Australian Government
Department of Health and Aged Care
Australian Industrial Chemicals Introduction Scheme

# Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, $N^1$,$N^3$-bis[3-[bis(2-hydroxyethyl)alkylammonio]propyl]-$N^1$,$N^3$-bis(2-hydroxyethyl)-$N^1$,$N^3$-dialkyl-1,3-propanediaminium (6:1), 1,1,3,3-tetrakis(hetero-acid), tetrakis(inner salt)

## Assessment statement (CA09435)

**13 September 2022**

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# AICIS assessment statement

## Chemical(s) in this assessment

| Name | CAS registry number |
|---|---|
| Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, $N^1$,$N^3$-bis[3-[bis(2-hydroxyethyl)alkylammonio]propyl]-$N^1$,$N^3$-bis(2-hydroxyethyl)-$N^1$,$N^3$-dialkyl-1,3-propanediaminium (6:1), 1,1,3,3-tetrakis(hetero-acid), tetrakis(inner salt) | AICIS Approved Chemical Name (AACN) |

## Reason for the assessment

An application for an assessment certificate under section 31 of the *Industrial Chemicals Act 2019* (the Act).

### Certificate Application Type

#### Very low to low risk

Based on introduction, use and end use information described in the application, the exposure band of the introduction is 4 for both human health and the environment [table item 6 clause 1 and table item 5 clause 3, Schedule 1 of the *Industrial Chemicals (General) Rules 2019* (the Rules)].

The assessed polymer does not have any of the hazard characteristics in human health hazard bands A, B or C and has the characteristics of environment hazard band A as prescribed in clauses 2 and 4 in Schedule 1 of the Rules. In accordance with table item 14, section 28 and table item 14, section 29 of the Rules, the indicative human health risk for the proposed introduction is very low and indicative environment risk for the proposed introduction is low.

#### Defined scope of assessment

The chemical was assessed for use by professionals and consumers as an ingredient in laundry detergents:

- imported into Australia at up to 200 tonnes per year
- imported in aqueous solutions at a concentration of 70% or less, for reformulation into finished laundry detergents at a maximum concentration of 3%
- imported at a concentration of 3% or less, in finished laundry detergents

## Summary of assessment

### Summary of introduction, use and end use

The assessed polymer will not be manufactured in Australia. It will be imported into Australia in intermediate bulk containers as an aqueous solution at a concentration of 70% or less for

reformulation into liquid laundry detergents at a concentration of 3% or less, or imported as a component of fully finished liquid laundry detergents at a concentration of 3% or less. These laundry detergents will be used by commercial laundry workers and also by the public. The laundry detergents containing the assessed polymer may also be packaged in dissolvable laundry capsules.

## Human health

### Summary of health hazards

The available toxicological data (see **Supporting information**) indicate that the assessed polymer is:

- of low acute oral toxicity
- non-irritating to the skin and eyes
- non-sensitising to the skin; and
- non-mutagenic.

### Hazard classifications relevant for worker health and safety

Based on the toxicological information available, the assessed polymer is not formally classified under the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) (UNECE 2017) for hazard classes relevant for worker health and safety. This does not consider classification of physical and environmental hazards.

### Summary of health risk

**Public**

When introduced and used in the proposed manner, there will be widespread and repeated exposure of the public to the assessed polymer at a concentration of 3% or less in liquid laundry detergents. The principal route of exposure will be dermal, while ocular exposure is also possible.

No risks were identified for public health during this assessment that require specific risk management measures if the assessed polymer is introduced and used in accordance with the terms of the assessment certificate.

**Workers**

Workers may experience exposure to the assessed polymer at a concentration of 70% or less or at a concentration of 3% or less during weighing, transfer, blending, quality control analysis and cleaning and maintenance of equipment, particularly where manual or open processes are used. No risks were identified for workers during these processes that require specific risk management. However, control measures to minimise inhalation exposure may be needed if aerosols or mists are formed during these processes.

Exposure to the assessed polymer in end-use products at a concentration of 3% or less may occur in commercial laundry operations. The frequency and extent of exposure of workers applying the detergent products is similar to public exposure or lower if personal protective equipment (PPE) is used.

## Environment

### Summary of environmental hazard characteristics

According to domestic environmental hazard thresholds and based on the available data the assessed polymer is:

- Persistent (P)
- Not bioaccumulative (not B)
- Not toxic (not T)

### Environmental hazard classification

Based on the ecotoxicological information available for the assessed polymer and an analogue of the assessed polymer, it is not expected to be harmful to aquatic life. Therefore, the assessed polymer is not formally classified under the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) for acute and chronic aquatic toxicities (UNECE 2017).

