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

2-Propen-1-aminium, *N*,*N*-dimethyl-*N*-2-propen-1-yl-, chloride (1:1), polymer with .alpha.-(2-methyl-1-oxo-2-propen-1-yl)-.omega.-methoxypoly(oxy-1,2-ethanediyl) and 2-propenamide

Assessment statement (CA09798)

5 February 2024

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AICIS assessment (CA09798)

Chemical in this assessment

Name	CAS registry number
2-Propen-1-aminium, *N*,*N*-dimethyl-*N*-2-propen-1-yl-, chloride (1:1), polymer with .alpha.-(2-methyl-1-oxo-2-propen-1-yl)-.omega.-methoxypoly(oxy-1,2-ethanediyl) and 2-propenamide	2715005-56-2

Reason for the assessment/evaluation

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

Certificate Application type

AICIS received the application in an Environment Focus type.

Defined scope of assessment

The polymer has been assessed:

- as having a number average molecular weight greater than or equal to 100,000 g/mol, having low molecular weight species less than 1,000 g/mol below 5% and less than 500 g/mol below 2%, and cationic density (functional group equivalent weight of cationic groups) ≥ 100 g/mol;
- as imported at a maximum concentration of 10% at up to 180 tonnes/year;
- for end use in liquid fabric softener products for machine washing and washing by hand at a concentration of up to 0.1%, for use by professional workers and the general public.

Summary of assessment

Summary of introduction, use and end use

The assessed polymer will not be manufactured in Australia. It will be imported at 10% concentration for reformulation into finished liquid fabric softener products at up to 0.1% concentration, as an antistatic/softening agent. These finished products will be packaged into 250 mL to 2,000 mL bottles suitable for retail sale and are proposed to be used by professional workers under commercial settings and by the general public.

Human health

Summary of health hazards

No toxicological data were submitted for the assessed polymer. Based on the limited read-across data provided, the assessed polymer is:

- slightly irritating to skin

No data on acute toxicity, skin sensitisation, genotoxicity or repeated dose toxicity were provided.

The assessed polymer contains quaternary ammonium groups, which are of concern for corrosion and skin sensitisation (Barratt *et al*., (1994), Tsakovska *et al*., (2007)). An analogue polymer at 10% concentration was found to be slightly irritating to skin and not irritating to eyes, in non-guideline studies. The potential for the assessed polymer to elicit sensitisation effects, and to elicit irritation/corrosion effects at higher concentrations cannot be ruled out.

The assessed polymer contains a residual monomer that is classified as carcinogenic, mutagenic and reprotoxic according to the GHS criteria. However, the concentration of this residual monomer in the assessed polymer is below the GHS cut-off concentration for hazard classification of the polymer.

No repeated dose toxicity data were provided on the assessed polymer. The assessed polymer has a high number average molecular weight (NAMW; > 100,000 g/mol) and low levels of low molecular weight species. Therefore, the assessed polymer is not expected to be absorbed across biological membranes to cause systemic toxicity effects.

Based on the information submitted the assessed polymer is considered to be soluble in water and is not introduced in particulate form, and so does not meet the definition of either a high molecular weight polymer that is water absorbing or a high molecular weight polymer that has lung overloading potential (as given in the Industrial Chemicals Categorisation Guidelines).

Hazard classifications relevant for worker health and safety

Based on limited data provided by the applicant, the assessed polymer cannot be classified, according to the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) (UNECE 2017) for hazard classes relevant for work health and safety as adopted for industrial chemicals in Australia.

Summary of health risk

Public

There will be widespread and repeated exposure of the public to the assessed polymer at up to 0.1% concentration through the use of liquid fabric softener products. The principal route of exposure will be dermal, while ocular exposure is also possible. The public may be exposed to the polymer while adding fabric softener during machine washing, or while using the fabric softener for hand washing. Some of the polymer may be deposited on washed fabrics.

Based on analogue data, the assessed polymer is expected to be slightly irritating to skin and non irritating to eyes at 10% concentration. However, skin irritation is not expected to occur from use of the assessed polymer in liquid fabric softener at the proposed low end use concentrations up to 0.1%.

Furthermore, the assessed polymer is not expected to pose systemic health effects to the public through repeated exposure at the proposed low end use concentration.

Overall, this assessment does not identify any risks to public health that would require specific risk management measures.

