File No: LTD/1970

December 2017

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

9-Octadecenoic acid (9*Z*)-, monoester with oxybis[propanediol] (INCI Name: Polyglyceryl-2 Oleate)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Energy.

This Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1970	L'Oreal Australia Pty Ltd	9-Octadecenoic acid (9Z)-, monoester with oxybis[propanediol] (INCI Name: Polyglyceryl-2 Oleate)	ND	≤ 1 tonne per annum	Ingredient in cosmetics

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

Human health risk assessment
Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified chemical is not considered to pose an unreasonable risk to public health.

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - Avoid contact with skin and eyes

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Protective gloves and goggles
  - Overalls

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the SDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by containment, physical collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
  - the importation volume exceeds one tonne per annum notified chemical;
  - the concentration of the notified chemical exceeds or is intended to exceed 10% in cosmetic products;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from ingredient in cosmetics or is likely to change significantly;
  - the amount of chemical being introduced has increased, or is likely to increase, significantly;
  - the chemical has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Safety Data Sheet
The SDS of the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
L'Oreal Australia Pty Ltd (ABN: 40 004 191 673)
564 St Kilda Road
MELBOURNE VIC 3004

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer (1 tonne or less per year)

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: trade name, other names, analytical data, purity, residual monomers and impurities, identity of manufacturer and supplier.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physico-chemical properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US FDA (2015)

2. IDENTITY OF CHEMICAL

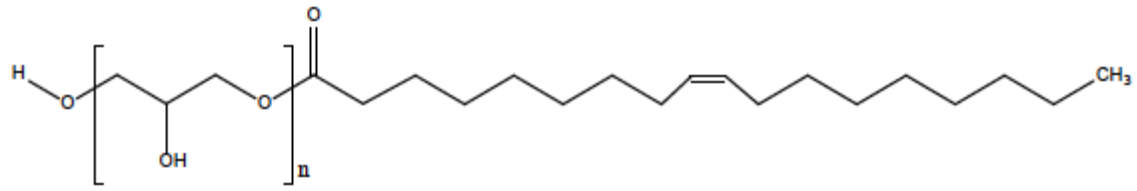
CHEMICAL NAME
9-Octadecenoic acid (9*Z*)-, monoester with oxybis[propanediol]

MARKETING NAME(S)
Polyglyceryl 2-oleate (INCI Name)

CAS NUMBER
49553-76-6

OTHER NAME(S)
Diglyceryl monooleate

STRUCTURAL FORMULA



Where n = 2
Representative structure

MOLECULAR FORMULA
$C_{24}H_{46}O_6$

MOLECULAR WEIGH
430 g/mol

3. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Light yellow/ light brown paste with a characteristic odour.

Property	Value	Data Source/Justification
Melting Point	Not determined	Estimated at 217°C, EPI Suite EPIwin v4.11. The notified chemical is a paste at room temperature.
Boiling Point	Not determined	Estimated at 531°C, EPI Suite EPIwin v4.11. The chemical is expected to degrade before boiling.
Density	Not determined	-
Vapour Pressure	Not determined	Estimated at 1.56×10^{-14} kPa, EPI Suite EPIwin v4.11
Water Solubility	Not determined	Estimated at 0.04126 g/L at 20 °C (WSKOW v 1.42, US EPA 2011)
Hydrolysis as a Function of pH	Not determined	The notified chemical contains hydrolysable functionality, however, due to its expected low water solubility it is expected to hydrolyse slowly in the environmental pH range (4-9) at ambient temperature.
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to phase boundaries based on surface activity. An estimated log Kow = 5.48 (WSKOW v 5.48, US EPA 2011).
Adsorption/Desorption	Not determined	The notified chemical is expected to partition to the solid phase in the environment based on its expected low water solubility and surface activity.
Dissociation Constant	Not determined	The notified chemical does not contain functionality that is expected to dissociate under environmental conditions.
Flash Point	264°C	SDS
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use.
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties.

