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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Docosanoic Acid, Ester with 1,2,3-Propanetriol

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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TABLE OF CONTENTS

SUMMARY 3
CONCLUSIONS AND REGULATORY OBLIGATIONS 3
ASSESSMENT DETAILS 5
1. APPLICANT AND NOTIFICATION DETAILS 5
2. IDENTITY OF CHEMICAL 5
3. COMPOSITION 5
4. PHYSICAL AND CHEMICAL PROPERTIES 5
5. INTRODUCTION AND USE INFORMATION 6
6. HUMAN HEALTH IMPLICATIONS 7
6.1. Exposure Assessment 7
6.1.1. Occupational Exposure 7
6.1.2. Public Exposure 8
6.2. Human Health Effects Assessment 9
6.3. Human Health Risk Characterisation 11
6.3.1. Occupational Health and Safety 11
6.3.2. Public Health 11
7. ENVIRONMENTAL IMPLICATIONS 12
7.1. Environmental Exposure & Fate Assessment 12
7.1.1. Environmental Exposure 12
7.1.2. Environmental Fate 12
7.1.3. Predicted Environmental Concentration (PEC) 12
7.2. Environmental Effects Assessment 13
7.2.1. Predicted No-Effect Concentration 13
7.3. Environmental Risk Assessment 13
APPENDIX A: TOXICOLOGICAL INVESTIGATIONS 14
A.1. Acute oral toxicity 14
A.2. Skin irritation – human volunteers 14
A.3. Eye irritation 15
A.4. Skin sensitisation – human volunteers 15
BIBLIOGRAPHY 17

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/2050	L'Oreal Australia Pty Ltd	Docosanoic Acid, Ester with 1,2,3-Propanetriol	ND*	≤ 1 tonne per annum	Component of cosmetic products

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is not recommended for classification 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.

Environmental risk assessment
On the basis of the low hazard and assessed 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 engineering controls to minimise occupational exposure to the notified chemical during reformulation processes:
  - Adequate ventilation to inhibit formation of aerosols or dusts

- 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 during reformulation processes:
  - Avoid skin and eye contact
  - Avoid inhaling aerosols or dusts

- 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 physical containment, 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;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a component of cosmetic products 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 and products containing the notified chemical provided by the notifier were 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: molecular and structural formulae, molecular weight, analytical data, degree of purity, residual monomers, impurities, additives/adjuvants, use details, and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: specific gravity/density, dissociation constant, particle size, and explosive and oxidising properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US FDA (2011)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Compritol 888 CG ATO

CAS NUMBER
77538-19-3

CHEMICAL NAME
Docosanoic acid, ester with 1,2,3-propanetriol

OTHER NAME(S)
(INCI Names)
Glyceryl behenate
Glyceryl dibehenate
Tribehenin

MOLECULAR WEIGHT
< 1,500 g/mol

ANALYTICAL DATA
Reference IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
≥ 75%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: White/light yellow powder

The notified chemical is a reaction product containing multiple constituents. Glycerol dibehenate predominates at > 50% by weight of the total mixture based on analysis provided by the notifier. Therefore the glycerol dibehenate is used in this assessment as a discrete organic substance for the purposes of estimating the physical and chemical properties using EPI Suite (EPHC, 2009).

Property	Value	Data Source/Justification
Melting Point	69 - 74 °C	CIR (2007)
Boiling Point	> 150 °C	CIR (2007)
Density	900-930 kg/m^3 at 20 °C	Calculated
Vapour Pressure	< 1.7 × 10^{-13} kPa at 25 °C	Estimated
Water Solubility	3.79 × 10^{-18} g/L at 25 °C	Calculated (WSKOW v1.42 US EPA, 2012)
Hydrolysis as a Function of pH	½ Life = 1.5 – 7 years	Calculated (HYDROWIN v2.00 US EPA, 2012)
Partition Coefficient (n-octanol/water)	log Pow = 19	Calculated (KOWWIN v1.68 US EPA, 2012)
Adsorption/Desorption	log Koc = 4.78 – 17.29	Calculated (KOCWIN v2.00 US EPA, 2012)
Dissociation Constant	Not determined	No dissociable functionality
Particle Size	35 – 65 µm	Measured
Flash Point	> 200°C	SDS
Flammability	Not determined	-
Autoignition Temperature	> 350 °C	SDS
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
No details of tests on physical and chemical properties were provided.

