

# Qualitative Tier 2 Assessment

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## Isotridecanol, ethoxylated

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 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

Isotridecanol, ethoxylated is a chemical in a workover product (AMC FS2000) used in hydraulic fracturing activities. The workover process is designed to remove any solids from the well and facilitate placement of the pump. As part of this process, fluids and some coal fines are removed from the well and transported to produced water ponds for management within the produced water stream. Once the well has been placed and commissioned, flowback and produced water is discharged into the water gathering pipelines and conveyed to the water ponds/water treatment facilities for treatment.

The purpose and maximum quantity for this chemical is summarized in **Table 1**. A safety data sheet (SDS) for the workover product is included as **Attachment 1**.

**Table 1 Initial and Underbalance Workover Fluid Chemicals**

Chemical Name	CAS No.	Use	Quantity <sup>1</sup>
Isotridecanol, ethoxylated-	69011-36-5	Activators, Emulsifiers and Neutralisers	NA

<sup>1</sup> Volume Percent in Treatment (%)

CAS No = Chemical Abstracts Service Number

NA = quantity used varies

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 isotridecanol, ethoxylated. The alcohol ethoxylates C<sub>12-13</sub>AE<sub>6.5</sub> and C<sub>14-15</sub>AE<sub>7</sub> were not carcinogenic to rats in a two-year dietary study. Thus, a cancer reference value was not derived 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)
Isotridecanol, ethoxylated (69011-36-5)	2-year dietary study in rats	Increased organ weight	50	100	0.5	1.8

Refer to **Attachment 2** for information on the key studies selected for oral reference dose and drinking water level development.

CAS = Chemical Abstracts Service

mg/kg-day = milligram per kilogram-day

mg/L = milligram per litre

NOAEL = No observed adverse effect level



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 rationale for PNECs that do not have a calculated PNEC.

**Table 3 PNECs Water – Tier 2 Chemicals**

Constituents	Endpoint	EC <sub>50</sub> or NOEC (mg/L)	Assessment Factor	PNEC <sub>water</sub> (mg/L)
Isotridecanol, ethoxylated (69011-36-5)	-	-	-	0.140 <sup>a</sup>

<sup>a</sup> PNEC<sub>water</sub> for isotridecanol, ethoxylated is the ANZG Water Quality Guideline – Freshwater Trigger Value for Alcohol Ethoxylates (AE).

EC<sub>50</sub> = 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 <sub>50</sub> or NOEC (mg/kg wet wt)	Assessment Factor	PNEC <sub>sed</sub> (mg/kg wet wt)
Isotridecanol, ethoxylated (69011-36-5)	<sup>a</sup>	-	-	0.71

<sup>a</sup> Calculated using equilibrium partitioning method

EC<sub>50</sub> = 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 <sub>50</sub> or NOEC (mg/kg dry wt)	Assessment Factor	PNEC <sub>soil</sub> (mg/kg dry wt)
Isotridecanol, ethoxylated (69011-36-5)	a	-	-	0.56

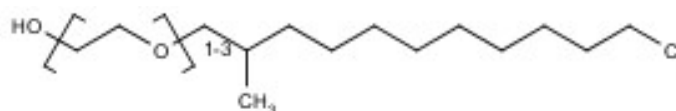
<sup>a</sup> Calculated using equilibrium partitioning method  
 EC<sub>50</sub> = effects concentration – 50%  
 mg/kg dry wt = milligram per kilogram dry weight  
 NOEC = no observable effects concentration  
 PNEC = predicted no effect concentration  
 Refer to **Attachment 2** for information on 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

Alcohol ethoxylates (AE) are a class of non-ionic surfactants that have the basic structure C<sub>x-y</sub>AE<sub>n</sub>. The subscript (x-y) following the ‘C’ indicates the range of carbon chain units. The hydrocarbon chain can be either linear or branched. AEs also contain an ethylene oxide (E) chain attached to the alcohol. The degree of ethylene oxide polymerisation is indicated by the subscript (n) which indicates the average number of ethylene oxide units. Isotridecanol, ethoxylated has an average number of 1 to 2.5 moles of ethylene oxide (EO) units.

Isotridecanol, ethoxylated is a substance of unknown or variable composition, complex reaction products or biological materials (UVCB). A representative molecular structure of an AE is presented in **Figure 1**.



**Figure 1 Representative Molecular Structure of Isotridecanol, ethoxylated<sup>1</sup>**

Isotridecanol, ethoxylated is readily biodegradable. It has a low potential for bioaccumulation and a moderate potential for absorption to soil and sediment.

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

<sup>1</sup> Source <https://echa.europa.eu/brief-profile/-/briefprofile/100.105.729>



## Human Health Hazards

The acute toxicity of isotridecanol, ethoxylates is low by the oral and dermal routes. The skin irritation rabbit studies on isotridecanol, ethoxylated and similar alcohol ethoxylates show that the degree of irritation depends on the testing conditions and length of the exposure period. Human patch studies on these alcohol ethoxylates do not support a skin irritant classification. Isotridecanol, ethoxylated with EO units of 1 to <2.5 are not irritating to the eyes of rabbits. Isotridecanol, ethoxylated is not a skin sensitiser.

Repeated dose toxicity studies on alcohol ethoxylates similar to isotridecanol, ethoxylates in rats do not indicate any target organ effects. These alcohol ethoxylates are not genotoxic or carcinogenic and have a low potential for reproductive and developmental toxicity.

A two-year dietary study in rats has been conducted on a similar alcohol ethoxylate (C<sub>12-13</sub>AE<sub>6.5</sub>) (HERA, 2009). The no observed adverse effects level (NOAEL) from this study is 50 milligrams per kilogram-day (mg/kg-day) based on increased organ weights. The NOAEL was used to derive the oral RfD and the drinking water guidance value (1.8 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 isotridecanol, ethoxylates, used during the hydraulic fracturing of wells includes the following general categories: transportation of chemicals; hydraulic fracturing activities; and, treatment, recycling, disposal and beneficial reuse. Without management controls in place, there is the potential for human receptors to be exposed to isotridecanol, ethoxylated in hydraulic fracturing workover chemicals during stimulation and completion operations and management of flowback and work-over fluids and during beneficial re-use. 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, injection and recovery of hydraulic fracturing and work-over fluids; recycling, reuse or disposal of recovered fluids including beneficial reuse activities such as land applications of drilling materials and dust suppression; and mitigating releases from the well lease to an adjacent water body.
2. Agricultural workers/residents at irrigation areas.