DISCUSSION OF PROPERTIES

Reactivity
The notified chemical is expected to be stable under normal conditions of use.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported into Australia by sea in its neat form or as a component of finished products at a concentration of up to 10% by weight.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤1	≤1	≤1	≤1	≤1

PORT OF ENTRY
The notified chemical will be imported into Australia through the ports of Sydney or Melbourne.

TRANSPORTATION AND PACKAGING
The notified chemical in its neat form will be imported in 16 kg tin canisters in cardboard carton cases. The other products containing the notified chemical will be contained in 5-500 mL plastic bottles and tubes that are packed in dozens inside a shipper, with multiple shippers per pallet and multiple pallets per container. The containers are taken from the wharf in Sydney and transported to the appropriate central distribution centres. They are then picked into individual orders for delivery by road to major retailer warehouses.

USE

The notified chemical will be used as an ingredient in leave on and rinse off cosmetic products (excluding aerosols) at up to 10% concentration.

OPERATION DESCRIPTION

The notified chemical will not be manufactured in Australia. It will be imported at 100% concentration or in finished cosmetic products at up to 10% concentration, for leave on and rinse off cosmetic use. The notified chemical in its neat form may be used for blending and reformulation into cosmetic premixes and finished cosmetic products.

Reformulation

Store persons will receive the notified chemical when first delivered and store it in the raw material store.

The Chemist will sample and test the ingredient for QA purposes. A sample will be taken using a scoop. Later samples of the finished product at bulk stages and finished product stages will be also sampled and tested. Samples will be retained for reference purposes.

Once cleared by QA, quantities of the notified chemical will be issued to a Compounder for production, as required. The Compounder will weigh an appropriate amount of the ingredient into a separate container then add the amount directly into a flame-proof mixing tank. Mixing and dispensing will be carried out in a closed system with flame-proof mixers and pumps designed not to create aerosols or a dust hazard and earthed for static discharges.

End Use

The finished cosmetic products containing the notified chemical at ≤ 10% concentration will be used for leave on and rinse off applications on the consumers' skin. Use in aerosols will not occur.

5. HUMAN HEALTH IMPLICATIONS

5.1. Exposure Assessment

5.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and Storage	4	12
Professional compounder	8	12
Chemist	3	12
Packers (Dispensing & Capping)	8	12
Store Persons	4	12
End Users	8	365

EXPOSURE DETAILS

Transport and Storage

Transport and storage workers may come into contact with the notified chemical at up to 100% concentration only in the unlikely event of an accidental spill or rupture of packaging.

Reformulation

Exposure to the notified chemical at up to 100% concentration may occur during weighing and transfer stages, quality control analysis and cleaning and maintenance of equipment. The primary route of exposure is expected to be dermal, whilst ocular exposure is also possible. Inhalation exposure of the notified chemical during blending is not expected, as the blending process will be automated and occurring in a closed vessel. Also, the notified chemical is not volatile and has a low vapour pressure, therefore, no atmospheric monitoring is proposed. Exposure is expected to be minimised through the use of exhaust ventilation and/or automated/enclosed systems as well as through the use of personal protective equipment (PPE) such as coveralls, eye protection, impervious gloves and respiratory protection (respirator with an organic vapour cartridge and P95 filter) if the ventilation is inadequate.

End-use
Exposure to the notified chemical in end-use products at ≤ 10% concentration may occur in professions where the services provided involve the application of cosmetic products to clients (e.g. workers in beauty salons). The principal route of exposure will be dermal, while ocular exposure is also possible. Such professionals may use some PPE to minimise repeated exposure, but this is not expected to occur in all workplaces. However, 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 products containing the notified chemical.

