Australian Government
Department of Health, Disability and Ageing
Australian Industrial Chemicals Introduction Scheme

1,2,3-Propanetriol, homopolymer, heptanoate

Assessment statement (CA09906)

12 August 2025

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AICIS assessment (CA09906)

Chemical in this assessment

Name	CAS registry number
1,2,3-Propanetriol, homopolymer, heptanoate	79956-60-8

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 chemical has been assessed:

- as imported into Australia at up to 10 tonnes/year
- as imported in neat form for local reformulation into finished end-use products at up to 25% concentration
- as imported or reformulated as a component at up to 25% concentration in finished end-use personal care products (cosmetics)

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% concentration (neat form) for reformulation into end-use personal care products (cosmetics) or directly imported as a component in the end-use products. The end-use personal care products (cosmetics) will contain the assessed polymer at up to 25% concentration and will be packaged in consumer containers suitable for retail.

Human health

Summary of health hazards

Limited toxicological data were provided on the assessed polymer. The assessed polymer is a homopolymer of glycerol esterified with heptanoic acid. This class of polymers known broadly as polyglyceryl fatty acid esters are widely used in cosmetic products and were evaluated by the Cosmetic Ingredient Review committee (CIR 2016). Many of these short chain polyglyceryl fatty acid esters are also used as food additives and were evaluated by the European Food Safety Authority (EFSA 2017). In addition to the toxicology data submitted on the assessed

polymer, information from the above evaluation reports was also used to determine the health hazards of the assessed polymer.

Based on the available data on the assessed polymer and the information from the CIR report (2016) on this class of polymers, the assessed polymer is expected to be:

- of low acute oral and dermal toxicity
- mildly irritating to the eyes and skin
- not considered to be a skin sensitiser
- not genotoxic

In a 90-day repeated dose oral toxicity study in rats on a close analogue (decaglycerol decaoleate) of the assessed polymer, the No Observed Adverse Effect Level (NOAEL) was 9,000 mg/kg bw/day (EFSA 2017; King et al 1971). Based on this information, the assessed polymer is not expected to cause systemic toxicity effects with repeated dermal or oral exposure.

No acute or repeated dose inhalation toxicity data were provided on the assessed polymer. Based on the chemical and biological properties of the polyglyceryl fatty acid esters, droplets/particles generated from spray applications of the end-use personal care products (cosmetics) do not present toxicological concerns (CIR 2016).

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

There will be widespread and repeated exposure of the public to the assessed polymer at up to 25% concentration through the use of a wide range of personal care products (cosmetics). The principal route of exposure will be dermal, while ocular and inhalation exposures are also possible, particularly when the products are applied by spray.

Many of the short chain polyglyceryl fatty acid esters are also used as food additives (EFSA 2017). Given the anticipated low repeated dose toxicity of the assessed polymer, risk of adverse systemic effects from repeated consumer use of the personal care products (cosmetics) containing the assessed polymer up to 25% concentration is not expected.

In aerosol cosmetic products, most droplets/particles would not be respirable to any appreciable amount, and droplets/particles deposited in the nasopharyngeal or bronchial regions of the respiratory tract present no toxicological concerns based on the chemical and biological properties of the polyglyceryl fatty acid esters (CIR 2016).

The assessed polymer may cause mild irritation effects to the skin and eyes if exposed at high concentrations. However, the assessed polymer is not classified as a skin or eye irritant under GHS.

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

Workers

Workers may have potential for incidental exposure to the assessed polymer at up to 100% concentration during reformulation processes particularly where manual or open processes are used. Therefore, workers may experience mild skin or eye irritation effects if direct skin or eye contact with the assessed polymer occurs during the activities. Control measures to minimise dermal and ocular exposure are required to manage the risks to workers involving reformulation operations (see **Means for managing risk** section).

Exposure to the assessed polymer in end-use products at up to 25% concentration may occur in workers of beauty salons where the services provided involve the application of personal care products (cosmetics) to clients. Based on the concentration of the assessed polymer in the personal care products (cosmetics) and low hazard of the assessed polymer, no risks are identified for workers when applying the end-use personal care products (cosmetics) to clients.

Environment

Summary of environmental hazard characteristics

According to the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* (DCCEEW 2022) 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 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

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.

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 cause 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

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 risk arising from exposure to the assessed polymer during reformulation of the end-use products:

- Use of safe work practices to avoid contact with skin and eyes

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:

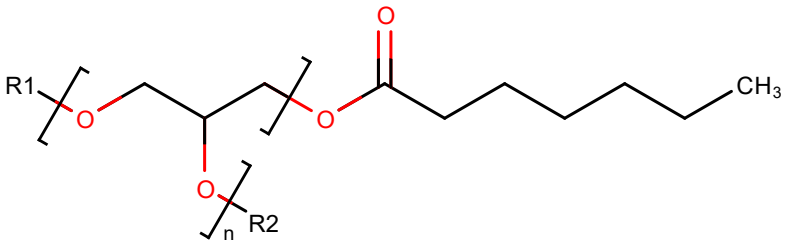
1. Obligations to report additional information about hazards under s 100 of the *Industrial Chemicals Act 2019* apply.
2. You should be aware of your obligations under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory.

