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

1,2,3-Propanetriol, homopolymer, isooctadecanoate

Assessment statement (CA09661)

11 September 2023

Table of contents

AICIS assessment statement (CA09661)

Chemical in this assessment

Name	CAS registry number
1,2,3-Propanetriol, homopolymer, isooctadecanoate	83138-62-9

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 Health Focus type.

Defined scope of assessment

The polymer was assessed for cosmetic use and imported into Australia:

- maximum 1 tonne per year
- up to 100% concentration for reformulation in Australia into finished cosmetic products containing up to 10% of the polymer
- up to 10% concentration in finished cosmetic products for use by consumers

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 a liquid formulation or as a liquid at up to 100% concentration for reformulation into finished cosmetic products, or as a component in finished cosmetic products. The finished end-use products will contain the assessed polymer at up to 10% concentration and will be packaged in containers suitable for retail sale.

Human health

Summary of health hazards

Limited toxicological data were provided for the assessed polymer. Based on the limited toxicological data available for the polymer and read-across data, the assessed polymer:

- is of low acute oral and dermal toxicity
- is not a skin sensitiser
- is not genotoxic

- is not expected to cause adverse effects following repeated oral and dermal exposure at up to 10% concentration

The assessed polymer was found to be non-irritating to skin or eyes in studies that were not conducted according to OECD test guidelines. The assessed polymer is a homopolymer of glycerol esterified with isostearic acid. This class of polymers (polyglyceryl fatty acid esters) showed a mixture of skin irritation effects, ranging from non-irritating, mildly irritating to moderately irritating, and showed non-irritating or mildly irritating effects to eyes (see **Supporting information**). Overall, the potential of mild skin and eye irritation effects of the assessed polymer cannot be ruled out.

No inhalation toxicity data were provided for the assessed polymer.

Hazard classifications relevant for worker health and safety

Based on the available data, 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

When introduced and used in the proposed manner, there will be widespread and repeated exposure of the public to the assessed polymer at up to 10% concentration through the use of a wide range of cosmetic products containing the assessed polymer. The principal route of exposure will be dermal, while ocular and inhalation exposures are also possible, particularly from products applied by spray.

Given the expected low toxicity of the assessed polymer and the proposed low end-use concentrations (at up to 10%) in cosmetic products, repeated dose toxicity effects from the assessed polymer are not expected. The assessed polymer is not persistent in the environment and therefore, not expected to cause inhalation risk when used at up to 10% concentration from cosmetic products applied by spray for short durations.

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

Workers may experience exposure to the assessed polymer at up to 100% concentration during formulation processes such as weighing and transfer stages, blending, quality control analysis, packaging, and cleaning and maintenance of equipment, particularly where manual or open processes are used.

Workers may experience slight skin or eye irritation effects if exposed to the assessed polymer during formulation activities. Specific risk management measures (see **Means for managing risk** section) are required to manage the risks to workers.

Exposure to the assessed polymer in end-use products (at up to 10% concentration) may occur in professions where the services provided involve the application of cosmetic products to clients (e.g. hairdressers and workers in beauty salons). The frequency and extent of exposure of workers applying products to clients is similar to public exposure or lower if personal protective equipment (PPE) is used. No specific controls are required for workers applying end-use products to customers.

Environment

Summary of environmental hazard characteristics

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

- Not Persistent (Not P)
- Not Bioaccumulative (Not B)
- Toxic (T)

Environmental hazard classification

No aquatic toxicity information was available for the assessed polymer. While read-across aquatic toxicity information is available, it is not sufficient to make a definitive hazard classification. Therefore, the assessed polymer is not formally classified under the *Globally Harmonized 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 an emulsifying agent for use in a wide range of cosmetic products which will result in a variety of potential exposure scenarios, including direct release of the assessed polymer to sewers.

No environmental hazard information was supplied for persistence or toxicity of the assessed polymer. Based on the available read-across information from analogue substances, the assessed polymer is expected to be toxic but is not expected to be persistent. Information was provided which indicates the assessed polymer will be metabolised or excreted if ingested. Therefore, the polymer is not expected to bioaccumulate.

While the assessed polymer is categorised as toxic, it is not persistent or bioaccumulative. As the assessed polymer 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 the expected 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 following control measures should be implemented to manage the risk arising from exposure to the assessed polymer during formulation activities:
    - Use of engineering controls such as
        - Enclosed and automated processes where possible
        - Adequate workplace ventilation to avoid accumulation of mists or aerosols
    - Use of safe work practices to
        - Avoid contact with skin and eyes
        - Avoid inhalation of mists or aerosols
    - Workers should wear the following personal protective equipment (PPE)
        - Respiratory protection where local ventilation may be inadequate
- A copy of the Safety Data Sheet (SDS) should be easily accessible to employees.

Conclusions

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

Considering the means for managing risks, the Executive Director is satisfied that when the 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
- the means of managing the risks identified during this assessment are implemented.

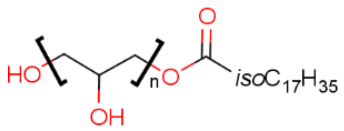
Note: Obligations to report additional information about hazards under section 100 of the *Industrial Chemicals Act 2019* apply.