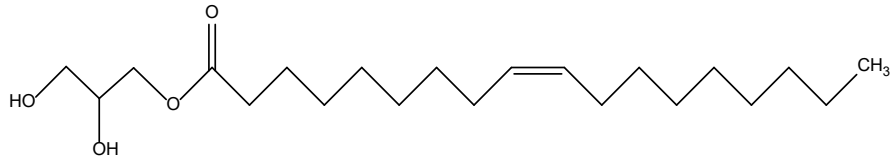
5.1.2. Public Exposure
Public exposure to the notified chemical is expected to be widespread and frequent through daily use of personal care products containing the notified chemical at concentrations of up to 10%. Exposure to the notified chemical will vary depending on individual use patterns. The principal route of exposure will be dermal, while ocular exposure is also possible. Inhalation exposure is not expected as the chemical will not be used in aerosols. Incidental ingestion from the use of these types of products is also possible from facial use.

The notifier has provided an estimate of the public exposure to the notified chemical in Australia. For the purposes of the exposure assessment via the dermal route, the notifier assumed that Australian use patterns for various product categories are similar to those in Europe (SCCS, 2012). Dermal absorption of 10% was assumed for the notified chemical and an average female body weight of 64 kg (enHealth, 2012) was used for calculation purposes. This resulted in a combined internal dose of 2.99 mg/kg bw/day. This estimate assumes that the consumer is a person who is a simultaneous user of all products that contain the notified chemical.

5.2. Human Health Effects Assessment
No toxicity data were submitted on the notified chemical. The information on the expected health effects of the notified chemical is based on analogues of the notified chemical, namely: polyglycerol fatty acid esters (PGFAs; Analogue 1), Glyceryl oleate (Octadecenoic acid (*9Z*)-, monoester with 1,2,3-propanetriol) (Analogue 2) and Diglyceryl monolaurate (Analogue 3).

Analogue 1 represents a generic class of compounds which are made up of polymerised glycerols reacted with fatty acids. The evaluation of the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1974) states that there is satisfactory evidence that alterations in the fatty acid distribution or polyglycerol content of individual members of PGFAs have no toxicological bearing and only affect the physical and emulsifying properties of each ester. Hence, the toxicological study results from this group of esters should be applicable to the individual members of the group, including the notified chemical.

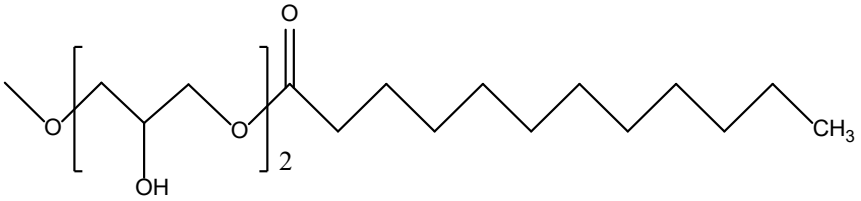
Analogue 2 is a monoester of glycerine and oleic acid that generally conforms to the formula:



Analogue 2

Analogue 2 can be considered a close structural analogue to the notified chemical as it contains one glycerol unit (i.e. n=1) rather than two (n=2). As analogue 2 has lower molecular weight than the notified chemical, it represents worse-case scenario for dermal/systemic absorption.

Analogue 3 is an ester of lauric acid and diglycerin with the following structural formula:



Analogue 3

Analogue 3 contains the same number of glycerol units as the notified chemical but differs in the carbon chain length of the fatty acid moiety (it has 6 less C atoms compared with the notified chemical).

Based on the above, analogues 1, 2 and 3 are considered acceptable analogues for the notified chemical to derive its hazardous properties.