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.

Unlike drilling there are no large volumes of premixed stimulation fluid systems stored on-site. The primary fluid stored on-site is water, and chemicals are blended into the fluid stream as it is used. Exposure of workers to stimulation 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.

In the unlikely event of a release to ground at the well lease, 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 stimulation fluid chemicals are spilled to ground, then investigation, remediation and rehabilitation activities would be implemented to address soil impacts.

On-lease storage may utilize 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. Releases from the gathering pipeline would be of higher potential volumes, but the flow back or workover fluid concentrations from an individual well would be diluted with other waters from other wells also flowing in this gathering network.

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 ponded irrigation water or irrigated soil 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 run-off 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 stimulation and workover activities are considered 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

In standard aquatic toxicity tests, isotridecanol, ethoxylated is of moderate toxicity concern to aquatic organisms. Acute toxicity towards fish, aquatic invertebrates and algae is of the same order of magnitude (ECHA).

Isotridecanol, ethoxylated is biodegradable and does not persist in the environment. The chemical also has a low potential for bioaccumulation.

PNECs for isotridecanol, ethoxyland are provided in **Tables 3-5**. Isotridecanol, ethoxylated is an alcohol ethoxylate (AE). ANZG has established a water quality guideline (ANZG, 2018) with a freshwater trigger value of 0.14 mg/L for AE. This value was derived using data normalised to an alkyl chain length of C13.3 and EO of 8.2 using the statistical distribution method with 95% protection.

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 included in the dossier provided in **Attachment 2**.

During the hydraulic fracturing process, there is the potential for environmental receptors to be exposed to workover fluid chemicals such as isotridecanol, ethoxylated. 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:

- 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 hydraulic fracturing activities or loss of containment.
- 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.
- Aquatic flora and fauna within a proximal surface water body that has received runoff from an accidental release during hydraulic fracturing activities or loss of containment, or from beneficial reuse applications.
- 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 hydraulic fracturing 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 also low.

## References

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

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

ECHA. ECHA REACH database: <https://echa.europa.eu/information-on-chemicals/registered-substances>

Human and Environmental Risk Assessment (HERA) on Ingredients of Household Cleaning Products: Alcohol Ethoxylates. (2009). <http://www.heraproject.com>.

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



# AMC FS2000

## AMC

Chemwatch: 25-1951

Version No: 4.1.1.1

Safety Data Sheet according to WHS and ADG requirements

Chemwatch Hazard Alert Code: 0

Issue Date: 12/16/2015

Print Date: 12/08/2017

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### SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

#### Product Identifier

Product name	AMC FS2000
Other means of identification	Not Available

#### Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Drilling additive.
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#### Details of the supplier of the safety data sheet

Registered company name	AMC
Address	216 Balcatta Rd Balcatta WA 6021 Australia
Telephone	+61 8 9445 4000
Fax	+61 8 9445 4040
Website	www.amcmud.com
Email	amc@imdexlimited.com

#### Emergency telephone number

Association / Organisation	Not Available
Emergency telephone numbers	1800 039 008 or +61 3 9573 3112,+800 2436 2255 +613 9573 3112
Other emergency telephone numbers	Not Available

### SECTION 2 HAZARDS IDENTIFICATION

#### Classification of the substance or mixture

**NON-HAZARDOUS CHEMICAL. NON-DANGEROUS GOODS. According to the WHS Regulations and the ADG Code.**

#### CHEMWATCH HAZARD RATINGS

	Min	Max
Flammability	0	
Toxicity	0	
Body Contact	0	
Reactivity	0	
Chronic	0	

0 = Minimum  
1 = Low  
2 = Moderate  
3 = High  
4 = Extreme

Poisons Schedule	Not Applicable
Classification	Not Applicable

#### Label elements

Hazard pictogram(s)	Not Applicable
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SIGNAL WORD

NOT APPLICABLE

**Hazard statement(s)**

Not Applicable

**Precautionary statement(s) Prevention**

Not Applicable

**Precautionary statement(s) Response**

Not Applicable

**Precautionary statement(s) Storage**

Not Applicable

**Precautionary statement(s) Disposal**

Not Applicable

**SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS****Substances**

See section below for composition of Mixtures

**Mixtures**

CAS No	%[weight]	Name
Not Available	30-60	carrier fluid
Not Available	30-60	anionic water soluble polymer
	balance	activators, emulsifiers and neutralisers

**SECTION 4 FIRST AID MEASURES****Description of first aid measures**

<b>Eye Contact</b>	<p>If this product comes in contact with eyes:</p> <ul style="list-style-type: none"> <li>▶ Wash out immediately with water.</li> <li>▶ If irritation continues, seek medical attention.</li> <li>▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul>
<b>Skin Contact</b>	<p>If skin or hair contact occurs:</p> <ul style="list-style-type: none"> <li>▶ Flush skin and hair with running water (and soap if available).</li> <li>▶ Seek medical attention in event of irritation.</li> </ul>
<b>Inhalation</b>	<ul style="list-style-type: none"> <li>▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area.</li> <li>▶ Other measures are usually unnecessary.</li> </ul>
<b>Ingestion</b>	<ul style="list-style-type: none"> <li>▶ Immediately give a glass of water.</li> <li>▶ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.</li> </ul>

**Indication of any immediate medical attention and special treatment needed**

Treat symptomatically.

**SECTION 5 FIREFIGHTING MEASURES****Extinguishing media**

- ▶ There is no restriction on the type of extinguisher which may be used.
- ▶ Use extinguishing media suitable for surrounding area.

**Special hazards arising from the substrate or mixture**

<b>Fire Incompatibility</b>	None known.
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**Advice for firefighters**

<b>Fire Fighting</b>	<ul style="list-style-type: none"> <li>▶ Use water delivered as a fine spray to control fire and cool adjacent area.</li> <li>▶ <b>Do not</b> approach containers suspected to be hot.</li> </ul>
<b>Fire/Explosion Hazard</b>	<ul style="list-style-type: none"> <li>▶ Non combustible.</li> <li>▶ Not considered a significant fire risk, however containers may burn.</li> </ul>
<b>HAZCHEM</b>	Not Applicable

## SECTION 6 ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures

See section 8

### Environmental precautions

See section 12

### Methods and material for containment and cleaning up

<b>Minor Spills</b>	<ul style="list-style-type: none"> <li>▶ Clean up all spills immediately.</li> <li>▶ Avoid breathing vapours and contact with skin and eyes.</li> </ul>
<b>Major Spills</b>	Very slippery when spilled. Do not use water initially, apply absorbent material such as sand, earth, sawdust or vermiculite then shovel into suitable container for removal. Then use large amounts of water to remove traces of the material [AMC]

Personal Protective Equipment advice is contained in Section 8 of the SDS.

