolescent may come in contact with redistributed soils (both untreated and treated) while trespassing on the well lease once partially or completely decommissioned and rehabilitated. The agricultural worker exposure pathway includes potential contact with untreated and treated soils through agricultural activity.

RfDs and total intake calculations are detailed in **Attachment 3, Tables 9 and 10. Attachment 3, Table 9** presents the calculated risk estimates for the resident. **Attachment 3, Table 10** presents the calculated risk estimates for the agricultural worker. As indicated in the tables, the calculated HQ for MITC did not exceed the risk threshold level of 1 for either receptor in any of the scenarios evaluated.

Cumulative Impacts

The potential for cumulative impacts associated with chemicals proposed for this project is limited based on the distance between well pad sites where the chemicals are being used. Modelling has demonstrated that the migration of drilling chemicals is limited in the subsurface with no potential to interact with those from other wells and hydraulic fracturing chemicals are contained within the target units. Residual chemicals may be entrained within produced water and subsequently transported for water treatment at a water management facility (WMF). However, these chemicals are removed by the treatment systems; and, therefore, no additional risk is provided during beneficial reuse, including irrigation. Likewise, the presence of water treatment chemicals at the point of produced water storage or during beneficial reuse also poses no significant increase in risk.

Only 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 2**), neither dazomet or MITC meet the criteria for persistence or bioaccumulation. Thus, there is negligible incremental risk posed by the use of these Tier 3 chemicals and the existing (and proposed) 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 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 6** provides an evaluation of uncertainty for this Tier 3 assessment, including elements previously discussed within this assessment.

Table 6 Evaluation of Uncertainty – Dazomet

Risk Characterisation Component	Description of Uncertainty	Magnitude of Uncertainty	Effect on Risk Assessment
Hazard Assessment – Chemical additive COPC concentrations	The concentrations of COPCs in residual drilling materials 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.
Hazard Assessment – Chemical additive COPC concentrations	Concentrations of residual COPCs evaluated in the quantitative risk assessment were assumed to be 100 percent of the injected mass. This is a conservative assumption for chemicals that may degrade rapidly or volatilise. For example, MITC through hydrolysis (half-life of 5 days); however, the initial concentration of dazomet evaluated is assumed to be 100 percent of the injected material. Additionally, MITC was conservatively assumed to be present in soil; however, as this chemical is a volatile the concentrations of MITC present in soil are expected to decrease.	Medium	This assumption may overestimate the calculated risks to receptors.
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
Exposure Assessment – EPC	The EPCs for drilling fluid chemicals used the maximum concentration of a COPC from all of the muds assessed.	Low to Medium	Low to medium potential to overestimate risks.
Exposure Assessment – EPC	The assessment for all receptors considers the maximum concentration in days 0, 3, and 7 in any one year and does not evaluate further degradation of residual concentrations	Medium	Medium to high potential to overestimate risks.
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 acute toxicity data (rather than chronic toxicity data) to calculate PNECs for water for dazomet and data from one trophic level to calculate a PNEC in soil for dazomet and MITC.	Medium	Medium to high potential to overestimate risks.

Risk Characterisation Component	Description of Uncertainty	Magnitude of Uncertainty	Effect on Risk Assessment
Toxicity Assessment	The use of 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

Australian Environmental Agency (AEA). (2009). Environmental Risk Assessment Guidance Manual for Industrial Chemicals, Commonwealth of Australia.

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

EHS Support. (2015). Santos GLNG Upstream Hydraulic Fracturing Risk Assessment Compendium of Assessed Fluid Systems. Revision 1. 23 November 2015.

EU. (2010). Dazomet Product-type 8 (Wood preservatives) Assessment Report. Directive 98/8/EC concerning the placing biocidal products on the market. Inclusion of active substances in Annex I or IA to Directive 98/8/EC. Annex I – Belgium. 11 march 2010. Available at: https://circabc.europa.eu/sd/a/4a7d3e6b-1de7-4e2b-a288-8b1b7e4e79dd/Dazomet%20Assessment%20report.pdf.

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

URS. (2014). Santos GLNG Project: Gas Field Development Project Environmental Impact Statement. Available online at: http://www.santosglng.com/environment-and-water/gas-field-development-project-eis.aspx

Attachment 1 Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DEXTRID® LTE

Revision Date: 30-Apr-2020 **Revision Number:** 33

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DEXTRID® LTE

Other means of Identification

Synonyms None

Hazardous Material Number: HM003615

Recommended use of the chemical and restrictions on use

Recommended Use Fluid Loss Additive

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Not classified

Label elements, including precautionary statements

Hazard Pictograms

Signal Word None

Hazard Statements: Not Classified

Precautionary Statements

Prevention None
Response None
Storage None
Disposal None

Contains

Substances	**CAS Number**
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA

Other hazards which do not result in classification
This substance is not considered to be persistent, bioaccumulating nor toxic (PBT).
This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	60 - 100%	Not classified

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.

Skin Wash with soap and water. Get medical attention if irritation persists.

Ingestion Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure
No significant hazards expected.

Medical Attention and Special Treatment
Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment
Suitable Extinguishing Media
Water fog, carbon dioxide, foam, dry chemical.
Extinguishing media which must not be used for safety reasons
None known.

Specific hazards arising from the chemical
Special exposure hazards in a fire
Organic dust in the presence of an ignition source can be explosive in high concentrations. Good housekeeping practices are required to minimize this potential. Decomposition in fire may produce harmful gases.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment. Avoid contact with skin, eyes and clothing. Avoid creating and breathing dust. Ensure adequate ventilation.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Avoid creating or inhaling dust. Avoid dust accumulations. Ensure adequate ventilation. Wash hands after use. Launder contaminated clothing before reuse. Use appropriate protective equipment.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from oxidizers. Store in a cool, dry location. Product has a shelf life of 12 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable	Not applicable

Appropriate engineering controls

Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.

Hand Protection Use gloves which are suitable for the chemicals present in this product as well as other environmental factors in the workplace.

Skin Protection Wear impervious protective clothing, including boots, gloves, lab coat, apron, rain jacket, pants or coverall, as appropriate, to prevent skin contact.

Eye Protection Wear safety glasses or goggles to protect against exposure.

Other Precautions None known.

Environmental Exposure Controls Do not allow material to contaminate ground water system.

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Powder
Color White to off white
Odor: Musty
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	10
Freezing Point / Range	No data available
Melting Point / Range	No data available
Pour Point / Range	No data available
Boiling Point / Range	No data available
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	1.5
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
Keep away from heat, sparks and flame.
10.5. Incompatible materials
Strong oxidizers.
10.6. Hazardous decomposition products
Oxides of sulfur. Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure
Most Important Symptoms/Effects
No significant hazards expected.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation

Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No data available	No data available	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.
Eye Contact May cause mechanical irritation to eye.
Skin Contact None known.
Ingestion May cause abdominal pain, vomiting, nausea, and diarrhea.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels
No data available

Interactive effects
None known.

Data limitations
No data available

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available	No information available	No information available	No information available

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.3. Bioaccumulative potential

Substances	CAS Number	Bioaccumulation
Contains no hazardous substances in concentrations above cut-off values according to	NA	No information available

the competent authority		

12.4. Mobility in soil

Substances	CAS Number	Mobility
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Bury in a licensed landfill according to federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IMDG/IMO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IATA/ICAO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport

None

HazChem Code

None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory All components are listed on the AICS or are subject to a relevant exemption, permit, or

	assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply.
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply.
Basel Convention - Hazardous Waste:	Does not apply.

16. Other information

Date of preparation or review

Revision Date: 30-Apr-2020

Revision Note
SDS sections updated:
2

Full text of H-Statements referred to under sections 2 and 3
None

Additional information For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/

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End of Safety Data Sheet

Attachment 2 Risk Assessment Dossier

TETRAHYDRO-3,5-DIMETHYL-1,3,5-THIADIAZINE-2-THIONE
(DAZOMET)

This dossier on tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione (dazomet) presents the most critical studies pertinent to the risk assessment of dazomet in its use in drilling muds. It does not represent an exhaustive or critical review of all available data. Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

Dazomet is rapidly hydrolysed to methylisothiocyanate (MITC). Hence, this dossier will include information on both dazomet and its hydrolysis product, MITC.

Screening Assessment Conclusion – Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione (dazomet) was not identified in chemical databases used by NICNAS as an indicator that the chemical is of concern and is not a PBT substance. Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione (dazomet) was assessed as a tier 3 chemical for acute toxicity and chronic toxicity based primarily on its dissociation to the more toxic MITC breakdown product. Therefore, tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione (dazomet) is classified overall as a **tier 3** chemical and requires a quantitative risk assessment for end uses.

1 BACKGROUND

Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione (dazomet) is a colourless solid that is rapidly hydrolysed to MITC. Dazomet is not readily biodegradable, but it is inherently biodegradable. Dazomet is not likely to volatilise due to its very low vapour pressure; however, MITC will rapidly evaporate. Both dazomet and MITC have a low potential to bioaccumulate. Dazomet is moderately to acutely toxic by the oral route, but exhibits low acute toxicity by the dermal and inhalation routes. MITC is highly acutely toxic by the oral and inhalation routes; by the dermal route, a wide range has been reported for rodents and rabbits that range from highly toxic to low toxicity. Dazomet is not irritating to the skin and eyes, and it is not a skin sensitiser when tested on animals. MITC is severely irritating to the skin and eyes; and it is a skin sensitiser. Repeated oral exposures to dazomet show the liver and red blood cell (RBC) as target organs in rats, mice, and dogs. No toxicity was seen in rats exposed repeatedly by inhalation to dazomet; nor any systemic toxicity in a rabbit dermal study. The nasal cavity is a target organ for repeated inhalation exposures to MITC. In oral studies, repeated exposures have resulted in systemic toxicity with no clear target organ effects. Lifetime studies showed no carcinogenic effects in rats and mice with either dazomet or MITC. Dazomet was weakly genotoxic in some in vitro assays, but was not genotoxic in the in vivo tests. MITC is not genotoxic. Dazomet and MITC are not a reproductive toxicants; developmental toxicity can occur at maternally toxic doses, but there is no teratogenicity. Dazomet exhibits high acute toxicity to aquatic organism, particularly to fish (96-hr LC_{50} = 0.16 mg/L). This effect, however, is unlikely to be attributed only to dazomet since dazomet is rapidly degraded to MITC in water. MITC exhibits a higher acute toxicity to fish compared to dazomet (96-hr LC_{50} = 0.053 mg/L). Both dazomet and MITC show moderate toxicity to earthworms.

2 CHEMICAL NAME AND IDENTIFICATION

Dazomet:

Chemical Name (IUPAC): Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione

CAS RN: 533-74-4

Molecular formula: $C_5H_{10}N_2S_2$

Molecular weight: 162.3

Synonyms: Dazomet; tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione; 3,5-dimethyl-1,3,5-thiadiazinane-2-thione

MITC:

Chemical Name (IUPAC): Methyl isothiocyanate

CAS RN: 556-61-6

Molecular formula: C_2H_3NS

Molecular weight: 73.12

Synonyms: Basamid, 3,5-Dimethyl-1,3,5-thiadiazinane-2-thione, Thiazone

3 PHYSICO-CHEMICAL PROPERTIES

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

Table 1 Overview of the Physico-Chemical Properties of Dazomet

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colourless solid	-	EU, 2010
Melting Point	103.2 – 105.2°C	-	EU, 2010
Boiling Point	Decomposes before boiling	-	EU, 2010
Density	1.33	-	EU, 2010
Vapour Pressure	5.8 x 10-4 Pa @ 20°C	-	EU, 2010
Partition Coefficient (log Pow)	0.3 @ 24°C (pH 5-9) 0.63 @ 20°C (pH 5.8)		EU, 2010 EFSA, 2010
Water Solubility	3.5 g/L @ 20°C (pH 6-7)	-	EU, 2010
Flammability	Not highly flammable	-	EU, 2010
Auto flammability	No auto-flammable	-	EU, 2010

Property	Value	Klimisch score	Reference
Henry's Law Constant	2.5 x 10-5 Pa m^3/mol at 20°C	-	EU, 2010

Table 2 Overview of the Physico-Chemical Properties of MITC

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	-	-	-
Melting Point	35.9°C	-	EU, 2010
Boiling Point	119°C	-	EU, 2010
Density	1.069 @ 37°C	-	EU, 2010
Vapour Pressure	2,500 Pa @ 20°C	-	EU, 2010
Partition Coefficient (log Pow)	1.2 at pH 6.8-7.1 @ 20°C	-	EU, 2010
Henry's Law Constant	22 Pa m^3/mol @ 20°C	-	EU, 2010

4 DOMESTIC AND INTERNATIONAL REGULATORY INFORMATION

A review of international and national environmental regulatory information was undertaken (Tables 3 and 4). 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 dazomet and MITC.

Table 3 Existing International Controls - Dazomet

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

Table 4 Existing International Controls – MITC

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

Convention, Protocol or other international control	Listed Yes or No?
United States Endocrine Disrupter Screening Program	No
European Commission Endocrine Disruptors Strategy	No

5 ENVIRONMENTAL FATE SUMMARY

A. Summary

Dazomet is rapidly hydrolysed to MITC (half-life of 5 hours at 25°C, pH = 7). It is not readily biodegradable, but it is inherently biodegradable. In biologically active soils, it is degraded to MITC with a half-life of 7-12 hours at 20°C. Dazomet does not adsorb substantially to soil and is rapidly degraded under the conditions of the tests. MITC adsorbs little to soil and is degraded with a half-life of 5-14 days at 20°C. Dazomet is not likely to volatilise due to its very low vapour pressure; however, MITC, with a vapour pressure of 2,500 Pa, will rapidly evaporate. Both dazomet and MITC have a low potential to bioaccumulate.

B. Abiotic Degradation

Hydrolysis

The hydrolysis rate of dazomet (DT50) in water was determined to be 0.36, 0.25, 0.21 and 0.12 days at pH values of 4, 5, 7 and 9 at 25°C (EU, 2010).

The hydrolysis rate of MITC in water was determined to be 107.25, 49.2, 104.59 and 11.14 days at pH values of 4, 5, 7 and 9 at 25°C (EU, 2010).

C. Biodegradation

Dazomet and MITC were not readily biodegradable in an OECD 301D test (EU, 2010). Dazomet is inherently biodegradable (EU, 2010).

D. Soil Degradation

The DT_{50} (20°C, aerobic) values in laboratory studies for dazomet were 0.28, 0.54 and 0.3 days (EU, 2010). The DT_{50} (10°C, aerobic) value in a laboratory study was 1.3 days (EU, 2010). In field studies, the DT_{50} values for dazomet ranged from 0.9 to 1.6 days (EU, 2010).

The DT_{50} laboratory study values for MITC ranged from 5.0 to 13.6 days (EU, 2010). The DT_{50} ($10^{°C}$, aerobic) value in a laboratory study was 32.7 days (EU, 2010). In field studies, the DT_{50} values for MITC of 1.3 (trial 2, with plastic cover) and 2.1 days (trial 2, without plastic cover) were determined. In trial 1, the dissipation was slightly retarded during coverage of the soil (12 days) yielding a DT_{50} value of 20.3 days. After removal of the plastic sheet and aeration of the soil, the dissipation of MITC was significantly enhanced resulting in a DT_{50} value of 6.1 days from day 12 onwards.

E. Environmental Distribution

Adsorption/desorption

Dazomet and MITC were found to adsorb very little to any soil type. For dazomet, K_{oc} values of 129 to 394 (mean: 260) have been determined for adsorption (EU, 2010; EFSA, 2010). For MITC, K_{oc} values of 9.0 to 27 (mean: 15.8) have been determined for adsorption (EU, 2010; EFSA, 2010).

F. Bioaccumulation

The calculated BCF values using the QSAR model BCFWIN for dazomet and MITC were 2.39 and 3.16 (EU, 2010). The octanol-water partition coefficient (log Pow) for dazomet and MITC are 0.3 and 1.2 at 20°C, respectively. Thus, dazomet and MITC are not expected to bioaccumulate.

6 HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Dazomet is moderately acutely toxic by the oral route but exhibits low acute toxicity by the dermal and inhalation routes. It is not irritating to the skin and eyes, and it is not a skin sensitiser when tested on guinea pigs. Repeated oral exposures to dazomet have shown the liver and RBC toxicity in rats, mice and dogs; the dog studies were not included in the dossier. There was no toxicity in rats exposed by inhalation for 21-days, or was there any indication of systemic toxicity in rabbits when dazomet was applied to the skin for 21 days. Long-term studies in mice and rats showed no carcinogenic effects from dazomet exposure in feed, although there was a slight increase in the incidence of female mouse liver adenomas (at the highest dose level). Dazomet was weakly genotoxic in some in vitro assays, but was not genotoxic in the in vivo tests. Dazomet is not a reproductive toxicant; developmental toxicity can occur at maternally toxic doses, but there is no teratogenicity.

MITC is highly acutely toxic by the oral and inhalation routes. By the dermal route, a wide range has been reported for rodents and rabbits that range from highly toxic to low toxicity. MITC is severely irritating to the skin and eyes, and it is a skin sensitiser. The nasal cavity is a target organ for repeated inhalation exposures to MITC. In oral studies, repeated exposures have resulted in systemic toxicity with no clear target organ effects. MITC is not genotoxic. Carcinogenicity studies showed no tumour increases in mice; in the rat studies, there was a slight increase in mammary gland tumours. MITC is not a reproductive toxicant; developmental toxicity can occur at maternally toxic doses, but there is no teratogenicity.

B. Toxicokinetics and Metabolism

Dazomet

Rats were given by gavage a single dose of 10 or 100 mg/kg radiolabelled dazomet. Oral absorption is rapid (within 24 hours) and complete. There is wide distribution, with affinity for the thyroid. Excretion is rapid (within 24 hours), with elimination predominantly in the urine (64-70%); exhaled air is 18-33%. Limited enterohepatic circulation was indicated. Extensive metabolism occurs with ring opening and formation of MITC. Further phase II detoxication pathway involves GSH, leading to M2 (cysteine conjugate, 4-6.5%), its oxidation product M4 (pyruvic derivative, 4-6%), and the N-

acetylcysteine conjugate (16-30%); formation of 4-10% highly polar metabolites. Exhaled metabolites include carbon disulphide (CS2) and carbonyl sulphide (COS) both 3-6% at a low dose, 5-19% at high dose) and CO2 (11-18%). Repeated dosing did not alter the excretion or distribution of radioactivity, indicating no bioaccumulation. (EFSA, 2010; CA EPA, 2002; NRA, 1997).

Dazomet applied topically to the skin of rats resulted in a dermal absorption of 3% of the undiluted product and 9% of a 10% aqueous solution after 168 hours (EU, 2010).