	Analogue 1	*Analogue 2*	*Analogue 3*
CAS name	Polyglycerol fatty acid esters (PGFAs)	Octadecenoic acid (*9Z*)-, monoester with 1,2,3-propanetriol	Dodecanoic acid, monoester with oxybis[propanediol]
CAS number	-	25496-72-4	96499-68-2
Molecular weight (Da)	-	356.5	699.1
Formula	Consist of polymerised glycerols reacted with fatty acids. Composed of ≥ 70% di-, tri-, and tetraglycerols and ≤ 10% polyglycerols.	$C_{21}H_{40}O_4$	$C_{18}H_{36}O_6$
Water solubility	-	Insoluble in water	Water dispersible
Partition co-efficient (log K_{ow})	-	6.7 (calculated)	-

Toxicological properties of analogues 1, 2 and 3 are summarised below:

Endpoint	*Analogue 1* (JECFA, 1974)	*Analogue 2* (CIR, 2016b)	*Analogue 3* (Reference confidential)
Acute oral toxicity	LD50 > 29,000 mg/kg bw (rat)	No signs of toxicity and lethality at 5% (rats)	-
Eye irritation	-	Moderately irritating undiluted and at 50% in corn oil and 19% fragrance formulation (rabbits) Non-irritating at 5% (rabbits)	Minimally irritating 20% in 1,3-butylene glycol (rabbits)
Skin irritation and sensitisation	-	Slightly irritating undiluted and at 50% (rabbits) Slightly irritating at 5% in sunscreen formulation (rabbits) Non-irritating at 15 and 30% (humans) Non-irritating at 5% in sunscreen formulation (humans) Severe irritation at 25% (20 days, rabbits) Moderately irritating at 5% in sunscreen formulation (4 weeks, rabbits) Non-irritating/sensitising at 15% (HRIPT) Non-irritating/sensitising at 50% (HRIPT)	Non-irritating at 10%, moderately-irritating undiluted (rabbits) Weak sensitiser at 30% in olive oil (Guinea pig maximisation test)
Repeat dose oral toxicity	(80 weeks, mice) NOAEL = 5% concentration in the diet (equivalent to 2,500 mg/kg bw/day)	-	-

Endpoint	*Analogue 1* (JECFA, 1974)	*Analogue 2* (CIR, 2016b)	*Analogue 3* (Reference confidential)
	Adverse effects include significantly higher liver and kidney weights in females. (5 weeks, rats) NOAEL = 15% concentration in the diet (90 days, rats) NOAEL = 10% concentration in the diet No adverse effects in humans fed up to 20 g/day over 3 weeks		
Mutagenicity / Genotoxicity	-	-	Non-mutagenic in bacterial reverse mutation test with two strains (no information on whether test included metabolic activation)
Developmental and reproductive effects	(three generations, rats) NOAEL = 1.5% concentration in feed	NOAELs = 1000 mg/kg bw/day for systemic toxicity, fertility and development of F1 generation (rats)	-

Toxicokinetics, metabolism and distribution

No data on toxicokinetics, metabolism and distribution of the notified chemical were provided. The notified chemical is a polyglycerol fatty acid ester composed of diglycerol esterified with the fatty acid octadecenoic acid and is therefore expected to be metabolised in a manner similar to the other polyglyceryl fatty acid esters. Various studies show that 95-98% of polyglyceryl fatty acid esters containing fatty acids of various chain lengths and homopolymers of glycerol containing 2-20 glycerol units are digested and utilised in the body when ingested via the oral route (CIR 2016a). The ester bond in the notified chemical is acted upon by lipases releasing the free fatty acid(s) and polyglycerol. The free fatty acids are readily absorbed via the thoracic duct pathway. Carbon dioxide is the major product of the fatty acid catabolism. The free or partially esterified polyglycerols are not as readily absorbed. Polyglycerols consisting of up to 3 glycerol monomers (such as the notified chemical) are absorbed and excreted via the kidneys, whereas polyglycerols with more than 4 glycerol monomers are not absorbed and are excreted via faeces (EFSA, 2013).

The notified chemical is of relatively low molecular weight (< 500 g/mol), however dermal absorption may be reduced by the estimated high partition coefficient ($logP_{o/w}$ >5). It may also have surfactant activity. Analogue 2, a close analogue to the notified chemical, has been indicated as dermal penetration enhancer (CIR, 2016b), suggesting similar properties for the notified chemical.

