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

Fatty acids, candelilla wax, mixed esters with jojoba fatty acids, polyglycerol and rice bran-oil fatty acids

Assessment statement (CA10064)

31 March 2026

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AICIS assessment (CA10064)

Chemical in this assessment

Name	CAS registry number
Fatty acids, candelilla wax, mixed esters with jojoba fatty acids, polyglycerol and rice bran-oil fatty acids	3064817-49-5

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 at up to 100% concentration for reformulation into consumer end use products
- for end use in personal care products (cosmetics) at concentrations of up to 5%

Summary of assessment

Summary of introduction, use and end use

The assessed chemical will not be manufactured in Australia. It will be imported into Australia in 20 kg plastic bags packed in cardboard cartons. The assessed chemical will be imported at up to 100% concentration for reformulation into personal care products (cosmetics) at up to 5% concentration.

The personal care products (cosmetics) containing the assessed chemical are expected to be in the forms of liquids, semi-solids, or gels, including various moisturisers, sunscreens, blushes, lipsticks, eyeliners and eye shadows. The finished cosmetic products containing the chemical at various concentrations at up to 5% will be packaged in containers suitable for retail sales at up to 1,000 mL.

Human health

Summary of health hazards

No toxicological data on the assessed chemical were provided. The submitted toxicological data on structurally similar analogues of the assessed chemical (see **Supporting information**) indicate that the assessed chemical is:

- likely of low acute oral toxicity
- unlikely to be a skin sensitiser
- unlikely to be genotoxic
- unlikely to cause adverse systemic health effects following repeated exposure (see below)

The toxicological information on the analogues also indicates that the assessed chemical is likely to be slightly to moderately irritating to the skin and slightly irritating to the eyes (see **Supporting information**). Although the assessed chemical is not classified as a skin irritant (due to limited information), skin irritation effects from the chemical cannot be ruled out.

The assessed chemical is a mixture of various polyglyceryl esters of long carbon chain fatty acids (mainly C_{18} to C_{36}). In a Cosmetic Ingredient Review report (CIR 2023), a group of polyglyceryl fatty acid esters were assessed, including candelilla/jojoba/rice bran polyglyceryl-3 esters, which is considered as a close analogue of the assessed chemical. The CIR report concluded that these polyglyceryl fatty acid esters are safe in cosmetics in the present practices of use and concentration described in the report when formulated to be non-irritating.

Several subchronic or chronic toxicity studies on various polyglyceryl esters in mice or rats were evaluated in the CIR report and there were no adverse systemic effects noted up to the dose level of 10% in diets (CIR 2023). The European Food Safety Authority also evaluated polyglycerol esters of fatty acids (PEFA) as a food additive (EFSA 2017). The published scientific opinion noted that absorption of intact PEFA in the gastrointestinal tract is low and it is rapidly and almost fully hydrolysed to polyglycerols and fatty acids, and then further metabolised through normal pathways. No adverse effects of PEFA at any dose were observed in short-term, subchronic or chronic toxicity studies. A no observed adverse effect level (NOAEL) of 9,000 mg/kg bw/day was identified from a 90-day subchronic study in rats on decaglycerol decaoleate (or polyglyceryl-10 decaoleate as reported in the above CIR report). Various NOAELs were also reported from other chronic toxicity studies in mice or rats, ranging from 2,500 to 7,500 mg/kg bw/day (EFSA 2017, CIR 2023). Based on the available information, the assessed chemical may have a systemic toxicity NOAEL of at least 2,500 mg/kg bw/day and is unlikely to cause adverse effects following repeated exposures (see **Supporting information**).

Hazard classifications relevant for worker health and safety

Based on the data provided by the applicant, the assessed chemical 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 chemical at various concentrations up to 5% through the use of a wide range of personal care products (cosmetics). The principal route of exposure will be dermal, while incidental ocular exposure is also possible. The assessed chemical is likely to be slightly to moderately irritating to the skin and slightly irritating to eyes. However, the applicant has confirmed that the cosmetics containing the assessed chemical will be formulated as non-irritating.

No quantitative risk assessment for repeated exposure of the public was conducted for the assessed chemical, as the analogue chemicals did not show systemic toxicity effects in various subchronic or chronic toxicity studies in mice or rats at up to 9,000 mg/kg bw/day (EFSA 2017, CIR 2023). No adverse health effects are expected from the repeated use of the finished consumer end use products containing the assessed chemical at up to 5% concentration.

Inhalation exposure to the assessed chemical may occur when the cosmetic products containing it are applied by spray. Based on its low systemic toxicity, the assessed chemical is not expected to pose a health risk through limited inhalation exposure.

Overall, this assessment does not identify any risks to public health that require specific risk management measures.

