Qualitative Tier 2 Assessment

Isotridecanol, ethoxylated

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

Consistent with National Industrial Chemicals Notification and Assessment Scheme (NICNAS), the human health hazards for each chemical are characterised by analysing the toxicokinetics (the absorption, distribution, metabolism and excretion of the chemical in humans or laboratory animals), acute toxicity, irritation and corrosivity, repeat dose toxicity, genotoxicity, carcinogenicity, reproductive toxicity, and other health effects. The environmental hazards for each chemical are 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.

Potentially complete exposure pathways (in that a source, a migration pathway, a mechanism for exposure, and a potential receptor are present) are qualitatively assessed herein to determine the potential for risk. An incomplete pathway precludes an exposure occurring and an associated potential risk. In this context, site setting and management protocols associated with the action are evaluated. Key controls limiting the potential for exposure include:

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

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

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

Background

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

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

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

Isotridecanol, ethoxylated is a chemical in a product used in drilling and completion activities, including workovers. 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, produced water is discharged into the water gathering pipelines and conveyed to the water ponds/water treatment facilities, such as ROP2, for treatment and beneficial use (such as dust suppression, construction, operational use and stock water for cattle).

The purpose and maximum quantity for this chemical is summarized in **Table 1**.

Table 1 Initial and Underbalance Workover Fluid Chemicals

Chemical Name	CAS No.	Use	Quantity[1]
Isotridecanol, ethoxylated-	69011-36-5	Activators, Emulsifiers and Neutralisers	NA

[1] 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 1**. There are no carcinogenicity studies on isotridecanol, ethoxylated. The alcohol ethoxylates $C_{12\text{-}13}AE_{6.5}$ and $C_{14\text{-}15}AE_{7}$ were not carcinogenic to rats in a two-year dietary study. Thus, a cancer reference value was not derived and, as a result, only a non-carcinogenic oral reference dose (RfD) was calculated. A detailed discussion of the derivation of the

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

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 1** 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 1** 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)
Isotridecanol, ethoxylated (69011-36-5)	-	-	-	0.140[a]

[a] $PNEC_{water}$ for isotridecanol, ethoxylated is the ANZG Water Quality Guideline – Freshwater Trigger Value for Alcohol Ethoxylates (AE).
EC_{50} = effects concentration – 50%
mg/L = milligram per litre
NOEC = no observable effects concentration
PNEC = predicted no effect concentration
Refer to **Attachment 1** for information on the development of PNECs listed above.

Table 4 PNECs Sediment – Tier 2 Chemicals

Constituents	Endpoint	EC_{50} or NOEC (mg/kg wet wt)	Assessment Factor	$PNEC_{sed}$ (mg/kg wet wt)
Isotridecanol, ethoxylated (69011-36-5)	[a]	-	-	0.71

[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 1** 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)
Isotridecanol, ethoxylated (69011-36-5)	[a]	-	-	0.56

[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 1** for information on the development of PNECs listed above.

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

General Overview

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 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**.

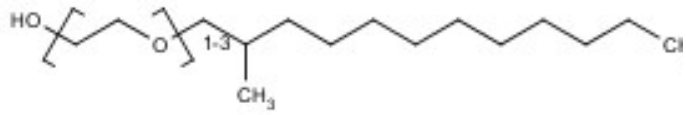

Figure 1 Representative Molecular Structure of Isotridecanol, ethoxylated[2]

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 1**. Based on physico-chemical properties and screening data detailed below, the overall conclusion was that the chemical is not a PBT substance.

Human Health Hazards

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 ($C_{12\text{-}13}AE_{6.5}$) (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 1**.

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

There is low potential for human receptors to be exposed to isotridecanol, ethoxylates in Dawson River discharge. The combination of mixing/dilution, storage (and associated biodecay) prior to treatment, treatment and retention (and associated biodecay) following treatment are all key components that will reduce the potential risk to potential receptors from discharges to surface water. For example, the concentration of residual chemicals in flowback water would be diluted by at least 90% in the water feed pond due to the aggregation of produced water from other wells within one pond. During water treatment, concentrations would be further reduced by efficiencies

[2] Source https://echa.europa.eu/brief-profile/-/briefprofile/100.105.729

of the reverse osmosis system. In addition, isotridecanol, ethoxylates is expected to be readily biodegradable in the environment. In an OECD 301B test, degradation was 75% in 28 days (ECHA). Estimated Water Management Facility (WMF) pond influent concentrations (2.2×10^{-7} mg/L, refer **Attachment 2**) are well less than the derived drinking water guideline value of 1.8 mg/L.