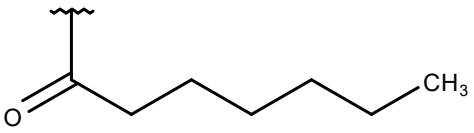
Supporting information

Chemical identity

Polymer name	1,2,3-Propanetriol, homopolymer, heptanoate
CAS Number	79956-60-8
Molecular formula	$C_7H_{14}O_2.x(C_3H_8O_3)_x$
Number average molecular weight (NAMW, g/mol)	655
Percentage of low molecular weight species (less than 1,000 g/mol)	39.89%
Percentage of low molecular weight species (less than 500 g/mol)	18.18%

Representative structure



R1, R2 =  or 

Chemical description

The assessed chemical is a polymer with 10 glycerol units (n = 10) on average with a typical purity of 82.5% and contains the following components.

Polymer component	CAS No.	Typical conc. (%)	Range conc. (%)
1,2,3-Propanetriol, homopolymer	25618-55-7	85	84 - 86
Heptanoic acid	111-14-8	15	14 - 16

Relevant physical and chemical properties

Physical form	Viscous liquid (amber colour)
Vapour pressure	0.4 kPa at 50 °C
Water solubility	346 g/L at 23 °C
Ionisable in the environment	No
log K_{ow}	1.77 at 20 °C

Human exposure

Public

No quantitative assessment for repeated exposure of the public was conducted for the assessed polymer as no significant adverse effects were observed up to 9,000 mg/kg bw/day of a similar chemical in a 90-day repeated dose dietary study in rats (King et al 1971).

Health hazard information

Toxicokinetics

When absorbed into human body, the assessed polymer is expected to be metabolised in a manner similar to other polyglyceryl fatty acid esters. Various studies show that, when ingested via the oral route, 95-98% of polyglyceryl fatty acid esters are hydrolysed into fatty acids and homopolymer of glycerol in physiological conditions. The resulting hydrolysis products are digested and utilised further via various metabolic pathways in the body (CIR 2016).

Acute toxicity

No data on acute toxicity potential of the assessed polymer were provided. Based on the weight of evidence from several acute oral and dermal toxicity studies in rats conducted on various polyglyceryl fatty acid esters (CIR 2016), the assessed polymer is likely to be of low acute toxicity. The median lethal doses (LD50) of the polymer are estimated to be greater than 2,000 mg/kg for oral route and greater than 5,000 mg/kg for dermal route. No acute inhalation toxicity information was provided in the submission.

Corrosion/Irritation

Skin irritation

The assessed polymer is not a skin irritant according to the results of an *in vitro* skin irritation test using the EpiDerm™ reconstructed human epidermis tissue model (OECD TG 439). The relative mean viability of the model tissues treated with undiluted assessed polymer was 75.3% after 1-hour exposure followed by a 42-hour post-exposure incubation. The relative mean viability of the tissues was above the criterion for hazard classification (≤ 50%).

However, many structurally similar polyglyceryl fatty acid esters evaluated by CIR were mildly irritating to the skin (CIR 2016). Based on the weight of evidence, the assessed polymer may have mild irritation potential to the skin at high concentrations but does not meet the criteria for classification under the GHS.

Eye irritation

The assessed polymer is not an eye irritant according to the results of an *in vitro* EpiOcular™ test (OECD TG 492). The undiluted assessed polymer was tested on the model tissues for 30 minutes followed by a post-exposure incubation of 120 minutes. The model tissues resulted in a relative mean viability of 78.7%, which is above the criterion for hazard classification (≤ 60%).

Many structurally similar polyglyceryl fatty acid esters evaluated in the CIR report were mildly irritating to the eyes (CIR 2016). Based on the weight of evidence, the assessed polymer may have mild irritation potential to the eyes at high concentrations but does not meet the criteria for classification under the GHS.

Sensitisation

Skin sensitisation

One Direct Peptide Reactivity Assay (DPRA) (OECD TG 442C), 2 ARE-Nrf2 Luciferase Tests (KeratinoSens) (OECD TG 442D) and 1 Human Cell Line Activation Test (h-CLAT) (OECD TG 442E) were provided by the applicant to evaluate the skin sensitisation potential of the assessed polymer. These tests form an Integrated Approach to Testing and Assessment (IATA) which address specific Key Events (KEs) of the Adverse Outcome Pathway (AOP) leading to development of skin sensitisation (OECD 2016).

The assessed polymer showed negative results in DPRA (KE1 of the AOP) and h-CLAT (KE3 of the AOP). First attempt of KeratinoSens assay (KE2 of the AOP) on the assessed polymer showed inconclusive results but a repeated KeratinoSens assay was negative. Based on the results of the above AOP KE assays and using the Defined Approach of ‘2 out of 3’ in the Defined Approaches for Skin Sensitization (DASS) guideline (OECD TG 497), the assessed polymer is considered as not sensitising to skin.