MITC

Rats were given by gavage a single dose of 4.4 or 33 mg/kg radiolabelled MITC. Within 24 hours, 88 to 96% of the administered dose was absorbed. The major elimination pathway was in the urine (80-82%), followed by excretion in expired air as CO2 (6-15%) and in the faeces (<1-2%). The remainder of the radioactivity was eliminated in the expired air as unmetabolised MITC (<1-2%) or as carbonyl sulphide/carbon disulphide (<1%), or bound to tissues (103% after 168 hours). Thyroid, liver, kidneys, whole blood and adrenals were sites of distribution. The major metabolites of MITC in the urine were N-acetyl-cysteine and cysteine conjugates. There was no unmetabolised MITC in the urine (CA EPA, 2002).

C. Acute Toxicity

Dazomet

The oral LD_{50} in rats is 596 mg/kg for males and 415 mg/kg for females (EFSA, 2010). The dermal LD_{50} in rats is >2,000 mg/kg (EFSA, 2010). The LC_{50} (time duration not stated) in rats is >8.4 mg/L in males and 7.3 mg/L in females (EFSA, 2010). Clinical signs of toxicity seen in the acute oral toxicity study include shaking, salivation, tonic convulsions, trembling, dyspnoea, and lassitude.

MITC

The oral LD_{50} values in rats and mice are 72 and 90 mg/kg, respectively (NRA, 1997). The dermal LD_{50} values in rabbits, mice, and rats are 33, 1,870, and approximately 1,000 mg/kg, respectively (NRA, 1997). The 4-hour LC_{50} in rats is 540 mg/m^3.

D. Irritation

Dazomet

Dermal irritation studies in rabbits have been conducted using a 50% aqueous solution of dazomet. When applied to the skin for four hours, there was no irritation; a longer exposure time (20 hours) resulted in moderated erythema and oedema (NRA, 1997). Instillation of 39 or 50 mg dazomet into the eyes of rabbits caused moderate conjunctival erythema and slight oedema.

MITC

MITC is a severe eye and skin irritant in rabbits (NRA, 1997).

E. Sensitisation

Dazomet

Dazomet was not a skin sensitiser to guinea pigs (NRA, 1997). There have been some reports of contact dermatitis has been reported in humans from exposure to dazomet (Warin, 1992).

MITC

MITC was considered a dermal sensitiser in a guinea pig maximisation test (NRA, 1997).

F. Repeated Dose Toxicity

Oral

Dazomet

Male and female mice were given in their diet 0, 800 or 1,200 ppm dazomet for 71 days. Body weight was reduced in the 1,200 ppm males. In the >800 ppm males and females, the following haematological changes were observed: decreased haemoglobin (Hb), RBC count, haematocrit (Hct) and corpuscular haemoglobin concentration (females only); and increased mean corpuscular haemoglobin (MCH), and mean corpuscular volume (MCV). (NRA, 1997).

Male and female mice were given in their diet 0, 20, 60, 180, 360 or 540 ppm dazomet for three months. There were no clinical signs of toxicity. In >360 ppm males and females, the haematological changes were reduced Hb, RBC counts, MCHC, and Hct (males only); and increased MCV, reticulocytes, polychromasia and anisocytosis. Splenic hemosiderin deposition was also observed. Absolute and relative liver weights were increased in the >180 ppm males and 540 ppm females. The NOAEL was considered to be 60 ppm (estimated to be 9 mg/kg-day) (NRA, 1997).

Male and female rats were given in their diet 0, 20, 60, 180 or 360 ppm dazomet for three months. Body weight gain was slightly reduced in the 540 ppm animals. Some changes were noted in the serum chemistry of the >180 ppm animals, and Hb was decreased in the 360 ppm dose group (both sexes). Liver weights were increased in the >60 ppm groups. Hepatocellular fatty degeneration was seen in the 60 ppm males and not at higher dose levels, indicating a possible spurious finding (lack of a consistent effect and a dose-response relationship). The NOAEL was considered to be 60 ppm (ca. 4.6 mg/kg-day) for males and females. (NRA, 1997).

Male and female mice were given in their diet 0, 20, 80 or 320 ppm dazomet for 78 weeks. The estimated mean daily intakes are: 0, 4, 16 and 68 mg/kg-day for males; and 0, 6, 22 and 93 mg/kg-day for females. There was no treatment-related mortality, clinical signs, body weight changes or feed consumption. Liver weights were significantly increased in the 320 ppm animals and an increased number in the 80 ppm animals. Liver discoloration, liver masses, and centrilobular lipid deposition occurred in the 320 ppm animals. Increased splenic hemosiderin deposition and extramedullary haematopoiesis were observed in the 320 ppm animals (both sexes) and in the 80 ppm males. The NOAEL for this study was considered to be 20 ppm (ca. 1 mg/kg-day) for males, and 80 ppm (ca. 4 mg/kg-day) for females (NRA, 1997).

Male and female rats were given in their diet 0, 5, 20, 80 and 320 ppm dazomet for two years. The estimated mean daily intakes are: 0, 0.3, 1, 4 and 18 mg/kg-day for males; and 0, 0.3, 1, 6 and 23 mg/kg-day for females. There was no treatment-related mortality, but body weight gain was reduced in the 320 ppm animals. The 320 ppm males and the >80 ppm females showed liver and RBC toxicity. The liver effects were increased relative weights, hepatocellular fat deposition, vacuolation, reduced plasma proteins and triglycerides; the RBC effects were reduced cell counts, Hb and Hct values. The NOAEL was 20 ppm (ca. 1 mg/kg-day) for females and 80 ppm (ca. 4 mg/kg-day) for males (NRA, 1997).

Male and female rats were given in their diet 0, 5, 20 or 80 ppm for two years. The estimated mean daily intakes were: 0, 0.3, 1 and 4 mg/kg-day for males; and 0, 0.1, 1 and 6 mg/kg-day for females. There was no treatment-related mortality, clinical signs, body weight gain and feed consumption. An increased incidence of diffuse hepatocellular fat deposition and vacuolation were noted in the 80 ppm animals, and mixed cell and basophilic cell foci in the 80 ppm females. The NOAEL was considered to be 20 ppm (ca. 1 mg/kg-day) (NRA, 1997).

Another rat chronic study was conducted on dazomet, which is older than the previous two studies. Male and female rats were given in their diet 0, 10, 40, 160 or 640 ppm dazomet for two years. The estimated mean daily intakes were: 0, 0.4, 1.7, 6.4 and 28 mg/kg-day for males; and 0, 0.5, 2.0, 7.4 and 31.8 mg/kg-day for females. There was no treatment-related mortality. Food consumption was reduced in the >160 ppm groups; and body weights were reduced in the 640 ppm males and >160 ppm females. Liver and kidney weights were increased in the 640 ppm animals. Histopathologic changes were glomerular nephritis and focal necrosis in the liver. The incidences of these histopathologic effects in the control and treated groups were not reported by NRA (1997), but the NRA (1997) concluded that there was no NOAEL for this study.

MITC

Male and female dd-strain mice were dosed by oral gavage with 0, 1, 5 or 20 mg/kg MITC for 3 months. At the high dose, there was thickening of the forestomach lining, inflammation of the liver, and slight disturbance of spermatogenesis with oedema of the interstitial area of the testis. These effects were seen occasionally in the mid-dose animals, and slight changes were seen at the low dose. Absolute and relative ovary weights were increased in the low-dose animals; there were also changes in the adrenal weights, but the details are lacking. There were no histopathologic changes in the ovaries or adrenal glands. A LOAEL for this study is 1 mg/kg-day, the lowest dose tested. A NOAEL was not established (CA EPA, 2002).

In a subsequent study to investigate the ovarian effects, mice were dosed by oral gavage with 0, 0.35, 0.5, 0.7 or 1.0 mg/kg MITC. Reduced body weight gain and increased liver weights were seen in the 1.0 mg/kg dose group; no other treatment-related effects were observed. The NOAEL for this study is 0.7 mg/kg-day (CA EPA, 2002).

Mice (dd strain) were dosed by oral gavage with 0, 2.5, 5 or 10 mg/kg MITC for three months. An increase in total white blood cells count was noted in the high-dose animals, which was characterised by an increased proportion of neutrophils and decreased proportion of lymphocytes. The NOAEL for this study is 5 mg/kg-day (CA EPA, 2002).

Male and female Wister rats were dosed by oral gavage with 0, 2, 10 or 40 mg/kg MITC for 3 months. The high-dose rats had undefined stomach lesions, inflammation of the liver, and a slight spermatogenic disorder. These changes were also seen in the mid-dose animals, with slight effects at the low dose. Absolute and relative ovary weights were increased in the low-dose animals; there were also changes in the adrenal weights, but the details are lacking. There were no histopathologic changes in the ovaries or adrenal glands. A LOAEL for this study is 2 mg/kg-day, the lowest dose tested. A NOAEL was not established (CA EPA, 2002).

Rats were dosed by oral gavage with 0, 3, 10 or 30 mg/kg MITC for 8 months, followed by a 6-month recovery period. In the high-dose animals, there was excessive salivation prior to dosing accompanied by rapid and unexpected aggressive movements after dosing. These clinical signs decreased in incidence by the end of the treatment period. There was significant body weight gain in the high-dose males which did not completely reverse following the 6-month recovery period. Absolute and relative liver weights were significantly reduced at the 5-month interim sacrifice. At the end of the treatment period, thickening of the lining of the stomach was observed at gross necropsy in the >10 ppm animals. Histopathologic examination in the animals at the end of the treatment period and the recovery period showed dose-related acanthosis, hyperkeratosis, and sub-mucosal cyst formation in the forestomach at all dose levels. The LOAEL for this study is 3 mg/kg-day, the lowest dose tested. A NOAEL was not established (CA EPA, 2002).

Male and female CD rats were given in their drinking water 0, 2, 10 or 50 ppm MITC for two years. The estimated daily intakes were: 0, 0.095, 0.463 and 2.075 mg/kg-day for males; and 0, 0.140, 0.692 and 3.189 mg/kg-day for females. The high-dose males had a 9-12% decrease in water consumption and body weight. The study authors considered the body weight change to be secondary to the reduced water consumption due to the palatability of the test material in the drinking water. There were no non-neoplastic lesions that were considered treatment-related. The NOAEL for this study is 10 ppm, which corresponds to 0.463 and 0.692 mg/kg-day for males and females, respectively (CA EPA, 2002).

Male and female ICI-JCR mice were given in their drinking water 0, 5, 20, 80 or 200 ppm MITC for two years. The estimated daily intakes were: 0, 0.68, 2.74, 9.82 and 21.34 mg/kg-day for males; and 0, 0.76, 3.04, 10.81 and 24.09 mg/kg-day for females. There was no treatment-related effect on survival. Clinical signs of toxicity (dull coat, raised hair), and decreased body weights were noted in the >80 ppm males and 200 ppm females. Water consumption was decreased in both sexes at >80 ppm. At study termination, serum glutamic-oxaloacetic transaminase (SGOT) levels were increased (125% compared to controls) in the 200 ppm females. Histopathologic examination showed small round cell infiltrations of the kidney in the >80 ppm females, and cellular infiltration of the spleen in the 200 ppm females. Ovarian cysts were increased in the 200 ppm females at study termination, with incidence rates showing a dose-response. The NOAEL for this study is considered to be 20 ppm, which corresponds to 2.74 and 3.04 mg/kg-day for males and females, respectively (CA EPA, 2002).

Inhalation

Dazomet

There were no observable signs of toxicity in a 21-day inhalation study in rats. Rats were exposed 6 hours/day to 33,000 mg/m^3 dazomet (NRA, 1997).

MITC

Male and female Wistar rats were exposed by inhalation to 0, 5, 20 or 100 mg/m^3 (0, 1.7, 6.8 or 34 ppm) MITC 6 hours/day, 5 days/week for four weeks. No deaths occurred during the study. Statistically significantly lower body weights were seen in the high-dose males. Clinical signs of toxicity in the high-dose animals were indicative of marked respiratory tract irritation that resulted in a change in breathing pattern of whooping respiration. As the study progressed, certain signs (ruffled fur and respiratory sound) stopped being reversible. At the mid dose, the clinical signs were less severe (i.e., eyelid closure, somnolence, and ruffled fur); unlike the high-dose animals these clinical signs would start disappearing before the end of the exposure period. Clinical chemistry changes were seen in the high-dose males (decreased serum urea, glucose, triglyceride and albumin) and the high-dose females (decreased urea and glucose). The study authors considered these changes to be metabolic changes in the animals as a result of reduced body weight gain. Total bilirubin concentrations and thromboplastin time were markedly increased in the high-dose males, but not the females. Increased numbers of neutrophilic polymorphonuclear granulocytes were significantly increased in the >20 mg/m^3 males and the 100 mg/m^3 females. Overall leukocyte counts were increased in the 100 mg/m^3 females and were considered the result of the inflammatory response occurring in the respiratory tract. Liver and kidney weights were significantly lower in the 100 mg/m^3 males compared to controls. The high-dose males and females had significantly increased lung weights. Histopathologic effects were seen in the nasal cavity. The LOAEL for this study is mg/m^3, the lowest exposure concentration tested, based on increased nasal epithelial atrophy in both males and females. A NOAEL was not established (CA EPA, 2002).

<u>Dermal</u>

Dazomet

Rabbits were dosed dermally with 0, 10 or 100 mg/kg dazomet 6 hours/day for 21 days. The abraded skin showed well-defined erythema and oedema. Skin lesions indicative of chemical burns (cutaneous hardening and discoloration) were seen in 8/10 and 10/10 animals in the 10 and 100 mg/kg dose groups, respectively (NRA, 1997).

Rabbits were dosed dermally with 0, 10, 100 or 1,000 mg/kg 6 hours/day, 5 days/week for 21 days. The unabraded skin showed no signs of irritation and no indication of systemic toxicity. The NOAEL for systemic toxicity is 1,000 mg/kg-day (NRA, 1997).

MITC

Rats were dosed dermally with 0, 120, 240 or 480 mg/kg MITC for one month. Depending on the dose given, there was damage to the skin which consisted of ulceration, crust formation and neutrophil infiltrations. There was also a treatment-related enlargement of the peri-bronchial lymph nodes. No effects were noted that were considered to be treatment-related. Based on the information, a NOAEL cannot be determined (CA EPA, 2002).

Male and female Wistar rats were dosed dermally with 0, 1, 10 or 100 mg/kg MITC for 31 days. Severe necrosis was noted in the skin of the high-dose animals. At 1 and 10 mg/kg, there was desquamation and erythema of the skin. Weight gain and food consumption was reduced in females, and weight loss and decreased eosinophil production by the bone marrow was seen in males. A dose-dependent decrease in serum albumin was seen in all dosed males. Plasma

cholinesterase inhibition was seen in the high-dose males and in all dosed females. The >10 mg/kg males and >1 mg/kg females had increased erythropoietic activity. The LOAEL for this study is 1 mg/kg-day, the lowest dose tested. A NOAEL was not established (CA EPA, 2002).

G. Genotoxicity

In Vitro Studies

Dazomet

Table 5 lists the results of the *in vitro* genotoxicity studies conducted on dazomet. Dazomet was weakly positive in some of the studies.

Table 5 Results of In vitro Genotoxicity Studies Conducted on Dazomet

Test System	Results[a]	Reference
Reverse mutation bacterial assays using *S. typhimurium* strains [five different studies]	-	NRA, 1997
Reverse mutation bacterial assays using *E. coli* strains	-	NRA, 1997
HGPRT mutation assay in CHO cells	+ (±S9)*	NRA, 1997
Mouse lymphoma assay	Equivocal**	NRA, 1997
Cytogenetics assay in mouse lymphoma L5178Y cells (chromosomal aberrations)	+ (-S9) - (+S9)	NRA, 1997
Cytogenetics assay in mouse lymphoma L5178Y cells (chromosomal aberrations)	+ (±S9)	NRA, 1997
Cytogenetics assay in human lymphocytes (chromosomal aberration)	-	NRA, 1997
Cytogenetics assay [cells not stated] (SCE)	-	NRA, 1997
Cytogenetics assay [cells not stated] (SCE)	+ (-S9) - (+S9)	NRA, 1997
Rat liver Unscheduled DNA Synthesis (UDS) assay	+ (weak)	NRA, 1997
Cell transformation assay (BALB/c-3T3 cells)	-	NRA, 1997
Cell transformation assay (BALB/c-3T3 cells)	-	NRA, 1997

[a]+, positive; -, negative

*Not concentration-dependent in the presence of metabolic activation.

**Negative in the presence of S9; positive in the absence of S9 but not concentration-dependent.

Additional information is provided in NRA (1997) on the two chromosomal aberration studies conducted *in vitro* in mouse lymphoma L5187Y cells. In the study in which positive results were seen only in the absence of metabolic activation, there was reproducible, concentration-dependent increases in both structural and numerical aberrations in two separate experiments. Endoreduplication, a rare numerical aberration, was observed at most concentrations levels of dazomet and translocations; triradials and quadriradial, which are rare structural aberrations, were also observed at some concentrations. In the other study, which was conducted at a different laboratory, there were significant increases in the number of cells with aberrations in the presence and absence of metabolic activation, but the increases were not dose-dependent. Some rare structural aberrations were also noted, mainly in the absence of metabolic activation.

MITC

MITC was not mutagenic in bacterial reverse mutation tests involving *S. typhimurium* or *E. coli* strains in the absence or presence of metabolic activation (CA EPA, 2002). MITC was not mutagenic in a mammalian cell assay with Chinese hamster V79 cells in the absence or presence of metabolic activation (CA EPA, 2002).

No chromosomal aberrations were observed when human peripheral lymphocytes were treated with MITC (CA EPA, 2002). No sister chromatid exchanges were observed when Chinese hamster V79 cells were treated with MITC in the absence of presence of metabolic activation (CA EPA, 2002). MITC did not induce unscheduled DNA synthesis (UDS) in rat primary hepatocytes (CA EPA, 2002).

In Vivo Studies

Dazomet

The *in vivo* studies conducted on Dazomet are presented below in Table 6. All of the studies show that dazomet is not mutagenic or genotoxic.

Table 6 *In Vivo* Genotoxicity Studies on Dazomet

Test System	Results*	Reference
Rat bone marrow (chromosomal aberration)	-	ECHA
Rat bone marrow (chromosomal aberration)	-	ECHA
Mouse bone marrow (micronucleus)	-	ECHA
Rat bone marrow (chromosomal aberration)	-	ECHA
Rat germ cell cytogenetic assay (alkaline elution)	-	ECHA
Drosophila SLRL Test	-	ECHA
Rat liver Unscheduled DNA Synthesis (UDS) Assay	-	ECHA
Rat germ cell cytogenetic assay (alkaline elution)	-	ECHA
Rat liver Unscheduled DNA Synthesis (UDS) Assay	-	Mirsalis *et al.* (1989)

a+, positive; -, negative

MITC

CD-1 mice were given by oral gavage 0 or 110 mg/kg MITC. Bone marrow was harvested 24, 48 and 72 hours after dosing. There was no significant increase in micronucleated polychromatic erythrocytes at any dose level (CA EPA, 2002).