Workers

Reformulation workers may be incidentally exposed to the assessed chemical at up to 100% concentration during reformulation processes, mainly via dermal route, while incidental ocular and inhalation exposures are also possible if spills or aerosol/dust formation occurs. The assessed chemical is likely to be slightly to moderately irritating to the skin and slightly irritating to the eyes. It is anticipated by the applicant that engineering controls such as enclosed and automated processes will be implemented where possible and workers will use appropriate personal protective equipment (PPE). As the skin irritation effects cannot be ruled out with exposure to the neat chemical during reformulation activities, control measures are required to reduce worker exposure.

Professional workers in cosmetic businesses may experience exposure to the assessed chemical at up to 5% concentration mainly via dermal and inhalation routes during applications of the end use products containing the assessed chemical to clients or customers. These professional workers may wear PPE, including gloves, protective clothing and face masks. If PPE is used, risk potential for such workers is expected to be of a similar or lesser extent than that of consumers using the same end use products containing the assessed chemical. This assessment does not identify any risks to workers using the finished end use products containing the assessed chemical that require specific risk management measures.

Environment

Summary of environmental hazard characteristics

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

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

Environmental hazard classification

Based on the ecotoxicological information available for the proposed analogue chemicals, the assessed chemical is not expected to be harmful to aquatic life. Therefore, the assessed chemical does not satisfy the criteria for classification 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 chemical will be imported for reformulation into personal care products. Use of these products is expected to result in the release of the assessed chemical "down the drain" and into the sewers. Consequently, the assessed chemical will be treated at sewage treatment plants (STPs) before release to surface waters.

The assessed chemical is not PBT according to the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* and is hence unlikely to have unpredictable long-term effects. The available ecotoxicity information indicates that the assessed chemical is not expected to be harmful to aquatic organisms at its saturation concentration. Therefore, based on the low hazards, the environmental risk from the introduction of the assessed chemical 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 reduce potential exposure of workers to the assessed chemical during reformulation:

- Use of engineering controls such as
  - Enclosed and automated systems where possible

- Use of safe work practices to
  - Avoid direct contact with skin and eyes
  - Avoid inhaling aerosols/dusts

- Use of personal protective equipment (PPE)
  - Gloves
  - Protective clothing
  - Goggles

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. A person introducing this chemical should be aware of their obligations under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Supporting information

Chemical identity

CAS number	3064817-49-5
CAS name	Fatty acids, candelilla wax, mixed esters with jojoba fatty acids, polyglycerol and rice bran-oil fatty acids
Molecular formula	Unspecified

Additional chemical identity information

The assessed chemical is an unknown or variable composition, complex reaction product or biological material (UVCB).

Relevant physical and chemical properties

Physical form	Solid with characteristic odour
Melting point	182 to 350 °C*
Vapour pressure	2.25×10^{-42} to 1.11×10^{-12} kPa at 25°C*
Water solubility	2.24×10^{-26} to 1.89×10^{-6} g/L at 25°C*
Ionisable in the environment	No
log K_{ow}	7.38 to 40.3*
log K_{oc}	3.55 to 22.6 (MCI method), 4.12 to 22.6 (log K_{ow} method)*

*Calculated using EPI Suite (US EPA 2012) based on the proposed analogue chemicals

Health hazard information

Acute toxicity

No acute toxicity study for the assessed chemical was provided by the applicant.

The CIR report on polyglyceryl fatty acid esters used in cosmetics (CIR 2023) and the EFSA scientific opinion on PEFA as a food additive (EFSA 2017) both reported low to very low acute oral toxicity in several acute oral toxicity studies in rats on the analogue chemicals.

The CIR report assessed various analogue chemicals with acute oral toxicity studies in rats (CIR 2023). These analogue chemicals included polyglyceryl-3 caprate, polyglyceryl-3 oleate and polyglyceryl-3 isostearate. The review panel determined the median lethal dose (LD50) to be greater than 2,000 mg/kg bw in rats. The EFSA scientific opinion (EFSA 2017) also indicated that rats administered a single dose of polyglycerol ester at 7,000, 14,000 or

29,000 mg/kg bw via oral gavage did not show any signs of toxic effects. Similarly, rabbits administered single doses of 10,000 to 29,000 mg/kg bw of the polyglycerol ester via oral gavage did not show adverse toxic effects. The LD50 was also determined by EFSA to be greater than 2,000 mg/kg bw in rabbits.

Therefore, the assessed chemical is likely to be of low acute oral toxicity.

Corrosion/Irritation

Skin irritation

No skin irritation study on the assessed chemical was provided by the applicant.

The CIR report (CIR 2023) indicated that some analogue chemicals were non-irritants to skin as shown in various skin irritation studies. These analogue chemicals included polyglyceryl-3 caprate, polyglyceryl-4 caprate, polyglyceryl-6 caprylate/caprate, and polyglyceryl-10 decaethylhexanoate and polyglyceryl-10 pentaisostearate.