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 physical hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported into Australia as the neat powder form (100% by weight) or as a component in finished cosmetic products.

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
Sydney, Melbourne

IDENTITY OF MANUFACTURER
Gattefosse SAS, France

TRANSPORTATION AND PACKAGING
The notified chemical will be imported into Australia in the neat form or in cosmetic products in retail containers by sea.

The neat form of the notified chemical will be imported in quantities of 25 kg in 60 L sealed bi-layer bags (metal coated polyester/polyethylene) in cardboard boxes, and transported by road from the wharf to the warehouse.

The finished products containing the notified chemical will be imported in consumer use (retail) containers up to 500 mL packed in cartons and stored in a warehouse before distribution. The containers may be bottles or tubes made mainly from high-density polyethylene (HDPE).

USE
The notified chemical will be used as a component in a variety of leave-on and rinse-off cosmetic products at concentrations up to 20%, including aerosol spray products such as deodorant and hair sprays.

OPERATION DESCRIPTION
The notified chemical will not be manufactured in Australia. It will be imported in neat form for reformulation locally into finished cosmetics.

Reformulation
Reformulation of the notified chemical into finished consumer goods at concentrations ≤ 20% will likely vary depending on the nature of the cosmetic products formulated. This may involve both automated and manual transfer steps. In general, it is expected that the products containing the notified chemical will be weighed and added to the mixing tank where mixing with additional additives will occur to form finished cosmetic products. Subsequently, automated filling of the reformulated products into containers of various sizes will be processed. The blending and filling operations are expected to be highly automated with enclosed systems and adequate ventilation. During the reformation process, samples of products containing the notified chemical will be taken for quality control purposes.

End use
The finished cosmetic products containing the notified chemical at concentrations up to 20% will be used by consumers and professionals such as beauticians and hairdressers. Depending on the nature of the products, applications may be by hand, spray or through the use of applicators.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. 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
Professional end users	1-8	200

EXPOSURE DETAILS
Transport and storage
Transport and storage workers may come into contact with the notified chemical in neat form or as a component of the imported preparations, only in the event of accidental rupture of containers. Incidental dermal or ocular exposure to the notified chemical may occur during the clean-up of any accidental spills.

Reformulation
During reformulation, dermal, ocular and inhalation exposure of workers to the notified chemical (up to 100% concentration) may occur during weighing, transfer, blending, quality control analysis, cleaning and maintenance. The use of engineering controls including local exhaust ventilation and enclosed systems, and the use of personal protective equipment (PPE) by workers (such as coveralls, goggles, impervious gloves and appropriate respiratory protections) are expected to minimise exposure to the notified chemical.

End-use
Exposure to the notified chemical in end-use products (at up to 20% concentration) may occur in professions where the services provided involve the application of cosmetic products to clients (i.e., at hair and beauty

salons). The principal route of exposure will be dermal, while ocular and inhalation exposure are also possible. Such professionals may use PPE to minimise repeated exposure and good hygiene practices are expected to be in place. If appropriate PPE is used, exposure of such workers to the notified chemical is expected to be similar to or less than that experienced by consumers using the same products.

6.1.2. Public Exposure

There will be widespread and repeated exposure of the public to the notified chemical at up to 20% concentration through the use of a wide range of cosmetic products. The main routes of exposure will be dermal, while ocular and inhalation exposure (e.g. through the use of spray products) are also possible.

Data on typical use patterns of product categories in which the notified chemical may be used are shown in the following tables provided in various literatures (SCCS, 2012; Cadby *et al.*, 2002; ACI, 2010; Loretz *et al.,* 2006). For the purposes of exposure assessment via the dermal route, Australian use patterns for various products are assumed to be similar to the consumer use patterns in Europe. A dermal absorption (DA) rate of 10% (estimated by the notifier), and an oral absorption rate of 100% was assumed for the notified chemical for calculation purposes. For inhalation exposure estimation of spray products, a 2-zone approach was used (Steiling *et al*., 2014; Rothe *et al*., 2011; Earnest, Jr, 2009) with an adult inhalation rate of 20 m^3/day (enHealth, 2012). It was conservatively assumed that the fraction of the notified chemical inhaled will be 50%, with the remainder ending up on the targets as intended. A lifetime average female body weight (BW) of 64 kg (enHealth, 2012) was applied in the calculations.