### Summary of environmental risk

Based on an end use in laundry detergents, the majority of the assessed polymer is expected to be released into sewage treatment plants (STPs).

The assessed polymer is not readily biodegradable and is considered persistent. The assessed polymer has a low potential to bioaccumulate. The assessed polymer is not toxic to aquatic organisms, based on data supplied for the assessed polymer and a suitable analogue.

As the assessed polymer is not PBT it is unlikely to have unpredictable long-term effects. Based on the assessed polymer's low toxicity and bioaccumulation hazards, it is expected that the environmental risk from the introduction of the assessed polymer can be managed.

# Proposed means for managing risk

No specific means for managing risk are proposed during the assessment, provided that the assessed polymer is introduced in accordance with the terms of the assessment certificate.

# Conclusions

The conclusions of this assessment are based on the information described in this statement.

The Executive Director is satisfied that when the assessed polymer is introduced and used in accordance with the terms of the assessment certificate the human health and environment risks can be managed within existing risk management frameworks. This is provided that all requirements are met under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory and the control measures described in the statement are utilised.

Note: Obligations to report additional information about hazards under section 100 of the *Industrial Chemicals Act 2019* apply.

# Supporting information

## Chemical identity

| | |
|---|---|
| Chemical name | Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, $N^1$,$N^3$-bis[3-[bis(2-hydroxyethyl)alkylammonio]propyl]-$N^1$,$N^3$-bis(2-hydroxyethyl)-$N^1$,$N^3$-dialkyl-1,3-propanediaminium (6:1), 1,1,3,3-tetrakis(hetero-acid), tetrakis(inner salt) (AACN) |
| Trade name | Sokalan© HP Ultimate (product containing up to 70% assessed polymer) |
| Molecular formula | Unspecified |
| Number Average Molecular Weight (Mn) | 2100 g/mol |
| Percentage of low molecular weight species (< 1,000 g/mol) | 4% |
| Percentage of low molecular weight species (< 500 g/mol) | 3% |
| Chemical description | Polymer |

## Relevant physical and chemical properties

All measured values are based on the studies provided on the assessed polymer and conducted according to OECD test guidelines.

| | |
|---|---|
| Physical form | Yellow liquid |
| Density | 1.15 g/cm$^3$ at 20 °C |
| Water solubility | Fully miscible in water |
| Ionisable in the environment? | Yes |

## Introduction and use

The assessed polymer will be imported into Australia by sea and transported from wharf to third party warehouses before distribution to formulators. Reformulation/re-packaging activity will not occur at the applicant's facility in Australia. The containers containing the assessed polymer will be transported mainly by road to the warehouse for storage and later distributed to the formulators.

At the reformulation sites, the intermediate bulk containers containing the assessed polymer at a concentration of 70% or less will be connected by hose to a delivery pump. The required amount of the assessed polymer will be pumped into a dipper or bucket and then poured into the blending vessel with other ingredients of the liquid laundry detergent under local exhaust ventilation. After blending, the finished product will be sampled for quality control. The formulated liquid laundry detergent containing the assessed polymer at a concentration of 3%

or less will then be transferred via automatic filling machines into appropriate retail containers ranging from 1 to 6 L and distributed by road to warehouses and retailers.

# Human exposure

## Workers

Transport, storage and warehouse workers are not expected to be exposed to the assessed polymer or products containing the assessed polymer, except in an unlikely event of an accidental rupture of containers.

### Reformulation

During reformulation, dermal, ocular and perhaps inhalation exposure (if aerosols or mists are formed) of workers to the assessed polymer at a concentration of 70% or less may occur during weighing, transfer, blending, quality control analysis, and cleaning and maintenance of equipment. Exposure is expected to be limited through the use of enclosed systems and PPE such as protective clothing, safety glasses and impervious gloves.

### Professional End Use

The liquid laundry detergents containing the assessed polymer at a concentration of 3% or less will be used by commercial laundry workers. These workers may be exposed to the assessed polymer when handling the containers and adding the detergent to the washing machine. The main route of exposure will be dermal, although some ocular exposure is also possible. Precautions such as PPE to reduce worker exposure in commercial laundries are likely to be based on the other ingredients of the laundry detergents, and good hygiene practices are expected to be in place. Therefore, the risk to workers who use the detergents containing the assessed polymer is expected to be of a similar or lesser extent than the risk to consumers who use such products on a regular basis.

## Public

Dermal and ocular exposure of the public to laundry detergents containing the assessed polymer at a concentration of 3% or less may occur through spills and splashes during handling. Exposure from hand-washing processes is expected to be low as the assessed polymer will be further diluted in the wash water.