Workers

Reformulation workers may experience exposure to the assessed polymer at a concentration of 10% or less during reformulation processes. While exposure to the assessed polymer will be mainly via the dermal route, ocular and inhalation exposure may also occur if there are splashes, or if aerosols or mists are generated during formulation. Workers may experience slight skin irritation to the assessed polymer if exposed to the assessed polymer during reformulation activities. To mitigate potential risks from skin irritation and repeated dermal exposure to reformulation workers, control measures would be required (see **Means for managing risk**) to minimise dermal exposure. Control measures to minimise inhalation exposure may be needed if aerosols or mists are formed during these processes. It is anticipated by the applicant that personal protective equipment (PPE) such as safety goggles, chemically impervious gloves and coveralls will be worn by reformulation workers and that engineering controls such as enclosed and automated processes, and adequate ventilation will be implemented where possible.

Professional workers may have incidental dermal and ocular exposure to the assessed polymer in end-use products at up to 0.1% during commercial laundry operations. This may occur through spills or splashes while workers are changing the containers of fabric softener. Exposure of these workers is likely to be at a similar or higher frequency than the public. It is expected that PPE and safe work practices may be used by these workers.

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

The assessed polymer satisfies the criteria for classification according to the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) (UNECE, 2017) based on the toxicity data for algae. Considerations were also made for the biodegradation of the assessed polymer.

Environmental Hazard	Hazard Category	Hazard Statement
Hazardous to the aquatic environment (acute / short-term)	Aquatic Acute 2	H401: Toxic to aquatic life
Hazardous to the aquatic environment (chronic / long-term)	Aquatic Chronic 2	H411: Toxic to aquatic life with long lasting effects

Summary of environmental risk

The assessed polymer will be introduced as an antistatic/softening ingredient for use in liquid fabric softener products. Use of the assessed polymer in these products is expected to result in the release of the assessed polymer “down the drain” and into the sewers. Consequently, the assessed polymer will be treated at sewage treatment plants (STPs) before release to surface waters.

Although the assessed polymer is persistent, it does not meet all three PBT criteria. It is hence unlikely to have unpredictable long-term environmental effects (EPHC 2009). An estimate of risk may therefore be determined using the risk quotient method (RQ = PEC ÷ PNEC). Based on calculated RQ values < 1 for the river and ocean compartments, the environmental risk from the introduction of the assessed polymer can be managed.

Means for managing risk

Workers

Information relating to safe introduction and use

The information in this statement should be used by a person conducting a business or undertaking at a workplace (such as an employer) to determine the appropriate controls under the relevant jurisdiction Work Health and Safety laws.

The following control measures could be implemented to manage the risks arising from exposure to the assessed polymer during reformulation:

- Use of safe work practices to
  - Avoid contact with skin
  - Avoid inhalation of mists/aerosols
- Use of personal protective equipment (PPE)
  - Impervious gloves
  - Protective clothing

Environment

No specific recommendations for the use of the assessed polymer are required.

Conclusions

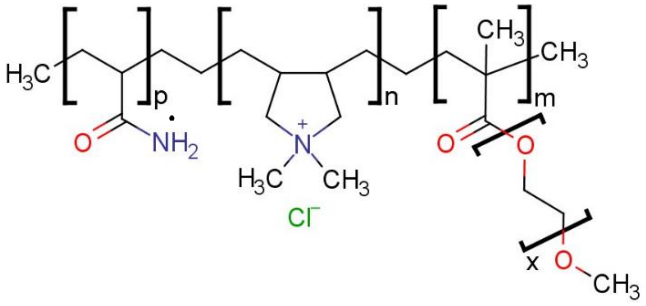
The Executive Director is satisfied that the risks to human health and the environment associated with the introduction and use of the industrial chemical can be managed.

Note:

1. Obligations to report additional information about hazards under s 100 of the *Industrial Chemicals Act 2019* apply.
2. You should be aware of your obligations under environmental, workplace health and safety and poisons legislation as adopted by the relevant State or Territory.

Supporting information

Chemical identity

Chemical name	2-Propen-1-aminium, *N*,*N*-dimethyl-*N*-2-propen-1-yl-, chloride (1:1), polymer with .alpha.-(2-methyl-1-oxo-2-propen-1-yl)-.omega.-methoxypoly(oxy-1,2-ethanediyl) and 2-propenamide
CAS No.	2715005-56-2
Molecular formula	$(C_8H_{16}N.C_3H_5NO.(C_2H_4O)_nC_5H_8O_2.Cl)_x$
Molecular weight	NAMW > 100,000 g/mol
Percentage of low molecular weight species (< 1,000 g/mol)*	4.39
Percentage of low molecular weight species (< 500 g/mol)*	0
Chemical description	Cationic polymer
Structural formula	

*Determined on filtered subset of assessed polymer

Relevant physical and chemical properties

Physical form	Viscous transparent liquid*
Melting point	Less than 5 °C*
Boiling point	Greater than 100 °C - decomposes at greater than 150 °C*
Relative density	1.02 – 1.04* g/mL
Water solubility	Miscible in water
Ionisable in the environment?	Yes

* Based on the assessed polymer at 10% concentration in aqueous solution

Health hazard information

The results from toxicological investigations provided by the applicant are discussed below. These investigations were conducted on a structural analogue* to the assessed polymer at 10% concentration. No toxicological data was provided for the assessed polymer.