Acute toxicity

No acute toxicity data are available for the notified chemical.

In an acute oral toxicity study conducted on analogue 1, no toxic effects were observed when administered as a single dose to rats by oral gavage at 7,000, 14,000 and 29,000 mg/kg bw (JEFCA, 1974). Analogue 2 produced no signs of toxicity and lethality in rats when given at 5% concentration by the oral rout (CIR, 2016b). The notified chemical is therefore expected to be of low acute oral toxicity.

Acute dermal toxicity data on the notified chemical or a close analogue were not available.

Irritation and sensitisation
Analogue 2 was found to be a moderate eye irritant in rabbits when administered undiluted or as a 50% or 19% formulation in corn oil or in a fragrance, respectively. Analogue 3 was a minimal eye irritant in rabbits at 20% concentration.

Several skin irritation studies on analogue 2 and 3 using different concentrations and durations of use (summarised in the table above) produced variable results ranging from non-irritating to severely irritating. Overall, based on the available analogue data, the notified chemical is expected to be slightly irritating to the skin. This is also consistent with the notified chemical being surface active.

In the human repeat insult patch tests (HIRPT), no signs of irritation or sensitisation were observed at 5% and 15% concentrations of analogue 2. The skin irritation and sensitisation potential of analogue 2 was also evaluated in a HRIPT (Finn chambers) test using 107 healthy subjects, 93 of whom completed the study. Analogue 2 was also tested at 50% in paraffin oil at which concentration it did not induce skin irritation or sensitisation. In a guinea pig maximisation test, analogue 3 was shown to be a weak skin sensitiser at 30% concentration; however, the study details were not reported. Based on the studies conducted on analogue 2, the lack of study details on analogue 3, and absence of structural alerts for skin sensitisation, there is not a strong suspicion of skin sensitisation for the notified chemical.

Repeated dose toxicity
No repeated dose toxicity studies are available for the notified chemical.

Mice fed with analogue 1 for 80 weeks at 5% concentration in the diet (equivalent to 2,500 mg/kg bw/day) showed no adverse effects on body weight, food consumption, peripheral blood picture and survival rates (JEFCA, 1974). Microscopic examination of all major organs showed nothing remarkable. However, liver and kidney weights of females were significantly higher. In other studies conducted on analogue 1, no adverse effects were observed in rats fed at 10% and 15% concentration in the diets in 5-week and 90-day repeat dose toxicity studies, respectively (JEFCA, 1974).

In human studies, 37 volunteers (aged 19 to 24) were fed analogue 1 at a dose of 2-20 g/day for three weeks in their diet (JEFCA, 1974). No abnormalities were observed in plasma proteins, serum amino acids, thymol and various other biochemical parameters as well as split faecal fat or total faecal nitrogen.

Overall, based on the weight of evidence, the notified chemical is expected to have low repeated dose oral toxicity.

Mutagenicity/Genotoxicity
No mutagenicity/genotoxicity studies are available for the notified chemical.

In an *in vitro* mutagenicity test on *Salmonella typhimurium* strains, analogue 3 was found to be non-mutagenic. Also, according to the European Food Safety Authority (EFSA) Panel, the impurities (free fatty acids and their esters) have no structural alerts for genotoxicity (CIR 2016a).

Reproductive and developmental toxicity
Rats kept on a diet containing 1.5% analogue 1 for three generations showed no significant variations in fertility or reproductive performance (JEFCA, 1974). In addition, no test substance related gross or histological abnormalities were noted.

In a reproductive/developmental toxicity screening test in rats, female and male animals were dosed by gavage with analogue 2 in corn oil at 0, 100, 300 or 100 mg/kg bw/day once daily for 14 days prior to mating and for 28 additional days in males, while the females were dosed until day 4 of lactation. There were 12 females in the control and 3 test groups, 7 males in the control and high dose groups and 12 males in the low- and mid-dose group. The NOAELs for systemic toxicity, fertility and development toxicity (F1 generation) were 1000 mg/kg bw/day.

