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

Amines, polyethylenepoly-, reaction products with 2-[(carbopolycyclicoxy) methyl]heteromonocycle and succinic anhydride monopolyisobutenyl derivs.

Assessment statement

19 October 2022

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AICIS assessment statement

Chemical in this assessment

Name	CAS registry number
Amines, polyethylenepoly-, reaction products with 2-[(carbopolycyclicoxy) methyl]heteromonocycle and succinic anhydride monopolyisobutenyl derivs.	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 human health (clause 1, table item 6 of Schedule 1) and 3 for the environment [clause 3, table item 3 of Schedule 1 of the *Industrial Chemicals (General) Rules 2019* (the Rules)].

The assessed polymer does not have any of the human health hazard characteristics in human health hazard bands A, B or C (clause 2, Schedule 1) and has the environment hazard characteristics in environment hazard band A (clause 4, table item 10 of Schedule 1).

In accordance with table item 14, section 28 and table item 13, section 29 of the Rules, the indicative human health risk for the proposed introduction is very low and the indicative environment risk for the proposed introduction is low.

Defined scope of assessment

The chemical has been assessed:

- as a polymer with a number average molecular weight greater than or equal to 1,000 g/mol, having low molecular weight species less than 1,000 g/mol below 5%, and functional group equivalent weight (FGEW) of amines greater than 1,000 g/mol;
- as imported into Australia at up to 200 tonnes per year;
- for use by workers only.

Summary of assessment

Summary of introduction, use and end use

The assessed polymer will be imported into Australia at up to 25% concentration, for reformulation into end use lubricant products, or as a component in finished lubricants for end use in engine oils, transmission and hydraulic fluids, and gear oil. The imported or reformulated end use products will contain the assessed polymer at up to 5% concentration.

The imported polymer at up to 25% concentration will be distributed to reformulation facilities, where the typical blending processes will be carried out in closed systems and under local and general ventilation. The finished lubricant containing the assessed polymer at up to 5% will be packed into 205 L drums or plastic bottles of 1 – 5 L size and distributed to a range of commercial sites. The lubricant will be transferred into equipment or machinery by automated or manual means. There will be no consumer use of products containing the assessed polymer.

Human health

Summary of health hazards

Although the assessed polymer has structural alerts for skin irritation and potentially skin sensitisation, the studies on the polymer with the stated molecular weight and chemical profile indicate that it is not classified under GHS for these health endpoints. Adverse effects were not found for the other endpoints tested. Based on the available toxicology data on the assessed polymer or analogue polymers, the assessed polymer is of:

- low acute oral and dermal toxicity
- not a skin or eye irritant
- not a skin sensitiser
- not expected to cause systemic effects from repeated exposure
- not genotoxic.

Health hazard classification relevant to worker health and safety

Based on the available data, the assessed polymer does not satisfy the criteria for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) (UNECE 2017), for hazard classes relevant for worker health and safety as adopted for industrial chemicals in Australia.

Summary of health risk

Public

The lubricants containing the assessed polymer will not be available for use by the public. When introduced and used in the proposed manner, it is unlikely that the public will be exposed to the assessed polymer. Therefore, there are no identified risks to the public that require management, if the assessed polymer is introduced and used by workers only, in accordance with the terms of the assessment certificate.

Workers

Workers may experience dermal and incidental ocular exposure to the assessed polymer at up to 25% concentration during the handling, reformulation and use of the lubricants containing the assessed polymer.

Based on the hazard profile, this assessment does not identify any risks to the health of workers that would require risk management measures when the assessed polymer is introduced in accordance with the terms of the assessment certificate.

Environment

Summary of environmental hazard characteristics

According to domestic environmental hazard thresholds and based on the available data the 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, it is not expected to be harmful to aquatic life. Therefore, the assessed polymer does not satisfy the criteria for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) (UNECE 2017) for acute and chronic aquatic toxicities.

Summary of environmental risk

The assessed polymer will not be available to “do it yourself” (DIY) users, which limits the volume that may be released through incorrect disposal.

No significant release of the assessed polymer is expected to occur as a result of its use as a lubricant additive.

The assessed polymer is expected to share the fate of the lubricant it is incorporated into.

Used lubricants are expected to be collected by licensed waste management contractors for recycling, re-refining or disposal under local government regulations.

The assessed polymer is not expected to bioaccumulate or cause toxic effects in aquatic organisms.

Based on its low hazards and the assessed use pattern, the assessed polymer is unlikely to cause environmental risks.

Means for managing risk

No specific means for managing risk are required when the assessed polymer is introduced in accordance with the terms of the assessment certificate.