Cosmetic products (Dermal exposure):

Product type	*Amount (mg/day)*	*C (%)*	*RF*	*Daily systemic exposure (mg/kg bw/day)*
Body lotion	7820	20	1	2.4438
Face cream	1540	20	1	0.4813
Hand cream	2160	20	1	0.6750
Fine fragrances	750	20	1	0.2344
Deodorant (non-spray)	1430	20	1	0.4688
Shampoo	10460	20	0.01	0.0327
Conditioner	3920	20	0.01	0.0123
Shower gel	18670	20	0.01	0.0583
Hand wash soap	20000	20	0.01	0.0625
Hair styling products	4000	20	0.1	0.1250
Foundation	510	20	1	0.1594
Eyeshadow	20	20	1	0.0063
Eye Liner	5	20	1	0.0016
Mascara	25	20	1	0.0078
Makeup remover	5000	20	0.1	0.1563
Facial cleanser	800	20	0.01	0.0025
Total				**4.9277**

C = maximum intended concentration of notified chemical; RF = retention factor.
Daily systemic exposure = (Amount × C × RF × DA)/BW

Cosmetic product (Oral exposure):

Product type	*Amount (mg/use)*	*C (%)*	*RF*	*Daily systemic exposure (mg/kg bw/day)*
Lipstick	57	20	1	**0.1781**

C = maximum intended concentration of notified chemical
Daily systemic exposure = (Amount × C × RF × oral absorption)/BW

Aerosol products (Inhalation exposure):

Product type	*Amount (g/use)*	*C (%)*	*Inhalation rate (m^3/day)*	*Exposure duration zone 1 (min)*	*Exposure duration zone 2 (min)*	*Fraction inhaled (%)*	*Volume zone 1 (m^3)*	*Volume zone 2 (m^3)*	*Daily systemic exposure (mg/kg bw/day)*

Product type	*Amount (g/use)*	*C (%)*	*Inhalation rate (m^3/day)*	*Exposure duration zone 1 (min)*	*Exposure duration zone 2 (min)*	*Fraction inhaled (%)*	*Volume zone 1 (m^3)*	*Volume zone 2 (m^3)*	*Daily systemic exposure (mg/kg bw/day)*
Deodorant	6.1	0.2	20	1	20	50	1	10	0.0040
Hairspray	9.89	0.2	20	1	20	50	1	10	0.0064
Total									**0.0104**

C = maximum intended concentration of notified chemical
Total daily systemic exposure = Daily systemic exposure in Zone 1 [(amount × C × inhalation rate × exposure duration (zone 1) × fraction inhaled)/(volume (zone 1) × body weight)] + Daily systemic exposure in Zone 2 [(amount × C × inhalation rate × exposure duration (zone 2) × fraction inhaled)/(volume (zone 2) × body weight)]

The worst case scenario estimation using these assumptions is for a person who is a simultaneous user of all products listed in the above tables that contain the notified chemical. This would result in a combined internal dose of 5.1162 mg/kg bw/day. It is acknowledged that inhalation exposure to the notified chemical from use of other cosmetic products (in addition to hair spray and aerosol deodorant) may occur. However, it is considered that the combination of the conservative (screening level) hair spray and aerosol deodorant inhalation exposure assessment parameters, and the aggregate exposure from use of the dermally applied products is sufficiently protective to cover additional inhalation exposure to the notified chemical from use of other spray cosmetic products with lower exposure factors.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical and the analogues are summarised in the following table. For full details of unpublished studies conducted on the notified chemical submitted with the application, refer to Appendix A.