* CAS Name: 2-Propen-1-aminium, *N*,*N*-dimethyl-*N*-2-propen-1-yl-, chloride (1:1), polymer with 2-propenamide; CAS No. 26590-05-6; NAMW: 600,000 g/mol.

Irritation

Eye irritation

An *in vitro* rabbit corneal fibroblast cytotoxicity assay (in-house method) was used to test the eye irritation potential of the aforementioned analogue of the assessed polymer, at 10% concentration in aqueous solution.

Seruminstitut Rabbit Cornea (SIRC) fibroblasts were exposed to the test substance for 30 minutes, 1 hour and 4 hours. A negative control (paraffin oil) was run in parallel with the test substance for 30 minutes. A cytotoxicity assay was then performed using MTT [3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide].

No cytotoxicity was observed in the treated and control samples. From these results an ocular irritation index score of 0.0 was calculated for the test substance which, according to the study authors, corresponded to a rating of slightly irritating. However, as the irritation score was zero, the results suggest that the assessed polymer is not irritating to the eye at 10% concentration.

Observation in humans: Skin irritation

A human occlusive patch test for skin irritation (in-house method) was conducted in 13 subjects. The test substance was the aforementioned analogue to the assessed polymer, at 10% concentration in aqueous solution. The test substance was applied under occlusive conditions for 24 hours. The test was completed by 11/13 subjects. The remaining subjects

(n = 2) were excluded from the study due to the slight erythema observed at the negative control (distilled water) site.

As only very slight erythema was observed in 1/11 subjects, the study authors concluded that the chemical was unlikely to be an irritant.

Based on the results, the assessed polymer at 10% concentration is considered as slightly irritating to the skin but does not meet the GHS criteria for classification as adopted by Australia for industrial chemicals.

Environmental exposure

The assessed polymer will be imported into Australia as a component of liquid formulations for reformulation into end-use products. Reformulation will occur through mostly closed processes. Significant releases of the assessed polymer to the environment are not expected during reformulation, transport or storage. Release of the products containing the assessed polymer to the environment due to accidental spills is expected to be absorbed on suitable materials, and disposed of in accordance with relevant Local, State, Territory and Federal regulations. Any unused product containing the assessed polymer is expected to be disposed of in accordance with relevant Local, State, Territory and Federal regulations.

The assessed polymer is an antistatic/softening ingredient to be included in liquid fabric softener products. Use of these products is expected to result in the release of the assessed polymer “down the drain” and into the sewers. Consequently, the assessed polymer will be treated at sewage treatment plants (STPs) before release to surface waters.

Environmental fate

Partitioning

As the assessed polymer is a cationic polymer, it is expected to have low mobility in soil and sediment due to ion exchange mechanisms (US EPA, 2013).

The assessed polymer is expected to be highly soluble in water based on its hydrophilic functional group and formulation as aqueous solutions. If the assessed polymer is released to surface waters, a proportion of the assessed polymer is expected to remain in water compartment and a proportion of it is expected to partition to sediment, based on its solubility in water, high molecular weight and cationicity.

As the assessed polymer has a very high molecular weight, its vapour pressure and volatility are expected to be negligible (US EPA, 2013).

Degradation

Based on the available information, the assessed polymer is categorised as persistent.

The assessed polymer is a high molecular weight cationic polymer. The polymer backbone is composed of C-C and C-N bonds which are expected to be resistant to biodegradation. The side chains consist of amide and polyethylene glycol moieties which may be susceptible to degradation. Overall, the polymer is not expected to be readily biodegradable.

The assessed polymer is not expected to hydrolyse under ambient environmental conditions.

Bioaccumulation

Based on its high molecular weight, the assessed polymer is considered not bioaccumulative.

No bioaccumulation information was provided for the assessed polymer. The assessed polymer has high molecular weight, which is usually of low concern for bioaccumulation (US EPA, 2013). Therefore, the assessed polymer is considered not bioaccumulative.

