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

Amines, polyalkenepoly-, reaction products with substituted heteromonocycle and succinic anhydride polyisobutenyl derivs.

Assessment statement (CA09858)

24 January 2025

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AICIS assessment (CA09858)

Chemical in this assessment

AICIS Approved Chemical Name (AACN)
Amines, polyalkenepoly-, reaction products with substituted heteromonocycle and succinic anhydride polyisobutenyl derivs.

Reason for the assessment

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 a Very Low to Low Risk type.

Defined scope of assessment

The chemical has been assessed:

- as a polymer with a number average molecular weight (NAMW) 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 100 tonnes per year
- imported as a component of lubricant additive at up to 60% concentration for local reformulation into end use lubricant oil products at up to 10% concentration
- for use as a lubricant oil additive in machinery and automotives by consumers and professional workers

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 at up to 100 tonnes per annum at up to 60% concentration as a component of lubricant additive for further local reformulation into end use lubricant oil products. Once imported into Australia, these products will be directly transported to the lubricant oil manufacturers for further reformulation into end use products. The reformulated end use lubricant oil products will contain the assessed polymer at up to 10% concentration.

The end use lubricant oil products containing the assessed polymer at up to 10% concentration will be used as a lubricant additive for machinery and automotives by professional mechanics, service technicians and by do-it-yourself (DIY) consumers.

Human health

Summary of health hazards

The submitted toxicological data on analogue polymers (see **Supporting information**) indicate that the assessed polymer is:

- of low acute oral and inhalation toxicity
- not a skin sensitiser
- not expected to cause systemic effects from repeated oral exposure, the No Observed Adverse Effects Level (NOAEL) being 1,000 mg/kg bw/day in a 28-days rat study
- not mutagenic in a bacterial reverse mutation assay

No skin or eye irritation data were provided for the assessed polymer or for an analogue polymer (see **Supporting information**).

Hazard classifications relevant for worker health and safety

Based on the data provided by the applicant, the assessed polymer does not satisfy the criteria for classification according to the *Globally Harmonized 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 general public (DIY consumers) will potentially be exposed to the end use lubricants oil products containing the assessed polymer at up to 10% concentration during the use of these products. However, considering the infrequent use and the use of small quantity, the exposure to the general public is expected to be minimal.

Therefore, this assessment does not identify any risks to public health that require specific risk management measures. However, as per the applicant, end use products will also contain other components in addition to the assessed polymer, which are likely to be hazardous and require the use of personal protective equipment (PPE). Products label will indicate the recommendations to use PPE as the general industry practice.

Workers

Workers may experience dermal and incidental ocular exposure to the assessed polymer at up to 60% concentration during handling, reformulation and at up to 10% concentration during use of the lubricant oil products containing the assessed polymer.

Based on the hazard profile, and considering the use of engineering controls/enclosed systems/PPE, this assessment does not identify any risks to workers that would require specific risk management measures.

Environment

Summary of environmental hazard characteristics

According to domestic environmental hazard thresholds and based on 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, 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

The assessed polymer will be introduced as a component in lubricant oils used in automotives.

No significant release of the assessed polymer is expected to occur as a result of its use as a lubricant additive. Used lubricants are expected to be collected by licensed waste management contractors for recycling, re-refining or disposal under local government regulations.

However, the assessed polymer will be available to DIY users, which will result in its release to wastewater treatment plants and sewers through incorrect disposal.

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

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

Although the assessed polymer is persistent, according to the Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals (DCCEEW, 2022), it does not meet all three PBT criteria. It is unlikely to have unpredictable long-term effects, and its risk may be estimated by 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

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 the risks to human health or 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

AACN	Amines, polyalkenepoly-, reaction products with substituted heteromonocycle and succinic anhydride polyisobutenyl derivs.

Relevant physical and chemical properties

Physical form	Brown liquid
Melting point	49 ± 3 °C
Boiling point	> 300 °C at 101.7 kPa
Density	911 kg/m^3 at 20.0 ± 1.0 °C
Vapour pressure	5.6 x 10^{-7} kPa at 25 °C
Water solubility	< 1 mg/L at 20°C, pH 6.7
Flash Point	≥ 175 °C at 101.3 kPa*
Ionisable in the environment	No
log K_{ow}	> 6.5 at 20°C

*SDS

Human exposure

Reformulation

Typically, reformulation processes may incorporate blending operations that involve pumping of the assessed polymer into blending tanks through computer-controlled and fully automated valves. The assessed polymer will be blended with other components in a fully enclosed and automated system leading to the reformulated end use lubricant oil products containing the assessed polymer at up to 10% concentration. The finished lubricant oil products will then be transferred to the storage tanks via an automated process. The finished lubricant oil products will then be packed into 205 L drums or small plastic bottles (1-5 L). While dermal, ocular and inhalation exposure (if aerosols or mists are formed) of workers to the assessed polymer is possible during reformulation processes, considering the use of computer controlled fully automated valves and the use of enclosed and automated blending process, minimal exposure is expected to workers.