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

Environmental Hazards

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, ethoxylated 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 1**.

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

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

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

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

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

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

Further, estimated WMF pond influent concentrations (2.2×10^{-7} mg/L, refer **Attachment 2**) are well less than PNECs for aquatic receptors (1.4×10^{-1} mg/L). Blending within the storage pond, degradation during storage and treatment would further reduce concentrations.

References

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

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

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

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

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

Attachment 1 Risk Assessment Dossier

ETHOXYLATED BRANCHED C13 ALCOHOL
[ISOTRIDECANOL, ETHOXYLATED]

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

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^3 @ 20°C	1	ECHA
Vapour Pressure	<5 Pa @ 20°C	2	ECHA
Partition coefficient (log K_{ow})	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^2/s (static) @ 20°C	1	ECHA

*Weight-averaged log K_{oc} 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) [Kl. score = 2].

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

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) [Kl. 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_{50} in rats for $C_{12\text{-}13}AE_{6.5}$ is 2,100 mg/kg (HERA, 2009) [Kl. score = 2]. The oral LD_{50} in rats for $C_{12\text{-}15}AE_7$ is 1,700 mg/kg (HERA, 2009) [Kl. score = 2].

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

An acute dermal LD_{50} values of >2,000 mg/kg were determined for $C_{12\text{-}14}AE_3$ and $C_{12\text{-}14}AE_6$ in two separate studies (HERA, 2009) [Kl. score = 2]. The acute dermal LD_{50} of $C_{12\text{-}15}AE_7$ is >2,000 mg/kg (HERA, 2009) [Kl. score = 2].

C. Irritation

<u>Skin</u>

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

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

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

Application of 0.5 mL $C_{12\text{-}13}AE_{<2.5}$ (CAS No. 66455-14-9) to the skin of rabbits for 24 hours under occlusive conditions was considered irritating (ECHA) [Kl. score = 2].

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

In a 24-hour human patch test, there was some short-lived redness in some individuals from the application of $C_{12\text{-}14}AE_3$, but there was no scaling or oedema in any subjects (HERA, 2009) [Kl. score = 2].

In a standard 4-hour human patch test, the irritation potential of $C_{12\text{-}15}AE_5$ and $C_{12\text{-}15}AE_5$ were compared to 20% sodium dodecyl sulfate (which is classified a skin irritant under GHS). The results showed that neither alcohol ethoxylate should be classified as a skin irritant (Basketter et al., 2004) [Kl. score = 2].

Eye

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

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

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

Instillation of 0.1 mL $C_{12\text{-}13}AE_{<2.5}$ (CAS No. 66455-14-9) into the eyes of rabbits was not irritating. The mean of the 24, 48, and 72-hour scores were: 0.00 for all endpoints (ECHA) [Kl. score = 2].

D. Sensitisation

No sensitisation studies are available on isotridecanol, ethoxylated.

In a guinea pig maximisation test, $C_{12\text{-}13}AE_{<2.5}$ (CAS No. 66455-14-9) was not considered a skin sensitiser (ECHA) [Kl. score = 2].

E. Repeated Dose Toxicity

Oral

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

Rats were given in their diet 0%, 0.0313%, 0.0625%, 0.125%, 0.25%, 0.5% or 1.0% $C_{12\text{-}15}AE_7$ for 90 days. The animals in the $\geq$0.25% groups showed significantly reduced body weight gain, which was associated with marked decreases in food and water consumption. Relative liver weights were significantly increased in the $\geq$0.5% male rats and $\geq$0.25% females. Histopathologic examination showed hepatocytic enlargement in the $\geq$0.125% groups, suggesting increased liver metabolism on the basis of increased alkaline phosphatase activity at the higher dose levels. The NOAEL was established at 0.0625% in the diet or 102 mg/kg-day (HERA, 2009) [Kl. score = 2].

Rats were fed $C_{12\text{-}14}AE_7$ in the diet at concentrations of 0%, 0.0313%, 0.0625%, 0.125%, 0.25%, 0.5% and 1.0% for 90 days. The animals in the $\geq$0.25% groups showed significantly reduced body weight gain, which was associated with marked decreases in food and water consumption. Relative liver weights were significantly increased in the $\geq$0.5% male rats and $\geq$0.25% females. Histopathologic examination showed hepatocytic enlargement in the $\geq$0.125% groups, suggesting increased liver metabolism on the basis of increased alkaline phosphatase activity at the higher dose levels. The NOAEL was established at 0.0625% in the diet or 110 mg/kg-day (HERA, 2009) [Kl. score = 2].