Supporting information

Chemical identity

Chemical name	1,2,3-Propanetriol, homopolymer, isooctadecanoate
CAS No.	83138-62-9
Molecular formula	$C_{18}H_{36}O_2.x(C_3H_8O_3)_x$
Number Average Molecular weight (Mn)	Less than 500
Chemical description	Polymer

Representative structure



Relevant physical and chemical properties

Physical form	Pale yellow to yellow liquid (viscous)
Vapour pressure	5.17×10^{-38} Pa (calc)*
Water solubility	Low solubility

* Calculated value for representative component of the polymer using MPBPVP v1.43 of EPI Suite v4.11 (US EPA, 2012)

Human exposure

Workers

Reformulation

Typically, reformulation processes may incorporate blending operations that are highly automated and occur in a fully enclosed/contained environment, followed by automated filling using sealed delivery systems into containers of various sizes. Dermal, ocular and inhalation exposure (if aerosols or mists are formed) of workers to the assessed polymer at up to 100% concentration is possible during weighing and transfer stages, blending, quality control analysis, packaging and cleaning, and during maintenance of equipment. However, the exposure is expected to be minimised through the use of mechanical ventilation and/or enclosed systems, and through the use of PPE such as protective clothing and gloves, eye protection and appropriate respiratory protection.

Professional End Use

Exposure to the assessed polymer in end-use products at up to 10% concentration may occur in professions where the services provided involve the application of cosmetic and personal care products to clients (e.g. hairdressers and workers in beauty salons). These products, depending on their nature, could be applied in a number of ways, such as by hand, using an applicator or sprayed. The principal route of exposure will be dermal and inhalation (if the products are applied by spray), while ocular exposure is also possible. Professionals may use PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using the end-use products containing up to 10% of the assessed polymer.

Public

There will be widespread and repeated exposure of the public to the polymer at up to 10% concentration through the use of a wide range of cosmetic products. The principal route of exposure will be dermal, while incidental ocular exposure is also possible. Due to the estimated low vapour pressure of the assessed polymer, inhalation exposure is not expected unless the products are applied by spray.

Health hazard information

Limited toxicological data for the assessed polymer were provided. The assessed polymer is a homopolymer of glycerol esterified with isostearic acid. The applicant submitted studies conducted on this class of polymers (polyglyceryl fatty acid esters) which have been used to estimate the toxicity of the assessed polymer.

Toxicokinetics

No study data on toxicokinetics, metabolism and distribution of the assessed polymer were provided. The assessed polymer is expected to be metabolised in a manner similar to other polyglyceryl fatty acid esters. Various studies show that 95-98% of polyglyceryl fatty acid esters containing fatty acids of various chain lengths and homopolymer of glycerol containing 2-20 glycerol units are digested and utilised in the body when ingested via the oral route (CIR 2016). The ester bond in the assessed polymer is expected to be acted upon by lipases, releasing the free fatty acid(s) and polyglycerol. Free fatty acids generated are expected to undergo normal degradation whereas polyglycerol has been found not be acted upon by enzymes (CIR 2016). The assessed polymer is of relatively low molecular weight (Mn less than 500 g/mol) and is surface active, hence dermal absorption may occur.

Acute toxicity

No data on acute toxicity potential of the assessed polymer were provided. Based on various acute oral and dermal toxicity studies conducted on this class of polymers (polyglyceryl fatty acid esters) (CIR 2016), the assessed polymer is likely to be of low toxicity via the oral (LD50 greater than 2 to 5 g/kg) and dermal routes (LD50 greater than 5 g/kg).

No acute inhalation toxicity data were provided for the assessed polymer.

Corrosion/Irritation

Skin Irritation

In a human acute cutaneous irritation test that was not conducted according to OECD test guidelines, the assessed polymer was considered not irritating to the skin when applied (semi-occlusive) at a concentration of 10% to the skin of the back of 48 human volunteers (18-80 age range) for 48 hours. No adverse reactions to the skin were observed in any of the participants of the study.

However, based on various skin irritation studies, this class of polymers (polyglyceryl fatty acid esters) show a mixture of skin irritation effects, ranging from non-irritating, mildly irritating to moderately irritating (CIR 2016).

Based on the limited information for the assessed polymer and the read-across data, the potential of mild skin irritation effects of the assessed polymer cannot be ruled out.

Eye Irritation

The assessed polymer was determined not to be irritating to eyes when tested in an *in vitro* Statens Seruminstitut Rabbit Cornea (SIRC) cell – neural red (NR) assay that was not conducted according to OECD test guidelines. Based on the results of this study, the assessed polymer does not require classification for eye irritation or serious damage.

Based on various eye irritation studies, this class of polymers (polyglyceryl fatty acid esters) show non-irritating or mildly irritating effects to eyes (CIR 2016).

Based on the in vitro data for the assessed polymer and the read-across data, the potential of mild eye irritation effects of the assessed polymer cannot be ruled out.

Sensitisation

Skin sensitisation

No studies on the assessed polymer were provided. Based on various skin sensitisation studies conducted on this class of polymers (polyglyceryl fatty acid esters) (CIR 2016), the assessed polymer is unlikely to be skin sensitising.