However, available skin irritation studies also showed skin irritation effects in other analogue chemicals. These analogues included polyglyceryl-2 isostearate, polyglyceryl-3 isostearate, glyceryl/polyglyceryl-6 isostearate, polyglyceryl-2 diisostearate and polyglyceryl-3 oleate. The skin irritation effects observed were slight to moderate (CIR 2023).

Based on the limited data available, the assessed chemical is likely to be slightly to moderately irritating to skin. Although the evidence is not sufficient to classify the chemical as a skin irritant according to the GHS criteria, skin irritation effects from the chemical cannot be ruled out.

Eye irritation

No eye irritation study on the assessed chemical was provided by the applicant.

The CIR report (CIR 2023) indicated that some polyglyceryl fatty acid esters are non-irritating to the eyes, including apricot kernel oil polyglyceryl-4 esters and palm oil polyglyceryl-4 esters. When tested in rabbit eyes, polyglyceryl-3 caprate and polyglyceryl-3 diisostearate were also not irritating, but polyglyceryl-3 isostearate and polyglyceryl-3 oleate were slightly irritating. Macadamia seed oil polyglyceryl-6 esters behenate and polyglyceryl-8 decabehenate caprate also caused slight irritation effects in rabbit eyes. Polyglyceryl-10 laurate was possibly slightly irritating to the eyes of humans (CIR 2023).

The assessed chemical is likely to be slightly irritating to the eyes based on the data available on analogue chemicals. However, the evidence is not sufficient to classify the chemical as an eye irritant according to the GHS criteria.

Sensitisation

Skin sensitisation

No skin sensitisation study on the assessed chemical was provided by the applicant.

The CIR report evaluated several skin sensitisation studies on various polyglyceryl fatty acid esters used in cosmetics, including guinea pig maximisation tests and mouse local lymph node assays (LLNA). The tested polyglyceryl fatty acid esters included polyglyceryl-3 caprate,

polyglyceryl-3 caprylate, polyglyceryl-3 isostearate and macadamia seed oil polyglyceryl-6 esters behenate. These studies did not reveal any evidence of skin sensitisation (CIR 2023).

Based on the available data, the assessed chemical is unlikely to be sensitising to the skin.

Repeat dose toxicity

The CIR report on polyglyceryl fatty acid esters used in cosmetics (CIR 2023) evaluated several subchronic or chronic toxicity studies in mice or rats. For polyglyceryl esters in general, groups of male and female mice (n = 25/sex) were fed a diet with polyglyceryl esters at 5% concentration (equivalent to 7,500 mg/kg bw/day) for 80 weeks. No adverse effects on body weight, food consumption, haematology parameters, or survival rate were noted. The only significant changes noted in organ weights were for the liver and kidneys of the females (details not available). However, microscopic examination of all major organs did not reveal anything with toxicological significance. Another 2-year dietary study in rats (n = 28/sex) with 5% polyglyceryl ester (equivalent to 2,500 mg/kg bw/day) showed similar results and a complete histological examination of major organs showed nothing remarkable.

EFSA scientific opinion on PEFA (EFSA 2017) evaluated a 90-day dietary study performed under conditions close to the current EFSA guideline. Groups of male and female rats (n = 10/sex) were fed on diets containing 2.5%, 5% or 10% of polyglyceryl-10 decaoleate. Urinalysis was performed at weeks 3 and 9 of the exposure period and blood samples were taken for haematology tests at weeks 5 and 11 as well as at the necropsy. At the end of the exposure period, the rats were sacrificed, necropsy was performed, the organ weights were measured, and tissues were examined for histopathology. The high dose treatment induced an increase in total nitrogen in the urine of treated females. However, no histopathological changes were detected in the kidney or the urinary bladder in these females. In treated males, food consumption was increased in the high dose group, however the body weight gain was not altered. No biologically significant adverse effects were reported in this study up to 10% concentration of polyglyceryl-10 decaoleate in the diet (equivalent to 9,000 mg/kg bw/day).

Based on above information, the NOAEL for repeated dose toxicity of the assessed chemical is likely to be at least 2,500 mg/kg bw/day.

Genotoxicity

The CIR report on polyglyceryl fatty acid esters used in cosmetics (CIR 2023) indicated that generally negative results were obtained in various genotoxicity studies. Polyglyceryl-3 caprate, polyglyceryl-3 caprylate, polyglyceryl-3 laurate, polyglyceryl-3 isostearate, and macadamia seed oil polyglyceryl-6 esters behenate tested negative in the Ames tests. In a chromosomal aberration assay using Chinese hamster V79 cells, polyglyceryl-6 caprylate/caprate at 125 µg/mL and polyglyceryl-10 laurate at 2,250 µg/mL gave positive results in the presence of metabolic activation. It was noted that *in vitro* chromosomal aberration studies may give a high frequency of false positives (EFSA 2017). Chromosomal aberration assays using human peripheral lymphocytes showed negative results for the two analogue chemicals with or without metabolic activation (CIR 2023).