Observations on human exposure
The safety profile of polyglycerol esters of fatty acids via the oral route is well established as evidenced by the fact that they are permitted as food additives. The US FDA in 2015 approved their use as an emulsifier in foods at levels needed to perform their emulsifying effect (FDA, 2015a). In the EU the esters are allowed at levels of

up to 10g/kg in some food. They are hydrolysed in the GI tract and fatty acid moiety is metabolised in the normal manner.

The Cosmetic Ingredient Review (CIR) Expert Panel has also concluded that 274 polyglyceryl fatty acid esters including the notified chemical are safe in cosmetics as used currently at concentration described in the safety assessment when formulated to be non-irritating (CIR, 2016a).

Health hazard classification
Based on the limited available information, the notified chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5.3. Human Health Risk Characterisation

5.3.1. Occupational Health and Safety
The notified chemical may be moderately irritating to the eyes and slightly irritating to the skin.

Transport and Reformulation
Workers may experience dermal and accidental ocular exposure to the notified chemical (at up to 100% concentration) during transport and formulation processes. This exposure may occur during handling of the product containers, cleaning and/or maintenance of the equipment. At these facilities, exposure may also extend to compounders and laboratory staff involved in the formulation of the end products containing the notified chemical and the sampling and quality control testing of these products. The notifier has stated that reformulation will include use of enclosed, automated processes and the use of PPE (impervious gloves, safety glasses and coveralls) that should minimise the potential for exposure. Therefore, under the expected scenarios for transport and reformulation, the risk to workers from use of the notified chemical is not considered to be unreasonable.

End-use
Beauty care professionals will handle the notified chemical at up to 10% concentration, similar to public use. Therefore the risk to workers who regularly use products containing the notified chemical is expected to be of a similar or lesser extent than that experienced by members of the public who use such products on a regular basis. For details of the public health risk assessment see Section 5.3.2.

5.3.2. Public Health
The public is likely to have repeated exposure to the notified chemical through use of cosmetic products containing it at ≤ 10% concentration. The notified chemical is expected to have a potential of moderate eye irritation and slight skin irritation. Furthermore, the notified chemical is expected to have low systemic toxicity based on information on the same class of chemicals.

Based on the proposed use, the notified chemical is not considered to pose an unreasonable risk to public health.

6. ENVIRONMENTAL IMPLICATIONS

6.1. Environmental Exposure & Fate Assessment

6.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will be imported neat or as a component of finished cosmetic products for leave on and rinse off cosmetic skin care. The chemical in its neat form may be used for blending and reformulation into cosmetic skin care products. There is unlikely to be any significant release of the notified chemical to the environment from transport and storage, except in the case of accidental spills and leaks. In the event of spills, the chemical or product containing the notified chemical is expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations.

The reformulation process will involve mixing and dispensing with flame-proof mixers and pumps and is expected to occur within a fully enclosed environment. Therefore, significant release of the notified chemical from this process to the environment is not expected. Wastes containing the notified chemical generated during reformulation include equipment wash water, residues in empty import containers and spilt materials. Wash

waters are expected to be recycled or released to on-site waste water treatment processes, or sewers in a worst case scenario.

RELEASE OF CHEMICAL FROM USE
The notified chemical is expected to be released to the aquatic compartment through sewers during its use in cosmetic skin care products.

RELEASE OF CHEMICAL FROM DISPOSAL
It is estimated by the notifier that up to 3% of the import volume of the notified chemical may remain in end-use containers once the consumer products are used up. Wastes and residues of the notified chemical in empty containers are likely to either share the fate of the container and be disposed of to landfill, or be released to the sewer system when containers are rinsed before recycling through an approved waste management facility.

