File No: LTD/2029

April 2019

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, ether with D-glucitol (6:1), tetra-(9*Z*)-9-octadecenoate

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/2029	Estee Lauder Pty Ltd Unilever Australia Trading Ltd Unilever Asia Private Ltd	Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, ether with D-glucitol (6:1), tetra-(9*Z*)-9-octadecenoate	ND*	≤ 6 tonnes per annum	Cosmetic ingredient

*Not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer 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 polymer is not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment
On the basis of the reported use pattern and import volume, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

CONTROL MEASURES

- 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 polymer during reformulation processes:
  - Avoid contact with skin

- 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 polymer [as introduced during reformulation processes:
  - Protective clothing
  - Impervious gloves

  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 polymer 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.

Public Health

- Formulators of end-use products should take into account the potential for the notified polymer to cause skin irritation when formulating cosmetic products containing the notified polymer to apply on skin.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer 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 polymer 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 notifiers, 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 polymer 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 polymer has a number-average molecular weight of less than 1000 g/mol;
- the final use concentration of the notified polymer exceeds 20% in cosmetic products;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a cosmetic ingredient or is likely to change significantly;
- the amount of polymer being introduced has increased, or is likely to increase, significantly;
- the polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the polymer 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 polymer and products containing the notified polymer 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

APPLICANTS
Estee Lauder Pty Ltd (ABN: 63 008 444 719)
165-175 Mitchell Road
ERSKINEVILLE NSW 2043

Unilever Australia Trading Ltd (ABN: 40 008 427 110)
219 North Rocks Road
NORTH ROCKS NSW 2151

Unilever Asia Private Ltd (ABN: 29 142 738 538)
Level 17, 2 Park Street
SYDNEY NSW 2000

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1,000 g/mol

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details exempt from publication include: other names, molecular weight, polymer constituents, residual monomers and import volumes.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Schedule data requirements are varied for all physico-chemical endpoints

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANTS
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

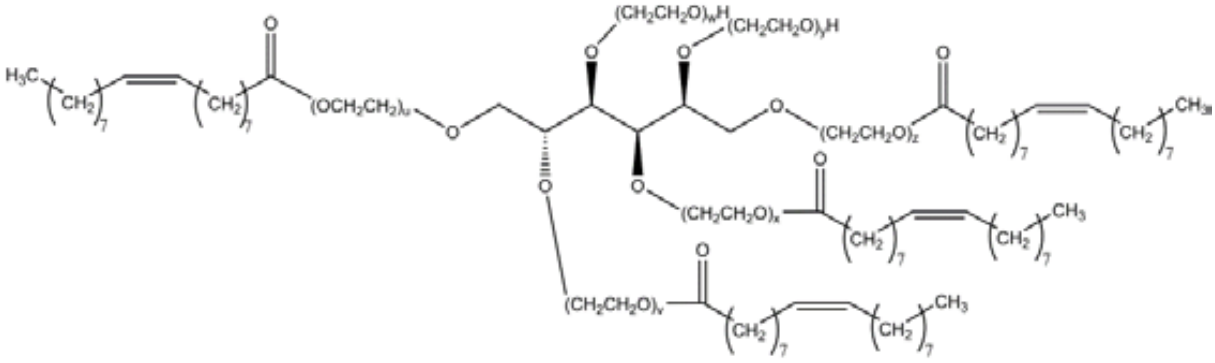
MARKETING NAME
Sorbeth-30 tetraoleate (INCI Name)
Sorbeth-40 tetraoleate (INCI Name)
Sorbeth-60 tetraoleate (INCI Name)

CAS NUMBER
63089-86-1

CHEMICAL NAME
Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, ether with D-glucitol (6:1), tetra-(9*Z*)-9-octadecenoate

MOLECULAR FORMULA
$(C_2H_4O)n$ $(C_2H_4O)n$ $(C_2H_4O)n$ $(C_2H_4O)n$ $(C_2H_4O)n$ $(C_2H_4O)n$ $C_{78}H_{142}O_{10}$

STRUCTURAL FORMULA



Representative structure of Sorbeth-30 tetraoleate, Sorbeth-40 tetraoleate and Sorbeth-60 tetraoleate; a tetraester of oleic acid and a polyethylene glycol ether of sorbitol containing an average of 30, 40 or 60 moles of ethylene oxide, respectively.

MOLECULAR WEIGHT
Number average molecular weight (Mn) is > 1,000 g/mol

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
Not determined.

The notifier has indicated that the mono-, di-, tri, penta- and hexa-oleate species are also present as impurities but it is not technically feasible to quantify the level of these impurities.