Based on the available information, the assessed chemical is unlikely to be genotoxic.

Environmental exposure

Significant release of the assessed chemical to the environment is not expected during transport, reformulation or storage. Release of the products containing the assessed chemical

to the environment due to accidental spills is expected to be collected on suitable materials, and disposed of in accordance with relevant Local, State, Territory and Federal regulations. Any unused product containing the assessed chemical is expected to be disposed of in accordance with relevant Local, State, Territory and Federal regulations.

The assessed chemical is an emulsifier to be included in personal care products. Use of these products is expected to result in the release of the assessed chemical "down the drain" and into the sewers. Consequently, the assessed chemical will be treated at sewage treatment plants (STPs) before release to surface waters.

Environmental fate

Partitioning

The assessed chemical has very high log K_{ow} and K_{oc} values (log K_{ow} = 7.38 to 40.3 and log K_{oc} = 3.55 to 22.6). Therefore, the chemical is expected to partition to and become immobile in soils and sediments.

The assessed chemical is very slightly water soluble (water solubility from 2.24×10^{-26} to 1.89×10^{-6} g/L at 25°C). If the assessed chemical is released to surface waters, the chemical is expected to partition to sediments based on its very low water solubility, and very high log K_{ow} and log K_{oc} values.

The assessed chemical is not expected to be volatile based on very low vapour pressure values calculated based on the analogue chemicals (2.25×10^{-42} to 1.11×10^{-12} kPa at 25°C).

Degradation

No degradation study was provided for the assessed chemical. The assessed chemical is not expected to be persistent based on its composition and structure. In addition, the CIR report on the polyglyceryl fatty acid esters used in cosmetics indicated that these esters are readily hydrolysed in the gastrointestinal tract, and utilisation and digestibility studies supported the assumption that the fatty acid moiety is metabolised in the normal manner (CIR 2023). Therefore, the assessed chemical is not expected to be persistent.

Bioaccumulation

No bioaccumulation data was provided for the assessed chemical. However, suitable read across chemicals were found to be metabolised or excreted by mammalian species (CIR 2023). Several dietary exposure tests were conducted on Wistar, Sprague-Dawley 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 chemical 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. The extent to which the assessed chemical is removed from the effluent in STP processes is based on its physicochemical properties and biodegradability, modelled by SimpleTreat 4.1 (Struijs 2014) which has been adjusted to suit Australian STP conditions.

In Australia, about 20% of sewage is treated to primary levels which is then discharged to ocean, and 80% of Australian sewage is treated to at least secondary levels which is then discharged to both ocean and rivers (Blue Environment 2020). Removal at the primary stage, and total removal percentages were calculated. A dilution factor of 1 was applied to river discharge and a dilution factor of 10 was applied to ocean discharge (EPHC 2009). PEC calculations for river and ocean discharges are summarised in the table below:

Total Annual Import Volume	10,000	kg/year
Proportion expected to be released to sewer	100%	
Days per year where release occurs	365	days/year
Emission rate	27.4	kg/day
Water use	200	L/person/day
Population of Australia	25.423	Million
Removal from primary treatment	21.7%	Mitigation
Removal from secondary treatment	33.1%	Mitigation
Daily effluent production	5,085	ML/day
PEC - River	3.61	µg/L
PEC - Ocean	0.42	µg/L

Environmental effects

Effects on aquatic life

Acute toxicity

The proposed analogue chemicals do not affect the aquatic organisms at their saturated concentrations as modelled by ECOSAR, EPI Suite (US EPA 2012). Therefore, the assessed chemical is not expected to be harmful to aquatic organisms.

Predicted no-effect concentration (PNEC)

The predicted no-effect concentration was not calculated as the assessed chemical is not expected to be harmful to aquatic organisms.

Categorisation of environmental hazard

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

Persistence

Not Persistent (Not P). Based on the weight of evidence, the assessed chemical is categorised as Not Persistent.

Bioaccumulation

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

Toxicity

Not Toxic (Not T). Based on calculated ecotoxicity results of the proposed analogue chemicals, the assessed chemical is categorised as Not Toxic.

Environmental risk characterisation

The assessed chemical is not PBT and is hence unlikely to have unpredictable long-term effects (EPHC 2009). The available ecotoxicity information indicates that the assessed chemical is not expected to be harmful to aquatic organisms at its saturation concentration. Therefore, based on the low hazards, the environmental risk from the introduction of the assessed chemical can be managed.

References

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