## SECTION 7 HANDLING AND STORAGE

### Precautions for safe handling

<b>Safe handling</b>	<ul style="list-style-type: none"> <li>▶ Limit all unnecessary personal contact.</li> <li>▶ Wear protective clothing when risk of exposure occurs.</li> </ul>
<b>Other information</b>	<ul style="list-style-type: none"> <li>▶ Store in original containers.</li> <li>▶ Keep containers securely sealed.</li> </ul>

### Conditions for safe storage, including any incompatibilities

<b>Suitable container</b>	20 kg plastic drums.
<b>Storage incompatibility</b>	Avoid contamination of water, foodstuffs, feed or seed.

## SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control parameters

#### OCCUPATIONAL EXPOSURE LIMITS (OEL)

#### INGREDIENT DATA

Not Available


#### EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
AMC FS2000	Not Available	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
carrier fluid	Not Available	Not Available
anionic water soluble polymer	Not Available	Not Available

#### MATERIAL DATA

### Exposure controls

<b>Appropriate engineering controls</b>	Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.
<b>Personal protection</b>	
<b>Eye and face protection</b>	<ul style="list-style-type: none"> <li>▶ Safety glasses with side shields</li> <li>▶ Chemical goggles.</li> <li>▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants.</li> </ul>
<b>Skin protection</b>	See Hand protection below

<b>Hands/feet protection</b>	Wear general protective gloves, eg. light weight rubber gloves. The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
<b>Body protection</b>	See Other protection below
<b>Other protection</b>	No special equipment needed when handling small quantities. <b>OTHERWISE:</b> ▶ Overalls.
<b>Thermal hazards</b>	Not Available

## SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

<b>Appearance</b>	Milky viscous liquid with a mild solvent odour, dispersible in water.		
<b>Physical state</b>	Liquid	<b>Relative density (Water = 1)</b>	1.0-1.1
<b>Odour</b>	Not Available	<b>Partition coefficient n-octanol / water</b>	Not Available
<b>Odour threshold</b>	Not Available	<b>Auto-ignition temperature (°C)</b>	Not Applicable
<b>pH (as supplied)</b>	6.0-8.0	<b>Decomposition temperature</b>	Not Available
<b>Melting point / freezing point (°C)</b>	Not Available	<b>Viscosity (cSt)</b>	Not Available
<b>Initial boiling point and boiling range (°C)</b>	Not Available	<b>Molecular weight (g/mol)</b>	Not Applicable
<b>Flash point (°C)</b>	Not Applicable	<b>Taste</b>	Not Available
<b>Evaporation rate</b>	Not Available	<b>Explosive properties</b>	Not Available
<b>Flammability</b>	Not Applicable	<b>Oxidising properties</b>	Not Available
<b>Upper Explosive Limit (%)</b>	Not Applicable	<b>Surface Tension (dyn/cm or mN/m)</b>	Not Available
<b>Lower Explosive Limit (%)</b>	Not Applicable	<b>Volatile Component (%vol)</b>	Not Available
<b>Vapour pressure (kPa)</b>	Not Available	<b>Gas group</b>	Not Available
<b>Solubility in water (g/L)</b>	Partly miscible	<b>pH as a solution (1%)</b>	Not Available
<b>Vapour density (Air = 1)</b>	Not Available	<b>VOC g/L</b>	Not Available

## SECTION 10 STABILITY AND REACTIVITY

<b>Reactivity</b>	See section 7
<b>Chemical stability</b>	Product is considered stable and hazardous polymerisation will not occur.
<b>Possibility of hazardous reactions</b>	See section 7
<b>Conditions to avoid</b>	See section 7
<b>Incompatible materials</b>	See section 7
<b>Hazardous decomposition products</b>	See section 5

## SECTION 11 TOXICOLOGICAL INFORMATION

### Information on toxicological effects

<b>Inhaled</b>	The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
<b>Ingestion</b>	The material has <b>NOT</b> been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence.

<b>Skin Contact</b>	The liquid may be miscible with fats or oils and may degrease the skin, producing a skin reaction described as non-allergic contact dermatitis. The material is unlikely to produce an irritant dermatitis as described in EC Directives .	
<b>Eye</b>	Although the liquid is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).	
<b>Chronic</b>	Long-term exposure to the product is not thought to produce chronic effects adverse to health (as classified by EC Directives using animal models); nevertheless exposure by all routes should be minimised as a matter of course.	
<b>AMC FS2000</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	Not Available	Not Available
<b>Legend:</b>	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances	

<b>Acute Toxicity</b>	☉	<b>Carcinogenicity</b>	☉
<b>Skin Irritation/Corrosion</b>	☉	<b>Reproductivity</b>	☉
<b>Serious Eye Damage/Irritation</b>	☉	<b>STOT - Single Exposure</b>	☉
<b>Respiratory or Skin sensitisation</b>	☉	<b>STOT - Repeated Exposure</b>	☉
<b>Mutagenicity</b>	☉	<b>Aspiration Hazard</b>	☉

**Legend:** ✘ – Data available but does not fill the criteria for classification  
✔ – Data available to make classification  
☉ – Data Not Available to make classification

## SECTION 12 ECOLOGICAL INFORMATION

### Toxicity

<b>AMC FS2000</b>	<b>ENDPOINT</b>	<b>TEST DURATION (HR)</b>	<b>SPECIES</b>	<b>VALUE</b>	<b>SOURCE</b>
	Not Available	Not Available	Not Available	Not Available	Not Available
<b>Legend:</b>	Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data				

- Fish : LC50/Danio rerio /96 hours gt; 100 mg/L (OECD 203) (Based on the toxicity of the components using the Conventional Method.)]- Daphnids : EC50/Daphnia magna /48 hours gt; 100 mg/L (OECD 202) (Based on the toxicity of the components using the Conventional Method.)]- Algae : IC50/Scenedesmus subspicatus /72 hours gt; 100 mg/L (OECD 201) (Based on the toxicity of the components using the Conventional Method.)]- Hydrolysis: Does not hydrolyse.]- Biodegradation: Not readily biodegradable.]- [AMC]  
May be harmful to fauna if not disposed of according to Section 13 and legislative requirements. [AMC]