Conclusions

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.

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

Supporting information

Chemical identity

Chemical name	Amines, polyethylenepoly-, reaction products with 2-[(carbopolycyclicoxy)methyl]heteromonocycle and succinic anhydride monopolyisobutenyl derivs. (AACN)
Synonyms	041419
Molecular formula	Unspecified
Number average molecular weight (Mn)	≥ 1,000 g/mol
Percentage of low molecular weight species (< 1,000 g/mol)	< 5%

Relevant physical and chemical properties

Physical form	Dark brown viscous liquid
Melting point	-3 °C (Pour point)
Boiling point	Decomposes at 268 °C
Density	917.8 kg/m^3
Vapour pressure	3 × 10^{-6} kPa at 20 °C
Water solubility	4.33 × 10^{-9} mg/L (calc.)
log K_{ow}*	9.58 (calc.)
log K_{oc}*	10.59 (calc.)

*Supplied calculation performed on a representative substance (MW: 955.39 g/mol) using EPI Suite v4.11.

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 the unlikely event of an accidental rupture of containers.

Reformulation

During reformulation/blending, there is a potential for worker exposure to the assessed polymer at up to 25% concentration. The manufacturing plants use automated systems that

transfer the formulation from transports to storage tanks. Blending operations are also expected to be automated and will be carried out in closed systems, limiting the potential exposure of workers. Worker exposure to the assessed polymer is possible during the changing of filling lines and drums. However, according to the applicant, this process is expected to be well-controlled to limit the potential for worker exposure.

Professional End Use

At end use sites, as the lubricants will be added to an enclosed system, the amount of lubricant oils released during use is expected to be negligible. Professional workers may experience dermal or ocular exposure to the end use products containing the assessed polymer at up to 5% concentration during the filling, draining out after service life, or replacement of lubricants, especially where this is a manual process.

Health hazard information

Toxicokinetics

No toxicokinetic data are provided for the assessed polymer.

The assessed polymer is not expected to be absorbed across biological membranes, given its:

- high number average molecular weight (≥ 1,000 g/mol)
- low water solubility
- low level of low molecular weight species.

Acute toxicity

Oral

Based on an acute toxicity study conducted following OECD TG 423 (Acute Toxic Class Method), the assessed polymer at 83.4% concentration was found to be of low acute oral toxicity in rats (LD50 > 2,000 mg/kg bw).

Dermal

Based on an acute toxicity study conducted following OECD TG 402, the assessed polymer at 83.4% concentration was found to be of low acute dermal toxicity in rats (LD50 > 2,000 mg/kg bw).

Corrosion/Irritation

Skin irritation

In an *in vitro* skin irritation study (OECD TG 439 - Reconstructed Human Epidermis Test) conducted using the assessed polymer at 83.4% concentration, the mean tissue viability was 56.8% after 1 h of exposure to the test substance. As the tissue viability was > 50%, the assessed polymer is not classified as a skin irritant according to the TG using the GHS criteria. However, based on the tissue viability being just above the 50% cut-off value in the TG for classification, slight skin irritation effects from the assessed polymer cannot be ruled out.

Eye irritation

In an *in vitro* eye irritation study (OECD TG 492 - Reconstructed Human Cornea-like Epithelium (RhCE) Test Method: EpiOcular™ Eye Irritation Test) conducted using the assessed polymer at 83.4% concentration, the mean tissue viability of the test substance was > 60% after 30 min of exposure to the test substance. Based on this result, the assessed polymer is not classified as an eye irritant according to the TG using the GHS criteria.

Sensitisation

Skin sensitisation

In a modified local lymph node assay (LLNA) conducted following the OECD TG 442b (LLNA: BrdU-ELISA), the assessed polymer at 10%, 25% and 50% concentrations caused none to very slight erythema in all treated animals, with some localized hair loss at the base of the ears in the high dose group. The Stimulation Indices (SI) were calculated, from 5-bromo-2-deoxyuridine (BrdU) incorporation in the lymph node cells (LNC) of treated animals compared to the control group, to be 0.7, 1.4 and 1.2 for 10%, 25% and 50% respectively. Based on the definitions of the test guideline, a 1.6-fold or greater increase (SI > 1.6) in LNC proliferation relative to the control, would be considered a positive or borderline result for sensitisation. None of the dose groups gave an SI > 1.6 and the results did not show a dose dependent response. Based on the SI, the test substance was not considered to be a skin sensitiser. An additional study was conducted concurrently with this LLNA using immunophenotyping, with the aim of distinguishing irritation and sensitisation effects. However, the study did not provide a conclusive outcome.

