Australian Government
Department of Health
Australian Industrial Chemicals Introduction Scheme

2-Propenoic acid, 2-methyl-, butyl ester, polymers with alkyl methacrylate, substituted-methylethyl-terminated hydrogenated polyalkene methacrylate, Me methacrylate and styrene

Assessment statement

10 January 2022

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AICIS assessment statement

Chemical(s) in this assessment

Name	CAS registry number
2-Propenoic acid, 2-methyl-, butyl ester, polymers with alkyl methacrylate, substituted-methylethyl-terminated hydrogenated polyalkene methacrylate, Me methacrylate and styrene	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

The assessed polymer meets the criteria as a polymer of low concern (PLC) [Schedule 2 of the *Industrial Chemicals (General) Rules 2019* (the Rules)] and is not a high molecular weight polymer that has lung overloading potential. Therefore the introduction of the assessed polymer meets the circumstances in which introductions are exempted introductions (Section 26 of the Rules). An exempted introduction is an industrial chemical introduction that poses a very low risk to human health and the environment.

Defined scope of assessment

The chemical has been assessed:

- as meeting the PLC criteria (Schedule 2 of the Rules) and
- as not meeting the definition of lung overloading potential [within the meaning given in the Industrial Chemicals Categorisation Guidelines (the Guidelines)]

Summary of assessment

Summary of introduction, use and end use

The assessed polymer will be imported into Australia as a component of a product at a concentration up to 45%. The product will be imported in tightly closed 170kg lacquered drums. The product will be used for reformulation into automotive gear oils. The gear oils will contain the assessed polymer, designed to improve the viscosity index and the low temperature fluidity characteristics of the product, at up to 5% concentration.

Reformulation/repackaging activity will not take place at the applicant's Australian facilities. Instead, the applicant will transport the drums, mainly by road, to a storage warehouse. They will later distribute it, mainly by road, either to lubricant blending facilities or to automobile

manufacturing plants for reformulation into gear oils for new vehicles. The gear oils are typically formulated to contain the assessed polymer at up to 5% concentration. The gear oils containing the assessed polymer will stay within closed systems in vehicles.

Human health

Summary of health hazards

No toxicology data were provided for the assessed polymer. The assessed polymer meets the PLC criteria and so is assumed to be of low hazard. The applicant has further commented that, based on toxicology data from similar polymers, the assessed polymer is expected to be:

- of low oral and dermal toxicity
- non- to slightly irritating to the skin and eyes
- non-sensitising to the skin
- non-mutagenic.

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

- high number average molecular weight (NAMW; >10,000 g/mol)
- low water solubility and
- negligible level of low molecular weight species.

Inhalation of high molecular weight polymers with low water solubility has been linked with irreversible lung damage due to lung overloading and impaired clearance of particles from the lung. This is particularly following repeated exposure (US EPA 2015). However, based on the information submitted, the assessed polymer does not become aerosolised during end use, so does not meet the definition of high molecular weight polymer that has lung overloading potential given in the Guidelines.

Thus, based on the available information, systemic toxicity effects are not expected from the use of the assessed polymer.

Health hazard classification

The applicant did not supply toxicology data for the assessed polymer. Thus, the assessed polymer is not classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (UNECE 2017), as adopted for industrial chemicals in Australia.

Summary of health risk

Public

The assessed polymer meets the PLC criteria and is thus assumed to be of low hazard. When it's introduced and used in the way proposed, in automotive gear oil, it's not expected the general public will be exposed to it. This is because the gear oil will be contained within a closed system in the vehicle.

This assessment does not identify any risks to public health that would require specific risk management measures when the assessed polymer is introduced in accordance with the terms of the assessment certificate.

Workers

The assessed polymer meets PLC criteria, so is assumed to be of low hazard. The assessed polymer will not become aerosolised during end use, so lung overloading potential is not expected.

This assessment does not identify any risks to the health of workers that would require specific risk management measures when the assessed polymer is introduced in accordance with the terms of the assessment certificate.

Environment

Summary of environmental hazard characteristics

No information about the degradation of the assessed polymer was available. The assessed polymer is expected to be stable and not readily undergo degradation.

No information about adverse effects of the assessed polymer to the aquatic environment was available. The assessed polymer is not expected to be bioavailable and so is not expected to bioaccumulate or cause ecotoxic effects.