Repeat dose toxicity

Oral

No studies on repeated dose toxicity of the assessed polymer were provided. Dietary studies conducted on various polyglyceryl fatty acid esters at up to 10% concentration did not produce any remarkable effects (CIR 2016; EFSA 2017).

Genotoxicity

No genotoxicity studies on the assessed polymer were provided. Polyglyceryl fatty acid esters were generally found negative in genotoxicity studies (CIR 2016).

Environmental exposure

The assessed polymer will be imported as an emulsifying agent into Australia for reformulation into wide variety of professional and consumer products. Reformulation processes are expected to be conducted in closed systems with engineering controls. Therefore, no releases of the assessed polymer to the environment are expected to occur during reformulation.

Use of the assessed polymer in a variety of products will result in multiple potential exposure scenarios. Use of the assessed polymer in personal care and cosmetic products is expected to be the scenario with highest potential release to the environment. Use of the assessed polymer in personal care and cosmetic products is expected to result in the release of the products “down the drain” to sewers. The assessed polymer will be then treated at sewage treatment plants (STPs) before being released to surface waters.

Environmental fate

Partitioning

The partitioning of the assessed polymer was not determined due to the absence of sufficient physical and chemical properties. The assessed polymer is treated as if it is mobile in the environment, as a worst-case scenario.

Degradation

Based on the biodegradation results in water for analogue substances, the assessed polymer is categorised as not persistent.

No information about the biodegradation of the assessed polymer was provided. However, ready biodegradability studies for structurally-similar analogue substances indicate that the assessed polymer is not persistent. The test results for the structurally-similar analogues demonstrated 54% removal after 28 days (OECD TG 301B) and 89% removal after 28 days (OECD TG 301B) based on information available to AICIS from assessments of analogues.

Bioaccumulation

Chemicals that are suitable analogues for the assessed polymer are metabolised or excreted by mammalian species (CIR, 2016). Several dietary exposure tests were conducted on Wistar, Sprague-Dewley and Sherman rats. The studies indicated that the esters are hydrolysed with the fatty acid component being metabolised normally. Accumulation of the polyglyceryl moiety was not detected in body tissues. Therefore, the assessed polymer is not expected to bioaccumulate.

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 (STP) over 365 days per annum. No removal of the assessed polymer from the effluent in STP processes was calculated as information on the physical and chemical properties were not provided.

This calculated value is conservative as not all uses of the assessed polymer are expected to result in release to STP.

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

Total Annual Import Volume	1,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	1,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release	2.74	kg/day
Water use	200	L/person/day
Population of Australia	25.423	Million
Removal within STP	0%	Mitigation
Daily effluent production	5,085	ML/day
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River	0.54	µg/L
PEC - Ocean	0.05	µg/L

Environmental effects

Effects on aquatic Life

Acute toxicity

No ecotoxicity data was provided for the assessed polymer. However, read-across information available to AICIS from assessments of analogues indicated that the most sensitive ecotoxicity endpoints were 72 hr algal ErC50's that range from 1 – 18.96 mg/L.

However, there is insufficient data on the physico-chemical properties of the assessed polymer to definitively determine the extent of the analogy between the assessed polymer and the related substances. Therefore, the applicability of these results to the assessed polymer should be considered to be a conservative estimate.

Predicted no-effect concentration (PNEC)

A predicted no-effect concentration (PNEC) of 1 µg/L was calculated for the assessed polymer in the aquatic environment. This value was derived using the most conservative read-across endpoint value of 1 mg/L. An assessment factor of 1,000 was applied to this endpoint as toxicity data were not provided for the assessed polymer (EPHC, 2009).

Categorisation of environmental hazard

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

Persistence

Not Persistent (P). Based on available read-across information for analogue substances, the assessed polymer is categorised as Not Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on evidence of metabolism in terrestrial organisms, the assessed polymer is categorised as Not Bioaccumulative.

Toxicity

Toxic (T). Based on available read-across information for acceptable analogue substances, the assessed polymer is categorised as Toxic.

Environmental risk characterisation

The assessed polymer is conservatively categorised as toxic, but evidence indicates it is not persistent or bioaccumulative. Correspondingly, 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	0.54 µg/L	1 µg/L	0.54
Ocean	0.05 µg/L	1 µg/L	0.05

The risk quotient for the aquatic compartment is expected to be less than 1. This is based on a conservative PEC, assuming 100% release to STPs and no removal from the aqueous stream during STP processes, and a conservative PNEC based on an assessment factor of 1,000 and ecotoxicity value of 1 mg/L.

Therefore, based on the expected RQ < 1 the assessed polymer is not expected to pose a significant risk to the environment. As such, the environmental risks associated with the assessed polymer can be managed.

References

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EFSA (2017) Re-evaluation of polyglycerol esters of fatty acids (E 475) as a food additive. European Food Safety Authority. EFSA Journal 2017;15(12):5089

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Struijs J (1996), SimpleTreat 3.0: a model to predict the distribution and elimination of chemicals by sewage treatment plants, National Institute of Public Health and the Environment.

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