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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Poly(oxy-1,2-ethanediyl), α-sulfo-ω-hydroxy-, C₉₋₁₁-branched and linear alkyl ethers, sodium salts

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Energy.

This Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address: Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.

Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.

TEL: + 61 2 8577 8800 FAX: + 61 2 8577 8888 Website: www.nicnas.gov.au

Director NICNAS

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SUMMARY

The following details will be published in the NICNAS Chemical Gazette:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1953	IXOM	Poly(oxy-1,2-	ND*	< 1 tonne per	Component of aerosol
	Operations Pty	ethanediyl), α-sulfo-		annum	oven cleaners
	Ltd	ω-hydroxy-, C ₉₋₁₁ -			
		branched and linear			
		alkyl ethers, sodium			
		salts			

^{*}ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

As no toxicity data were provided, the notified chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

Human health risk assessment

Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified chemical is not considered to pose an unreasonable risk to public health.

Environmental risk assessment

On the basis of the assessed use pattern and expected low exposure to aquatic environment, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified chemical during reformulation:
 - Enclosed and automated processes, where possible
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical during reformulation:
 - Avoid skin and eye contact
- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical during reformulation:
 - Coveralls
 - Impervious gloves
 - Protective goggles
- A copy of the (M)SDS should be easily accessible to employees.

• If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

 Where reuse or recycling are not appropriate, dispose of the notified chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency procedures

• Spills or accidental release of the notified chemical should be handled by containment, physical collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the importation volume exceeds one tonne per annum notified chemical;
 - the concentration of the notified chemical exceeds or intended to exceed 1% in end-use products;

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from component of aerosol oven cleaners, or is likely to change significantly;
 - the amount of chemical being introduced has increased, or is likely to increase, significantly;
 - the chemical has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

(Material) Safety Data Sheet

The (M)SDS of the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT

IXOM Operations Pty Ltd (ABN: 51 600 546 512)

Level 8, 1 Nicholson Street EAST MELBOURNE VIC 3000

NOTIFICATION CATEGORY

Limited-small volume: Chemical other than polymer (1 tonne or less per year)

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: molecular weight, analytical data, degree of purity, impurities, additives/adjuvants, use details, import volume, and site of manufacture

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for all physico-chemical endpoints

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

EU (2013)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

STEOL® DES32-IS (product containing the notified chemical at < 40% concentration)

CAS NUMBER

160901-28-0

CHEMICAL NAME

Poly(oxy-1,2-ethanediyl), α-sulfo-ω-hydroxy-, C₉₋₁₁-branched and linear alkyl ethers, sodium salts

OTHER NAME(S)

STEOL® DES-32 (product containing the notified chemical at < 40% concentration)

STEOL® DES32 (product containing the notified chemical at < 40% concentration)

MOLECULAR FORMULA

Unspecified

STRUCTURAL FORMULA

$$C_{9-11} H_{19-23}$$
 O n Na (average $n = 2.5$)

MOLECULAR WEIGHT

< 500 Da

ANALYTICAL DATA

Reference NMR, IR, GC and UV spectra were provided.

3. COMPOSITION

Degree of Purity > 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Light yellow liquid*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Introduced in aqueous solution
Boiling Point	Not determined	Introduced in aqueous solution
Density	$1,030 \text{ kg/m}^3 \text{ at } 25 ^{\circ}\text{C}$	(M)SDS*
Vapour Pressure	2.13×10^{-8} - 5.84×10^{-11} kPa	Estimated. EPIWIN v. 4.1 (modified grain method)
Water Solubility	Miscible in water	M)SDS*
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities; however, not expected to significantly hydrolyse under environmental conditions (pH 4-9)
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to phase boundaries based on surface activity
Adsorption/Desorption	Not determined	Expected to adsorb to soil and sediment based on surface activity
Dissociation Constant	Not determined	The notified chemical is a salt and is expected to be ionised under environmental conditions (pH 4-9)
Flash Point	> 94 °C	(M)SDS*
Flammability	Not determined	Introduced in aqueous solution
Autoignition Temperature	Not determined	Introduced in aqueous solution
Explosive Properties	Not explosive	Estimated. The notified chemical does not contain chemical groups which confer explosive properties
Oxidising Properties	Not oxidising	Estimated. The notified chemical does not contain chemical groups which confer oxidising properties

^{*}For notified chemical at < 40% concentration in aqueous solution

DISCUSSION OF PROPERTIES

Reactivity

The notified chemical is expected to be stable under normal conditions of use.

Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

Mode of Introduction of Notified Chemical (100%) Over Next 5 Years The notified chemical will be introduced into Australia at < 40% concentration in aqueous solution.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	1	2	3	4	5
Tonnes	< 1	< 1	< 1	< 1	< 1

PORT OF ENTRY Sydney

TRANSPORTATION AND PACKAGING

The product containing the notified chemical at < 40% concentration will be packaged in 200 L steel drums and transported by road within Australia. The finished product containing the notified chemical at $\le 1\%$ concentration will be stored and transported in consumer-size aerosol cans.

USF

The notified chemical will be used as a component of aerosol-based oven cleaners at $\leq 1\%$ concentration.

OPERATION DESCRIPTION

The notified chemical will not be manufactured in Australia. The product containing the notified chemical at < 40% concentration will be used for the formulation of aerosol-based oven cleaners.

During reformulation, the product containing the notified chemical at < 40% concentration will be manually transferred by drum lifter to a 10,000 L stainless steel tank and blended with other components to form the final formulation. This formulation containing the notified chemical at $\le 1\%$ concentration will be pumped via stainless steel transfer lines to a filling line where it will be filled, via a rotary volume filler, into aerosol cans. These cans will then have aerosol valves inserted, be crimped and filled with gas on the filling line. Reformulation and filling processes will be carried out under enclosed and automated conditions.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	Exposure Duration	Exposure Frequency
	(hours/day)	(days/year)
Transportation	0.3	4
Sampler	0.2	2
QA/QC Analyst	1.0	2
Pre-weigher	0.2	5
Compounder/mixer	0.1	5
Retailers	0.2	52

EXPOSURE DETAILS

Transport and storage workers are not expected to be exposed to the notified chemical except in the unlikely event of an accident.

Reformulation workers may be exposed to the notified chemical at < 40% concentration during sampling, quality control analysis, weighing and mixing tasks. The primary routes of exposure to the notified chemical (at < 40% concentration) are expected to be dermal and ocular. Exposure to the notified chemical is expected to be minimised through the stated use by the notifier of PPE such as coveralls, goggles and impervious gloves. Inhalation exposure is not expected given the expected low vapour pressure of the notified chemical and the use of enclosed processes.

6.1.2. Public Exposure

Public exposure to the notified chemical (at \leq 1% concentration) may occur through the use of aerosol-based oven cleaners containing it. The principal routes of exposure will be dermal and inhalation. Exposure is expected to be infrequent and short term. It is expected that exposure to the notified chemical will be minimised through following the use directions and safe handling precautions stated on the product label.

6.2. Human Health Effects Assessment

No toxicological data for the notified chemical was submitted. The notified chemical is an anionic surfactant belonging to the class of compounds known as the Alcohol Ethoxysulphates (AES). Information on the toxicokinetics and toxicity of AES is available (HERA, 2003).

Given the ionic character of AES, they are poorly dermally absorbed. However AES are readily absorbed in the gastrointestinal tract and excreted principally via the urine. AES with longer ethoxylate chains (>7-9 EO units)

are excreted at a higher proportion in the faeces. Once absorbed, AES is extensively metabolized by beta- or omega oxidation.

AES are of low acute toxicity, non sensitising, non genotoxic and are not reproductive or developmental toxicants. AES are also of low repeated dose toxicity. In the available chronic and subchronic oral toxicity studies, no adverse effects of AES were observed at the highest tested dose level of 250 mg/kg/day. In 2 subchronic oral feeding studies a slight, but significant increase of organ weights ((liver in males and females in both studies, male kidney in one study) was observed at the dose of 250 mg/kg bw/day but these increases were not accompanied by histological changes and were therefore considered to be adaptive in nature and not a toxic effect of the AES. However, AES have been shown to be moderately to severely irritating to the eyes and skin which is consistent with their structure and surfactant properties.

Health hazard classification

As no toxicity data were provided, the notified chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Based on the available information, the critical health effect of the notified chemical is as a potential skin and eye irritant.

Dermal and ocular exposure to the notified chemical at < 40% concentration may occur during reformulation processes. At these concentrations, workers are at risk of skin and eye irritation effects. The stated use by the notifier of PPE such as coveralls, goggles and impervious gloves in conjunction with engineering controls including the use of enclosed and automated reformulation and filling processes should minimise the risk for workers.