### Persistence and degradability

<b>Ingredient</b>	<b>Persistence: Water/Soil</b>	<b>Persistence: Air</b>
	No Data available for all ingredients	No Data available for all ingredients

### Bioaccumulative potential

<b>Ingredient</b>	<b>Bioaccumulation</b>
	No Data available for all ingredients

### Mobility in soil

<b>Ingredient</b>	<b>Mobility</b>
	No Data available for all ingredients

## SECTION 13 DISPOSAL CONSIDERATIONS

**Waste treatment methods**

<b>Product / Packaging disposal</b>	Product and packaging must be disposed of in accordance with local regulations. Clean packaging material should be subjected to waste disposal schemes (recycling/reuse etc) according to local legislation. [[AMC]
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**SECTION 14 TRANSPORT INFORMATION****Labels Required**

<b>Marine Pollutant</b>	NO
<b>HAZCHEM</b>	Not Applicable

**Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS****Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS****Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS****Transport in bulk according to Annex II of MARPOL and the IBC code**

Not Applicable

**SECTION 15 REGULATORY INFORMATION****Safety, health and environmental regulations / legislation specific for the substance or mixture**

National Inventory	Status
Australia - AICS	Y
Canada - DSL	Y
Canada - NDSL	Y
China - IECSC	Y
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	Y
Korea - KECI	Y
New Zealand - NZIoC	Y
Philippines - PICCS	Y
USA - TSCA	Y
<b>Legend:</b>	Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)

**SECTION 16 OTHER INFORMATION****Other information**

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings.

**Definitions and abbreviations**

PC—TWA: Permissible Concentration-Time Weighted Average  
 PC—STEL: Permissible Concentration-Short Term Exposure Limit  
 IARC: International Agency for Research on Cancer  
 ACGIH: American Conference of Governmental Industrial Hygienists  
 STEL: Short Term Exposure Limit  
 TEEL: Temporary Emergency Exposure Limit.  
 IDLH: Immediately Dangerous to Life or Health Concentrations  
 OSF: Odour Safety Factor  
 NOAEL :No Observed Adverse Effect Level  
 LOAEL: Lowest Observed Adverse Effect Level  
 TLV: Threshold Limit Value  
 LOD: Limit Of Detection  
 OTV: Odour Threshold Value  
 BCF: BioConcentration Factors

BEI: Biological Exposure Index

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## Attachment 2 Risk Assessment Dossier

## ETHOXYLATED BRANCHED C13 ALCOHOL [ISOTRIDEKANOL, ETHOXYLATED]

This dossier on isotridecanol, ethoxylated presents the most critical studies pertinent to the risk assessment of isotridecanol, ethoxylated in its use in hydraulic fracturing fluids. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained primarily from the Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Alcohol Ethoxylates (HERA, 2009). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

Screening Assessment Conclusion – Isotridecanol, ethoxylated was not identified in chemical databases used by NICNAS as an indicator that the chemical is of concern and is not a PBT substance. Isotridecanol, ethoxylated was assessed as a tier 2 chemical for acute and chronic toxicity. Therefore, this substance is classified overall as a **tier 2** chemical and requires a hazard assessment and qualitative assessment of risk.

### 1 BACKGROUND

Alcohol ethoxylates (AE) are a very widely used class of non-ionic surfactants. Significant quantities of AE are converted to alcohol ethoxysulphates (AES) with the remaining AE used primarily in household laundry detergents. AE have many desirable characteristics such as rapid biodegradation, low to moderate foaming ability, superior cleaning of man-made fibres and tolerance of water hardness. AE are also used in lesser quantities in household cleaners, institutional and industrial cleaners, cosmetics, agriculture and in textile, paper, oil and other process industries.

Isotridecanol, ethoxylated is readily biodegradable. It has a low potential for bioaccumulation and a moderate potential for adsorption to soil and sediment.

The acute toxicity of isotridecanol, ethoxylates is low by the oral and dermal routes. The skin irritation rabbit studies on isotridecanol, ethoxylated and similar alcohol ethoxylates show that the degree of irritation depends on the testing conditions and length of the exposure period. Human patch studies on these alcohol ethoxylates do not support a skin irritant classification. Isotridecanol, ethoxylated with EO units of 1 to <2.5 are not irritating to the eyes of rabbits. Isotridecanol, ethoxylated is not a skin sensitiser. Repeated dose toxicity studies on alcohol ethoxylates similar to isotridecanol, ethoxylates in rats do not indicate any target organ effects. These alcohol ethoxylates are not genotoxic, carcinogenic and have a low potential for reproductive and developmental toxicity. Isotridecanol, ethoxylated has moderate chronic toxicity concern to aquatic life.

### 2 CHEMICAL NAME AND IDENTIFICATION

**Chemical Name (IUPAC):** Isotridecanol, ethoxylated

**CAS RN:** 69011-36-5

**Molecular formula:** Not available (UVCB substance)

**Molecular weight:** Not available (UVCB substance)

**Synonyms:** Isotridecanol, ethoxylated; C13 ethoxylated alcohol; Alcohol C13 ethoxylated; ethoxylated branched C13 alcohol

### 3 PHYSICO-CHEMICAL PROPERTIES

Alcohol ethoxylates (AE) are a class of non-ionic surfactants that have the basic structure  $C_{x-y}AE_n$ . The subscript (x-y) following the 'C' indicates the range of carbon chain units. The hydrocarbon chain can be either linear or branched. AEs also contain an ethylene oxide (E) chain attached to the alcohol. The degree of ethylene oxide polymerisation is indicated by the subscript (n) which indicates the average number of ethylene oxide units. Isotridecanol, ethoxylated (CAS No. 69011-36-5) has an average number of 1 to 2.5 moles of ethylene oxide units.

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

**Table 1 Overview of the Physico-chemical Properties of Isotridecanol, ethoxylated (1 to 2.5 moles ethoxylated)**

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Clear liquid with a rancid odour	2	ECHA
Melting Point	-11.6°C @ 101.3 kPa	1	ECHA
Boiling Point	>280°C @ 101.3 kPa	1	ECHA
Density	907 kg/m <sup>3</sup> @ 20°C	1	ECHA
Vapour Pressure	<5 Pa @ 20°C	2	ECHA
Partition coefficient (log K <sub>ow</sub> )	4.9* (calculated) @25°C	2	ECHA
Water Solubility	0.02-0.029 g/L @ 21°C	1	ECHA
Dissociation Constant (pKa)	Not applicable	-	ECHA
Viscosity	38.2 mm <sup>2</sup> /s (static) @ 20°C	1	ECHA

\*Weight-averaged log K<sub>oc</sub> of whole substance based on normalised composition.