H. Carcinogenicity

Oral

Dazomet

Male and female mice were given in their feed 0, 20, 80 or 320 ppm dazomet for 78 weeks. The estimated daily intake is: 0, 4, 16 and 68 mg/kg-day for males; and 0, 6, 22 and 93 mg/kg-day for females. The 320 ppm females had a slightly increased incidence of hepatocellular adenomas. The incidences were 3/50, 0/50, 1/50 and 7/50 for the 0, 20, 80 and 320 ppm dose groups. The 320 ppm females also had significant increased incidence of basophilic foci. Malignant lymphomas at one or more sites in females in all dose groups at an incidence of 3/60. Since the incidence was low, there was no dose-response, and the lymphomas were not observed in males, the malignant lymphomas were not considered to the treatment-related (NRA, 1997).

Male and female rats were given in their feed 0, 5, 20, 80 and 320 ppm dazomet for two years. The estimated daily intakes are: 0, 0.3, 1, 4 and 18 mg/kg-day for males; and 0, 0.3, 1, 6 and 23 mg/kg-day for females. There was no evidence of a carcinogenic effect from dazomet exposure (NRA, 1997).

Male and female rats were given in their diet 0, 5, 20 or 80 ppm. The estimated mean daily intakes were: 0, 0.3, 1 and 4 mg/kg-day for males; and 0, 0.1, 1 and 6 mg/kg-day for females. There was no evidence of a carcinogenic effect from dazomet exposure (NRA, 1997).

Male and female rats were given in their diet 0, 10, 40, 160 or 640 ppm dazomet for two years. There was no evidence of a carcinogenic effect from dazomet exposure (NRA, 1997).

MITC

Male and female CD rats were given in their drinking water 0, 2, 10 or 50 ppm MITC for two years. The estimated daily intakes were: 0, 0.095, 0.463 and 2.075 mg/kg-day for males; and 0, 0.140, 0.692 and 3.189 mg/kg-day for females. The high-dose males had a 9-12% decrease in water consumption and body weight. The study authors considered the body weight change to be secondary to the reduced water consumption due to the palatability of the test material in the drinking water. An increased incidence in mammary gland tumours (multiple fibroadenomas) was observed in surviving female rats, which achieved statistical significance at the 50 ppm dose level. The incidences were 24%, 40%, 44% and 48% for the controls, 2, 1, and 50 ppm dose groups, respectively. Mammary gland carcinomas were only observed in the low- and mid-dose groups (1/20 and 2/32, respectively) (CA EPA, 2002).

Male and female **ICI-JCR** mice were given in their drinking water 0, 5, 20, 80 or 200 ppm MITC for two years. The estimated daily intakes were: 0, 0.68, 2.74, 9.82 and 21.34 mg/kg-day for males; and 0, 0.76, 3.04, 10.81 and 24.09 mg/kg-day for females. There was no treatment-related effect on survival. Of the mice that survived the study, there were no increased incidences of tumours that were considered to be treatment-related (CA EPA, 2002).

Inhalation

No studies were identified.

Dermal

No studies were identified.

I. Reproductive Toxicity

Dazomet

A two-generation reproductive toxicity study was conducted on dazomet. Rats were given 0, 5, 30 or 180 ppm dazomet in their feed. There were no treatment-related effects on fertility or reproductive performance, as well as reproductive organs and pup development. Effects indicative of liver toxicity was observed in the parental animals in both generations in the 180 ppm group and, to some extent, in the 30 ppm group. The NOAEL for reproductive and developmental toxicity is 180 ppm (calculated to be approximately 18 mg/kg-day). The NOAEL for systemic toxicity is 5 ppm (calculated to be approximately 0.5 mg/kg-day) (NRA, 1997).

MITC

In a two-generation rat reproductive toxicity study, SD rats were given MITC in their drinking water at concentrations of 0, 2, 10 or 50 ppm. The calculated equivalent doses are: 0, 0.16, 0.7 or 3.49 mg/kg-day for males; and 0, 0.2, 0.94 or 4.49 mg/kg-day for females. Pre-weaning viability was decreased in F1 pups at all dose levels (pre-weaning loss was 6.6%, 17.8%, 17.1% and 14.4% for the 0, 2, 10 and 50 ppm groups, respectively). This effect was not considered to be a treatment-related effect because there was no dose-response; there was no statistical significance; pup weights indicated that growth was normal; pup deaths did not occur within a discrete window, but appeared to occur randomly; and the pattern of pre-weaning loss was not repeated in the F2 pups. At 10 and 50 ppm, parental water consumption was significantly decreased in both generations, and decreased body weight gains were reported during various time points of the study. The NOAEL for reproductive toxicity is 50 ppm, which corresponds to 3.49 and 4.49 mg/kg-day for males and females, respectively (CA EPA, 2002).

In a three-generation reproductive toxicity study, CD rats were dosed by oral gavage with 0, 1, 3 or 10 mg/kg-day. The body weights of the >3 mg/kg F0 males were reduced compared to the controls. The 3 mg/kg females weaned fewer F3a progeny than controls. The study authors concluded that there were not treatment-related reproductive effects. Histopathologic examination of the parental animals showed lesions in the non-glandular stomach. The NOAEL for reproductive toxicity was considered to be 10 mg/kg-day (CA EPA, 2002).

J. Developmental Toxicity

Dazomet

Pregnant female rats were given in their feed 0, 3, 10 and 30 mg/kg-day dazomet (GD days not stated). Maternal body weights, feed consumption and uterine weights were reduced at the high-dose and, to a lesser extent, at the mid-dose. A higher incidence of runts was noted in the >10 mg/kg dose groups, but there was no dose-response relationship. There was no evidence of teratogenicity. The NOAEL for maternal and developmental toxicity is 3 mg/kg-day (NRA, 1997).

Pregnant female rabbits were dosed by oral gavage with 0, 25, 50 or 75 mg/kg dazomet (GD days not stated). In the 50 and 75 mg/kg does, clinical signs of toxicity (severe diarrhoea, apathy and unsteady gait), and reduced body weights and feed consumption were noted. The number of live foetuses was reduced by 80% in the 50 and 75 mg/kg dose groups, which corresponded to a high

number of dead implantations. Foetal abnormalities were similar across all groups, but the conclusion is unreliable because of the small numbers of foetuses in the 50 and 75 mg/kg groups. The NOAEL for maternal and developmental toxicity is 25 mg/kg-day (NRA, 1997).

Pregnant female rabbits were dosed by oral gavage with 0, 6.25, 12.5 or 25 mg/kg dazomet (GD days not stated). There is conflicting information about the maternal toxicity in this study. The NRA (1997) states that there was no maternal toxicity. However, the EU (2010) report states that there was marked maternal toxicity, as indicated by one death and clinical signs at the same dose where fetotoxicity was observed. At 25 mg/kg, dead implantations, particularly increased early resorptions, were noted, resulting in reduced numbers of live foetuses. There was no evidence of teratogenicity. The NOAELs for maternal and developmental toxicity are 12.5 mg/kg-day (NRA, 1997; EU, 2010).

MITC

Pregnant female SD rats were dosed by oral gavage with 0, 1, 5 or 25 mg/kg MITC on GD 6 to 15. Dams dosed with 25 mg/kg exhibited significant reduction in body weight gain and food consumption during the treatment period, and gross necropsy showed thickening of the stomach lining. Dams dosed with 5 mg/kg had only reduced body weight gain. Mean foetal body weights and mean foetal size were reduced in the 25 mg/kg group compared to controls. The NOAELs for maternal and developmental toxicity is 1 and 5 mg/kg-day, respectively (CA EPA, 2002).

Pregnant NZW rabbits were dosed by oral gavage with 0, 1, 3 or 5 mg/kg MITC on GD 7-19. Those in the 5 mg/kg dose group exhibited marginal reductions in body weight gain and feed consumption during the early stages of treatment. Mean foetal weights were reduced in the 5 mg/kg group compared to controls. The NOAEL for maternal and developmental toxicity is 3 mg/kg-day (CA EPA, 2002).

Pregnant female rabbits were given via gelatine capsules 0, 1, 3 or 10 mg/kg MITC on GD 6 to 18. At 10 mg/kg, there was maternal toxicity, embryotoxicity, reduced foetal body weights, and a reduction in Day 1 pup survival. There was possible maternal toxicity also at the 3 mg/kg dose level. The study report stated that prenatal MITC may have increased the incidence of incidental skeletal findings. The NOAELs for maternal and developmental toxicity are 1 and 3 mg/kg-day, respectively (CA EPA, 2002).

K. Derivation of Toxicological Reference and Drinking Water Guidance Values

The toxicological reference values developed for dazomet 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

<u>Oral (Dazomet)</u>

The NOAEL or LOAEL values from key toxicity studies on dazomet are listed in Table 7.

Table 7 Lowest NOAEL Values from Key Toxicity Studies on Dazomet by the Oral Route

Species/sex	Study Duration	(L)NOAEL mg/kg-day	Endpoint	Reference
Mice, male	3-month (feed)	9	Increased liver weights	NRA (1997)
Rats, male	3-month (feed)	4.6	Increased liver weights	NRA (1997)
Mice, female	78-month (feed)	1	Splenic hemosiderin deposition; extramedullary haematopoiesis	NRA (1997)
Rats, female	2-year (feed)	1	Liver and RBC toxicity	NRA (1997)
Rats	2-year (feed)	1	Liver effects	NRA (1997)
Rats	2-year (feed)	0.4	Liver and kidney effects	NRA (1997)
Rats	2-generation (feed)	0.5	Liver effects (parental)	NRA (1997)
Rats	GD not specified	3	Developmental	NRA (1997)
Rabbits	GD not specified	12.5	Developmental	NRA (1997)

Four chronic feeding studies have been conducted on dazomet: a 78-week study in mice and three 2-year studies in rats. The NOAEL for two of the rat chronic studies was 1 mg/kg-day based on RBC effects (indicative of haemolytic anaemia) and/or liver effects. The third rat chronic study, which was considered an "old" study by NRA (1997), showed liver and kidney effects in rats; NRA (1997) concluded that a NOAEL was not established. Unfortunately, NRA (1997) did not provide any information on the incidences and dose levels of the liver and kidney effects in the treated rats, and whether the effects were seen in males, females or both sexes. Furthermore, this is the only study conducted on dazomet in which kidney effects were seen in dazomet-treated rats. Studies in rats and dogs (data not provided in this dossier but summarised in NRA [1997]) did not develop kidney effects from dazomet treatment. While the histopathologic details of the glomerular nephritis were not described in NRA (1997), it is entirely possible it could be chronic progressive nephropathy (CPN), also known as glomerulosclerosis, progressive glomerulonephrosis or old rat nephropathy. CPN is a spontaneous renal disease seen in aging rats of which there is no counterpart in humans and therefore has no relevance for extrapolation in human risk assessment (Hard and Khan, 2004).

Because of the inconsistency of this "older" rat chronic feeding study with the other two chronic rat feeding studies, along with the lack of details on the study findings and no information in NRA (1997) on the justification of a lack of NOAEL, this study will not be used for the risk assessment of dazomet. Furthermore, there are two chronic feeding studies that reported similar findings for the liver effects; both studies had the same NOAEL of 1 mg/kg-day. Haemolytic anaemia, an effect that has been consistently reported in dazomet-treated rats and mice, was seen in one, but not both, of these two chronic studies. Haemolytic anaemia was observed in males and female rats at 320 ppm; only one study included this dose level. Both studies included a dose level of 80 ppm, and haemolytic anaemia was reported in females in only one of the two studies. The reason for this difference is unclear, but it may represent biological variation or perhaps strains differences; the study summaries provided in NRA (1997) are insufficient for an analysis. Nevertheless, the NOAEL of 1 mg/kg-day will be used for determining the oral RfD and the drinking water guidance value.

Oral Reference Dose (oral RfD) - Dazomet

$$\text{Oral RfD} = \text{NOAEL} / (UF_A \times UF_H \times UF_L \times UF_{Sub} \times UF_D)$$

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

$$\text{Oral RfD} = 1/(10 \times 10 \times 1 \times 1 \times 1) = 1/100 = 0.01 \text{ mg/kg-day}$$

Drinking water guidance value - Dazomet

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 = (0.01 x 70 x 0.1)/2 = 0.04 mg/L

Oral (MITC)

The NOAEL or LOAEL values from key toxicity studies on MITC are listed in Table 8.

Table 8 Lowest NOAEL Values from Key Toxicity Studies on MITC by the Oral Route

Species/sex	Study Duration	(L)NOAEL mg/kg-day	Endpoint	Reference
Rat	3-month oral gavage	2 (LOAEL)	Liver inflammation, stomach lesions, ovary weight change, spermatogenic disorder	CA EPA, 2002
Mouse	3-month oral gavage	1 (LOAEL)	Liver inflammation, stomach lesions, ovary weight change, spermatogenic disorder	CA EPA, 2002
Mouse	3-month oral gavage	0.7 (NOAEL)	Reduced body weight gain, increased liver weights	CA EPA, 2002
Mouse	3-month oral gavage	5 (NOAEL)	Increased total WBC counts	CA EPA, 2002

Species/sex	Study Duration	(L)NOAEL mg/kg-day	Endpoint	Reference
Rat	8-month oral gavage	3 (LOAEL)	Forestomach lesions	CA EPA, 2002
Rat	2-yr drinking water	0.46 (NOAEL)	Decreased water consumption, body weights	CA EPA, 2002
Mouse	2-yr drinking water	2.74 (NOAEL)	Clinical signs, decreased water consumption, body weights	CA EPA, 2002
Rat	2-generation oral gavage	3.49 (NOAEL)	None (highest dose tested for reproductive toxicity)	CA EPA, 2002
Rat	3-generation oral gavage	10 (NOAEL)	None (highest dose tested for reproductive toxicity)	CA EPA, 2002
Rat	GD 6-15	5 (NOAEL)	Decreased foetal body weights and size	CA EPA, 2002
Rabbit	GD 7-19	3 (NOAEL)	Decreased foetal body weights	CA EPA, 2002
Rabbit	GD 6-18	3 (NOAEL)	Decreased foetal body weights	CA EPA, 2002

The NOAEL of 0.46 mg/kg-day (rounded off to 0.5) from the two-year rat drinking water study will be used for determining the oral RfD and the drinking water guidance value.

Oral Reference Dose (oral RfD) - MITC

$$\text{Oral RfD} = \text{NOAEL} / (UF_A \times UF_H \times UF_L \times UF_{Sub} \times UF_D)$$

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

$$\text{Oral RfD} = 0.5/(10 \times 10 \times 1 \times 1 \times 1) = 0.5/100 = \underline{0.005 \text{ mg/kg-day}}$$

Drinking water guidance value - MITC

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

Using the oral RfD:

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

Where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG 2011)

Volume of water consumed = 2L (ADWG 2011)
Drinking water guidance value = (0.005 x 70 x 0.1)/2 = 0.018 mg/L

L. Cancer

Dazomet

Dazomet was not carcinogenic to mice or rats in chronic feeding studies. Thus, no cancer reference value was derived.

MITC

An increased incidence of mammary gland tumours (fibroadenomas) in female rats was reported in the two-year drinking water study. The increase was marginally statistically significant in the highest dose tested (50 ppm). MITC was not carcinogenic in mice when given in drinking water for two years. A cancer reference value was not derived.

M. Human Health Hazard Assessment Of Physico-Chemical Properties

Dazomet does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential.

MITC is considered a flammable liquid.

7 ENVIRONMENTAL EFFECTS SUMMARY

A. Summary

Dazomet exhibits high acute toxicity to aquatic organism, particularly to fish (96-hr LC_{50} = 0.16 mg/L). This effect, however, is unlikely to be attributed only to dazomet since dazomet is rapidly degraded to MITC in water. MITC exhibits a higher acute toxicity to fish compared to dazomet (96-hr LC_{50} = 0.053 mg/L). Both dazomet and MITC show moderate toxicity to earthworms.

B. Aquatic Toxicity

Acute Studies

Tables 9A and 9B list the results of acute aquatic toxicity studies conducted on Dazomet and MITC, respectively.

Table 9A Acute Aquatic Toxicity Studies on Dazomet

Test Species	Endpoint	Results (mg/L)	Reference
Lepomis macrochirus	96-hr LC50	0.3	HSDB
Lepomis macrochirus	96-hr LC50	1.3	HSDB
Oncorhynchus mykiss	96-hr LC50	0.48	HSDB

Test Species	Endpoint	Results (mg/L)	Reference
Oncorhynchus mykiss	96-hr LC50	16.2	HSDB
Oncorhynchus mykiss	96-hr LC50	0.16	HSDB
Oncorhynchus mykiss	96-hr LC50	2.4	HSDB
Daphnia magna	48-hr EC50	11.9	HSDB
Daphnia magna	48-hr EC_{50}	0.31	HSDB
Daphnia magna	48-hr EC_{50}	0.88	HSDB
Daphnia magna	48-hr EC_{50}	0.55	HSDB
Pseudokirchneriella subcapitata	72-hr EC_{50} NOEC	Biomass: 0.16 Growth rate: 0.59 0.056	EFSA, 2010
Desmodesmus subspicatus	96-hr EC_{50}	Biomass: 1.015	EFSA, 2010

Table 9B Acute Aquatic Toxicity Studies on MITC

Test Species	Endpoint	Results (mg/L)	Reference
Oncorhynchus mykiss	96-hr LC_{50}	0.0531	EFSA, 2010
Oncorhynchus mykiss	28-d NOEC (growth)	0.004	EFSA, 2010
Daphnia magna	48-hr EC_{50}	0.076	EFSA, 2010
Daphnia magna	21-d NOEC (reproduction)	0.01275	EFSA, 2010
Daphnia magna	21-d NOEC (reproduction)	0.00625	EFSA, 2010
Pseudokirchneriella subcapitata	72-hr EC_{50}	Biomass: 0.28 (initial measured) Growth rate: 0.58 (initial measured) Biomass: 0.075 (mean measured) Growth rate: 0.275 (mean measured)	EFSA, 2010

Terrestrial Toxicity

The terrestrial toxicity studies conducted on dazomet and MITC are presented in Table 10.

Table 10 Terrestrial Toxicity Studies on Dazomet and MITC

Test Species (method)	Test Substance	Endpoint	Results (mg/kg soil dw)	Reference
Eisenia fetida	Dazomet	14-day LC_{50}	6.7	EU, 2010
Eisenia fetida	MITC	14-day LC_{50}	2.79	EU, 2010

C. Calculation of PNEC

The PNEC calculations for dazomet and MITC follow the methodology discussed in DEWHA (2009).

PNEC water

Dazomet

Experimental results are available for three trophic levels. Acute EC_{50} values are available for fish (0.16 mg/L), *Daphnia* (0.31 mg/L), and algae (0.16 mg/L). No chronic toxicity studies have been conducted on dazomet. On the basis of the short-term results from three trophic levels, an assessment factor of 1,000 has been applied to the lowest reported effect concentration of 0.16 mg/L for fish and algae. The $PNEC_{water}$ is 1.6 x 10-4 mg/L or 0.16 µg/L.