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

Inhalation

No studies are available.

Dermal

No adequate studies are available.

F. Genotoxicity

In Vitro Studies

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

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

Test Substance	Test System	Results*		Klimisch Score	References
		-S9	+S9		
$C_{14\text{-}15}AE_7$	Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	HERA, 2009
$C_{14\text{-}15}AE_7$	Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	HERA, 2009
$C_{14}AE_{12}$	Chromosomal aberrations (CHO cells)	-	-	2	HERA, 2009

*+, positive; -, negative

In Vivo Studies

In two separate studies, CD-1 mice were given an intraperitoneal dose of 0, 50, or 100 mg/kg $C_{12\text{-}15}AE_3$ or $C_{12\text{-}14}AE_9$. There were no increases in the frequency of micronuclei in the bone marrow cells (Talmage, 1994) [Kl. score = 2].

Male and female Tunstall rats were given a single oral gavage dose of 0, 250, 500, or 1,000 mg/kg $C_{14\text{-}15}AE_7$. There were no increases in chromosomal aberrations in the bone marrow cells (HERA, 2009) [Kl. score = 2].

G. Carcinogenicity

No studies are available on isotridecanol, ethoxylated.

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

Male and female Charles River rats were given in their diet 0, 0.1, 0.5 or 1% $C_{14\text{-}15}AE_7$ for two years. There were no treatment-related changes in general behaviour and appearance. The survival rate of the test animals was comparable if not better than the controls. Body weights of the 0.5% females and the 1% males and females had significantly lower weight gains than the control. There were no treatment-related effects on organ weights and tumour incidence (HERA, 2009) [Kl. score = 2]

Male and female Sprague-Dawley rats were given in their diet $C_{14\text{-}15}AE_7$ at 0.1%, 0.5% and 1% for two years. A treatment-related body weight depression was observed in females at the two highest treatment levels and in males at the 1% dose level, probably due to the poor palatability of the diet. There was no evidence for any carcinogenic activity (HERA, 2009) [Kl. score = 2].

H. Reproductive Toxicity

No studies are available on isotridecanol, ethoxylated.

CD rats were given in their diet 0%, 0.05%, 0.1% or 0.5% (approximately 0, 25, 50 or 250 mg/kg-day) $C_{12}AE_6$ in a two-generation reproductive toxicity study. There were no treatment related effects in the parents or pups on general behaviour, appearance or survival. At 0.5%, there was reduced weight gain in both the parental animals and the pups compared to the controls. Fertility was unaffected by treatment. The NOAEL for reproductive toxicity is 0.5% in the diet, which corresponds to 250 mg/kg-day (HERA, 2009) [Kl. score = 2].

In a two-generation developmental and teratogenicity study, CD rats were given in their diet 0%, 0.05%, 0.1% or 0.5% $C_{14\text{-}15}AE_7$ (approximately 0, 25, 50 or 250 mg/kg-day). Three of the treated groups were given the test substance continuously throughout the study; in the other three groups the females received the test substance on GD 6-15 and the males were untreated. None of the deaths of parental rats during the study was considered to be compound-related. There were no treatment-related changes in behaviour or appearance in the parental rats or pups. Slightly lower body weight gain was noted in the 0.5% continuously treated females. Food consumption was similar for control and treated rats. Fertility, gestation and viability indices were similar across groups. The average 21-day body weights for the 0.5% continuous treated pups were significantly lower than that of the control. Relative liver weights of the 0.5% continuously treated F_1 parental animals were increased at the 91-day sacrifice; relative liver weights of the 0.5% continuously treated males were also increased at the 60-day and caesarean section sacrifices. There were no treatment-related histopathological lesions in any of the tissues from the F_0 and F_1 generations. The NOAEL for reproductive toxicity is 0.5% in the diet or 250 mg/kg-day (HERA, 2009) [Kl. score = 2].

I. Developmental Toxicity

No studies are available on isotridecanol, ethoxylated.

In a two-generation reproductive toxicity study, Charles River rats were given in their diet 0, 0.05, 0.1 or 0.5% (about 0, 25, 50 or 250 mg/kg-day) $C_{12}AE_6$. General behaviour, appearance and survival were unaffected by treatment. At the 0.5% dose level, adults and pups gained less weight than the control rats. In the 0.5% dose group, there was a statistical increase in embryo lethality and soft tissue anomalies, and at the 0.1% there was a statistical decrease in mean foetal liver weight. Neither of these effects was considered to be treatment-related by the authors as they showed no dose response characteristics. The NOAEL for maternal toxicity is 50 mg/kg-day. The NOAEL for developmental and teratogenicity is 0.1% in the diet or 50 mg/kg-day (HERA, 2009) [Kl. score = 2].