There are no structural alerts for skin sensitisation identified for the assessed polymer using Quantitative Structure-Activity Relationship (QSAR) (Nexus v2.6).

Repeat dose toxicity

Oral

No studies on repeated dose toxicity of the assessed polymer were provided. Dietary studies on various polyglyceryl fatty acid esters at up to 10% concentration (equivalent to 9,000 mg/kg bw/day) did not produce any systemic adverse effects in rats (CIR 2016; EFSA 2017).

In a 90-day feeding study (King et al 1971), groups of Sprague-Dawley rats (n = 10/sex/dose) were maintained on isocaloric diets based on soybean oil with decaglycerol decaoleate (a close analogue of the assessed polymer) at 0%, 2.5%, 5% or 10% concentrations. Increased total nitrogen content in the urine of females at the high-dose group was reported compared with the control group. However, no histopathological changes were observed in the kidney or bladder. Food consumption was increased in the high-dose males, but with normal body weight

gain. Based on these results, the NOAEL for the analogue was estimated to be 9,000 mg/kg bw/day, the highest dose tested.

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

Reformulation and repackaging will occur in both closed and open processes. Significant releases of the assessed polymer to the environment are not expected during reformulation, transport or storage. Release of 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.

Consumer and professional end-use of the assessed polymer in personal care products (cosmetics) 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 non-ionic polymer, it is expected to have low mobility in soil and sediment due to its strong absorption to soil and sediment (US EPA 2013).

The assessed polymer is readily soluble in water (water solubility = 346 g/L). If the assessed polymer is released to surface waters, a proportion of the assessed polymer is expected to remain in the water compartment with the remaining expected to partition to sediment, based on its ready solubility in water and high molecular weight.

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

Degradation

Based on its measured degradation value, the assessed polymer is persistent.

A degradation study in water indicates that the assessed polymer is not readily biodegradable. The OECD TG 301B biodegradation study for the assessed polymer demonstrated 25.84% and 34.93% degradation of the assessed polymer over 28 and 63 days, respectively.

Bioaccumulation

Based on its log K_{OW} value, the assessed polymer has low potential to bioaccumulate.

No bioaccumulation information was provided for the assessed polymer. The experimental partition coefficient of the assessed polymer (log K_{OW} = 1.77) is below the domestic bioaccumulation threshold of log K_{OW} = 4.2 (EPHC 2009).

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 non-ionic polymer with NAMW greater than 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 is detailed in the table below:

Total Annual Import Volume	10,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	10,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release	27.4	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	0.54	µg/L
PEC - Ocean	0.05	µg/L

Environmental effects

Effects on aquatic Life

Acute toxicity

The following median effective concentration (EC50) values for model organisms across two trophic levels were provided by the applicant:

Taxon	Endpoint	Method
Invertebrate	48 h EC50 > 100 mg/L	*Daphnia magna* (Water flea) Immobility/other effect OECD TG 202 Static conditions Nominal concentration
Algae	72 h ErC50 > 100 mg/L	*Raphidocelis subcapitata* (Green algae) Growth rate OECD TG 201 Static conditions Nominal concentration

Chronic toxicity

The following no-observed-effect concentrations (NOEC) value for model organism was provided by the applicant:

Taxon	Endpoint	Method
Algae	72 h NOErC = 50 mg/L	*Raphidocelis subcapitata* (Green algae) Growth rate OECD TG 201 Static conditions Nominal concentration

Predicted no-effect concentration (PNEC)

A predicted no-effect concentration (PNEC) of 100 µg/L was calculated for the assessed polymer in the aquatic environment. This value was derived using the endpoint value for daphnids and algae (100 mg/L). An assessment factor of 1,000 was applied to this endpoint as acute toxicity data were not provided for all three trophic levels and chronic toxicity data were incomplete (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 a measured degradation study, the assessed polymer is categorised as Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on low measured log k_{ow} value, 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	0.54 µg/L	100 µg/L	< 0.005
Ocean	0.05 µg/L	100 µg/L	< 0.001

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

CIR (Cosmetic Ingredient Review committee) (2016) Final Report for Panel Review: Safety Assessment of Polyglyceryl Fatty Acid Esters as Used in Cosmetics (Release date November 14, 2016). Cosmetic Ingredient Review, Washington DC, USA.

DCCEEW (2022) Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals, DCCEEW, accessed 14 June 2024.

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

EPHC (Environment Protection and Heritage Council) (2009), 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.

King W, Michael R and Coots R.H (1971) Subacute oral toxicity of polyglycerol ester, Toxicology and Applied Pharmacology, 20(3):327-333.

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UNECE (United Nations Economic Commission for Europe) (2017) Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Seventh Revised Edition. UNECE, accessed 14 July 2025.

US EPA (US Environmental Protection Agency) (2013) Interpretive Assistance Document for Assessment of Polymers – Sustainable Futures Summary Assessment. US EPA, accessed 14 July 2025.