MITC

Experimental results are available for three trophic levels. Acute EC_{50} values are available for fish (0.0531 mg/L), *Daphnia* (0.076 mg/L), and algae (0.275 mg/L). Chronic toxicity values are available for fish (0.004 mg/L) and invertebrates (0.00625 mg/L). On the basis that the data consists of short-term and results from three trophic levels and long-term results from two trophic levels, an assessment factor of 50 has been applied to the lowest reported NOEC of 0.004 mg/L for fish. The $PNEC_{water}$ is 8 x 10-5 mg/L or 0.08 µg/L.

PNEC sediment

Dazomet

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 1.05 x 10-3 mg/kg wet weight or 1.05 µg/kg wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (8.4/1280) \times 1000 \times 0.00016$
$= 0.00105$

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$PNEC_{water}$ = predicted no effect concentration in water

$K_{sed\text{-}water} = 0.8 + (0.2 \times KP_{sed})/1000 \times BD_{soilid}$
$= 0.8 + (0.2 \times 15.8)/1000 \times 2400$
$= 8.4$

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

$Kp = K_{0c} \times f_{oc}$
$= 394 \times 0.04$

= 15.8

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for dazomet in sediment is 394.
F_{oc} = fraction of organic carbon suspended sediment = 0.04 [default]

MITC

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 8.1 x 10^{-5} mg/kg wet weight or 0.081 µg/kg wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (1.3/1280) \times 1000 \times 0.00008$
$= 8.1 \times 10^{-5}$

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$PNEC_{water}$ = predicted no effect concentration in water

$K_{sed\text{-}water} = 0.8 + (0.2 \times KP_{sed})/1000 \times BD_{soilid}$
$= 0.8 + (0.2 \times 1.1)/1000 \times 2400$
$= 1.3$

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

$Kp = K_{oc} \times f_{oc}$
$= 27 \times 0.04$
$= 1.1$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for MITC in sediment is 27.
F_{oc} = fraction of organic carbon suspended sediment = 0.04 [default]

<u>PNEC soil</u>

Dazomet

Experimental results are available for earthworms, with 14-day LC_{50} value of 4.0 mg/kg soil dry weight. On the basis that the data consists of one short-term result from one trophic level, an assessment factor of 1,000 has been applied to LC_{50} value of 6.5 mg/kg soil dry weight for earthworms. The $PNEC_{soil}$ is 0.004 mg/kg dry weight.

MITC

Experimental results are available for earthworms, with 14-day LC_{50} value of 2.79 mg/kg soil dry weight. On the basis that the data consists of one short-term result from one trophic level, an assessment factor of 1,000 has been applied to LC_{50} value of 6.5 mg/kg soil dry weight for earthworms. The $PNEC_{soil}$ is 0.00279 mg/kg dry weight.

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).

Dazomet

There is rapid degradation of dazomet by hydrolysis in the aquatic environment and soil. Therefore, it does not meet the criteria for persistence.

The calculated BCF value for dazomet is 2.39. Therefore, it does not meet the screening criteria for bioaccumulation.

No chronic aquatic toxicity studies are available for dazomet. The lowest acute LC_{50} value is >0.1 mg/L. Therefore, dazomet does not meet the criteria for toxicity.

The overall conclusion is that dazomet is not a PBT substance.

MITC

MITC does not degrade in freshwater by hydrolysis. It is also not readily biodegradable. However, it is expected to be removed rapidly from water by volatilisation. In soil, the degradation half-life is 5-13 days (<6 months). MITC also disappears rapidly in sediment: <2% can be found in sediment after 14 days (EU, 2010). Therefore, MITC does not meet the criteria for persistence.

The calculated BCF value for MITC is 3.16. Therefore, it does not meet the screening criteria for bioaccumulation.

A chronic NOEC value is available for *daphnia*, with the value being <0.1 mg/L. Therefore, MITC meets the screening criteria for toxicity.

The overall conclusion is that MITC 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, neither dazomet or MITC meet the criteria for persistence or bioaccumulation.

No other characteristics of concern were identified for dazomet or MITC.

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]	
Dazomet	533-74-4	Not a PBT	No	No	No	No	No	No	3	No chronic data	3
MITC	556-61-6	Not a PBT	No	No	No	No	No	No	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:

NA = not applicable

PBT = Persistent, Bioaccumulative and Toxic

B = bioaccumulative

P = persistent

T = toxic

10 REFERENCES, ABBREVIATIONS AND ACRONYMS

A. References

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B. Abbreviations and Acronyms

°C	degrees Celsius
ADWG	Australian Drinking Water Guidelines
AICS	Australian Inventory of Chemical Substances
BALB	Bagg Albino
BCF	Bioconcentration factor
BCFWIN™	USEPA program to estimate BCF
CA EPA	California Environmental Protection Agency
CD®	(Sprague Dawley) IGS Rat
CHO	Chinese hamster ovary
COC	constituent of concern
CPN	chronic progressive nephropathy
DEWHA	Department of the Environment, Water, Heritage and the Arts
DT	Degradation time
EC	effective concentration
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EU	European Union
g/L	grams per litre
GD	Gestation day
GSH	glutathione - reduced
Hb	haemoglobin
Hct	haematocrit
HGPRT	hypoxanthine-guanine phosphoribosyltransferase
HHRA	enHealth Human Risk Assessment

HSDB	Hazardous substances database
ICI-JCR	Institute for Chemical Immunology – jCR strain
IUPAC	International Union of Pure and Applied Chemistry
kg/m^3	kilograms per cubic metre
KI	Klimisch scoring system
kPa	Kilo pascal
L/kg	litres per kilogram
LC	lethal concentration
LD	lethal dose
LOAEL	lowest observed adverse effect level
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular hemoglobin concentration
MCV	mean corpuscular volume
mg/kg	milligrams per kilogram
mg/kg-day	milligrams per kilogram-day
mg/L	milligrams per litre
mg/m^3	milligrams per cubic metre
MITC	methylisothiocyanate
NICNAS	The National Industrial Chemicals Notification and Assessment Scheme
NOAEL	no observed adverse effect level
NRA	National Registration Authority for Agricultural and Veterinary Chemicals
NZW	New Zealand White rabbits
OECD	Organisation for Economic Co-operation and Development
Pa m^3/mol	Pascal meter cubed per gram molecular weight
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No Effect Concentration
ppm	parts per million
RBC	red blood cell
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RfD	reference dose
SCE	Sister chromatid exchange
SD	Sprague Dawley
SGG	Synthetic Greenhouse Gases
SGOT	serum glutamic-oxaloacetic transaminase

SLRL	sex-linked recessive lethal
UDS	unscheduled DNA synthesis
WBC	White blood cell
µg/kg	micrograms per kilogram
µg/L	micrograms per litre

Attachment 3 Risk Characterisation Tables

Attachment 3, Table 1
Summary of Theoretical Biodegradation of Vendor Chemicals in Aqueous Drilling Fluids

Constituent Name	CAS No.	Estimated concentration in pre-injection fluid systems (mg/L)	Fate and Transport Properties	Estimated Initial Vendor Chemical Concentration In Drilling Fluids Including Biodegredation Half-Life (mg/L)		
				Temporal Scenario (days)		
		Drilling Fluids	Half-Life (days)	0	3	7
Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione	533-74-4	51	0.21	51	0	0
Methylisothiocyanate (MITC)	556-61-6	-	NA	0	51	51

Notes:
Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione hydrolizes/metabilizes to 100% MITC after 3-5 days based on degredation.
- not present in product, forms as a degradate
CAS = Chemical Abstracts Service
mg/L = milligrams per litre
NA = not applicable

Attachment 3, Table 2
Comparison of Theoretical Concentrations of COPCs to Drinking Water Guidelines

Constituent Name	CAS No.	Estimated concentration in pre-injection fluid systems (mg/L)	Fate and Transport Properties	Estimated Initial Vendor Chemical Concentration In Drilling Fluids Including Biodegredation Half-Life (mg/L)			Drinking Water Screning Level	Ratio of COPC Concentrations and Screening Criteria (Ratio greater than one = unacceptable potential risk)		
				Temporal Scenario (days)				Temporal Scenario (days)		
		Drilling Fluids	Half-Life (days)	0	3	7		0	3	7
Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione	533-74-4	51	0.21	51	0	0	0.04	1.3E+03	5.9E-02	9.8E-08
Methylisothiocyanate (MITC)	556-61-6	-	NA	0	51	51	0.018	NA	2.8E+03	2.8E+03

Notes:
Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione hydrolizes/metabilizes to 100% MITC after 3-5 days based on degredation.
- not present in product, forms as a degradate
CAS = Chemical Abstracts Service
COPC = constituent of potential concern
mg/L = milligrams per litre
NA = not applicable

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

Constituent Name	CAS No.	Estimated concentration in pre-injection fluid systems (mg/L)	Fate and Transport Properties	Estimated Initial Vendor Chemical Concentration In Drilling Fluids Including Biodegredation Half-Life (mg/L)			PNEC aquatic (mg/L)	Ratio of COPC Concentrations and Screening Criteria (Ratio greater than one = unacceptable potential risk)		
				Temporal Scenario (days)				Temporal Scenario (days)		
		Drilling Fluids	Half-Life (days)	0	3	7		0	3	7
Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione	533-74-4	51	0.21	51	0	0	1.60E-04	3.2E+05	1.5E+01	2.4E-05
Methylisothiocyanate (MITC)	556-61-6	-	NA	0	51	51	8.00E-05	0.0E+00	6.4E+05	6.4E+05

Notes:
Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione hydrolizes/metabilizes to 100% MITC after 3-5 days based on degredation.
- not present in product, forms as a degradate
CAS = Chemical Abstracts Service
COPC = constituent of potential concern
mg/L = milligrams per litre
NA = not applicable
PNEC = predicted no effects concentration

Attachment 3, Table 4
Summary of Theoretical Concentrations of Vendor Chemicals in Drilling Fluid Solids

Constituent Name	CAS No.	Estimated Vendor Chemical Concentration in Drilling Fluids (Solids Unmixed) (mg/kg)	Estimated Vendor Chemical Concentration in Drilling Fluids (Solids Mixed [Unmixed Muds Concentration x MBC factor]) (mg/kg)
Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione	533-74-4	-	0.0
Methylisothiocyanate (MITC)	556-61-6	30.6	0.61

Notes:

- not present in product, forms as a degradate
Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione hydrolizes/metabilizes to 100% MITC after 3-5 days based on degredation. Therefore, mass of Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione in muds will be assumed to be 0 mg/kg.
Mix Bury Cover (MBC) treatment includes mixing 20m^3 of solid drilling injected material in 1 ha/ 100 mm deep. Therefore, the MBC factor is 20 m^3/1000 m^3 or 0.02.

CAS = Chemical Abstracts Service
ha = hectare
m^3 = cubic metres
mg/kg = milligrams per kilogram
mm = millimetres

EHS Support

Attachment 3, Table 5
Comparison of Theoretical Concentrations of COPCs to PNECs (Solid)

Constituent Name	CAS No.	Estimated Vendor Chemical Concentration in Drilling Fluids (Solids – Unmixed) (mg/kg)	Estimated Vendor Chemical Concentration in Drilling Fluid (Solids – Mixed) (mg/kg)	PNECsoil (mg/kg)	Ratio of COPC Concentrations and Screening Criteria (Ratio greater than one = unacceptable potential risk)	
					Spent Muds	Mixed Spent Muds
Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione	533-74-4	-	-	4.0E-03	NA	NA
Methylisothiocyanate (MITC)	556-61-6	30.6	0.61	2.8E-03	1.1E+04	2.2E+02

Notes:

- not present in product, forms as a degradate
CAS = Chemical Abstracts Service
COPC = constituent of potential concern
mg/kg = milligrams per kilogram
NA = not applicable
PNEC = predicted no effects concentration

Attachment 3, Table 6
Risk Estimates for Small Mammal from Vendor Chemicals in Drilling Fluids

Constituent Name	CAS No.	Mammal NOAELt	Mammal NOAEL		Avian NOAELt [1]	Avian NOAEL		Mammal		Avian Receptor	
			Test Animal			Test Animal		Northern Quoll		Cattle Egret	
			Animal	Body Weight (kg)		Animal	Body Weight (kg)	Body Weight	Derived TRV	Body Weight (kg)	Derived TRV
Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione	533-74-4	1	Rat	0.35	14.7	bobwhite quail	0.178	0.8	8.1E-01	0.39	1.2E+01
Methylisothiocyanate (MITC)	556-61-6	0.5	Rat	0.35	NA	NA	NA	0.8	4.1E-01	0.39	4.9E-01

Notes:
1/ Avian NOAEL for Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione developed by applying an uncertainty factor of 10 to the NOEC for bobwhite quail.
1/ If an avian NOAEL was not available, the mammal NOAEL was used to derive the TRV for the avian receptor.
CAS = Chemical Abstracts Service
kg = kilogram
NA = not applicable
NOAEL = No observed adverse effect level
NOAELt = No observed adverse effect level test animal
NOEC = no observed effect concentration
TRV = toxicity reference value

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

Exposure Route	Parameter Code	Parameter Definition	Units (a)	Parameter Value	Source (b)
Ingestion	IR-S	Ingestion rate soil	kg/day	0.000274	Calculated with average ingestion rate (2.74 g/day) and assumption of 10% soil intake through ingestion.[1]
	IR-F	Ingestion rate food	kg/day	0.00137	Calculated with average ingestion rate (2.74 g/day) and assumption of diet composition of 50% earthworms (USEPA, 1993).[1]
	HR	Home Range ratio	unitless	0.25	The home range for Northern quoll varies from 10 ha to 1000 ha, depending upon habitat. Given that the well leases range from 1 ha to 2.5 ha, a conservative home range ratio of 0.25 is assumed.[2]
	BW	Body weight	kg	0.80	Average body weight from Menkhorst & Knight 2001. Weight ranges from 0.7 kg to 0.1 kg.[3]

Notes:
a/ Units:
kg = kilogram
kg/day = kilograms per day
b/ Source:
1 - USEPA. (1993) Wildlife Exposure Factors Handbook United States Environmental Protection Agency Office of Research and Development. EPA/600/R-93/187. December 1993.
2 - Australian Government Department of the Environment."Pseudomys pilligaensis". Available online at: http://www.environment.gov.au/cgi-bin/sprat/public/publicspecies.pl?taxon_id=99 . Retrieved 2 June 2015.
3 - Menkhorst, Peter; Knight, Frank (2001). A field guide to the mammals of Australia. South Melbourne, Australia: Oxford University Press. pp. 194–195. ISBN 019550870X.
g/day = grams per day
ha = hectare

Constituent Name	CAS No.	EPC [1] Surface Cuttings (Unmixed)	EPC [1] Surface Cuttings (Mixed)	Toxicity	Total Intake (mg/kg/day)	Hazard Quotient	Total Intake (mg/kg/day)	Hazard Quotient
		CS (mg/kg)	CS (mg/kg)	TRVs	Unmixed	Incidental Ingestion	Mixed	Incidental Ingestion
Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione	533-74-4	-	-	8.1E-01	-	NA	-	NA
Methylisothiocyanate (MITC)	556-61-6	30.6	0.6	4.1E-01	5.2E-03	1.3E-02	1.0E-04	2.6E-04

Notes:
1/ EPC is estimated concentration in drilling fluid solids presented in Attachment 3, Table 4.
CAS = Chemical Abstracts Service
CS = concentration in soil
EPC = exposure point concentration
mg/kg = milligrams per kilogram
mg/kg/day = milligrams per kilograms per day
NA = not applicable
TRV = toxicity reference value
- not present in spent muds

$$Total\ Intake = \frac{[(EPC\ x\ IR - S) + (EPC\ x\ IR - F\ )]\ x\ HR}{BW}$$

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

Attachment 3, Table 7
Risk Estimates for Avian Receptor from Vendor Chemicals in Drilling Fluids

Constituent Name	CAS No.	Mammal NOAELt	Mammal NOAEL		Avian NOAELt [1]	Avian NOAEL		Mammal		Avian Receptor	
			Test Animal			Test Animal		Northern Quoll		Cattle Egret	
			Animal	Body Weight (kg)		Animal	Body Weight (kg)	Body Weight	Derived TRV	Body Weight (kg)	Derived TRV
Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione	533-74-4	1	Rat	0.35	14.7	bobwhite quail	0.178	0.8	8.1E-01	0.39	1.2E+01
Methylisothiocyanate (MITC)	556-61-6	0.5	Rat	0.35	NA	NA	NA	0.8	4.1E-01	0.39	4.9E-01

Notes:
1/ Avian NOAEL for Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione developed by applying an uncertainty factor of 10 to the NOEC for bobwhite quail.
1/ If an avian NOAEL was not available, the mammal NOAEL was used to derive the TRV for the avian receptor.
CAS = Chemical Abstracts Service
kg = kilogram
NA = not applicable
NOAEL = No observed adverse effect level
NOAELt = No observed adverse effect level test animal
NOEC = no observed effect concentration
TRV = toxicity reference value

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

Exposure Route	Parameter Code	Parameter Definition	Units (a)	Parameter Value	Source (b)
Ingestion	IR-S	Ingestion rate soil	kg/day	0.031	BPJ
	IR-F	Ingestion rate food	kg/day	0.157	The Cattle Egret feeds mostly on grasshoppers, other insects, and small mammals (Marchant& Higgins, 1990). For this evalution, diet is assumed to consist entirely of earthworms (BPJ) to link the potential COPCs in soil and feed habits of egret. The ingestion rate is calculated using USEPA T-REX model equations.
	HR	Home Range ratio	unitless	0.5	BPJ
	BW	Body weight	kg	0.390	Siegfried, 1969
	PR	Prey Ratio	unitless	0.50	The cattle egret mainly consumes insects; a prey ratio of 0.5 is conservatively assumed and likely overestimates potential consumption of worms.