Pregnant rabbits were given by oral gavage 0, 50, 100 or 200 mg/kg $C_{12}AE_6$ from gestational days 2 to 16. Nine control rabbits and 31 treated rabbits died during the study. Surviving rabbits at the 200 mg/kg dose group generally showed slight losses of body weight. At 100 and 200 mg/kg, ataxia and a slight decrease in body weight was observed in the pregnant animals. In seven treated and two control rabbits, early deliveries were recorded. There were no treatment-related effects on corpora lutea, implantations, number of live foetuses and spontaneous abortions. The NOAEL for maternal toxicity is 50 mg/kg-day; the NOAEL for developmental toxicity is 200 mg/kg-day (HERA, 2009) [Kl. score = 2].

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 $C_{12\text{-}13}AE_{6.5}$ (HERA, 2009). The NOAEL from this study is 50 mg/kg-day based on increased organ weights. The NOAEL of 50 mg/kg-day will be used to derive an oral reference dose and drinking water guidance value for isotridecanol, ethoxylated.

Oral Reference Dose (oral RfD)

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

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

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

Drinking water guidance value

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

Using the oral RfD,

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

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

Drinking water guidance value = (0.5 x 70 x 0.1)/2 = 1.8 mg/L

Cancer

The alcohol ethoxylates $C_{12\text{-}13}AE_{6.5}$ and $C_{14\text{-}15}AE_{7}$ were not carcinogenic to rats in a two-year dietary study. Thus, a cancer reference value was not derived.

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

The PNEC calculations for isotridecanol, ethoxylated follow the methodology discussed in DEWHA (2009).

PNEC water

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 $PNEC_{water}$ will be 0.14 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 0.71 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (6.53/1280) \times 1000 \times 0.14$
$= 0.71$ 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

$K_{sed\text{-}water} = 0.8 + [0.2 \times (Kp_{sed}/1000) \times BD_{solid}]$
$= 0.8 + [0.2 \times (11.94/1000) \times 2400]$
$= 6.53\ m^3/m^3$

And:

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

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

$Kp_{sed} = K_{oc} \times f_{oc}$
= 298.6 x 0.04
= 11.94 L/kg

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:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
= (5.97/1500) x 1000 x 0.14
= 0.56 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

$Kp_{soil} = K_{oc} \times f_{oc}$
= 298.6 x 0.02
= 5.97 m^3/m^3

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 (IChEMS, 2022; ECHA, 2017).

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 [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]	
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

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B. Abbreviations and Acronyms

°C	degrees Celsius
ADWG	Australian Drinking Water Guidelines
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
CAS	Chemical Abstracts Service
CHO	Chinese hamster ovary
COC	constituent of concern
DEWHA	Department of the Environment, Water, Heritage and the Arts

DoEE	Department of Environment and Energy
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
HERA	Human and Environmental Risk Assessment
hPa	hectopascal
IChEMS	Industrial Chemicals Environmental Management Standard
IUPAC	International Union of Pure and Applied Chemistry
kg/d	kilograms per day
kg/m^3	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^3	cubic metre
mg/kg	milligrams per kilogram
mg/kg-day	milligrams per kilogram per day
mg/L	milligrams per litre
mg/m^3	milligrams per cubic metre
mL	millilitre
mm^2/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

Attachment 2 Mass Balance Calculations

Attachment 2
Summary of Exposure Point Concentration Development
(Initial and Underbalance Workover Fluid Chemicals)

Mass Balance

In other Santos project areas, approximately 1,540 mg/L of the product is being dosed (5 L of product added to 3,250 litres of water) during each well treatment. The product dose is apportioned between the constituents of potential concern (COPCs) based on the COPC percent weight in the product (composition information in the safety data sheet) for COPC dosage rate per well. The eight-well COPC flowback concentrations are calculated based on the treatment of eight wells per day, and dilution by produced water (3,250 L) during well flush. The concentration of the COPCs in the water storage pond influent was based on dilution from the combined average field and groundwater bore water productions (0.5 ML/d).

On this basis, the concentration of COPCs in the water storage pond influent are calculated as follows:

COPC	CAS Number	Percent Weight Product	Dosage Rate per Well (mg/L)	8-Well Flowback (mg/L)	Storage Pond Influent (mg/L)
Isotridecanol, ethoxylated	69011-36-5	3.3	51	1.2E-01	2.2E-07

CAS = Chemical Abstracts Service
COPC = constituent of potential concern
mg/L = milligrams per litre