Dermal exposure to the assessed polymer from washed clothing/linen is expected to be low as the amount of residual polymer left on clothing is expected to be very low after the washing processes are complete.

# Health hazard information

## Toxicokinetics

No toxicokinetic data were provided for the assessed polymer. As the majority of the species of the assessed polymer are greater than 500 g/mol, limited absorption across biological membranes is expected.

## Acute toxicity

### Oral

In an acute oral toxicity study (OECD TG 423), the assessed polymer as a single dose of 2000 mg/kg bw was administered to 2 groups of fasted female Wistar rats (n=3/group) via oral gavage. The animals were observed for 14 days after administration. No signs of clinical toxicity and no mortalities occurred during the observation period. All animals showed the expected body weight gains over the study period. No treatment-related gross necropsy findings were observed. The acute oral LD50 of the assessed polymer was determined to be > 2000 mg/kg bw.

## Corrosion/Irritation

### Skin irritation

The assessed polymer was determined not to be irritating to the skin in an in vitro skin irritation test using the EpiDerm™ reconstructed human epidermis tissue model (EpiDerm™ tissue) (OECD TG 439). The relative mean viability of the test substance-treated tissues was 95.7% after 60 minutes exposure (followed by 42 hours post-exposure incubation). Under the conditions of this study and according to the test guideline, the assessed polymer was not considered to be irritating to the skin.

### Eye irritation

The eye irritation potential of the assessed polymer was determined using a reconstructed Human EpiOcular™ Cornea-like Epithelial Model (OECD TG 492). The relative mean tissue viability following 30 minutes treatment was 101.8%, as compared to the negative control. Under the conditions of this study and according to the test guideline, the assessed polymer was not considered to be irritating to the eye.

## Sensitisation

### Skin sensitisation

The skin sensitisation potential of the assessed polymer was determined using a local lymph node assay (LLNA) in mice (OECD TG 429). Each test animal was treated by daily application of 25 µL of the test substance at concentrations of 25%, 50% and undiluted, to the dorsal surface of each ear for three consecutive days.

There were no deaths or signs of systemic toxicity in the treatment groups, and body weights were comparable to controls apart from a slight reduction in mean body weight of the animals treated with the highest dose of the test substance.

The stimulation indices were 1.27, 1.04 and 2.15 at 25%, 50% and undiluted concentrations, respectively, indicating a non-sensitising response. As none of the test concentrations induced a biologically relevant increase in stimulation index (SI ≥ 3), the assessed polymer was not considered to be sensitising under the conditions of the test.

## Genotoxicity

The assessed polymer was found to be non-mutagenic in a bacterial reverse mutation assay using *Salmonella typhimurium* strains TA98, TA100, TA1535 and TA1537 and *Escherichia coli* strain WP2uvrA-, with or without metabolic activation (OECD TG 471). No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains at any dose tested (33, 100, 333, 1000, 3650, 7300 µg/plate), with or without metabolic activation (S9-mix).

# Environmental exposure

The assessed polymer will be imported into Australia in aqueous solution for reformulation into end-use products or imported as a component of fully finished liquid laundry detergents. Following reformulation, the liquid laundry detergents containing the assessed polymer will be transferred via automatic filling machines into retail containers and distributed by road to warehouses and retailers.

Significant releases of the assessed polymer to the environment are not expected during reformulation, transport or storage.

Use of the assessed polymer in liquid laundry detergents is expected to result in the complete release of the polymer “down the drain” into sewerage treatment plants and aquatic environments.

## Environmental fate

### Dissolution, speciation and partitioning

The assessed polymer is fully miscible in water and expected to be cationic under environmental conditions (pH 4-7). Due to the high molecular weight and cationic functionality, the assessed polymer is expected to remain in water but will eventually partition to soils and sediment (US EPA 2013).

### Degradation

Based on the biodegradation results in water, the assessed polymer is considered persistent.

Degradation studies conducted on a product containing the assessed polymer indicates that it is not readily biodegradable. Test results demonstrated 9% degradation after 28 days (OECD TG 301B). Furthermore, this result does not meet the required threshold to be regarded as evidence of inherent, primary biodegradability (OECD 2006).

### Bioaccumulation

The assessed polymer has a high molecular weight (NAMW > 1,000 g/mol) and is not expected to be bioavailable. Therefore, the assessed polymer is not expected to bioaccumulate.