Notes:

a/ Units:
kg/day = kilograms per day
kg = kilogram
b/ Source:
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
Marchant & Higgins (1990). Handbook of Australian, New Zealand and Antarctic Birds : Volume 1: Ratites to Ducks : Part B: Australian Pelican to Ducks
COPC = constituent of potential concern
USEPA = United States Environmental Protection Agency

Constituent Name	CAS No.	EPC [1] Surface Cuttings (Unmixed)	EPC [1] Surface Cuttings (Mixed)	Toxicity	Total Intake (mg/kg/day)	Hazard Quotient	Total Intake (mg/kg/day)	Hazard Quotient
		CS (mg/kg)	CS (mg/kg)	TRVs	Unmixed	Incidental Ingestion	Mixed	Incidental Ingestion
Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione	533-74-4	-	-	1.2E+01	-	NA	-	NA
Methylisothiocyanate (MITC)	556-61-6	30.6	0.6	4.9E-01	4.3E+00	8.9E+00	8.6E-02	1.8E-01

Notes:
1/ EPC is estimated concentration in drilling fluid solids presented in Attachment 3, Table 4.
CAS = Chemical Abstracts Service
CS = concentration in soil
EPC = exposure point concentration
mg/kg = milligrams per kilogram
mg/kg/day = milligrams per kilograms per day
NA = not applicable
TRV = toxicity reference value
- not present in spent muds

$$Total\ Intake = \frac{(EPC\ x\ IR - S) + (EPC\ x\ IR - F\ x\ PR)\ x\ HR}{BW}$$

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

Attachment 3, Table 8
Human Receptor Exposure Assumptions

Media	Exposure Route	Parameter Code	Parameter Definition	Units (a)	Parameter Value - Resident	Source (b)	Parameter Value - Agricultural Worker	Source (b)
Soil	Ingestion	IR	Ingestion rate	mg/day	100	enHealth, 2012, USEPA, 2016	100	enHealth, 2012
		EF	Exposure frequency	day/yr	20	BPJ	4	BPJ
		ED	Exposure duration	yr	10	BPJ	35	BPJ
		RBA	Relative bioavailability factor	unitless	chemical-specific	enHealth, 2012	chemical-specific	(f) enHealth, 2012
		BW	Body weight	kg	51	(c) enHealth, 2012	85	enHealth, 2012
		LT	Lifetime	yr	82	enHealth, 2012	79	(f) enHealth, 2012
		AT-NC	Averaging time - noncancer	days	3,650	enHealth, 2012	12,775	enHealth, 2012
		AT-C	Averaging time - cancer	days	25,550	enHealth, 2012	25,550	enHealth, 2012
		CF	Conversion factor	kg/mg	1.0E-06	enHealth, 2012	1.0E-06	enHealth, 2012
	Dermal	SA	Surface area for contact (exposed)	cm^2/day	4,700	(d) enHealth, 2012, USEPA, 2016	5,664	(d) enHealth, 2012, USEPA, 2016
		ABS	Absorption Factor	unitless	chemical-specific	enHealth, 2012	chemical-specific	BPJ
		EF	Exposure frequency	day/yr	20	BPJ	4	BPJ
		ED	Exposure duration	yr	10	BPJ	35	(f) enHealth, 2012
		BW	Body weight	kg	51	(c) enHealth, 2012	85	(f) enHealth, 2012
		LT	Lifetime	yr	82	enHealth, 2012	79	enHealth, 2012
		AT-NC	Averaging time - noncancer	days	3,650	enHealth, 2012	12,775	enHealth, 2012
		AT-C	Averaging time - cancer	days	25,550	enHealth, 212	25,550	enHealth, 2012
		AF	Soil Adherence Factor	mg soil/cm^2 skin	0.07	(e) enHealth, 2012, USEPA, 2016	0.08	(e) enHealth, 2012, USEPA, 2016
		CF	Conversion factor	kg/mg	1.0E-06	enHealth, 212	1.0E-06	enHealth, 2012

Notes:
a/ Units:
l/hr = litres per hour
hr/day = hours per day
day/yr = days per year
yr = year
kg = kilogram
cm^2 = square centimetre
cm/h = centimetre per hour
l/cm^3 = litre per cubic centimetre
cm^2/day = square centimetre per day
mg soil/cm^2 skin = milligrams soil per square centimetre skin
kg/mg = kilogram per milligram

b/ References:
enHealth, 2012:
enHealth. (2012). Australian Exposure Factor Guidance. enHealth Subcommetee of the Australian Health Protection Principal Committee, Canberra, Australia.
BPJ:
Best Professional Judgement
USEPA, 2016
USEPA. (2016). EPA-Expo-Box (A Toolbox for Exposure Assessors). Available at http://www.epa.gov/expobox

c/ The body weight is the time weighted average calculated from enHealth exposure factors for a male or female child aged 8 to 18 years old
d/ Exposed body surface area is the time weighted average of head, forearms, hands, lower legs, and feet.
Forearms are considered 45% of arm surface area; lower leg is considered 40% of leg surface area (USEPA, 2016).
e/ Adherence factor calculated for exposed body part surface area is the time weighted average of head, forearms, hands, lower legs, and feet.
f/ Male exposure factor used based on enHealth recommendation.

Attachment 3, Table 9
Risk Estimates for Resident from Vendor Chemicals in Drilling Fluids

Exposure to Soils Before Treatment							
Constituent Name	**CAS No.**	**EPC [1] Surface Cuttings (Unmixed)**	**Toxicity mg/kg-day**	**Oral Intake**	**Dermal Intake**	**Hazard Quotient**	
		CS (mg/kg)	**RfDo**	**CADDoral**	**CADDderm**	**Incidental Ingestion**	**Dermal**
Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione	533-74-4	-	1.0E-02	-	-	NA	NA
Methylisothiocyanate (MITC)	556-61-6	30.6	5.0E-03	3.3E-06	1.1E-05	6.6E-04	2.2E-03

Exposure to Soils After Treatment							
Constituent Name	**CAS No.**	**EPC [1] Surface Cuttings (Mixed)**	**Toxicity mg/kg-day**	**Oral Intake**	**Dermal Intake**	**Hazard Quotient**	
		CS (mg/kg)	**RfDo**	**CADDoral**	**CADDderm**	**Incidental Ingestion**	**Dermal**
Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione	533-74-4	-	1.0E-02	-	-	NA	NA
Methylisothiocyanate (MITC)	556-61-6	0.61	5.0E-03	6.6E-08	2.2E-07	1.3E-05	4.3E-05

Notes:
1/ EPC is estimated concentration in drilling fluid solids presented in Attachment 3, Table 4.
CAS = Chemical Abstracts Service
CS = concentration in soil
CADD = chronic average daily dose
EPC = exposure point concentration
mg/kg = milligrams per kilogram
mg/kg/day = milligrams per kilograms per day
NA = not applicable
RfDo = oral reference dose
- not present in spent muds
Consistent with enHealth guidance a default value of 1 used for both the RBA and ABS values (see Table 8).

$$Oral\ Intake = \frac{EPC\ x\ IR\ x\ EF\ x\ ED\ x\ RBA\ x\ CFsoil}{BW\ \times AT}$$

$$Dermal\ Intake = \frac{EPC\ x\ EF\ x\ ED\ x\ SAexp\ x\ AF\ x\ ABS\ x\ CFsoil}{BW\ \times AT}$$

Attachment 3, Table 10
Risk Estimates for Agricultural Worker from Vendor Chemicals in Drilling Fluids

Exposure to Soils Before Treatment							
Constituent Name	**CAS No.**	**EPC [1] Surface Cuttings (Unmixed)**	**Toxicity mg/kg-day**	**Oral Intake**	**Dermal Intake**	**Hazard Quotient**	
		CS (mg/kg)	**RfDo**	**CADDoral**	**CADDderm**	**Incidental Ingestion**	**Dermal**
Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione	533-74-4	-	1.0E-02	-	-	NA	NA
Methylisothiocyanate (MITC)	556-61-6	30.6	5.0E-03	3.9E-07	1.8E-06	7.9E-05	3.6E-04

Exposure to Soils After Treatment							
Constituent Name	**CAS No.**	**EPC [1] Surface Cuttings (Mixed)**	**Toxicity mg/kg-day**	**Oral Intake**	**Dermal Intake**	**Hazard Quotient**	
		CS (mg/kg)	**RfDo**	**CADDoral**	**CADDderm**	**Incidental Ingestion**	**Dermal**
Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione	533-74-4	-	1.0E-02	-	-	NA	NA
Methylisothiocyanate (MITC)	556-61-6	0.61	5.0E-03	7.9E-09	3.6E-08	1.6E-06	7.2E-06

Notes:
1/ EPC is estimated concentration in drilling fluid solids presented in Attachment 3, Table 4.
CAS = Chemical Abstracts Service
CS = concentration in soil
CADD = chronic average daily dose
EPC = exposure point concentration
mg/kg = milligrams per kilogram
mg/kg/day = milligrams per kilograms per day
NA = not applicable
RfDo = oral reference dose
- not present in spent muds
Consistent with enHealth guidance a default value of 1 used for both the RBA and ABS values (see Table 8).

$$Oral\ Intake = \frac{EPC\ x\ IR\ x\ EF\ x\ ED\ x\ RBA\ x\ CFsoil}{BW\ \times AT}$$

$$Dermal\ Intake = \frac{EPC\ x\ EF\ x\ ED\ x\ SAexp\ x\ AF\ x\ ABS\ x\ CFsoil}{BW\ \times AT}$$

Appendix 8 – Exposure Pathways

	Lifecycle Primary Source	Potential Drilling and Completion Chemical Exposure - Activities						
	Modes of Release	Blending & Storage of Products	Drilling Operations	Storage & Recycling of Fluids and Cuttings	Land Application/Beneficial Reuse of Muds and Cuttings	Irrigation Beneficial Reuse	Stockwater Beneficial Reuse	Dust Suppression, Construction and Operational Beneficial Reuse
Affected Media/Environment	**Stored Fluids**	Yes	Yes	Yes	Yes	Yes	Yes	No
	Soils	No	No	No	Yes	Yes	No	Yes
	Surface Water	No	No	No	Yes	Yes	No	Yes
	Groundwater	No	Yes	No	No	No	No	No
Stored Fluids								
Human Receptors	Worker	NA	NA	NA	NA	NA	NA	-
Ecological Receptors	Terrestrial flora	IC	IC	IC	I/LP	IC	IC	-
	Terrestrial fauna	I/LP	IC	I/LP	C	I/LP	I/LP	-
	Aquatic flora[1]	IC	IC	IC	I/LP	IC	IC	-
	Aquatic fauna[1]	IC	IC	IC	I/LP	IC	IC	-
Soils								
Human Receptors	Worker	-	-	-	NA	NA	-	NA
	Agricultural Worker or Resident	-	-	-	NA	NA	-	NA
Ecological Receptors	Terrestrial flora	-	-	-	I/LP	I/LP	-	I/LP
	Terrestrial fauna	-	-	-	C	C	-	I/LP
	Aquatic flora[1]	-	-	-	I/LP	IC	-	IC
	Aquatic fauna[1]	-	-	-	I/LP	IC	-	IC
Surface Water								
Human Receptors	Worker	-	-	-	NA	NA	-	NA
	Agricultural Worker or Resident	-	-	-	NA	NA	-	NA
Ecological Receptors	Terrestrial flora	-	-	-	IC	IC	-	IC
	Terrestrial fauna	-	-	-	IC	IC	-	IC
	Aquatic flora	-	-	-	I/LP	IC	-	IC
	Aquatic fauna	-	-	-	I/LP	IC	-	IC
Groundwater								
Human Receptors	Worker	-	NA	-	-	-	-	-
	Agricultural Worker or Resident	-	C	-	-	-	-	-
Ecological Receptors	Terrestrial flora	-	IC	-	-	-	-	-
	Terrestrial fauna	-	C a	-	-	-	-	-
	Aquatic flora	-	IC	-	-	-	-	-
	Aquatic fauna	-	IC	-	-	-	-	-

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)*
a	*Livestock only*

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 2021 update) (2021).
  - 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).

The screening criteria hierarchy utilised the following for solid residual drilling material includes:

- Human Health Environmental and ecological (including phytotoxicity)
  - The National Environment Protection (Assessment of Site Contamination) Measure 1999, as amended 2013 (ASC NEPM)
  - CRC CARE Technical Report 10: Health screening levels for petroleum hydrocarbons in soil and groundwater (Friebel and Nadebaum, 2011, CRC CARE Technical Report no. 10)
  - USEPA May 2016 RSLs (RSL TR = 1.0, THQ = 0.1)
  - Risk-Based Screening Levels for the Protection of Livestock Exposed to Petroleum Hydrocarbons, Publication Number 4733 (API, 2004).

Appendix 10 – Contingency Response Actions

NARRABRI GAS PROJECT

Pollution Incident Response Management Plan

Date	Revision	Reason for Issue	Author	Checked	Approved
25 November 2020	A	Draft for Santos review	Onward Consulting		
16 February 2021	B	Pre-consultation review	Onward Consulting		
14 May 2021	C	For consultation	Onward Consulting		

Prepared by:

Title	Name	Signature	Date
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Reviewed by:

Title	Name	Signature	Date

Approved by:

Title	Name	Signature	Date

Onward document number:
NGP-001N-0C1 REP

Document review history

In accordance with consent condition D4, this document has been reviewed as follows:

Review Date	Reason for review	Reviewed by	Revision required (Y/N)

Acronyms and abbreviations

Acronym	Description
AHD	Australian Height Datum
CCC	Community Consultative Committee
CMT	Crisis Management Team
CoC	Conditions of consent for the NGP SSD 6456
CSG	coal seam gas
DPIE	The NSW Department of Planning, Industry and Environment
DSMP	Dam Safety Management Plan
EIS	environmental impact statement
EMP	environmental management plan
EOC	Emergency Operations Centre
EPA	The NSW Environment Protection Authority
EP&A Act	*Environmental Planning and Assessment Act 1979* (NSW)
EP&A Regulation	Environmental Planning and Assessment Regulation 2000
EPBC Act	*Environment Protection and Biodiversity Conservation Act 1999* (Cth)
EPL	environment protection licence under the POEO Act
ERC	Emergency Response Coordinator
ERP	Emergency Response Plan
ERT	Emergency Response Team
FCNSW	Forestry Corporation of NSW
FRT	Field Response Team
GIS	geographical information systems
ha	hectare
HDPE	high density polyethylene
HSE	health, safety and environment
IMP	Incident Management Plan
IMT	Incident Management Team
m	metre
m^2	square metre
m^3	cubic metre
ML	megalitre
mm	millimetre
NGP	Narrabri Gas Project
NP&W Act	*National Parks and Wildlife Act 1974* (NSW)
OSC	On-Scene Commander
PAL	petroleum assessment lease under the PO Act
PEL	petroleum exploration licence under the PO Act

Acronym	Description
PIRMP	Pollution Incident Response Management Plan
PO Act	*Petroleum (Onshore) Act 1991* (NSW)
POEO Act	*Protection of the Environment Operations Act 1997* (NSW)
POEO Regulation	Protection of the Environment Operations (General) Regulation 2009
PPL	petroleum production lease under the PO Act
PPLA	petroleum production lease application under the PO Act
QIMS	Queensland Incident Management System
RFS	The NSW Rural Fire Service
SitRep	Emergency Situation Report Form
SDS	safety data sheets
SMS	Santos Management System
WBTP	water and brine treatment plant

Table of contents

Tables

Figures

1. Introduction

1.1 Purpose

The purpose of this Pollution Incident Response Management Plan (**PIRMP** or **Plan**) is to identify the specific pollution incident management response requirements for Santos' NSW operations, including the coal seam gas operations activities, operational facilities and activities associated with the Narrabri Gas Project (**NGP** or **Project**). The PIRMP has been developed to address Part 5.7A of the *Protection of the Environment Operations Act 1997* (**POEO Act**) which requires holders of an environment protection licence (**EPL**) issued by the NSW Environment Protection Authority (**EPA**) to prepare, keep, test and implement a PIRMP. It also addresses the requirement of the relevant consent conditions of State significant development (**SSD**) 6456, which Santos NSW (Eastern) Pty Ltd (**Santos**) obtained for the development of the Project on 30 September 2020, on behalf of its joint venture participants.

This PIRMP has been prepared in accordance with Part 3A of the Protection of the Environment Operations (General) Regulation 2009 (**the POEO Regulation**) and the EPA's *Guideline: Pollution Incident Response Management Plans* (2020) (**PIRMP Guideline**).

In NSW, all CSG exploration, assessment and/or production activities are required to hold an EPL under the POEO Act. Santos holds several EPLs for its coal seam gas operations in tenures within the Gunnedah Basin area. EPL 20350 is held for CSG activities in Petroleum Exploration Licence (**PEL**) 238, Petroleum Assessment Lease (**PAL**) 2 and Petroleum Production Lease (**PPL**) 3[1]. Santos has submitted petroleum production licence applications (**PPLAs**) to cover the Narrabri Gas Project SSD 6456 area. EPL 20351 is for CSG activities in PEL 1 and PEL 12, EPL 20352 is for CSG activities in PEL 456; and EPL 20378 is for the fluid treatment facility at the Narrabri Operations Centre.

This PIRMP applies to all of Santos' licenced coal seam gas exploration, assessment and production activities in NSW for which an EPL has been issued, as well as other supporting facilities which are not scheduled activities under the POEO Act, including the Narrabri Operations Centre and the Wilga Park Power Station. This PIRMP acts as a guide and provides information on site responsibilities, actions, reporting requirements, community consultation and resources available to ensure an effective and timely response is undertaken for pollution incidents or emergencies.

It achieves this by:

- identifying the Santos incident management structure;
- displaying notification and escalation criteria;
- defining roles and responsibilities of the Incident Management Team (IMT) members;
- describing scenario-based response procedures;
- identifying key resource contact details;
- describing community consultation requirements following an incident; and
- providing tools and templates for use in an incident response and recovery.

The Plan forms part of the organisation's overall emergency response, being supplementary to the Narrabri Gas Project Emergency Response Plan (NGP ERP) and the Queensland Incident Management System (**QIMS**) Incident Management Plan (**QIMS IMP**), providing the necessary information to deal with emergencies at the site and asset level.

[1] Refer to the Glossary for details on the titleholders for PEL 238, PAL 2 and PPL 3

1.2 NGP operations

Santos' NSW operations comprise both 'permanent' and 'mobile' facilities located within NSW, and Santos operates a variety of assets as part of its NSW operations based in Narrabri, including the NGP.

1.2.1 Permanent facilities

The Santos permanent facilities comprise administration/support centres and storage/treatment facilities as detailed below:

Administration/support centres

- Narrabri Operations Centre; and
- Community Office in Maitland Street, Narrabri.

Storage/treatment facilities

- Leewood produced water and brine water ponds;
- Leewood water treatment plant including a 5 ML treated water storage tank;
- Leewood irrigation area (centre pivot);
- Tintsfield produced water ponds and flare;
- Bibblewindi water transfer facility (5 ML tank);
- Bibblewindi compressor facility and flare;
- Wilga Park Power Station;
- water storage facilities (pilot sites and pipelines);
- water and gas gathering systems (i.e. pipelines); and
- well pads.

1.2.2 Facilities

Santos facilities comprise a number of drilling & completions operations (both operational and under construction) throughout the Project area, and its other facilities within NSW. The locations of Santos' NSW facilities outlined in the Plant Dossier are available as geographical information systems (**GIS**) maps on the Santos intranet.

1.3 Scope

This PIRMP has been developed to meet statutory requirements associated with activities relating to Santos' EPLs. The EPLs relate to those activities associated with exploration, assessment and production of coal seam gas and covers activities at Santos well pads and storage and treatment facilities detailed above in sections 1.2.1 and 1.2.2.

The PIRMP will be referenced and actioned in the event of a pollution incident at the storage/treatment facilities or mobile sites. The operational rules and emergency response associated with these sites will vary during their life cycle through construction, operation and decommissioning stages.

Santos maintains records of plant to which this PIRMP relates. This includes the name of the asset, its type, location, and status.