Endpoint	*Result and Assessment Conclusion*	*Data Source*
Rat, acute oral toxicity*	LD50 > 5000 mg/kg bw; low toxicity	Notified chemical
Mouse, acute oral toxicity	LD50 = 5000 mg/kg bw; low toxicity	Analogue 2 (CIR, 2001)
Eye irritation – *in vitro* Episkin Cytotoxicity study	Non-irritating	Notified chemical
Rabbit, eye irritation (OECD TG 405)*	Slightly irritating	Notified chemical
Rabbit, eye irritation	Slightly irritating at 5%	Analogue 1 (CIR, 2007)
Rabbit, eye irritation	Non-irritating undiluted	Notified chemical (CIR, 2016)
Rabbit, skin irritation	Non-irritating undiluted	Notified chemical (CIR, 2016)
Rabbit, skin irritation	Slightly irritating at 20%	Analogue 2 (CIR, 1999)
Human, skin irritation (in house method)*	Slightly irritating at 10%	Notified chemical
Guinea pig, skin sensitisation – adjuvant test	No evidence of sensitisation	Analogue 2 (CIR, 1999)
Human, skin sensitisation – RIPT*	No evidence of sensitisation at 17.5%	Notified chemical in a product
Human, skin sensitisation – RIPT	No evidence of irritation or sensitisation up to 0.4%	Analogue 2 (CIR, 1999)
Rat, combined repeated dose oral toxicity with reproduction and developmental toxicity screening test	NOAEL = 1000 mg/kg bw/day for systemic and reproductive / developmental toxicity	Analogue 3 (SIDS, 2001)
Mutagenicity – bacterial reverse mutation	Non mutagenic	Analogue 3 (SIDS, 2001)
Genotoxicity – *in vitro* mammalian chromosome aberration test	Non genotoxic	Analogue 3 (SIDS, 2001)

* Study details in Appendix A

Toxicokinetics, metabolism and distribution

No toxicokinetics, metabolism and distribution study data were submitted for the notified chemical. Based on metabolism data for analogue 2, the notified chemical may be absorbed by the gastrointestinal tract.

Based on the molecular weight range of the notified chemical and an estimated dermal absorption rate of 10%, percutaneous absorption is expected to be limited.

Acute toxicity
The notified chemical has low acute oral toxicity in rats, with an LD50 > 5000 mg/kg bw (Appendix A.1). Analogue 2 has a reported low acute oral toxicity in mice, with an LD50 of 5000 mg/kg bw (CIR, 2001).

No information was submitted for the notified chemical or analogues on acute dermal and acute inhalation toxicity.

Irritation and sensitisation
Three eye irritation studies in rabbits and one *in vitro* study using Episkin model for the notified chemical are available.

In an eye irritation study, the undiluted notified chemical was tested on 6 New Zealand White (NZW) rabbits. Moderate conjunctival redness was observed in 5/6 animals one hour after treatment. This was reduced to minimal conjunctival irritation at the 24 hour time point. Slight chemosis and iridial congestion were observed up to 48 hours. All signs of irritation were reversible at the 48-hour time point. No corneal effects were noted during the study (Appendix A.3).

In the second eye irritation study (CIR, 2016), the undiluted notified chemical was tested on 3 NZW rabbits. Slight lacrimation in all animals was observed at one hour and in one animal at 24 hours. No other effects were observed. In the third eye irritation study (CIR, 2007), analogue 1 was slightly irritating when instilled into the eyes of 3 male NZW rabbits at 5% (w/w) in kernel oil (0.1 mL). Effects were observed at one hour following administration, but were reversible by day 3.

In an *in vitro* eye irritation study summary provided for the notified chemical using Episkin reconstructed human corneal epithelium, the notified chemical was considered to be non-irritating to the eyes. However, no details of the study were provided.

In a skin irritation study in 3 male NZW rabbits, the notified chemical was applied (semi-occlusive) undiluted to the shaved and abraded skin for 4 hours, with observation up to 7 days. Slight erythema was observed in 1 animal at 24 hours. The notified chemical was not considered a skin irritant.

In another skin irritation study conducted in albino rabbits, analogue 2 was slightly irritating when applied (occlusive) at a concentration of 20% to intact and abraded skin for 24 hours. A primary irritation index (PII) of 0.3 was determined. The analogue was slightly irritating to the skin (CIR, 1999).

In a human acute cutaneous irritation test, the notified chemical was slightly irritating to 4/10 human volunteers when applied (occlusive) at a concentration of 10% to the skin of the back for 48 hours. No reactions were observed in the rest of the volunteers. The notified chemical was reported to not induce significant cutaneous intolerance or pathological irritation (Appendix A.2).