Provided that the protective measures and engineering controls proposed are implemented, the use of the notified chemical is not expected to pose an unreasonable risk to workers under the occupational conditions described.

6.3.2. Public Health

Aerosol-based oven cleaner containing the notified chemical at < 1% concentration will be sold to the public. At the low proposed use concentration, local and systemic effects are not expected.

Therefore, based on the proposed low end use concentration, the risk of the notified chemical to public health is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported at < 40% concentration in aqueous solution for the formulation of aerosol-based oven cleaners. There is unlikely to be any significant release to the environment from transport and storage, except in the case of accidental spills and leaks. In the event of spills, the product containing the notified chemical is expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations.

The reformulation process will involve blending operations and is expected to occur within a fully enclosed environment. Therefore, significant release of the notified chemical from this process to the environment is not expected. Release of the notified chemical during reformulation in Australia is expected to be limited to accidental spills or leaks and residue in import containers. These releases are expected to be collected and disposed of in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The majority of the notified chemical is expected to be released to sewer across Australia as a result of its use in oven cleaners. A small proportion of the notified chemical is expected to be disposed of to landfill as residues in empty end-use containers.

RELEASE OF CHEMICAL FROM DISPOSAL

A small proportion of the notified chemical may remain in end-use containers once the consumer products are used up. Wastes and residues of the notified chemical in empty containers are likely either to share the fate of the container and be disposed of to landfill, or to be released to sewer when containers are rinsed before recycling through an approved waste management facility.

7.1.2. Environmental Fate

No environmental fate studies were submitted for the notified chemical. Based on its chemical structure, the notified chemical is likely to be biodegradable.

Following its use in oven cleaning in Australia, the majority of the notified chemical is expected to enter the sewer system before potential release to surface waters nationwide. Due to its anionic functional group and surface activity, a significant amount of the notified chemical is expected to sorb to sludge in STPs. The notified chemical in sewage sludge is expected to be disposed of to landfill, or applied to land when sludge is used for soil remediation. Notified chemical released to surface waters is expected to partition to suspended solids and organic matter, and disperse. Consequently, the notified chemical is not expected to be significantly bioavailable. Based on its surface activity and expected biodegradability, the notified chemical is not expected to bioaccumulate. The notified chemical is expected to ultimately degrade through biotic and abiotic processes to form water and oxides of carbon and sulfur.

7.1.3. Predicted Environmental Concentration (PEC)

Based on the reported use in oven cleaners, it is assumed that 100% of the total import volume of the notified chemical will be released to the sewer. The release is assumed to be nationwide over 365 days per year. It is conservatively assumed that 0% of the notified chemical will be removed during sewage treatment processes (STP).

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	1,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.74	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.61	μg/L
PEC - Ocean:	0.06	μg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m²/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1,500 kg/m³). Using these assumptions, irrigation with a concentration of 0.61 μ g/L may potentially result in a soil concentration of approximately 4.04 μ g/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 20.19 μ g/kg and 40.39 μ g/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. The calculated PEC is well below the EC50 for algae (the most sensitive species) of the most toxic anionic chemical (EC50 > 1 mg/L).

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) was not calculated since no ecotoxicity data were available for the notified chemical. Due to its low import volume and likelihood for adsorption to sludge and sediment, the notified chemical is not expected to be present in water at concentrations that could be hazardous to aquatic organisms.

7.3. Environmental Risk Assessment

A risk quotient (PEC/PNEC) for the notified chemical was not calculated, as a PNEC was not derived. The notified chemical is unlikely to reach ecotoxicologically significant concentrations in the environment based on its annual importation quantity and use pattern. The notified chemical is expected to be readily biodegradable, and is not expected to be bioaccumulative. Therefore, based on its annual importation quantity and assessed use pattern of the notified chemical, it is not expected to pose an unreasonable risk to the environment.

BIBLIOGRAPHY

HERA (2003) Alcohol Ethoxysulphates Human Health Risk Assessment – Draft. Human and Environmental Risk Assessment on ingredients of European Household Cleaning Products. January 2003. http://www.heraproject.com/files/1-hh-04-hera%20aes%20hh%20web%20wd.pdf. Last accessed January 2017.