1.4 Objectives

The objective of the PIRMP is to set out the requirements for the notification, response and management of pollution incidents as defined in the POEO Act and the POEO Regulation, and the conditions of consent for the NGP SSD 6456 (hereafter referred to as the **CoC**).

The PIRMP has been developed to meet the requirements of Santos and POEO legislation and nominates the appropriate responsibilities and actions to ensure the requirements and obligations as set out in this Plan are strictly followed and adhered to.

1.5 Pollution incident definition

A ”pollution incident” means an incident or set of circumstances during or as a consequence of which there is or is likely to be a leak, spill or other escape or deposit of a substance, as a result of which pollution has occurred, is occurring or is likely to occur.

It includes an incident or set of circumstances in which a substance has been placed or disposed of on premises, but it does not include an incident or set of circumstances involving only the emission of any noise.

A pollution incident is required to be notified if there is a risk of ‘material harm to the environment’, which is defined in Section 147 of the POEO Act as:

(a) harm to the environment is material if:

(i) it involves actual or potential harm to the health or safety of human beings or to ecosystems that is not trivial, or

(ii) it results in actual or potential loss or property damage of an amount, or amounts in aggregate, exceeding $10,000 (or such other amount as is prescribed by the regulations), and

(b) loss includes the reasonable costs and expenses that would be incurred in taking all reasonable and practicable measures to prevent, mitigate or make good harm to the environment.

1.6 Emergency response document framework

Santos has a four-tiered response structure for managing emergencies and incidents:

- Field Response Team (**FRT**);
- Emergency Response Team (**ERT**);
- Incident Management Team (**IMT**); and
- Crisis Management Team (**CMT**).

Each tier has defined responsibilities. Depending upon the complexity of the incident, multiple tiers may be activated to provide response and recovery services with the PIRMP as an integrated part of this system of emergency response.

1.7 Document structure

The structure of the PIRMP is as follows:

Sections

Section 1	Provides an introduction to the Project and defines the purpose of the PIRMP and how it will be conveyed
Section 2	Provides the details regarding pollution incident response, and identifies Santos' responsibilities and management measures to minimise harm to Santos employees and the community
Section 3	Details pollution incident communication and training, and outlines the requirements and contacts detail needed by employees, contractors and/or staff working within Santos
Section 4	Provides details regarding the pollution incident response plan, and provides details on the main environmental hazards associated with the NSW Operational area.
Section 5	Provides the details regarding the auditing, review and revision of the PIRMP
Section 6	Glossary

Appendices

Appendix A	Emergency Incident Notification Checklist, to be used for all incidents to document the agency notification
Appendix B	Emergency Situation Report (**SitRep**) form, to be used for reporting the details of the actual incident and the planning of the immediate incident response

Attachments

Attachment 1	NGP Dam Safety Emergency Plan

Table 1.1 provides the details where the requirements of the PIRMP Guideline are addressed in this document.

Table 1.1 - Section references to the PIRMP Guideline requirements

EPA PIRMP guideline (2020) requirement	POEO Regulation clause*	Section reference
Description and likelihood of hazards	98C (1)(a) and (1)(b)	4.2
Pre-emptive actions	98C (1)(c)	4.4
Inventory of pollutants	98C (1)(d) and (1)(e)	4.3
Safety equipment	98C (1)(f)	4.5
Contact details	98C (1)(g) and (1)(h)	3.2
Communicating with neighbours and the community	98C (1)(i)	3.3
Minimising harm to people on the premises	98C (1)(j)	2.3
Maps	98C (1)(k)	4.1
Actions to be taken during or immediately after a pollution incident	98C (1)(l)	2.4
Staff training	98C (1)(m)	3.5
Testing and updating the PIRMP	98C (1)(n), (o) and (p)	3.5, 5

* Protection of the Environment Operations (General) Regulation 2009

1.8 Reference documents

This document makes reference to or relates to the NGP ERP and the QIMS IMP for incident management. Current versions of these documents are available on the Santos intranet. In the event of a failure of the Leewood ponds, the NGP Dam Safety Management Plan (**DSMP**) (document number 7056-650-PLA-0001), included in Attachment 1, would be invoked.

The relationship between the various plans is presented in Figure 1.1. The key stand-alone difference with the PIRMP and all other plans is the planning for the timely notifications of relevant stakeholders, particularly Project neighbours.

1.9 Distribution

This is the full version of the PIRMP and is maintained at the premises to which the relevant licence relates and is readily available to the persons responsible for implementing the Plan and to an authorised officer of the EPA or Department of Planning, Industry and Environment (**DPIE**) on request. A copy of the approved PWMP is available to all Santos personnel via the Santos intranet. In accordance with consent condition D13, a controlled copy can also be found on the NGP website[2].

In accordance with specific licence, approval or code of practice conditions, a copy of this PIRMP is available at the Santos' Operations Centre located at 300 Yarrie Lake Road in Narrabri. This is where operational and field staff commence and finish each working day.

Note that any printed copies of the PIRMP are uncontrolled, unless explicitly stated.

[2] For privacy and security purposes, the public version of this Plan, as available on the NGP website, does not contain the personal contact details or phone numbers of Santos', contractors', agencies', authorities' and organisations' personnel.

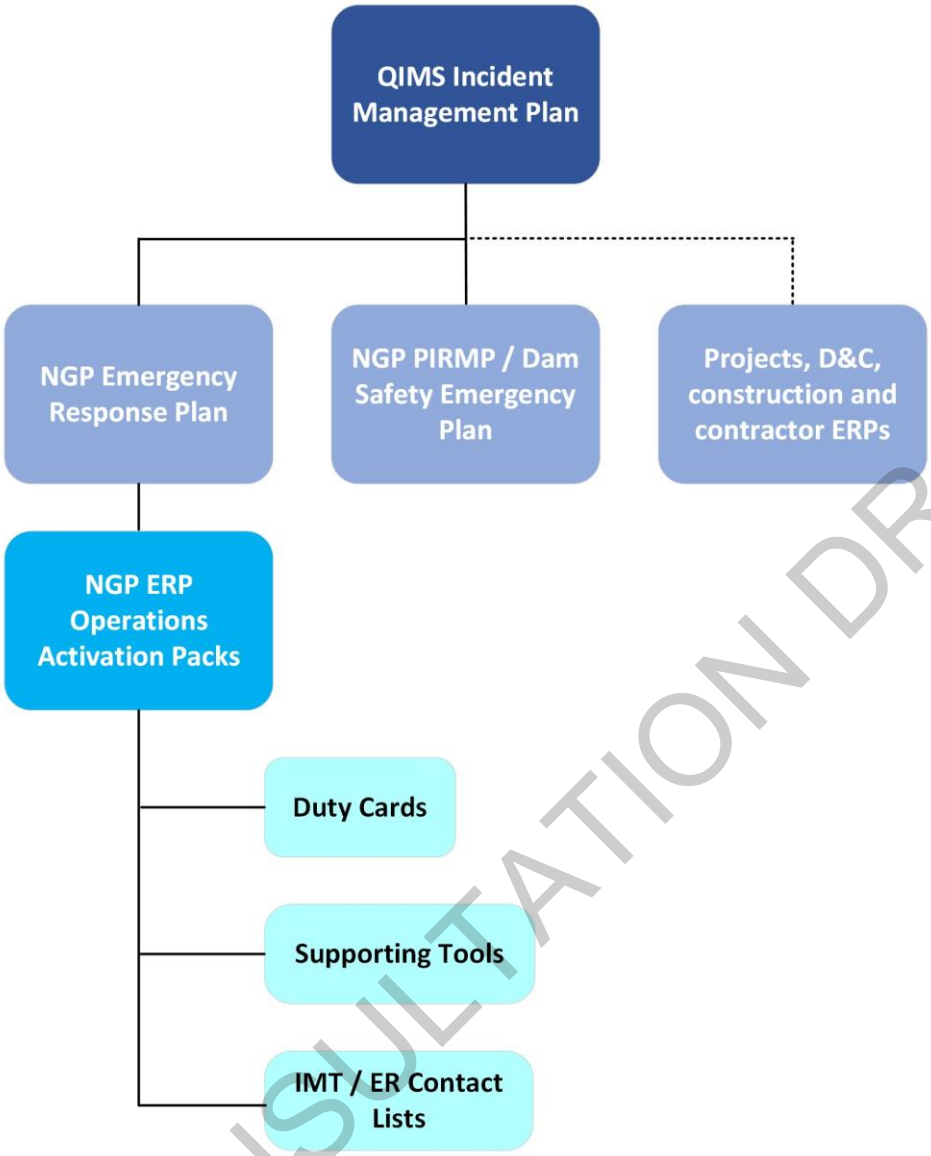

Figure 1.1 - The relationship between NGP Project ERP, QIMS IMP and other supporting plans

2. Pollution incident response

2.1 Responsibilities during a pollution incident

As mentioned in section 1.6, Santos has a four-tiered response team structure for managing emergencies and incidents - the Field Response Team (FRT), the Emergency Response Team (ERT), Incident Management Team (IMT) and the Crisis Management Team (CMT). This is presented in Figure 2.1.

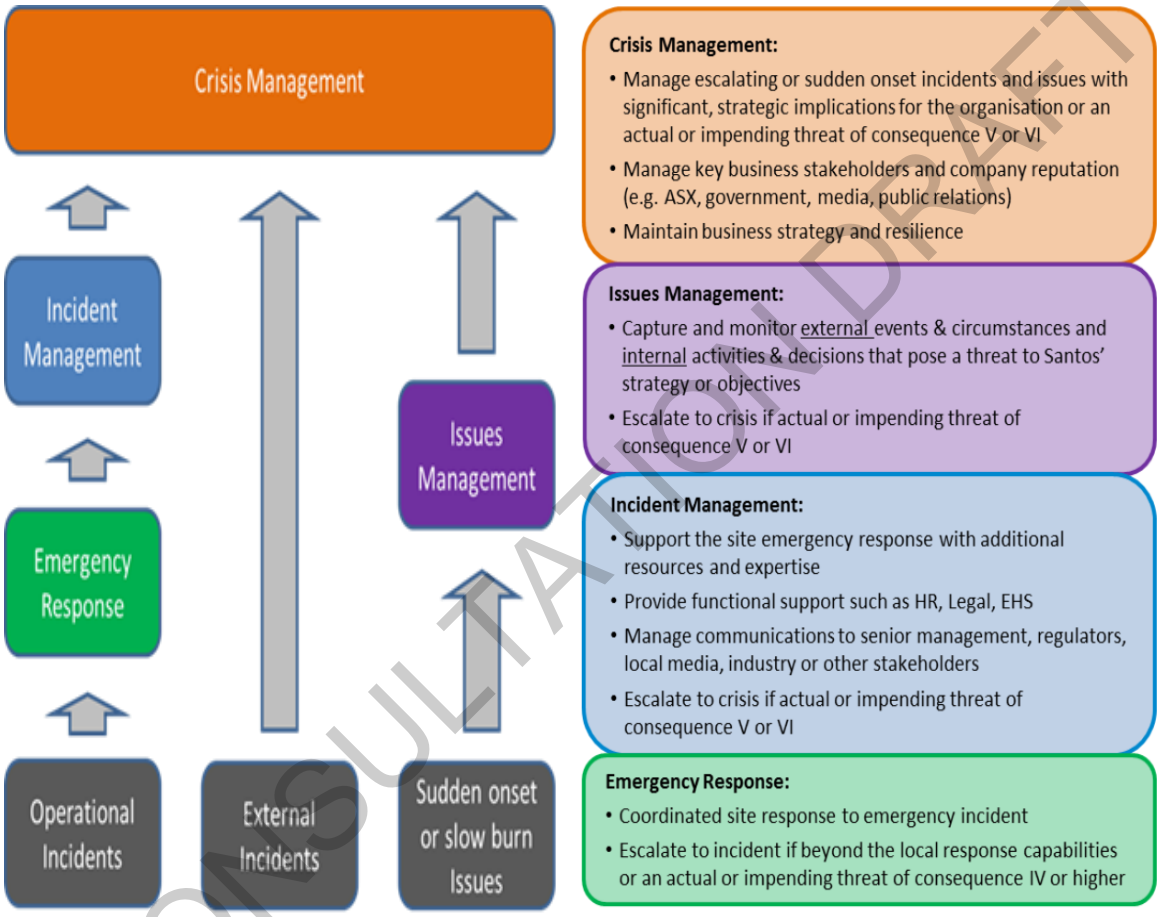

Figure 2.1 - Emergency response structure

The FRT or the ERT will generally be mobilised to respond to a pollution incident at Santos NSW Operations, including the storage/treatment facilities and mobile sites that are the subject of this PIRMP.

The ERT is responsible for triggering and implementing the PIRMP for a pollution incident. Should the incident be escalated to the IMT or CMT, the ERT continues to be responsible for the implementation of the PIRMP.

The structure of field and emergency response teams is detailed in Figure 2.2 below.

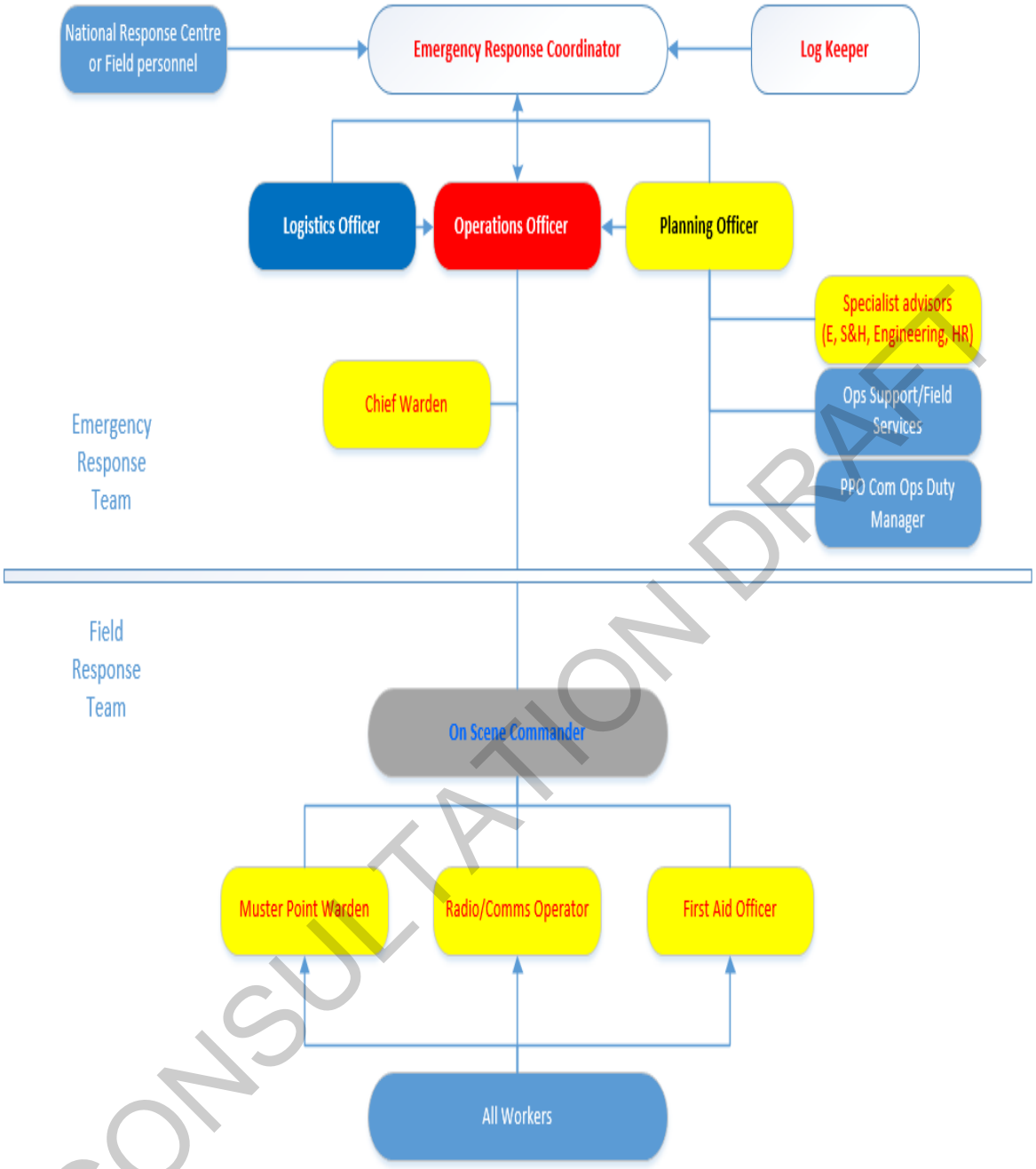

Figure 2.2 - Structure of Emergency Response and Field Response Teams

2.2 Santos emergency response responsibilities

Duty Cards are intended to provide clarity around key roles and responsibilities, to minimise confusion, and to ensure that all essential emergency response activities are carried out and that operations resume as quickly as possible after the conclusion of the emergency.

A particular “role” is not a fixed set of prescribed rules or duties allocated to a specific level of position, title or person. Rather, they are designed as a pro-active checklist of flexible suggestions or prompts, nominated to the best incumbent, capable of assuming the “role”. The checklists can cater for an escalation or change in the severity of any emergency.

The “role” prompts are not designed to cater for every specific, likely or prescribed emergency occasion, nor is it intended for every prompt to be used sequentially, but only as appropriate to the emergency and response required at the time. They are simply suggestions to consider during any, or all, emergencies that assist to move the response along effectively.

Duty cards for all ERT and FRT positions are located in section 9 of the NGP ERP. All ERT members are expected to be fully prepared to carry out their respective roles and responsibilities efficiently. It is expected that personnel will have a sound knowledge of the ERP and their requisite functions within ERT operations. The ERT is based at the Emergency Operations Centre (**EOC**).

Depending on the emergency type, severity and timeframe, the ERC may enlist other individuals to assist the ERT, relief ERT members, undertake specific tasks or even scale back the full activation of the ERT to a monitoring function only. Additional functions may include a Recovery Officer to coordinate the activities which follow the immediate response.

2.2.1 Emergency Response Team

The NSW NGP ERT is comprised of the following:

- Emergency Response Coordinator (ERC);
- ERT Support Officer;
- ERT Logistics Officer;
- ERT Planning Officer; and
- ERT Operations Officer.

Emergency Response Coordinator

- The ERT is led by the ERC who maintains close consultation with the Operations Officer, Logistics Officer and Planning Officer. Both the Government and Public Affairs Advisors and Legal Advisors may consult directly with the ERC, dependant on the scenario. The ERC is a dedicated person that is the point of contact based at the EOC who is in control of the on-ground emergency response aspects of an emergency in consultation with ERT and IMT personnel.
- The ERC duty card is included in section 9.1 of the NGP ERP.

ERT Support Officer

- The ERT Support Officer is responsible for keeping a running record of all key decisions, actions and activities undertaken to respond to and recover from the emergency.
- The ERT Support Officer duty card is included in section 9.2 of the NGP ERP.