Repeat dose toxicity

Oral

No repeat dose toxicity study data are provided for the assessed polymer. Considering the high molecular weight and low water solubility of the assessed polymer, absorption of it through biological membranes to cause systemic toxicity effects will be limited.

A summary of a non-guideline 28-day study in rats was provided for a structurally similar analogue polymer. The study summary reported an increased level of bilirubin in rats treated at 1,000 mg/kg bw/day. However, it was reported that there were no signs of liver damage or notable effects in the organs observed during necropsy. The study authors determined the no-observed-adverse-effect level (NOAEL) as 250 mg/kg bw/day for the analogue polymer.

Genotoxicity

The assessed polymer at 83.4% concentration was found to be non-mutagenic in a bacterial reverse mutation assay (OECD TG 471) using TA1535, TA1537, TA98 and TA100 strains of *Salmonella typhimurium* and WP2uvrA strain of *Escherichia coli*. No signs of cytotoxicity were observed, and no positive results for mutagenicity were observed in any of the tested strains, up to a concentration of 5,000 µg/plate.

A structurally similar analogue polymer was found to be non-genotoxic in an *in vitro* mammalian chromosome aberration test (similar to OECD TG 473), up to a concentration of 1,000 µg/mL.

Environmental exposure

The assessed polymer will be imported into Australia and will be blended into lubricants before use. Sealed delivery systems will be used to transfer products containing the assessed polymer from product containers into blending vessels. Blending operations are expected to be automated and will be carried out in closed systems. This limits the potential for release. Any spills that occur during the blending process are expected to be collected for appropriate disposal.

Blended lubricants containing the assessed polymer will be used within closed systems in machinery. The filling of these systems for new machinery is expected to be automated, but manual filling by professional workers may occur during service activities. Any spills that occur during these filling processes are expected to be collected for appropriate disposal.

The assessed polymer is expected to remain in the finished products during its useful lifetime. Some lubricants are formulated to be “fill for life” but may need replacement during unscheduled servicing. Others are replaced during scheduled servicing. Lubricant replacement is expected to be performed by professional workers. The used lubricants are expected to be collected and disposed of through waste management contractors for recycling, re-refining or disposal under local government regulations. Any spills that occur during these filling processes are expected to be collected for appropriate disposal.

Environmental fate

Partitioning

The assessed polymer has a high molecular weight (≥ 1,000 g/mol) and is not expected to be water soluble. Calculated values for partition coefficient (log Kow = 9.58) and adsorption (log Koc = 10.59), for a representative substance, indicate that if the assessed polymer is released to the environment, it will partition to, and be immobile in, soils and sediments.

Degradation

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

Degradation studies conducted on the assessed polymer indicate that it is not readily biodegradable. Test results demonstrated 2% degradation after 28 days (OECD TG 301B). Furthermore, this resulting degradation 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 (≥ 1000 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 concentration (PEC) has not been calculated, as release of the assessed polymer to the aquatic environment will be negligible based on its assessed use pattern.

Environmental effects

Acute toxicity

The following measured median effective loading (EL50) values for aquatic invertebrates and algae were supplied for the assessed polymer:

Taxon	Endpoint	Method
Invertebrate	EL50 > 100 mg/L	*Daphnia magna* (water flea) Immobility OECD TG 202 Static conditions Nominal concentration
Algae	ErL50 > 100 mg/L	*Pseudokirchneriella subcapitata* (Green algae) Growth rate OECD TG 201 Static conditions Nominal concentration

The assessed polymer is expected to have negligible solubility in water. Provided *in silico* ecotoxicity calculations (ECOSAR v1.11) support the provided measured ecotoxicity endpoints and indicate that no effects are expected up to saturation.

Predicted no-effect concentration (PNEC)

A predicted no-effect concentration (PNEC) for the aquatic compartment could not be calculated.

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 not bioaccumulative.

Toxicity

Not Toxic (Not T). Based on available acute ecotoxicity values for the assessed polymer, low water solubility and calculated ecotoxicity, the assessed polymer is categorised as Not Toxic.

Environmental risk characterisation

A Risk Quotient (PEC/PNEC) for the aquatic compartment could not be calculated. However, the assessed polymer is not expected to be harmful to aquatic life, and release of the assessed polymer to the aquatic environment will be negligible based on its assessed use pattern.

Thus, based on its low hazard and the assessed use pattern, the assessed polymer is unlikely to cause environmental risks.

References

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 Publishing, Paris, https://doi.org/10.1787/9789264030213-en.

UNECE (2017). Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Seventh Revised Edition. New York and Geneva: United Nations.