### 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 other specific environmental regulatory controls or concerns were identified within Australia and internationally for isotridecanol, ethoxylated.

**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

Isotridecanol, ethoxylated is readily biodegradable. It has a low potential for bioaccumulation and a moderate potential for adsorption to soil and sediment.

### B. Partitioning

Abiotic degradation like hydrolysis and photolysis is not an important process in case of alcohol ethoxylates due to the chemical structure of these substances (ECHA).

### C. Biodegradation

Isotridecanol, ethoxylated is readily biodegradable. In an OECD 301B test, degradation was 75% in 28 days (ECHA) [KI. score = 2].

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

### D. Environmental Distribution

Using KOCWIN v2.00, the following calculated  $K_{oc}$  values were obtained: 441.7 for alcohol, C13, branched; 359.3 for alcohol ethoxylate, C13, branched, 1 EO; and 237.8 for alcohol ethoxylate, C13, branched, 3 EO (ECHA) [KI. Score = 2]. The average of the  $K_{oc}$  values for the C13 ethoxylated alcohols, which is 298.6 L/kg, will be used to calculate the PNEC values for sediment and soil.

If released to soil, the average  $K_{oc}$  values for the C13 ethoxylated alcohols indicate a moderate potential for both adsorption and mobility. If released to water, based on these  $K_{oc}$  values and slight solubility, this substance may have moderate adsorption to suspended solids or sediment.

### E. Bioaccumulation

The BCF values for alcohol ethoxylates in fathead minnows have been reported to range from <5 to 387.5 (Toll et al., 2000). The uptake rates varied from 330 to 1660 (L x kg/d) and elimination rates varied from 3.3 to 59 per day (Toll et al., 2000). The high concentrations in fish are thought to be prevented by an efficient biotransformation of the alcohol ethoxylates, leading to a high elimination rate. Thus, it can be stated that bioaccumulation of alcohol ethoxylates is regarded to be negligible as the surfactants will be rapidly metabolised (ECHA).

## 6 HUMAN HEALTH HAZARD ASSESSMENT

### A. Summary

The acute toxicity of isotridecanol, ethoxylates is low by the oral and dermal routes. The skin irritation rabbit studies on isotridecanol, ethoxylated and similar alcohol ethoxylates show that the degree of irritation depends on the testing conditions and length of the exposure period. Human patch studies on these alcohol ethoxylates do not support a skin irritant classification. Isotridecanol, ethoxylated with EO units of 1 to <2.5 are not irritating to the eyes of rabbits. Isotridecanol,

ethoxylated is not a skin sensitiser. Repeated dose toxicity studies on alcohol ethoxylates similar to isotridecanol, ethoxylates in rats do not indicate any target organ effects. These alcohol ethoxylates are not genotoxic, carcinogenic and have a low potential for reproductive and developmental toxicity.

## B. Acute Toxicity

The oral LD<sub>50</sub> in rats for C<sub>12-13</sub>AE<sub>6.5</sub> is 2,100 mg/kg (HERA, 2009) [Kl. score = 2]. The oral LD<sub>50</sub> in rats for C<sub>12-15</sub>AE<sub>7</sub> is 1,700 mg/kg (HERA, 2009) [Kl. score = 2].

An OECD Guideline 403 (Acute Inhalation Toxicity) study was conducted using Sprague Dawley rats exposed to 1600 mg/m<sup>3</sup> over a four hour period. The LC<sub>50</sub> for this test was determined to be > 1 600 mg/m<sup>3</sup> (ECHA)[Kl Score = 2].

An acute dermal LD<sub>50</sub> values of >2,000 mg/kg were determined for C<sub>12-14</sub>AE<sub>3</sub> and C<sub>12-14</sub>AE<sub>6</sub> in two separate studies (HERA, 2009) [Kl. score = 2]. The acute dermal LD<sub>50</sub> of C<sub>12-15</sub>AE<sub>7</sub> is >2,000 mg/kg (HERA, 2009) [Kl. score = 2].

## C. Irritation

### Skin

Application of 0.5 mL isotridecanol, ethoxylated (3 EO) to the skin of rabbits for 4 hours under occlusive conditions was considered irritating (ECHA) [Kl. score = 2].

Application of 0.5 mL isotridecanol, branched, ethoxylated (3-4 EO) to the skin of rabbits for 24 hours under occlusive conditions was considered irritating (ECHA) [Kl. score = 2].

Application of 0.5 mL isotridecanol, ethoxylated (3 EO) to the skin of rabbits for 4 hours under semi-occlusive conditions was not considered irritating (ECHA) [Kl. score = 2].

Application of 0.5 mL C<sub>12-13</sub>AE<sub><2.5</sub> (CAS No. 66455-14-9) to the skin of rabbits for 24 hours under occlusive conditions was considered irritating (ECHA) [Kl. score = 2].

Application of 0.5 mL alcohols C12-13, branched and linear, <2.5 EO to the skin of rabbits for 4 hours under occlusive conditions was not considered irritating (ECHA) [Kl. score = 2].

In a 24-hour human patch test, there was some short-lived redness in some individuals from the application of C<sub>12-14</sub>AE<sub>3</sub>, but there was no scaling or oedema in any subjects (HERA, 2009) [Kl. score = 2].

In a standard 4-hour human patch test, the irritation potential of C<sub>12-15</sub>AE<sub>5</sub> and C<sub>12-15</sub>AE<sub>5</sub> were compared to 20% sodium dodecyl sulfate (which is classified a skin irritant under GHS). The results showed that neither alcohol ethoxylate should be classified as a skin irritant (Basketter et al., 2004) [Kl. score = 2].

## Eye

Instillation of 0.1 mL isotridecanol, ethoxylated (3 EO) (CAS No. 69011-36-5) into the eyes of rabbits was severely irritating. The means of the 24, 48 and 72-hour scores were: 1.6 for corneal opacity; 0.6 for iridial lesions; 2.2 for conjunctival redness; and 0.7 for chemosis. The effects were not fully reversible within 21 days (ECHA) [Kl. score = 2].