ERT Logistics Officer

- The ERT Logistics Officer is responsible for coordinating the resources (including additional personnel, transport, food and shelter etc.) that are not currently in the ERT/FRT, to address and respond to the emergency.
- The ERT Logistics Officer duty card is included in section 9.3 of the NGP ERP.

ERT Planning Officer

- The ERT Planning Officer is responsible for coordinating and liaising with advisors who will provide input on the emergency response and recovery activities on an as-required basis.
- The ERT Planning Officer duty card is included in section 9.4 of the NGP ERP.

ERT Operations Officer

- The ERT Operations Officer is responsible for maintaining contact with the FRT via the On-Scene Commander, to have a clear idea of the progress of the emergency, and to plan the response activities required to recover from the emergency.
- The ERT Operations Officer duty card is included in section 9.5 of the NGP ERP.

2.2.2 Field Response Team

The FRT is typically comprised of the following:

- an On-Scene Commander;
- a Muster Point Warden; and
- one of more First Aid Operators.

Duty cards detailing the roles and responsibilities of the members of the FRT are included in section 9 of the NGP ERP. All FRT members are expected to be fully prepared to carry out their respective roles and responsibilities and to have a sound understanding of the NGP ERP, including the field-specific arrangements e.g. muster points and contact details. If there are multiple emergencies occurring concurrently, multiple On-Scene Commanders and FRTs may be required, who will be coordinated by a central Lead On-Scene Commander.

On-Scene Commander

- The FRT is led by the On-Scene Commander who is responsible for coordination of the field-level response for the emergency at the affected site.
- Refer to section 9.6 of the NGP ERP for the duty card of the On-Scene Commander.

Muster Point Warden

- The Muster Point Warden is responsible for accounting for all Santos staff and contractors at the muster location. The warden will report back to the On-Scene Commander.
- The Muster Point Warden duty card is included in section 9.7 of the NGP ERP.

First Aid Officer

- The First Aid Officer is responsible for the provision of first aid treatment to all injured personnel involved in the emergency whilst ensuring that his/her own safety and the safety of others is not compromised.
- The First Aid Officer duty card is included in section 9.8 of the NGP ERP.

2.3 Management measures to minimise harm to site personnel

Physical and managerial management measures have been developed and implemented by Santos to minimise the potential harm to Santos employees and the community resulting from a pollution incident. Physical measures such as alarms and emergency response equipment have been installed and provided at active work sites.

Santos has developed a number of management plans and procedures to respond to emergencies and incidents, including the NGP ERP and QIMS IMP. All documents, including this PIRMP, have been

developed to meet both legislative and safety obligations and all approval, licencing and consent requirements associated with operations.

All site staff, contractors and visitors are inducted when first attending a site and advised of emergency procedures, warning alarms (where applicable) and each site's muster location. Relevant requirements relating to the PIRMP are conveyed to personnel as part of the induction process.

Santos has designated emergency response roles as detailed in section 2.2. The designated staff members have been advised of the requirements relating to their respective roles and also trained in emergency response through desk-top and simulated emergency situations. Santos staff training packages are regularly updated to include response and notification requirements for the PIRMP and associated pollution incidents. Further details relating to staff training and testing of the PIRMP are provided in section 3.5.

2.4 Actions to be taken during and immediately after a pollution incident

2.4.1 First strike action

It is imperative that first-strike action be taken quickly to contain any spill. This first strike action, determined by the On-Scene Commander and implemented by the field response team or the emergency response team (depending on the scale of the incident), is to be aimed at achieving isolation and containment of the spill to prevent any further leakage or spread to the surrounding environment. If the spill is minor, clean-up procedures will be implemented as required. Additional resources can be called upon depending on the extent of the incident.

Specific management plans have been developed by Santos for managing incidents and emergencies at the Wilga Park Power Station and the Leewood ponds (refer to the DSMP presented in Attachment 1). Prior to the commissioning and operation of the Bibblewindi pond and Tintsfield ponds, the DSMP will be revised and updated to include these two locations.

2.4.2 NGP Spill Response Guide

All Project environmental spill incidents shall be reported and managed in accordance with the incident notification requirements of CoC D6; Section 148 of the POEO Act; and the Santos Management Standard: *Incident Investigation and Response SMS - MS11 Incident and Crisis ST2 Incident reporting, Investigation and Learning*. Verbal notification shall be used as the first form of notification followed up by written detailed notification to ensure adequate details are provided.

The Santos onshore environment team shall determine any potential external notification triggers. Any external notifications are the responsibility of the HSER Onshore Manager. The following is a step-by-step guide for roles and responsibilities when managing spill incidents within the Project area:

Person reporting incident

- ensure the spill has been stopped and has been contained safely (if safe to do so);
- follow NGP Emergency Response Management plan if the spill is uncontrolled or is released offsite; and
- immediately notify supervisor & onsite environmental team of incident, if possible, take pictures of the spill and affected or impacted area, equipment and/or infrastructure (also if possible, record the impacted area (in m^2) and volume released (in m^3)).

Supervisor

- implement response protocols as required – ensure contact is made with the environmental team to arrange clean up and sampling of site;
- review incident in conjunction with environmental team in accordance with the NGP Incident Reporting Guidelines;
- confirm classification with asset/activity manager; and
- initiate IMS entry as required.

Asset/Activity Manager

- validate incident classification with Supervisor/Environment team and ensure notification against NGP Incident Reporting Guidelines;
- classify the incident in accordance with the Santos standards (in consultation with Santos onshore environment team);
- action and communicate in accordance with Santos Management Standard SMS – *MS11 Incident and Crisis- ST2 Incident reporting, Investigation and learning procedure*); and
- initiate the investigation as needed.

2.4.3 Incident response procedures

Santos has established incident response procedures which detail the actions to be taken by staff after a pollution incident to reduce or control any pollution. The incident response procedures are to be followed where there is no threat to the safety of site personnel responding to the incident.

Figure 2.3 details the emergency activation and escalation process in the event that a pollution incident escalates in severity. Site-specific incident response procedures which detail the actions to be taken by staff after a pollution incident to reduce or control any pollution are outlined in the following documents, provided in section 8 of the NGP ERP:

- chemical and produced water spills/gas release situation checklist;
- fire/explosion situation checklist;
- pipeline integrity compromised checklist;
- dam collapse; and
- severe weather event.

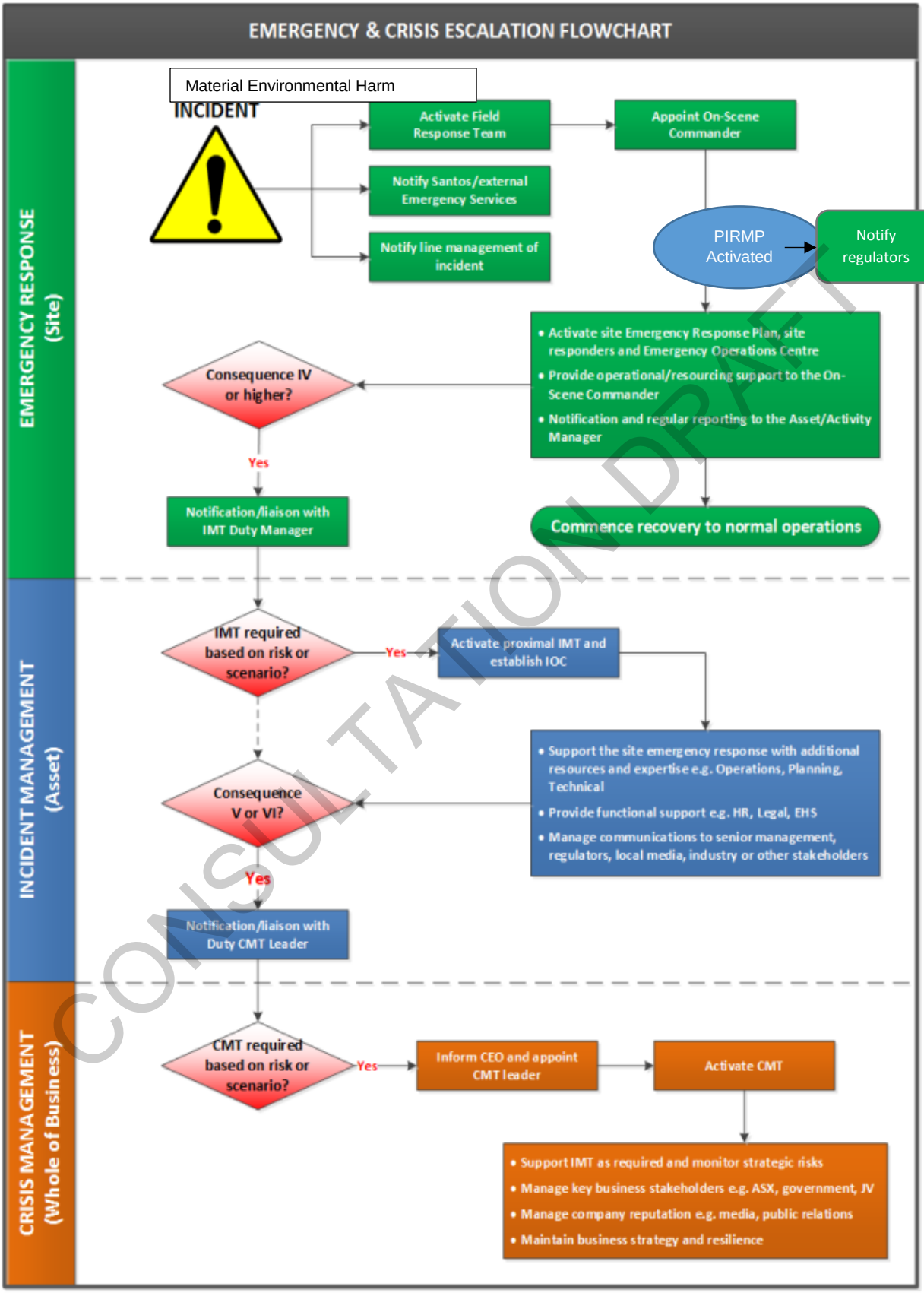

Figure 2.3 - Emergency activation and escalation flowchart

2.4.4 Pollution incident clean-up

Procedures for the clean-up of pollution incidents will largely depend on the type and extent of the pollution incident. Clean-up procedures will take into account the following:

- type of pollutant;
- extent and area of pollution impact;
- medium in which pollution has occurred (land, air, water, or any combination);
- requirements for specialist advice in relation to the removal and remediation of the pollution;
- potential additional environmental impacts by the proposed clean-up processes; and
- costs to remove the polluted material to a waste facility licensed to accept the waste.

The OSC is responsible for determining the method of clean-up, in consultation with the ERC and Santos environmental staff. Consultants may be engaged to provide advice where required.

3. Pollution incident communication and training

3.1 Immediate incident notification to relevant authorities

Depending on the location and nature of the incident, Santos is required to immediately notify all or some of the following regulatory authorities where a pollution incident has occurred or is likely to occur:

- DPIE;
- EPA;
- Resources Regulator;
- Narrabri Shire Council;
- Fire and Rescue NSW
- NSW Health (local Public Health Unit); and
- SafeWork NSW.

The NSW Resources Regulator must also be immediately notified if the incident occurs in PEL 238. 'Immediately' has its ordinary dictionary meaning of promptly and without delay.

If the incident relates to a facility covered under the Wilga Park Power Station approval, then DPIE is to be notified within 12 hours of becoming aware of the incident.

Santos is required to report all pollution incidents to the relevant authorities immediately the incident is identified and determined to meet the threshold of 'Material Environmental Harm'. The Emergency Incident Notification Checklist should be used to document the agency notification. As per CoC D6, DPIE and any other relevant agencies are to be notified via the Major Projects Portal immediately after Santos becomes aware of the incident. This notice must describe the location and nature of the incident.

The information required to be provided as part of the notification process includes:

(a) the time, date, nature, duration and location of the incident;
(b) the location of the place where pollution is occurring, or is likely to occur;
(c) the nature, the estimated quantity or volume and the concentration of any pollutants involved, if known;
(d) the circumstances in which the incident occurred (including the cause of the incident, if known);
(e) the action taken or proposed to be taken to deal with the incident and any resulting pollution or threatened pollution, if known; and
(f) other information prescribed by the regulations, as is identified on the notification checklist.

Lack of any of the above information should not prevent immediate notification.

The Emergency Situation Report (SitRep) form should be used to document additional information as it becomes available. The Situation Report and Emergency Incident Notification Checklist are to be updated as required and used to document any information updates made to the relevant agencies.

The Emergency Incident Notification Checklist and the Situation Report are attached as Appendix A and B respectively.

For any incident notification notified above, a full report is to be provided to regulatory authorities (including DPIE, NSW, Resources Regulator where relevant), within 7 days of the incident.

3.2 Contact details

The 'Emergency Contact List' is a critical component of this PIRMP as it contains a list of the contact details for personnel who are most likely required to assist in the event of an emergency, including key emergency response personnel from NSW sites, local emergency services, relevant Government agencies, contractors and other external services. The NGP Emergency Contact List can be accessed via the Santos intranet and within the nominated EOC in document emergency response activation packs on site.

3.3 Communicating with neighbours and the community

During an emergency situation it may be necessary to communicate with all potential stakeholders regarding the type and scale of the emergency, the possible cause, its effects and consequences and the likely duration and potential impacts.

All information that is communicated to other external stakeholders must be authorised by the ERC and/or the IMT. The ERT Operation Officer will be responsible for co-ordinating the notification and update of information to neighbours and local stakeholders.

Relevant stakeholders that may require notification include:

- neighbours, local landowners and community representatives;
- Santos employees and family members;
- customers and producers;
- FCNSW;
- the media; and
- insurers and lawyers.

It is imperative that all communications with the media be properly authorised by NSW Santos management. For this reason, the ERT should refer all media communication issues to the Government and Public Affairs team or the IMT Communications Group if the IMT has been activated. Contact details for other stakeholders for each asset covered by the PIRMP are provided in the Santos Community Database for this purpose.

3.4 Information to be provided to the community

Advice provided to the community will depend on the type and extent of the pollution incident. The method of communication to the community will depend on the nature and extent of the incident. The Community Database details the preferred communication for each stakeholder.

The following examples for the type of advice are provided as a guide:

- uncontrolled emission of air pollutant (gas emission) per determined risk:
  - community advised via a phone call/message (phone numbers provided in Santos Community Database) and advised to take appropriate actions (e.g. close windows and doors, turn off air conditioning equipment and stay indoors);
  - media outlets such as radio are contacted requesting a public announcement be made (following authorisation by the Government and Public Affairs team or IMT Communications Group).
- uncontrolled release of contaminated water into a waterway per determined risk

- FCNSW contacted and requested to advise state forest users of incident;
- immediate neighbours contacted via phone, and local community contacted through media outlets (radio or newspaper).

Decisions to notify neighbours and the local community will be made in consultation with regulatory authorities based on an initial risk assessment (for example, considering the type of pollutant, concentration of emission, prevailing wind and height of the emission).

Notification of the community and media is to be undertaken in consultation with the Government and Public Affairs team and local authorities.

3.5 Staff training and testing of the PIRMP

Personnel shall be trained in line with the Santos Training Standard to effectively fulfil their roles and responsibilities. Training personnel and exercising the PIRMP may be in the form of simulated emergencies, practical drills, desktop exercises, resources and equipment checks, or other exercises designed to systematically include all personnel likely to be involved.

Emergency exercises shall be conducted to:

- verify that the emergency plans provide adequate coverage across the range of incident categories;
- test the effectiveness of the PIRMP;
- validate the competency and response times of key emergency response personnel, including knowledge of individual roles and responsibilities;
- assess the capability to respond to an emergency;
- reinforce prior training;
- identify opportunities for improvement to the PIRMP;
- provide confidence to participants around emergency decision-making; and
- verify adequacy of communication channels, both internally and externally.

Santos will at minimum conduct an annual exercise incorporating aspects of this PIRMP, which could initiate the activation of the NSW IMP. The PIRMP will also be deemed to be exercised if an actual emergency occurs and components of the PIRMP are activated. In the event of an actual emergency, the PIRMP will be reviewed and updated accordingly.

Any non-conformance or improvements of the procedures outlined in the PIRMP shall be identified and action taken to remedy as recorded in the ‘Emergency Response Exercise’ module of the Santos database. All exercises and outcomes also to be recorded in the Santos database and training records are to be maintained and kept for a minimum period of 5 years.

4. Pollution incident response planning

4.1 Pollution incident response maps

Details of potential pollutants and safety equipment are provided in site plans for each fixed facility. The following site plans are available for NSW Operations on the Santos intranet.

- Narrabri Operations Centre;
- Wilga Park Power Station;
- Leewood Ponds;
- Bibblewindi Ponds;
- Tintsfield Ponds;
- Bibblewindi compressor facility, and flare; and
- well pads.

Progressive erosion and sediment controls plans are developed for each well pad prior to site disturbance. These are stored in Santos records management system.

Site plans have also been developed for each gas well pad for both construction and operation. Refer to each facility's site plan.

4.2 Main hazards NGP operations

A site-wide hazard assessment was undertaken at Santos to identify the main hazards on the site that pose a risk of causing actual or potential material harm to the environment. The main hazards identified have been detailed in Table 4.1 below.