Predicted environmental concentration (PEC)

A predicted environmental concentration (PEC) for Australian waters was calculated assuming 100% of the introduction volume is released into sewage treatment plants (STPs) over 365 days per annum. As the assessed polymer is a cationic polymer with NAMW far above 1,000 g/mol, its removal through STP process is expected to be 90% (US EPA, 2013). Therefore 10% of the total introduction volume is estimated to be released to the aquatic environment. The calculation of the PEC (US EPA, 2013; EPHC, 2009) is detailed in the table below:

Total Annual Import Volume	180,000	kg/year
Proportion expected to be released to sewer	100 %	
Annual quantity of chemical released to sewer	180,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release	493	kg/day
Water use	200	L/person/day
Population of Australia	25.423	Million
Removal within STP	90 %	Mitigation
Daily effluent production	5,085	ML/day
Dilution Factor – River	1	
Dilution Factor – Ocean	10	
PEC – River	10.67	µg/L
PEC – Ocean	1.07	µg/L

Environmental effects

Effects on aquatic Life

Acute toxicity

The following measured median lethal concentration (LC50) and median effective concentration (EC50) values for model organisms were supplied for the assessed polymer:

Taxon	Endpoint	Method
Fish	96 h LC50 > 3.4 mg/L*	*Brachydanio rerio* (Zebra fish) Mortality OECD TG 203 Static conditions Nominal concentration
Invertebrate	48 h EC50 > 100 mg/L	*Daphnia magna* (Water flea) Immobility OECD TG 202 Static conditions Nominal concentration
Algae	72 h ErC50 = 3.37 mg/L	*Raphidocelis subcapitata* (Green algae) Growth rate inhibition OECD TG 201 Static conditions Nominal concentration

*This is a threshold test; the test concentration was selected based on ErC50 of the algal test

Chronic toxicity

The following measured 10th-percentile effective concentration (EC10) value for model organism was supplied for the assessed polymer:

Taxon	Endpoint	Method
Algae	72 h ErC10 = 0.9 mg/L	*Raphidocelis subcapitata* (Green algae) Growth rate inhibition OECD TG 201 Static conditions Nominal concentration

Predicted no-effect concentration (PNEC)

A predicted no-effect concentration (PNEC) of 33.7 µg/L was calculated for the assessed polymer in the aquatic environment. This value was derived using the most conservative acute endpoint value for algae (3.37 mg/L). An assessment factor of 100 was applied to this endpoint as acute toxicity data was available for three trophic levels and chronic toxicity data was incomplete (EPHC, 2009). The acute endpoint was selected, over the algal chronic endpoint, in the absence of additional chronic endpoints to support the algal growth rate ErC10 (ECHA 2008).

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 the available information, the assessed polymer is categorised as Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on its very high molecular weight, the assessed polymer is categorised as Not Bioaccumulative.

Toxicity

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

Environmental risk characterisation

Although the assessed polymer is persistent, it does not meet all three PBT criteria. It is hence unlikely to have unpredictable long-term effects (EPHC 2009). An estimate of risk may therefore be determined using the risk quotient method.

Based on the PEC and PNEC values determined above, Risk Quotients (RQ = PEC ÷ PNEC) have been calculated for release of the assessed polymer to water:

Compartment	PEC	PNEC	RQ
River	10.67 µg/L	33.7 µg/L	0.317
Ocean	1.07 µg/L	33.7 µg/L	0.032

For the river and ocean compartments, an RQ less than 1 indicates that introduction of the assessed polymer, in line with the terms outlined in this assessment certificate, is not expected to pose a significant risk to the environment. As such, the risk from the assessed polymer can be managed, based on consideration of the environmental hazard characteristics and estimated releases.

References

Barratt *et al.,* (1994) Development of an expert system rulebase for identifying contact allergens. Toxicology In Vitro. 8:837-839.

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

EPHC (2009) Environment Protection and Heritage Council, Environmental Risk Assessment Guidance Manual for industrial chemicals, Prepared by: Chris Lee-Steere Australian Environment Agency Pty Ltd, February 2009. ISBN 978-1-921173-41-7.

Tsakovska *et al.,* (2007) Evaluation of SARs for the prediction of eye irritation/corrosion potential - structural inclusion rules in the BfR decision support system. SAR and QSAR in Environmental Research. 18: 221-235.

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

US EPA (2013) Interpretive Assistance Document for Assessment of Polymers – Sustainable Futures Summary Assessment, US Environmental Protection Agency, accessed February 2024 at https://www.epa.gov/sites/production/files/2015-05/documents/06-iad_polymers_june2013.pdf.