The finished lubricant oil products will be transferred from the containers by automated or manual means into the machinery or automotives requiring lubrication. Professional users may

experience incidental dermal or ocular exposure to the oil products containing the assessed polymer (at ≤ 10% concentration) when transferring oil into the equipment or during draining used oil.

The potential for dermal and ocular exposure could be reduced through the use of PPE (e.g., gloves, coveralls and eye protection). Inhalation exposure is not expected due to the very low vapour pressure of the assessed polymer (5.6 x 10^{-7} kPa at 25 °C).

End Use

The lubricating oil products containing the assessed polymer at up to 10% concentration will be used by the professional mechanics and service technicians. There is a potential for dermal and ocular exposure during the use of lubricant oil products. However, exposure will be reduced if PPE such as gloves, coveralls and eye protection is used.

Health hazard information

Toxicokinetic

No toxicokinetic studies were submitted for the assessed polymer. Based on its high molecular weight (NAMW > 1,000 g/mol), low level (< 5%) of low molecular weight species < 1,000 g/mol and measured low water solubility (< 1 mg/L at 20°C), absorption across biological membranes is expected to be limited.

Acute toxicity

Oral

In an acute oral toxicity study (OECD TG 420), an analogue polymer in arachis oil BP was administered orally by gavage to a group of four fasted Wistar female rats at 2,000 mg/kg bw. No deaths or signs of systemic toxicity were observed, and all treated animals showed expected body weight gains during the study. All animals survived until the end of the study period and no abnormalities were observed at necropsy. The acute oral LD50 value for the analogue polymer was determined to be > 2,000 mg/kg bw. Therefore, the assessed polymer is expected to be of low acute oral toxicity.

Inhalation

In an acute inhalation toxicity study (OECD TG 403), Wistar Han rats (5/sex/group) were exposed to an analogue polymer (liquid aerosol) as a single 4-hour nose-only exposure at 2.11 mg/L. Animals were observed for a 14-day post exposure observation period.

No mortalities occurred during the study. Slow breathing was observed for all animals during exposure and no clinical signs of systemic toxicity or abnormalities were noted after exposure. However, as no other signs of systemic toxicity were seen after exposure, the slow breathing was considered to be of no toxicological relevance. Overall, the body weight gain shown by the animals over the study period was within the range expected for rats of this strain and age used in this type of study. Macroscopic post-mortem examination did not reveal any abnormalities.

The inhalation LC50 (4 hours) of the analogue polymer was > 2.11 mg/L (the top dose tested), therefore, greater than the GHS threshold for classification (> 1 mg/L). Based on the absence

of toxicological relevant findings, the study authors considered that LC50 will most likely exceed 5 mg/L, indicating low acute inhalation toxicity. Therefore, the assessed polymer is expected to be of low acute inhalation toxicity.

Corrosion/Irritation

No irritation studies were submitted for the assessed polymer or for an analogue polymer.

The assessed polymer contains amine groups, which are functional groups of concern for corrosion/skin irritation (Hulzebos et al., 2005). However, the potential for irritation of the assessed polymer is likely to be minimised by its high molecular weight (NAMW > 1,000 g/mol), low level (< 5%) of low molecular weight species (< 1,000 g/mol), log K_{ow} of > 6.5, and low water solubility (< 1 mg/L).

Therefore, the assessed polymer is not expected to cause irritation.

Sensitisation

In a skin sensitisation study in the Guinea pig (Buehler method (OECD TG 406), albino guinea pigs (n = 10/sex) were subject to 6 hours occluded topical application of an analogue polymer (63% concentration in mineral oil) on day 1, 8 and 15. On day 29 all tested and control animals (using paraffin oil as a vehicle) (n = 5/sex)) were challenged by 6 hours occluded topical application of the analogue polymer. No significant dermal reaction was observed in either test or control animals following topical induction or challenge applications of the analogue polymer (at up to 63% concentration) or paraffin oil.

Under the conditions of this study, dermal application of the analogue polymer did not cause delayed contact hypersensitivity in guinea pigs and, therefore, the assessed polymer is not expected to be a skin sensitiser.

Repeat dose toxicity

A 28-day repeated dose oral toxicity study (with a 14-day recovery period) (OECD TG 407) were submitted for an analogue polymer. Wistar Han rats (n = 5/sex/group) were administered the analogue polymer at 0 (Arachis Oil BP), 100, 300 and 1,000 mg/kg bw/day. Control recovery group rats (n = 5/sex/group) were administered the test substance at 0 and 1,000 mg/kg bw/day. No mortalities or treatment-related adverse effects were observed. There was no effect of treatment on body weight gain, food consumption, or water consumption. There were no treatment-related haematological effects. Organ weights were unaffected by treatment and there were no treatment-related macroscopic or histopathological findings. A NOAEL of 1,000 mg/kg bw/day was established for the analogue polymer, indicating a similar NOAEL for the assessed polymer.

Genotoxicity

No mutagenicity/genotoxicity studies were submitted for the assessed polymer.