In a human repeated insult patch test (HRIPT), a product containing the notified chemical at 17.5 % was tested on 101 volunteers whereupon 99 subjects completed the test. No skin irritation or skin sensitisation was observed for the full duration of the test (Appendix A.4).

Two HRIPTs were reported for analogue 2 for use in cosmetic products up to 0.4%. In the first study, 198 subjects were tested with an eye enhancer containing analogue 2. In the second study, 200 subjects were tested with a hand cream and a lip cream. Analogue 2 was not considered to be a skin irritant or a sensitiser in these studies (CIR, 1999).

In a guinea pig maximisation test, analogue 2 did not induce sensitisation. However, no details of the test were provided (CIR, 1999).

Repeated dose toxicity and reproductive/developmental toxicity
In a combined repeated dose and reproductive/developmental oral toxicity study, analogue 3 was administered by gavage at dose levels of 0, 100, 300 and 1000 mg/kg bw/day in Sprague-Dawley (SD) rats (SIDS, 2001). No deaths or abnormalities in clinical signs were observed. No treatment-related effects were observed for haematological, biochemical, organ weights, gross findings and histopathological examinations.

No treatment-related adverse parental, reproduction or developmental toxicity effects or toxicologically relevant changes were observed in any of the dose levels tested. A no observed adverse effect Level (NOAEL) was determined by the study authors for analogue 3 as 1000 mg/kg bw/day in rats for systemic toxicity and reproduction/developmental toxicity.

Mutagenicity/Genotoxicity
Analogue 3 was negative in an *in vitro* bacterial reverse mutation assay at concentrations up to 5 mg/plate, with or without metabolic activation; and in an *in vitro* chromosomal aberration test in Chinese hamster lung (CHL/IU) cells up to 3.5 mg/mL, with or without metabolic activation (SIDS, 2001).

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

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on the toxicological information provided, the notified chemical is of low hazard with potential for slight eye and skin irritation. However, a concentration of 17.5 % of the notified chemical was not irritating and sensitising to humans. No inhalation toxicity data are provided, although the notified chemical will be introduced as a powder form for reformulation.

Reformulation
During reformulation, workers may come into contact with the neat form of the notified chemical and may be at risk of slight eye and skin irritation effects. The notifier anticipates that worker exposure will be limited through the use of engineering controls such as enclosed systems, automated processes and mechanical ventilation. The use of appropriate PPE (coveralls, imperious gloves and eye protection) will also be used to limit worker exposure.

End-use
Workers involved in professions where the services provided involve the application of cosmetic products containing the notified chemical to clients (*e.g.*, hairdressers and beauty salon workers) may be exposed to the notified chemical at up to 20% concentration. Such professionals may use PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, the risk to such workers is expected to be of a similar or lesser extent than that experienced by consumers using the various products containing the notified chemical.

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

6.3.2. Public Health
Based on the available data for the notified chemical and analogues (including study summaries), irritation and sensitisation effects on the notified chemical are not expected at ≤ 20% concentration.

Although in worst case scenario repeated use of cosmetics containing the notified chemical may result in a systemic absorption of 5.1162 mg/kg bw/day for an average female (see section 6.1.2), based on the toxicological information provided (NOAEL = 1000 mg/kg bw/day for analogue 3 in a repeated dose oral toxicity study), the notified chemical is considered to be of low hazard.

Inhalation toxicity of the notified chemical has not been determined. However, use of cosmetic products in powder form (compact powder and eye shadow) containing the notified chemical is not considered to generate inhalable dust due to the nature of the products as indicated by the notifier. Use of aerosol deodorant and hairspray products containing the notified chemical may result in an internal dose of 0.0104 mg/kg bw/day for an average female (see Section 6.1.2). Similar chemicals to the notified chemical have been used in cosmetics including aerosol spray products and the Cosmetic Ingredient Review (CIR) Expert Panel considered that these chemicals are safe as cosmetic ingredients (CIR, 2007 and 2016).