6.1.2. Environmental Fate
The majority of the notified chemical is expected to be released to sewers across Australia. No environmental fate data were submitted. The notified chemical is predicted to be readily biodegradable (BIOWIN v 4.10, US EPA 2011).

In sewage treatment plants (STPs) the notified chemical is expected to be efficiently removed (based on its estimated low water solubility) and high potential to biodegrade from influent and only a small portion may be released to surface waters. A proportion of the notified chemical may be applied to land when effluent is used for irrigation, or disposed of to landfill as waste. The notified chemical residues in landfill and soils are expected to have low mobility based on its estimated low water solubility and surface active properties. The notified chemical has low potential to bioaccumulate based on its ready biodegradability and expected surface active properties. In surface waters, soils and landfill, the notified chemical is expected to eventually degrade through both biotic and abiotic processes to form water and oxides of carbon.

6.1.3. Predicted Environmental Concentration (PEC)
The predicted environmental concentration (PEC) has been calculated to assume a worst case scenario, with 100% release of the notified chemical into sewer systems nationwide and no removal within sewage treatment plants (STPs).

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured 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	200.0	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	82%*	Mitigation
Daily effluent production:	4,877	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.10	µg/L
PEC - Ocean:	0.01	µg/L

*The removal of up to 82% of the notified chemical from influent during sewage treatment plant (STP) processes is predicted based on 31% degradation and 51% partitioning to sludge (SimpleTreat; Struijs 1996).

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.10 µg/L may potentially result in a soil concentration of approximately 0.67 µg/kg.

6.2. Environmental Effects Assessment
No ecotoxicity data were submitted. The ecotoxicity effects of the notified chemical were predicted using non-ionic surfactant model ECOSAR v1.10 (US EPA 2012). The model was developed for the linear non-ionic surfactants containing different number of ethoxylate units and alkyl chains between C8 and C18. Number of

ethoxylates (2) had a minor effect on the ecotoxicity endpoints when C=18. Therefore, the ecotoxicity endpoints for the notified chemical were modelled based on C18 and without ethoxylation. The modelled endpoints were also found to be consistent with measured ecotoxicity to fish, daphnia and algae of non-ionic surfactants of varying chain lengths and alkoxylation, which has been found to be no more toxic than 0.05 mg/L (Madsen et al. 2001).

Endpoint	*Result (*)*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 = 0.051 mg/L	Potentially very toxic to fish
Daphnia Toxicity	48 h LC50 = 0.051 mg/L	Potentially very toxic to aquatic invertebrates

The notified chemical is predicted to be very toxic to fish and aquatic invertebrates. The ECOSAR estimation is considered a conservative approach to provide general indications of the likely environmental effects of the chemical. However, this method is not considered sufficient to formally classify the hazards of the notified chemical to aquatic life under the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*.

6.2.1. Predicted No-Effect Concentration

The endpoints from the ecotoxicity calculations on the notified chemical were similar for fish and aquatic invertebrates, and this was selected for the calculation of the predicted no-effect concentration (PNEC). A conservative assessment factor of 500 is applied given two acute ecotoxicity endpoints are available and these values are comparable to species sensitive to non-ionic surfactants.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish/Daphnia)	0.051	mg/L
Assessment Factor	500	
Mitigation Factor	1.00	
PNEC:	0.10	µg/L

6.3. Environmental Risk Assessment

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	0.10	0.10	0.991
Q - Ocean:	0.01	0.10	0.099

The Risk Quotients (Q = PEC/PNEC) for discharge of treated effluents containing the notified chemical have been calculated to be < 1 for both river and ocean compartments indicating that the notified chemical is unlikely to reach ecotoxicologically significant concentrations in surface waters based on its maximum annual importation quantity. In addition, the notified chemical is likely to be readily biodegradable and has low potential for bioaccumulation. On the basis of assessed use pattern in cosmetic formulations, the notified chemical is not expected to pose an unreasonable risk to the environment.

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