## Predicted environmental concentration (PEC)

The predicted environmental concentrations (PEC) in water (receiving environments) have been calculated based on 100% release of the assessed polymer (from the introduction volume) into sewer systems nationwide over 365 days per annum. The extent to which the assessed polymer is removed from the effluent in STP processes was assumed to be 90% as

the assessed polymer is cationic and has a high molecular weight (US EPA 2013). The calculation of the PEC is detailed in the table below:

| | | |
|---|---|---|
| Total Annual Import Volume | 200,000 | kg/year |
| Proportion expected to be released to sewer | 100% | |
| Annual quantity of chemical released to sewer | 200,000 | kg/year |
| Days per year where release occurs | 365 | days/year |
| Daily chemical release | 547.95 | kg/day |
| Water use | 200.0 | L/person/day |
| Population of Australia | 24.386 | Million |
| Removal within STP | 90% | Mitigation |
| Daily effluent production | 4,877 | ML |
| Dilution Factor – River | 1.0 | |
| Dilution Factor – Ocean | 10.0 | |
| PEC – River | 11.24 | µg/L |
| PEC – Ocean | 1.12 | µg/L |

# Environmental effects

## Effects on Aquatic Life

### Acute toxicity

The following measured median lethal concentration (LC50) value for fish and median effective concentration (EC50) value for algae were supplied for an acceptable analogue polymer. The following EC50 value for invertebrates was supplied for the assessed polymer:

| Taxon | Endpoint | Method |
|---|---|---|
| **Fish** | LC50 > 985 mg/L | *Pimephales promelas*<br>(fathead minnow)<br>Mortality<br>OECD TG 202<br>Semi-static<br>Nominal concentration |
| **Invertebrate** | EC50 > 116 mg/L | *Daphnia magna*<br>(water flea)<br>Immobility<br>OECD TG 202<br>Semi-static<br>Nominal concentration |
| **Algae** | ErC50 > 100 mg/L | *Pseudokirchneriella subcapitata*<br>(green algae)<br>Growth rate<br>OECD TG 201<br>Static conditions<br>Nominal concentration |

### Chronic toxicity

The following measured no observed effect concentration (NOEC) value for model organisms was supplied for an acceptable analogue polymer:

| Taxon | Endpoint | Method |
|---|---|---|
| **Algae** | 72 h NOEC ≥ 100 mg/L | *Pseudokirchneriella subcapitata*<br>(green algae)<br>Growth rate<br>OECD TG 201<br>Static conditions<br>Nominal concentration |

## Predicted no-effect concentration (PNEC)

A Predicted No-Effect Concentration (PNEC) was not calculated as, based on the available ecotoxicity studies on the assessed polymer and acceptable analogues, the assessed polymer is not expected to be harmful to aquatic organisms.

# Categorisation of environmental hazard

The categorisation of the environmental hazards of the assessed polymer according to domestic environmental hazard thresholds is presented below:

## Persistence

Persistent (P). Based on a supplied degradation study, the assessed polymer is categorised as Persistent.

## Bioaccumulation

Not Bioaccumulative (Not B). Based on its expected low bioavailability, the assessed polymer is categorised as Not Bioaccumulative.

## Toxicity

Not Toxic (Not T). Based on available ecotoxicity values above 1 mg/L for the assessed polymer and suitable analogue, the assessed polymer is categorised as Not Toxic.

# Environmental risk characterisation

The assessed polymer is not PBT and is hence unlikely to have unpredictable long-term effects (EPHC 2009). The Risk Quotient (PEC/PNEC) for the aquatic compartment was not calculated as the assessed polymer is not expected to be harmful to aquatic organisms.

Correspondingly, based on the assessed polymer's low toxicity and low bioaccumulation potential, the overall hazard is low and the assessed polymer's risk to the environment can likely be managed.

# References

ECHA (European Chemicals Agency) (2008) *Guidance on information requirements and chemical safety assessment* Chapter R.10: Characterisation of dose [concentration]-response for environment, ECHA, accessed March 2022.

EPHC (Environment Protection and Heritage Council) (2009), *Environmental Risk Assessment Guidance Manual for industrial chemicals*, EPHC, accessed February 2022.

OECD (Organisation for Economic Co-operation and Development) (2006), *Revised Introduction to the OECD Guidelines for Testing of Chemicals, Section 3, OECD Guidelines for the Testing of Chemicals, Section 3*, OECD, accessed March 2022.

UNECE (United Nations Economic Commission for Europe) (2017) *Globally Harmonized System of Classification and Labelling of Chemicals (GHS) Seventh Revised Edition*, UNECE, accessed February 2022.

US EPA (United States Environmental Protection Agency) (2013), *Interpretive Assistance for the Assessment of Polymers*, US EPA, accessed June 2022.