Therefore, based on the available information, the risk associated with use of the notified chemical up to 20% concentration in cosmetics is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported into Australia as a component of end use cosmetic products; or imported in neat form for local reformulation into the end-use products. In general, the reformulation processes are expected to involve automated blending operation in an enclosed environment, followed by packing of the finished products into end-use containers. Wastewater containing the notified chemical from reformulation equipment cleaning is expected to be disposed of to sewer. Release of the notified chemical in the event of accidental spills or leaks during reformulation, storage and transport is expected to be collected for disposal, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The majority of the notified chemical is expected to be released to sewers across Australia as a result of its use in cosmetic products, which are washed off hair and skin of consumers.

RELEASE OF CHEMICAL FROM DISPOSAL

A small proportion of the notified chemical estimated to be ≤ 3% may remain as residues within end use containers. Another proportion estimated to be ≤ 1% may remain in raw material containers. Residues of the notified chemical in empty import and end-use containers are likely to either share the fate of the containers 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.

7.1.2. Environmental Fate

Following its use in cosmetic products, the majority of the notified chemical will enter the sewers and be treated at sewage treatment plants (STPs) before potential release to surface waters nationwide.

A ready biodegradation calculation based on EPA Suite indicates that the notified chemical is expected to be readily biodegradable (BIOWIN v4.1 US EPA, 2012). The notified chemical is expected to highly sorb to sludge at STPs based on its calculated low water solubility (3.79×10^{-18} g/L, US EPA, 2012) and calculated high partition coefficient (log Pow = 19, US EPA, 2012). Therefore, the notified chemical is expected to be removed effectively at STPs through biodegradation and adsorption to sludge, and only a small portion of the notified chemical may be released to surface waters.

A proportion of the notified chemical may be applied to land when effluent is used for irrigation or when sewage sludge is used for soil remediation, or disposed of to landfill. The notified chemical residues in landfill and soils are expected to have low mobility based on its calculated soil adsorption coefficient (log K_{oc} = 4.78 – 17.29, US EPA, 2012).

The notified chemical is not expected to be bioaccumulative based on its ready biodegradability. In the aquatic and soil compartments, the notified chemical is expected to degrade through biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated to assume the worst case scenario with 100% release of the notified chemical into sewer systems nationwide over 365 days per annum. It is also assumed under the worst-case scenario that there is no removal of the notified chemical during sewage treatment processes. The resultant PEC in sewage effluent on a nationwide basis is estimated as follows:

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	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	0	%
Daily effluent production	4,877	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River	0.56	µg/L
PEC - Ocean	0.06	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 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 1,500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.56 µg/L may potentially result in a soil concentration of approximately 3.74 µg/kg. Due to the ready biodegradability of the notified chemical, annual accumulation is not expected.

7.2. Environmental Effects Assessment

The calculated water solubility for notified chemical is very low (3.79×10^{-18} g/L). Therefore, the notified chemical is not expected to be harmful to aquatic organisms up to the limit of its water solubility. The notified chemical is expected to be readily biodegradable. Therefore, under *the Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) (United Nations, 2009), the notified chemical is not formally classified.

7.2.1. Predicted No-Effect Concentration

It is not necessary to calculate the Predicted No-Effect Concentration (PNEC) since the notified chemical is not harmful to aquatic organisms.

7.3. Environmental Risk Assessment

The risk quotient (RQ = PEC/PNEC) has not been calculated. The notified chemical is not harmful to the aquatic environment. The notified chemical is not expected to persist in the environment due to its expected biodegradability. Therefore, based on the low aquatic hazard and the assessed use pattern, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Acute oral toxicity

TEST SUBSTANCE	Notified chemical
METHOD	Acute oral toxicity – in-house test guideline
Species/Strain	Rat/ Sprague-Dawley
Vehicle	Hydroxyl cellulose gel 1%
Remarks - Method	Purity of test substance was > 80%. 10 animals (5/sex) starved 15-20 hours before intubation One dose level of 5000 mg/kg bw Observation at 1 and 2 hours, then once daily on Days 2, 3, 4, 7 and 14

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	5M/5F	5000	0/10

LD50	> 5000 mg/kg bw
Signs of Toxicity	No signs of toxicity noted
Effects in Organs	No effects in organs noted
Remarks - Results	Only summary of the study was provided. No mortalities occurred following a 14-day observation period.
CONCLUSION	The notified chemical is of low acute toxicity via the oral route.
TEST FACILITY	Test Facility A (1980) (Exempt information)