An analogue polymer was not mutagenic in the bacterial reverse mutation assay (Ames Test) when tested in *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537, and in the tryptophan locus of *Escherichia coli strain* WP2 uvrA, 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 tested concentration (10.0, 33.3, 100, 333, 667, 1,000, 3,333 and 5,000 µg/plate), with or without metabolic activation (S9-mix).

Therefore, the assessed polymer is not expected to be genotoxic.

Environmental exposure

The assessed polymer will not be manufactured in Australia. It will be imported into Australia at up to 100 tonnes per annum as a component of lubricant additive for reformulation into end use lubricant oil products.

The assessed polymer will be used as an additive in lubricant oils products for end use by professional mechanics, service technicians and DIY consumers.

Reformulation of the assessed polymer into lubricant oils products will occur locally. At reformulation sites, the assessed polymer will be transferred from the import containers into on-site storage tanks, where the assessed polymer will be transferred into blending tanks. The assessed polymer will be blended with other components in a fully closed system. The finished lubricant oil products will then be transferred to the storage tanks for distribution. All transfers and blending processes of the assessed polymer will be done through a fully automated system.

Any environmental releases of the assessed polymer from reformulation are expected to be minimal due to the fully automated transfers and blending processes. Any incidental releases during reformulation and professional use are expected to be collected for appropriate disposal. Wastes and residues in empty containers are expected to be collected and disposed of to landfill according to local government regulations.

A 2013 report found that only 4% of households were disposing of motor oil (either correctly or incorrectly) in Australia (Aither 2013). This suggests that DIY users may make up a small portion of all consumers of vehicle maintenance products, and that the vast majority of vehicle maintenance is performed through professional mechanic services. On this basis, the worst-case exposure scenario arising from DIY uses would be a situation where all DIY users incorrectly disposed of lubricant oils containing the assessed polymer, estimated to be 4% of the introduction volume.

Environmental fate

Partitioning

The assessed polymer has a high molecular weight (NAMW > 1,000 g/mol), is slightly soluble (water extractability < 1 mg/L) and has a high partition coefficient (log K_{ow} > 6.5). If the assessed polymer is released to the environment, it is expected to partition to and adsorb strongly to soils and sediments and become immobile (US EPA, 2013).

As the assessed polymer has a high molecular weight (NAMW > 1,000 g/mol), its vapour pressure and volatility are expected to be negligible (US EPA, 2013). As such, the assessed polymer is not expected to evaporate and partition to air.

Degradation

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

Results from supplied degradation studies conducted on a suitable analogue of the assessed polymer showed 0% degradation after 28 days (OECD TG 301D). Therefore, the assessed polymer is not readily biodegradable.

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 concentration (PEC) has been predicted for Australian waters assuming 4% of the total introduction volume used in lubricant oils is expected to be released to sewers due to improper disposal from DIY users.

The calculation of the PEC is detailed in the table below:

Total Annual Import Volume	100,000	kg/year
Proportion expected to be released to sewer	4 %	
Annual quantity of chemical released to sewer	4,000,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release	10.96	kg/day
Water use	200.0	L/person/day
Population of Australia	25.423	million
Removal within STP	85 %	mitigation
Daily effluent production	5,085	ML/day
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River	0.32	µg/L
PEC - Ocean	0.03	µg/L

Environmental effects

Acute toxicity

The following measured median lethal loading (LL50) and effective loading (EL50) values for fish, aquatic invertebrates and algae were supplied for a suitable analogue of the assessed polymer:

Taxon	Endpoint	Method
Fish	96hr LL50 > 100 mg/L	*Oncorhynchus mykiss* (rainbow trout) Mortality OECD TG 203 Static conditions Nominal concentration
Invertebrate	48hr EL50 > 100 mg/L	*Daphnia magna* (water flea) Immobility OECD TG 202 Static conditions Nominal concentration
Algae	72hr EL50 > 100 mg/L	*Pseudokirchneriella subcapitata* (Green algae) Growth rate OECD TG 201 Static conditions Nominal concentration

Predicted no-effect concentration (PNEC)

A predicted no-effect concentration (PNEC) of > 1 mg/L was calculated based on a suitable analogue of the assessed polymer in the aquatic environment. This value was derived using the endpoint value for fish (LL50 > 100 mg/L). An assessment factor of 100 was applied to this endpoint as acute toxicity data were provided for all three trophic levels and chronic toxicity data were not provided (EPHC, 2009).

Categorisation of environmental hazard

The categorisation of the environmental hazards of the assessed polymer according to the Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals (DCCEEW, 2022) is presented below:

Persistence

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

Bioaccumulation

Not Bioaccumulative (Not B). The assessed polymer has a high molecular weight (NAMW > 1000 g/mol) and is not expected to be bioavailable. As such, 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, soil and sediment:

Compartment	PEC	PNEC	RQ
River	0.32 µg/L	1,000 µg/L	0.003
Ocean	0.03 µg/L	1,000 µg/L	0.0003

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

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