Table 4.1 - Main NGP environmental hazards

Facility	Hazard	Description	Likelihood of causing environmental harm	Consequence	Management measure	Circumstances that may increase the likelihood of causing environmental harm
Narrabri Operation Centre	Dangerous goods/ Hazardous substance spill/leak	Leak/spill of dangerous goods and/or hazardous chemicals	Low	Localised contamination of the ground surface	Bunded dangerous goods cabinets Chemical spill kits Scheduled inspections of storage area.	Improper chemical/dangerous goods handling
Wilga Park Power Station	Dangerous goods/ Hazardous substance spill/leak	Leak/spill of dangerous goods and/or hazardous chemicals	Low	Localised contamination of the ground surface	Bunded dangerous goods cabinets Chemical spill kits Scheduled inspections of storage area.	Improper chemical/dangerous goods handling
Wilga Park Power Station	Uncontrolled air emissions	Uncontrolled emission of methane from site infrastructure	Low	Uncontrolled emission of methane into the atmosphere	Alarm systems on plant infrastructure	Plant failure
Wilga Park Power Station	Man-made fire	Fire caused directly or indirectly by site activities	Medium	Flora and fauna loss. Damage to infrastructure Loss of life	Hot work permits Training for staff to prevent accidental ignition, have fire breaks and fire extinguishers located throughout the Site	Undertaking hot works during dry/hot weather
Wilga Park Power Station	Fuel (Distillate) leak/spill	Leak/spill of diesel from the storage tanks	Low	Localised contamination of the ground surface	Bunded fuel storage area. Spill kits. Alarm systems on plant infrastructure Scheduled inspections of storage area.	Improper fuel refuelling/storage
Wilga Park Power Station	Bush fire	Natural occurring bushfire burning surrounding vegetation and materials	Medium	Flora and fauna loss. Damage to infrastructure Loss of life	Severe weather warnings to be communicated to site staff Have fire breaks and fire extinguishers located throughout the Site	Storm events
Well pads under construction	Sediment-laden runoff from topsoil stockpiles	Sediment-laden runoff caused by erosion of the topsoil stockpiles	Low	Sediment-laden runoff into the surrounding environment and potentially waterways	Environmental controls around stockpiles. Scheduled site inspections	Storm events/ heavy rainfall
Well pads under construction	Spill/leak of drilling muds	Sediment-laden runoff onto the site surrounding the well head/storage containers	Low	Localised contamination of the ground surface surrounding the well head/storage containers	Spill kits Scheduled site inspections	Failure of well head during drilling Failure of storage tanks
Well pads under construction	Dangerous goods/ Hazardous substance spill/leak	Leak/spill of dangerous goods and/or hazardous chemicals	Low	Localised contamination of the ground surface or potentially waterways	Bunded dangerous goods cabinets Chemical spill kits Scheduled inspections of storage area.	Improper chemical/dangerous goods handling
Well pads under construction	Bush fire	Natural occurring bushfire burning surrounding vegetation and materials	Medium	Flora and fauna loss. Damage to infrastructure Loss of life	Severe weather warnings to be communicated to site staff Have fire breaks and fire extinguishers located throughout the Site	Storm events
Operational well pads	Uncontrolled air emissions	Uncontrolled emission of methane from site infrastructure	Low	Uncontrolled emission of methane into the atmosphere	Alarm systems on plant infrastructure	Plant failure
Operational well pads	Produced water pipeline failure	Uncontrolled discharge of produced water from pipeline	Medium	Uncontrolled discharge of produced water into the environment (land and potentially water ways)	Alarm systems on plant infrastructure Scheduled site inspections	Plant failure

Facility	Hazard	Description	Likelihood of causing environmental harm	Consequence	Management measure	Circumstances that may increase the likelihood of causing environmental harm
Leewood, and Tintsfield brine and produced water ponds	Movement within the pond embankment structure	Deterioration/cracks/settlement or mounding at toe of embankment	Medium	Discharge of brine/produced water causing pollution to land and potentially waterways	Regular monitoring Drain pond or transfer water until embankment is remediated.	Major storm events
Leewood, and Tintsfield brine and produced water ponds	Overtopping of ponds	The capacity of the pond is exceeded due to a rain event or blockage	Medium	Overtopping of pond causing pollution to land and potentially waterways.	Regular monitoring; Implementation of TARP Unblock spillway and drawdown pond	Major storm events
Leewood, and Tintsfield brine and produced water ponds	Defects in pond liners	Large volume of seepage water continuously pumped from sumps. Floating geomembrane liner.	Medium	Discharge of brine/produced water causing pollution to land and potentially waterways	Regular monitoring Scheduled maintenance of pond liners.	Major storm events
Leewood, and Tintsfield brine and produced water ponds	Piping and tunnelling erosion	Sediment laden seepage from embankment surface with visible flow and possible sediment fans on the downstream slope or toe area of the embankment	Low	Discharge of sediment-laden water causing pollution of waterways	Regular monitoring Scheduled maintenance of pond liners Drain pond, inspect liner for defects and remediate embankment	Major storm events
Leewood, and Tintsfield brine and produced water ponds	Bush fire	Natural occurring bushfire burning surrounding vegetation and materials	Medium	Flora and fauna loss. Damage to infrastructure Loss of life	Severe weather warnings to be communicated to site staff Have fire breaks located throughout the site	Storm events/lightning
Leewood, and Tintsfield brine and produced water ponds	Man-made fire	Fire caused directly or indirectly by site activities	Medium	Flora and fauna loss Damage to infrastructure Loss of life	Training for staff to prevent accidental ignition, have fire breaks and located throughout the Site	Improper fuel refuelling/storage Storm events

4.3 Inventory of pollutants

A number of potential pollutants are stored, used, treated and disposed of at the various operational sites. These include product, fuels, chemicals, oils, lubricants, wastewater, sewerage water, sediment-laden storm water and waste materials. All dangerous goods and hazardous substances at each facility are recorded on ChemAlert and available for download.

Safety data sheets (SDS) for all hazardous chemicals are also available at each site that these are stored or used. A list of potential pollutants is detailed in Table 4.2.

Table 4.2 - Potential pollutants at Santos NSW operation facilities

Facility	Pollutant	Storage quantity
Wilga Park Power Station	Methane (uncontrolled discharge)	Not applicable
	Hazardous chemicals	Refer to ChemAlert for specific quantities
Narrabri Operation Centre	Hazardous chemicals	Refer to ChemAlert for specific quantities
Bibblewindi	Hazardous chemicals	Refer to ChemAlert for specific quantities
Produced water pipeline	Produced water	Not applicable
Leewood, and Tintsfield brine and produced water ponds	Brine water Produced water	Tintsfield Pond 1: Not currently operational Leewood Pond 1: Max operating level volume 346 ML Leewood Pond 2: Max operating level volume 364 ML
	Sediment-laden runoff	Not applicable
Leewood water and brine treatment plant (**WBTP**)	Hazardous chemicals	Refer to ChemAlert for specific quantities
Wells under construction	Methane (uncontrolled discharge)	Not applicable
	Hazardous chemicals	Refer to ChemAlert for specific quantities
	Sediment laden runoff	Not applicable
Operational wells	Methane (uncontrolled discharge)	Not applicable

4.4 Pre-emptive actions to minimise risks

The following general pre-emptive actions are undertaken by Santos for its NSW operations in order to minimise risks to human health and/or the environment:

- provision, training and use of spill containment kits and fire extinguishers;
- installation of alarms on key infrastructure;
- bunding of bulk chemical, fuel, oil and lubricant storage containers including the installation of safety showers and eye-wash facilities;
- isolation valves on well infrastructure;
- regular and routine condition assessments of key infrastructure, based on preventative maintenance regimes, and integrity and reliability management documentation;
- regular and routine environmental inspections across the sites; and
- internal and external audits assessing environmental compliance of the site.

4.5 Safety equipment at facilities

Safety equipment available at the various NSW operational facilities and construction sites are listed in Table 4.3.

Table 4.3 - Safety equipment at Santos NSW facilities

Facility	Item
Wilga Park	Dry chemical portable fire extinguishers throughout the building
Wilga Park	Dry chemical portable fire extinguishers (50kg)
Wilga Park	Portable gas detectors
Wilga Park	Mobile firefighting trailer
Wilga Park	First aid equipment in the kitchen and workshop
Wilga Park	Plant fire detection and alarm
Wilga Park	Vehicle mounted UHF and VHF radio
Wilga Park	First aid kit (vehicle units)
Wilga Park	Portable handheld fire extinguisher
Bibblewindi	Dry chemical portable fire extinguishers throughout the building
Bibblewindi	Dry chemical portable fire extinguishers (50kg)
Bibblewindi	Portable gas detectors
Bibblewindi	Mobile firefighting trailer
Bibblewindi	First aid equipment in the kitchen and workshop

Facility	Item
Bibblewindi	Plant fire detection and alarm
Bibblewindi	Vehicle mounted UHF and VHF radio
Bibblewindi	First aid kit (vehicle units)
Bibblewindi	Portable handheld fire extinguisher
Leewood	First aid kit, safety shower and eye-wash
Leewood	Dry chemical portable fire extinguishers throughout the building
Leewood	Dry chemical portable fire extinguishers (50kg)
Leewood	Water portable fire extinguishers
Leewood	Vehicle mounted UHF and VHF radio and base station
Leewood	Portable Gas detectors
Leewood	Mobile firefighting trailer
Leewood	First aid kit (vehicle units)
Narrabri Operation Centre	Dry chemical portable fire extinguishers throughout the building
Narrabri Operation Centre	Dry chemical portable fire extinguishers (50kg)
Narrabri Operation Centre	Portable Gas detectors
Narrabri Operation Centre	Mobile firefighting trailer
Narrabri Operation Centre	First aid equipment in the kitchen and workshop, including a defibrillator
Narrabri Operation Centre	Plant fire detection and alarm
Wells under construction	First aid kit
Wells under construction	Trauma first aid pack
Wells under construction	Handheld fire extinguishers (9 kg Dry power and 2 kg dry powder)
Wells under construction	Portable gas detector
Wells under construction	Spill kits
At each active pilot set	Mobile firefighting trailer

5. Review, audit and revision

5.1 Annual monitoring of performance

In accordance with CoC D8, by the end of March each year, Santos will submit an Annual Review of the environmental performance of the Project to DPIE. This review will evaluate and report on compliance with the performance measures, criteria and operating conditions of SSD 6456 and to ensure that all implementation is consistent with all relevant management plans and procedures, including this PIRMP. Santos will identify potential non-compliances, analyse the causes of these potential non-compliances and describe the measures that will be implemented to ensure compliance in the future.

Santos also submits an Annual Return for EPL 20350 to NSW EPA as a condition of the EPL. The Annual Return includes details on the status of this PIRMP and when it was last tested.

5.2 Independent environmental audit

In accordance with CoC D9 and D10, within one year of commencement of Phase 1 and every three years thereafter, Santos will facilitate an independent environmental audit (IEA) to ensure compliance with the following:

- implementation consistent with the PIRMP;
- conditions of all relevant approvals, permits and licences;
- relevant State and Commonwealth legislation;
- management plans, protocols and procedures; and
- any annual compliance review obligations for the period.

The IEA will be led and conducted by a suitably qualified, experienced and independent team of experts whose appointment has been endorsed by the Planning Secretary, and be carried out in consultation with the relevant agencies, the Community Consultative Committee (**CCC**) and the various advisory groups.

Within 3 months of commencing an IEA, unless the Planning Secretary agrees otherwise, Santos will submit a copy of the IEA report to DPIE (and any other NSW agency that requests it) together with its response to any recommendations contained in the IEA report, and a timetable for the implementation of the recommendations.

5.3 Revision of the PIRMP

Consent condition D4 states that Santos must review the suitability of existing strategies, plans and programs required under this consent, within two months of:

(g) the submission of an incident report;
(h) the submission of an Annual Review;
(i) the submission of an Independent Environmental Audit;
(j) the submission of a Field Development Plan;
(k) the submission of a Groundwater Model Update; or
(l) the approval of any modification of the conditions of SSD 6456.

This is to ensure the PIRMP is updated on a regular basis and to incorporate any recommended measures to improve the environmental performance of the Project.

In view of the various conditions requiring annual reviews, suitability assessments and performance evaluations, it is recommended that this PIRMP be reviewed and, if necessary, updated in at least the following circumstances:

- in accordance with any direction from the NSW EPA or the Minister administering the PO Act;
- due to any significant change to the intent of the operations as covered under this document. If there is ambiguity in relation to whether there is a significant change, Santos must consult with the Secretary to determine whether the PIRMP must be reviewed; and
- otherwise at intervals of no longer than one year.

The review history table in the front of this Plan provides the details of each review, conducted in accordance with condition D4.

Consent condition D5 in turn states that if the review under condition D4 determines that the strategies, plans and programs required under this consent require revision - to either improve the environmental performance of the development, cater for a modification or comply with a direction - then Santos must submit the revised document to the Secretary for approval within 6 weeks of the review.

Note that consent condition B42 requires Santos to implement the Water Management Plan (which includes this PIRMP) once it has been approved by the Planning Secretary.

Further details on the reporting, evaluation and review of the PIRMP is provided in section 8 of the EMS.

6. Glossary

Term	Definition[3]
Council	Narrabri Shire Council
Department	NSW Department of Planning, Industry and Environment (DPIE)
EIS	The Environmental Impact Statement titled Narrabri Gas Project Environmental Impact Statement, dated 31 January 2017, submitted with the development application, including the response to submissions and supplementary response to submissions, and the additional information provided to the Department in support of the application
Gas compression facility	A facility that houses multiple compressor units, either nodal or hub compressors or a mixture of both used to increase the pressure of gas for the purpose of transmission; may be collocated with a gas treatment facility and/or water management facility
Gas field infrastructure	All Project-related infrastructure, excluding the Leewood facility, Bibblewindi facility and the road upgrades required under SSD 6456
Gas well	Pilot wells and production wells
Gathering lines	Pipelines used to transfer gas and produced water from wells
Incident	An occurrence or set of circumstances that causes or threatens to cause material harm and which may or may not be or cause a non-compliance
Linear infrastructure	Project related infrastructure of a linear nature including gas and water gathering lines, gas and water pipelines, access tracks, power lines, communication lines and other service lines
Major facilities	Leewood facility and Bibblewindi facility
Material harm	Material harm to the environment is defined in section 147 of the POEO Act
Minimise	Implement all reasonable and feasible mitigation measures to reduce the impacts of the Project
Mitigation	Activities associated with reducing the impacts of the development
Petroleum Assessment Lease 2 (PAL 2)	A PAL is required to hold the exclusive right to prospect for petroleum and to assess any petroleum deposit over a specified area of land in NSW. A lease allows the holder to maintain a title over a potential area, without having to commit to further exploration. The holder can, however, continue prospecting operations and to recover petroleum in the course of assessing the viability of commercial mining. PAL 2 is held by the following titleholders: • Santos NSW Pty Ltd; and • EnergyAustralia Narrabri Gas Pty Ltd.
Petroleum Exploration Licence 238 (PEL 238)	Before exploring for minerals or petroleum in NSW, an explorer must first obtain a Petroleum Exploration Licence (PEL) under the *Petroleum (Onshore) Act 1991*. An exploration licence gives the licence holder exclusive rights to explore for petroleum or specific minerals within a designated area but it does not permit mining, nor does it guarantee a mining or production lease will be granted. PEL 238 is held by the following titleholders: • Santos NSW Pty Ltd; and • EnergyAustralia Narrabri Gas Pty Ltd.

[3] The majority of the definitions are as provided in the consent for SSD 6456.

Term	Definition[3]
Petroleum Production Lease 3 (PPL 3)	A petroleum production lease gives the holder the exclusive right to extract petroleum within the production lease area during the term of the lease. PPL 3 is held by the following titleholders: • Santos QNT Pty Ltd; • Santos NSW (Hillgrove) Pty Ltd; • Santos NSW (Eastern) Pty Ltd; and • EnergyAustralia Narrabri Gas Pty Ltd.
Petroleum production lease application (PPLA)	A petroleum production lease gives the holder the exclusive right to extract petroleum within the production lease area during the term of the lease. Development consent under the *Environmental Planning and Assessment Act 1979* must be in place before a petroleum production lease can be granted. Santos, on behalf of its joint venture partner lodged four petroleum production lease applications under the PO Act in May 2014 for the Project area, being PPLAs 13, 14, 15 and 16. The ownership of the application is as follows: • Santos NSW Pty Ltd; and • EnergyAustralia Narrabri Gas Pty Ltd
Pilot well	A well for gas and water extraction, for the purpose of exploration, appraisal and assessment of the gas field potential
Planning Secretary	Planning Secretary under the EP&A Act, or nominee
Pollution incident	Has the same meaning as in the POEO Act
Produced water	Any form of groundwater that is actively extracted from a borehole, well or excavation, excluding incidental groundwater mixed with drilling fluids
Production well	A well for gas and water extraction, for the purpose of commercial gas production and/or use
Project area	The area of approximately 95,000 hectares that encompasses the Project
Project footprint	The area of surface expression being about 1,000 hectares occupied by the infrastructure components of the Narrabri Gas Project
Project-related infrastructure	All infrastructure and other structures associated with the development. This includes linear infrastructure and non-linear infrastructure, surface infrastructure and subsurface infrastructure, major facilities, wells and well pads and other gas field infrastructure
Public infrastructure	Linear and related infrastructure that provides services to the general public, such as roads, railways, water supply, drainage, sewerage, gas supply, electricity, telephone, telecommunications, etc.
Unacceptable risk	The level of risk at which mitigation actions are deemed to be warranted.
Well	Pilot wells and production wells
Well pad	An area of up to 1 hectare in size upon which the gas wells are to be located, with the area decreasing to no more than 0.25 hectares following rehabilitation[4], or other area as may be approved in the Field Development Plan

[4] Workover activities will be contained within the operational area of the well pad area of around 0.2 ha, with an additional laydown area that could be approximately 0.2 ha in size.

Appendix A - Emergency incident notification checklist

EMERGENCY INCIDENT NOTIFICATION CHECKLIST

NOTIFICATION		
Notification taken by:		**Date / time:**
Notification provided by		**Date / time:**
Dedicated phoneline to site?	**Yes / No**	**Phone number:**

INCIDENT DESCRIPTION	DETAILS
What has happened?	
Where did it happen?	
When did it happen?	
What is at risk	
Is everyone accounted for? **Are there casualties?**	
Have any external agencies been advised (police, ambulance, etc.)	
INCIDENT DESCRIPTION	**DETAILS**
Contained or escalating? **Potential to escalate?**	
What are your objectives? **What are you trying to prevent from happening?**	
What actions are being taken? **Is the area secured?**	
Who is taking the actions? **Who is responding?** **What resources are used?**	
ADDITIONAL SUPPORT	**DETAILS**
Personnel	
Resources	
Specialist equipment	

Appendix B - Emergency Situation Report

EMERGENCY SITUATION REPORT

INCIDENT LOCATION			
Reported By:	Contact No:	Date:	Time:

EMERGENCY TYPE: (circle)						
INJURY	FIRE	MEDICAL	ACCIDENT	SPILL	PIPELINE	POLLUTION RELEASE
FATALITY	BUSHFIRE	COLLISION	ENVIRONMENT	DISTURBANCE	EXPLOSION	OTHER:

Provide description: (indicate if situation is under control or escalating)

INJURY DETAILS: (for multiple injuries attach separate sheet/s)		
Number of fatalities:	Number of serious injuries:	Number of minor injuries:
Name of Injured:	Position:	
Injuries:	Location:	Date:

WEATHER CONDITIONS:				
DRY	Wind Direction:		Temperature:	
WET	Wind Speed:		Forecast:	

EXTERNAL ASSISTANCE: (circle)					
MEDICAL	FIRE	POLICE	AMBULANCE	EPA	MUTUAL AID

Other:

IMPACT ON OPERATIONS:

INFRASTRUCTURE DAMAGED:	OPERATIONS SHUT DOWN:

AREA/SITE AFFECTED:

RESPONSE FORWARD PLAN:
Next 30 minutes: Next 6 hours: Next 12 hours:

LAST EXTERNAL CONTACT

AGENCY	CONTACT NAME	TIME	BY WHOM	AGENCY	CONTACT NAME	TIME	BY WHOM
EOC				MEDICAL			
ERC				POLICE			
FIRE				EPA			

Nature of assistance or resources required:

Further remarks:

Prepared by:	Time:	Date:
Authorised by:	Time:	Date:

MARK ANY SPECULATIVE INFORMATION WITH AN ASTERISK (*) Completed SITREP to be retained at EOC – if requested – forward to DM/IMT

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			
Assessment Section	**Check if**		**Comments (if applicable)**
	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?	