Instillation of 0.1 mL isotridecanol, branched, ethoxylated (3-4 EO) (CAS No. 24938-91-8) into the eyes of rabbits was severely irritating. The means of the 24, 48, and 72-hour scores were: 1.0 for corneal opacity; 0.1 for iridial lesions; 1.7 for conjunctival redness; and 0.6 for chemosis. The effects were not fully reversible within 8 days (ECHA) [Kl. score = 2].

Instillation of 0.1 mL alcohols C12-13, branched and linear, <2.5 EO (CAS No. 160901-19-9) into the eyes of rabbits was not irritating. The means of the 24, 48, and 72-hour scores were: 0.00 for corneal opacity; 0.00 for iridial lesions; 0.83 for conjunctival redness; and 0.50 for chemosis (ECHA) [Kl. score = 2].

Instillation of 0.1 mL C<sub>12-13</sub>AE<2.5 (CAS No. 66455-14-9) into the eyes of rabbits was not irritating. The mean of the 24, 48, and 72-hour scores were: 0.00 for all endpoints (ECHA) [Kl. score = 2].

### **D. Sensitisation**

No sensitisation studies are available on isotridecanol, ethoxylated.

In a guinea pig maximisation test, C<sub>12-13</sub>AE<2.5 (CAS No. 66455-14-9) was not considered a skin sensitiser (ECHA) [Kl. score = 2].

### **E. Repeated Dose Toxicity**

#### Oral

No repeated dose toxicity studies are available on isotridecanol, ethoxylated.

Rats were given in their diet 0%, 0.0313%, 0.0625%, 0.125%, 0.25%, 0.5% or 1.0% C<sub>12-15</sub>AE<sub>7</sub> for 90 days. The animals in the ≥0.25% groups showed significantly reduced body weight gain, which was associated with marked decreases in food and water consumption. Relative liver weights were significantly increased in the ≥0.5% male rats and ≥0.25% females. Histopathologic examination showed hepatocytic enlargement in the ≥0.125% groups, suggesting increased liver metabolism on the basis of increased alkaline phosphatase activity at the higher dose levels. The NOAEL was established at 0.0625% in the diet or 102 mg/kg-day (HERA, 2009) [Kl. score = 2].

Rats were fed C<sub>12-14</sub>AE<sub>7</sub> in the diet at concentrations of 0%, 0.0313%, 0.0625%, 0.125%, 0.25%, 0.5% and 1.0% for 90 days. The animals in the ≥0.25% groups showed significantly reduced body weight gain, which was associated with marked decreases in food and water consumption. Relative liver weights were significantly increased in the ≥0.5% male rats and ≥0.25% females. Histopathologic examination showed hepatocytic enlargement in the ≥0.125% groups, suggesting increased liver metabolism on the basis of increased alkaline phosphatase activity at the higher dose levels. The NOAEL was established at 0.0625% in the diet or 110 mg/kg-day (HERA, 2009) [Kl. score = 2].

Rats were given in their diet 0%, 0.1%, 0.5% or 1% C<sub>12-13</sub>AE<sub>6.5</sub> for two years. Body weight gain was reduced in the 1% males and  $\geq 0.5\%$  females, which was likely due to the reduced food consumption in these animals. At study termination, organ to body weight ratios were increased in the  $\geq 0.5\%$  females (liver, kidney and brain), 1% females (heart), and 1% males (liver). A dose-related focal myocarditis was observed in males. While focal myocarditis is commonly observed in non-treated aging rats, the incidence in the treated animals were higher than in the controls. The NOAEL was established at 0.1% or 50 mg/kg-day (HERA, 2009) [Kl. score = 2].

#### Inhalation

No studies are available.

#### Dermal

No adequate studies are available.

### F. Genotoxicity

#### In Vitro Studies

The genotoxicity studies conducted on alcohol ethoxylates are reviewed in HERA (2009). The results of few of the *in vitro* studies on similar alcohol ethoxylates to isotridecanol, ethoxylated are presented in Table 3.

**Table 3 In Vitro Genotoxicity Studies on Selected Alcohol Ethoxylates**

Test Substance	Test System	Results*		Klimisch Score	References
		-S9	+S9		
C <sub>14-15</sub> AE <sub>7</sub>	Bacterial reverse mutation ( <i>S. typhimurium</i> strains)	-	-	2	HERA, 2009
C <sub>14-15</sub> AE <sub>7</sub>	Bacterial reverse mutation ( <i>S. typhimurium</i> strains)	-	-	2	HERA, 2009
C <sub>14</sub> AE <sub>12</sub>	Chromosomal aberrations (CHO cells)	-	-	2	HERA, 2009

\*+, positive; -, negative

#### In Vivo Studies

In two separate studies, CD-1 mice were given an intraperitoneal dose of 0, 50, or 100 mg/kg C<sub>12-15</sub>AE<sub>3</sub> or C<sub>12-14</sub>AE<sub>9</sub>. There were no increases in the frequency of micronuclei in the bone marrow cells (Talmage, 1994) [Kl. score = 2].

Male and female Tunstall rats were given a single oral gavage dose of 0, 250, 500, or 1,000 mg/kg C<sub>14-15</sub>AE<sub>7</sub>. There were no increases in chromosomal aberrations in the bone marrow cells (HERA, 2009) [Kl. score = 2].

## G. Carcinogenicity

No studies are available on isotridecanol, ethoxylated.

Male and female Sprague-Dawley rats were given in their diet C<sub>12-13</sub>AE<sub>6.5</sub> in the diet at doses up to 1% (500 mg/kg-day). Reduced food consumption was noted at the higher dose levels (*i.e.*, 0.5% and 1% for females and 1% for males), resulting in a lower body weight gain compared to the control group. No treatment-related histopathology was found and no increase in tumour incidence was observed (HERA, 2009) [Kl. score = 2].

Male and female Charles River rats were given in their diet 0, 0.1, 0.5 or 1% C<sub>14-15</sub>AE<sub>7</sub> for two years. There were no treatment-related changes in general behaviour and appearance. The survival rate of the test animals was comparable if not better than the controls. Body weights of the 0.5% females and the 1% males and females had significantly lower weight gains than the control. There were no treatment-related effects on organ weights and tumour incidence (HERA, 2009) [Kl. score = 2]

Male and female Sprague-Dawley rats were given in their diet C<sub>14-15</sub>AE<sub>7</sub> at 0.1%, 0.5% and 1% for two years. A treatment-related body weight depression was observed in females at the two highest treatment levels and in males at the 1% dose level, probably due to the poor palatability of the diet. There was no evidence for any carcinogenic activity (HERA, 2009) [Kl. score = 2].