A.2. Skin irritation – human volunteers

TEST SUBSTANCE	Notified chemical
METHOD	Acute cutaneous irritation test – in-house test guideline
Study Design	Patches containing 0.02 mL test substance at 10% concentration were applied (occlusive) on the back of healthy adults for 48 hours. Observation at 30 minutes after removal of patch.
Study Group	10 subjects (8 F, 2 M), age range 21 – 54 years, 3 atopic
Vehicle	Kernel stone oil
Remarks - Method	Occluded. The test substance was spread onto a disc of filter paper of 7 mm in diameter.
RESULTS	
Remarks - Results	In this study, 12 volunteers were selected and 10 subjects completed the study. Very slight erythema (hardly visible on at least 3/4 of the application area, or well visible in a smaller area) was reported in 2/10 subjects. Slight rugosity (slightly worn aspect on at least 3/4 of the application area, or clearly worn aspect on a surface smaller than 3/4 of the application area) was reported in 2/10 subjects. No reactions were observed in 6/10 subjects, including the atopic volunteers. No significant cutaneous intolerance or pathological irritation was observed.

CONCLUSION	The notified chemical at 10% concentration was slightly irritating under the conditions of the test.
TEST FACILITY	Test Facility B (1996) (Exempt Information)

A.3. Eye irritation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion
Species/Strain	Rabbit/New Zealand White
Number of Animals	6 M
Observation Period	24, 48 and 72 hours
Remarks - Method	Only males tested. No other protocol deviations

RESULTS

Lesion	*Mean Score**						*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3	4	5	6			
Conjunctiva: redness	0.66	0.0	0.0	0.33	0.0	0.66	2**	48 h	0.0
Conjunctiva: chemosis	0.0	0.0	0.0	0.0	0.0	0.0	1**	1 h	0.0
Corneal opacity	0.0	0.0	0.0	0.0	0.0	0.0	0.0	Nil	0.0
Iridial inflammation	0.66	0.0	0.0	0.33	0.0	0.0	1	48 h	0.0

* Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal
** At the 1-hour observation

Remarks - Results	Moderate reddening of the conjunctivae (grade 2) was observed in 5 animals at the 1-hour observation. Slight reddening (grade 1) was observed in 1 animal at the 1-hour observation, in 3 animals at 24 hours, and in 2 animals at 48 hours. Slight chemosis (grade 1) was observed in all animals at the 1-hour observation. Slight congestion of the iris (grade 1) was observed in all animals at the 1-hour observation, in 2 animals at 24 hours and in 1 animal at 48 hours. All signs of irritation were resolved at the 48-hour observation. No mortality was observed.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	Test Facility C (1999) (Exempt Information)

A.4. Skin sensitisation – human volunteers

TEST SUBSTANCE	Product containing notified chemical at 17.5 %
METHOD	Repeated insult patch test with challenge
Study Design	Induction Procedure: Patches containing 20 mg test substance were applied 3 times per week (Monday, Wednesday and Friday) for a total of 9 applications. Patches were removed after 48 hours and the sites evaluated 15 – 30 minutes after removal. Patches applied on a Friday remained for

	72 hours until Monday. Rest Period: 14 days Challenge Procedure: 2 weeks after the final induction application, a patch was applied to the original site and to a naïve site for 48 hours. Sites were evaluated at 30 minutes and 48 hours post-patch removal.
Study Group	93 F, 17 M; age range 18 – 64 years
Vehicle	None
Remarks - Method	Occluded. The test substance was spread on a 2 cm × 2 cm (or 8 mm diameter) patch.
RESULTS	
Remarks - Results	In this study, 101 qualified test subjects completed the induction phase, and 99 subjects completed the challenge phase. 11 subjects discontinued in the challenge phase for reasons unrelated to the study. No visible skin reactions were observed for any test subject throughout the test.
CONCLUSION	The test substance (product containing 17.5 % notified chemical) was non-irritating and non-sensitising under the conditions of the test.
TEST FACILITY	Test Facility D (2010) (Exempt Information)

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