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

No aquatic toxicity information was available for the assessed polymer. Thus, the assessed polymer is not able to be formally classified under *the Globally Harmonised System of Classification and Labelling of Chemicals* for acute and chronic toxicities (UNECE 2017).

Summary of environmental risk

No significant release of the assessed polymer is expected to occur as a result of its use as an additive in gear oils.

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

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

The assessed polymer will be sold to industrial and commercial facilities. It is not expected to be available to “do it yourself” (DIY) users, limiting the volume that may be released through incorrect disposal.

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

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

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 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. 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

The assessed polymer has a typical degree of purity of > 99%.

Chemical name	2-Propenoic acid, 2-methyl-, butyl ester, polymers with alkyl methacrylate, substituted-methylethyl-terminated hydrogenated polyalkene methacrylate, Me methacrylate and styrene (AACN)
Trade name	VISCOPLEX® 12/10301 (product containing up to 45% assessed polymer)
Molecular formula	Unspecified
Number Average Molecular Weight (Mn)	> 10,000 g/mol
Percentage of low molecular weight species (<1,000 g/mol)	< 0.1%
Percentage of low molecular weight species (<500 g/mol)	< 0.1%
Chemical description	Polymer

Relevant physical and chemical properties

Physical form	Semi-solid (amorphous), colourless gel
Relative density	1040 kg/m^3 at 20 °C
Water solubility	< 0.7 mg/L at 20 °C (pH 4-8)

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 risk of worker exposure to the assessed polymer at up to 45% concentration. The manufacturing plants use automated, sealed delivery systems that transfer the gear oils from bulk tanker trucks 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. There is potential for worker exposure to the assessed polymer during the changing of filling lines and drums. However, according to the applicant, this potential for worker exposure is expected to be well controlled.

Professional End Use

Most of the product containing the assessed polymer will be supplied to automobile manufacturing plants for use in new vehicles. There is a risk of worker exposure to the assessed polymer at up to 5% concentration as the metered amounts of the gear oils are dispensed into automobiles on an assembly line by trained staff, also using sealed delivery.

As the entire process is automated and computer-controlled, the amount of gear oils released during the process of filling new vehicles is expected to be negligible. In the event that some of the gear oil is spilled during the filling process, the actual amount of assessed polymer that will be released will be small.

Professional workers such as mechanics may experience dermal or ocular exposure to the end use products containing the assessed polymer at up to 5% concentration during the replacement of gear oils.

Environmental exposure

The assessed polymer will be imported into Australia and will be blended into gear oils 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 oil containing the assessed polymer will be used within closed systems in vehicles. The filling of these systems for new vehicles is expected to be automated, but manual filling by professional workers may occur during vehicle service activity. 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 blended gear and driveline oil during its useful lifetime. Gear and driveline oils are generally formulated to be “fill for life” but they may need replacement during unscheduled servicing. The oil replacement is expected to be performed by professional workers. The used oil is expected to be collected and disposed 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 (NAMW > 10,000 g/mol) and is not expected to be water soluble. As such, if the assessed polymer is released to the environment, it is expected to partition to and be immobile in soils and sediments.

Degradation

No information about the degradation of the assessed polymer is available. The assessed polymer is expected to be stable but will eventually degrade to simpler organic molecules.

Bioaccumulation

The assessed polymer has a high molecular weight (NAMW > 10,000 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 not been calculated as release of the assessed polymer to the aquatic environment will be negligible based on its assessed use pattern.

Environmental effects

No information about the toxicity of the assessed polymer is available. The assessed polymer is not expected to be bioavailable and does not contain functional groups of concern. Thus, it is not expected to cause toxic effects in the environment.

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 its assumed stability, and lack of demonstrated degradation, the assessed polymer is 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 its expected low bioavailability and lack of concerning functional groups, the assessed polymer is 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 risk.

References

UNECE (United Nations Economic Commission for Europe) (2017) *Globally Harmonized System of Classification and Labelling of Chemicals (GHS) 7th Revised Edition*, UNECE, accessed November 2021.

US EPA (United States Environmental Protection Agency) (2015) *High Molecular Weight Polymers in the New Chemicals Program*, US EPA website, accessed December 2021.