## H. Reproductive Toxicity

No studies are available on isotridecanol, ethoxylated.

CD rats were given in their diet 0%, 0.05%, 0.1% or 0.5% (approximately 0, 25, 50 or 250 mg/kg-day) C<sub>12</sub>AE<sub>6</sub> in a two-generation reproductive toxicity study. There were no treatment related effects in the parents or pups on general behaviour, appearance or survival. At 0.5%, there was reduced weight gain in both the parental animals and the pups compared to the controls. Fertility was unaffected by treatment. The NOAEL for reproductive toxicity is 0.5% in the diet, which corresponds to 250 mg/kg-day (HERA, 2009) [Kl. score = 2].

In a two-generation developmental and teratogenicity study, CD rats were given in their diet 0%, 0.05%, 0.1% or 0.5% C<sub>14-15</sub>AE<sub>7</sub> (approximately 0, 25, 50 or 250 mg/kg-day). Three of the treated groups were given the test substance continuously throughout the study; in the other three groups the females received the test substance on GD 6-15 and the males were untreated. None of the deaths of parental rats during the study was considered to be compound-related. There were no treatment-related changes in behaviour or appearance in the parental rats or pups. Slightly lower body weight gain was noted in the 0.5% continuously treated females. Food consumption was similar for control and treated rats. Fertility, gestation and viability indices were similar across groups. The average 21-day body weights for the 0.5% continuous treated pups were significantly lower than that of the control. Relative liver weights of the 0.5% continuously treated F<sub>1</sub> parental animals were increased at the 91-day sacrifice; relative liver weights of the 0.5% continuously treated males were also increased at the 60-day and caesarean section sacrifices. There were no treatment-related histopathological lesions in any of the tissues from the F<sub>0</sub> and F<sub>1</sub> generations. The NOAEL for reproductive toxicity is 0.5% in the diet or 250 mg/kg-day (HERA, 2009) [Kl. score = 2].



## I. Developmental Toxicity

No studies are available on isotridecanol, ethoxylated.

In a two-generation reproductive toxicity study, Charles River rats were given in their diet 0, 0.05, 0.1 or 0.5% (about 0, 25, 50 or 250 mg/kg-day) C<sub>12</sub>AE<sub>6</sub>. General behaviour, appearance and survival were unaffected by treatment. At the 0.5% dose level, adults and pups gained less weight than the control rats. In the 0.5% dose group, there was a statistical increase in embryo lethality and soft tissue anomalies, and at the 0.1% there was a statistical decrease in mean foetal liver weight. Neither of these effects was considered to be treatment-related by the authors as they showed no dose response characteristics. The NOAEL for maternal toxicity is 50 mg/kg-day. The NOAEL for developmental and teratogenicity is 0.1% in the diet or 50 mg/kg-day (HERA, 2009) [KI. score = 2].

Pregnant rabbits were given by oral gavage 0, 50, 100 or 200 mg/kg C<sub>12</sub>AE<sub>6</sub> from gestational days 2 to 16. Nine control rabbits and 31 treated rabbits died during the study. Surviving rabbits at the 200 mg/kg dose group generally showed slight losses of body weight. At 100 and 200 mg/kg, ataxia and a slight decrease in body weight was observed in the pregnant animals. In seven treated and two control rabbits, early deliveries were recorded. There were no treatment-related effects on corpora lutea, implantations, number of live foetuses and spontaneous abortions. The NOAEL for maternal toxicity is 50 mg/kg-day; the NOAEL for developmental toxicity is 200 mg/kg-day (HERA, 2009) [KI. score = 2].

## J. Derivation of Toxicological Reference and Drinking Water Guidance Values

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

### Non-Cancer

#### Oral

A two-year dietary study in rats has been conducted on C<sub>12-13</sub>AE<sub>6.5</sub> (HERA, 2009). The NOAEL from this study is 50 mg/kg-day based on increased organ weights. The NOAEL of 50 mg/kg-day will be used to derive an oral reference dose and drinking water guidance value for isotridecanol, ethoxylated.

#### Oral Reference Dose (oral RfD)

$$\text{Oral RfD} = \text{NOAEL} / (\text{UF}_A \times \text{UF}_H \times \text{UF}_L \times \text{UF}_{\text{Sub}} \times \text{UF}_D)$$

Where:

UF<sub>A</sub> (interspecies variability) = 10

UF<sub>H</sub> (intraspecies variability) = 10

UF<sub>L</sub> (LOAEL to NOAEL) = 1

UF<sub>Sub</sub> (subchronic to chronic) = 1

UF<sub>D</sub> (database uncertainty) = 1

Oral RfD =  $50 / (10 \times 10 \times 1 \times 1 \times 1) = 50 / 100 = \underline{0.5 \text{ mg/kg-day}}$

Drinking water guidance value

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

Using the oral RfD,

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

Where:

Human weight = 70 kg (ADWG, 2011)

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

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

Drinking water guidance value =  $(0.5 \times 70 \times 0.1) / 2 = \underline{1.8 \text{ mg/L}}$

**Cancer**

The alcohol ethoxylates C<sub>12-13</sub>AE<sub>6.5</sub> and C<sub>14-15</sub>AE<sub>7</sub> were not carcinogenic to rats in a two-year dietary study. Thus, a cancer reference value was not derived.

**K. Human Health Hazard Assessment of Physico-Chemical Properties**

Isotridecanol, ethoxylated does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

**7 ENVIRONMENTAL EFFECTS SUMMARY**

**A. Summary**

Isotridecanol, ethoxylated has moderate chronic toxicity concern to aquatic life.

**B. Aquatic Toxicity**

In developing a water quality guideline for alcohol ethoxylates ANZG (2018), the toxicity data was normalised for a specific alkyl chain length or a specific number of ethoxylate (EO) groups. The NOECs listed below were normalised to an alkyl chain length of C13.3 and EO of 8.2.

Freshwater fish: 2 species, 720 to 1,500 µg/L.

Freshwater crustaceans: 2 species, 590 to 860 µg/L.

Freshwater rotifers: 1 species, *Brachionus calyciflorus*, 1,300 µg/L

Freshwater algae, diatoms and blue-green algae: 6 species, 200 to 8,700 µg/L.

Freshwater mesocosms: 4 NOEC data for multiple species tests were 80, 80, 320, and 330 µg/L, although replication was insufficient to meet OECD (1992) requirements. Normalised data were 380, 380, 320, and 1,520 µg/L.

### C. Terrestrial Toxicity

No studies are available.

### D. Calculation of PNEC

PNEC<sub>water</sub>: The ANZG water quality guideline (2018) for freshwater is: “A high reliability trigger value of 140 µg/L was derived for AE (normalised data) using the statistical distribution method with 95% protection.”

For the purposes of calculating the PNEC values for sediment and soil, the PNEC<sub>water</sub> will be 0.14 mg/L.

#### PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the PNEC<sub>sed</sub> was calculated using the equilibrium partitioning method. The PNEC<sub>sed</sub> is 0.71 mg/kg sediment wet weight.

The calculations are as follows:

$$\begin{aligned} \text{PNEC}_{\text{sed}} &= (K_{\text{sed-water}}/\text{BD}_{\text{sed}}) \times 1000 \times \text{PNEC}_{\text{water}} \\ &= (6.53/1280) \times 1000 \times 0.14 \\ &= 0.71 \text{ mg/kg} \end{aligned}$$

Where:

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

$\text{BD}_{\text{sed}}$  = bulk density of sediment ( $\text{kg}/\text{m}^3$ ) = 1,280 [default]

PNEC<sub>water</sub> = predicted no effect concentration in water

$$\begin{aligned} K_{\text{sed-water}} &= 0.8 + [0.2 \times (K_{\text{p}_{\text{sed}}}/1000) \times \text{BD}_{\text{solid}}] \\ &= 0.8 + [0.2 \times (11.94/1000) \times 2400] \\ &= 6.53 \text{ m}^3/\text{m}^3 \end{aligned}$$

And:

$K_{\text{p}_{\text{sed}}}$  = solid-water partition coefficient (L/kg).

$\text{BD}_{\text{solid}}$  = bulk density of the solid phase ( $\text{kg}/\text{m}^3$ ) = 2,400 [default]

$$\begin{aligned}
 K_{p_{sed}} &= K_{oc} \times f_{oc} \\
 &= 298.6 \times 0.04 \\
 &= 11.94 \text{ L/kg}
 \end{aligned}$$

Where:

$K_{oc}$  = organic carbon normalised distribution coefficient (L/kg). The  $K_{oc}$  for isotridecanol, ethoxylated is 298.6 L/kg.

$f_{oc}$  = fraction of organic carbon in sediment = 0.04 [default].

### PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the  $PNEC_{soil}$  was calculated using the equilibrium partitioning method. The  $PNEC_{soil}$  is 0.56 mg/kg soil dry weight.

The calculations are as follows:

$$\begin{aligned}
 PNEC_{soil} &= (K_{p_{soil}}/BD_{soil}) \times 1000 \times PNEC_{water} \\
 &= (5.97/1500) \times 1000 \times 0.14 \\
 &= 0.56 \text{ mg/kg}
 \end{aligned}$$

Where:

$K_{p_{soil}}$  = 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

$$\begin{aligned}
 K_{p_{soil}} &= K_{oc} \times f_{oc} \\
 &= 298.6 \times 0.02 \\
 &= 5.97 \text{ m}^3/\text{m}^3
 \end{aligned}$$

Where:

$K_{oc}$  = organic carbon normalised distribution coefficient (L/kg). The  $K_{oc}$  for isotridecanol, ethoxylated is 298.6 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).

Isotridecanol, ethoxylated is readily biodegradable and thus does not meet the screening criteria for persistence.

The bioconcentration factors (BCF) in fish for ethoxylated alcohols (which includes isotridecanol, ethoxylated) have been reported to range from <5 to 387.5. Thus, isotridecanol, ethoxylated does not meet the screening criteria for bioaccumulation.

The chronic NOEC values for alcohols ethoxylates are >0.1 mg/L. Thus, isotridecanol, ethoxylated alcohol does not meet the criteria for toxicity.

The overall conclusion is that isotridecanol, ethoxylated is not a PBT substance.

**B. Other Characteristics of Concern**

No other characteristics of concern were identified for isotridecanol, ethoxylated.

**9 SCREENING ASSESSMENT**

Chemical Name	CAS No.	Overall PBT Assessment <sup>1</sup>	Chemical Databases of Concern Assessment Step		Persistence Assessment Step		Bioaccumulative Assessment Step	Toxicity Assessment Step			Risk Assessment Actions Required <sup>3</sup>
			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 <sup>2</sup>	Chronic Toxicity <sup>2</sup>	
Isotridecanol, ethoxylated	69011-36-5	Not a PBT	No	No	No	No	No	No	2	2	2

**Footnotes:**

1 - PBT Assessment based on PBT Framework.

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

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

**Notes:**

NA = not applicable

PBT = Persistent, Bioaccumulative and Toxic

B = bioaccumulative

P = persistent

T = toxic

## 10 REFERENCES, ABBREVIATIONS AND ACRONYMS

### A. References

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## **B. Abbreviations and Acronyms**

°C	degrees Celsius
AE	alcohol ethoxylates
AES	alcohol ethoxy sulphates
AICS	Australian Inventory of Chemical Substances
ANZG	Australian and New Zealand Environment Guidelines
ARMCANZ	Agriculture and Resource Management Council of Australia and New Zealand
BCF	bioconcentration factor
CHO	Chinese hamster ovary
COC	constituent of concern
DEWHA	Department of the Environment, Water, Heritage and the Arts
ECHA	European Chemicals Agency
EO	ethoxylate
EU	European Union
g/L	grams per litre
GD	gestational day
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
hPa	hectopascal
IUPAC	International Union of Pure and Applied Chemistry
kg/d	kilograms per day
kg/m <sup>3</sup>	kilograms per cubic metre
KI	Klimisch scoring system
KOCWIN™	USEPA organic carbon partition coefficient estimation model
kPa	kilopascal
L	litre



L/kg	litres per kilogram
LC	lethal concentration
LD	lethal dose
LOAEL	lowest observed adverse effect level
m <sup>3</sup>	cubic metre
mg/kg	milligrams per kilogram
mg/kg-day	milligrams per kilogram per day
mg/L	milligrams per litre
mg/m <sup>3</sup>	milligrams per cubic metre
mL	millilitre
mm <sup>2</sup> /s	square millimetres per second
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
Pa	pascal
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SGG	Synthetic Greenhouse Gases
USEPA	United States Environmental Protection Agency
UVCB	Unknown or Variable Composition, Complex Reaction Products and Biological Materials
µg/L	micrograms per litre