IMPURITIES

Chemical Name	Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, ether with D-glucitol (6:1), mono-(9Z)-9-octadecenoate		
CAS No.	72642-93-4	*Weight %*	Not determined
Chemical Name	Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, ether with D-glucitol (6:1), di-(9Z)-9-octadecenoate		
CAS No.	67503-53-1	*Weight %*	Not determined
Chemical Name	Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, ether with D-glucitol (6:1), tri-(9Z)-9-octadecenoate		
CAS No.	72642-92-3	*Weight %*	Not determined
Chemical Name	Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, ether with D-glucitol (6:1), penta-(9Z)-9-octadecenoate		
CAS No.	9011-34-1	*Weight %*	Not determined
Chemical Name	Poly(oxy-1,2-ethanediyl), α-hydro-ω-[[(9Z)-1-oxo-9-octadecen-1-yl]oxy]-, ether with D-glucitol (6:1)		
CAS No.	57171-56-9	*Weight %*	Not determined

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Light yellow to clear liquid

Property	Value	Data Source/Justification
Melting Point	- 7.4 °C	SDS
Boiling Point	Not determined	Expected to degrade before boiling
Density	1,003 kg/m^3 at 30 °C	SDS
Vapour Pressure	Not determined	Expected to be low based on high molecular weight
Water Solubility	Not determined	Expected to be surface active and water dispersible due to the combination of hydrophobic end groups on a hydrophilic backbone.
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to phase boundaries based on surface activity
Adsorption/Desorption	Not determined	Expected to adsorb to soil and sediment based on surface activity
Dissociation Constant	Not determined	No dissociable functionalities
Flash Point	273 °C	SDS
Flammability	Not determined	Not expected to be flammable based on flash point
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 polymer is expected to be stable under normal conditions of use.

Physical hazard classification
Based on the limited physico-chemical data depicted in the above table, the notified polymer cannot be recommended for 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 polymer will not be manufactured in Australia. The notified polymer will be imported into Australia neat for reformulation into cosmetic products, or as a component of finished cosmetic products at ≤ 20% concentration.

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

Estee Lauder Pty Ltd

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

Unilever Australia Trading Ltd & Unilever Asia Private Ltd (combined)

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

PORT OF ENTRY
Sydney and Melbourne

TRANSPORTATION AND PACKAGING

The notified polymer will be imported neat packed in 100 kg drums or 17 kg tin canisters. Finished cosmetic products containing the notified polymer at ≤ 20% concentration will be imported in containers suitable for retail sale (i.e. 5-500 mL plastic bottles and tubes).

Within Australia the neat notified polymer will be transported by road to the warehouse for storage and later distributed to industrial customers for reformulation into finished cosmetic products by road. Finished cosmetic products containing the notified polymer will be transported primarily by road to retail stores in packages suitable for retail sale.

USE

The notified polymer will be used as a cosmetic ingredient in a variety of products at a proposed usage concentration of ≤ 20%.

OPERATION DESCRIPTION

Reformulation

Reformulation of the neat notified polymer into finished cosmetic products may vary depending on the type of product, and may involve both automated and manual transfer steps. Typically, reformulation processes may incorporate blending operations that are highly automated and occur in a fully enclosed/contained environment, followed by automated filling of the reformulated cosmetic products into containers of various sizes.

End-use

Finished cosmetic products containing the notified polymer at ≤ 20% concentration will be used by consumers and professionals (such as beauticians and hairdressers). Depending on the nature of the product, application of the products could be by hand, sprayed or through the use of an applicator.

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
Compounder	8	12
Chemist	3	12
Dispensing and packaging	8	12
Retailer workers	4	12
End users (professionals)	8	365

EXPOSURE DETAILS

Transport and storage

Transport, storage and warehouse workers may come into contact with the notified polymer (in neat form or at ≤ 20% concentration in final formulated products), only in the unlikely event of an accidental rupture of containers.

Reformulation

During reformulation, dermal, ocular and perhaps inhalation exposure of workers to the notified polymer at ≤ 100% concentration may occur during handling of drums/canisters, during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment. The notifier states that exposure is expected to be minimised through the use of local ventilation and/or enclosed systems, pumps designed not to create aerosols and through the use of personal protective equipment (PPE) such as protective clothing, eye protection and impervious gloves.

End use professionals
Workers involved in professions which involve application of cosmetic products containing the notified polymer to clients (e.g. beauty salon workers) may be exposed to the notified polymer at ≤ 20% concentration. The principal route of exposure will be dermal, while ocular and inhalation exposure are also possible. Such professionals may use some PPE to minimise repeated exposure and good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified polymer.

6.1.2. Public Exposure

There will be widespread and repeated exposure of the public to the notified polymer (at ≤ 20% concentration) through the use of a wide range of cosmetic products. The principal route 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 (SCCS, 2012; Cadby *et al*., 2002; ACI, 2010; Loretz *et al.,* 2006) in which the notified chemicals may be used are shown in the following tables. For the purposes of the exposure assessment, Australian use patterns for the various product categories are assumed to be similar to those in Europe. A dermal absorption (DA) rate of 100% was assumed for the notified chemicals for calculation purposes. For the inhalation exposure assessment, 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 chemicals inhaled is 50%. A lifetime average female body weight (BW) of 64 kg (enHealth, 2012) was used for calculation purposes.

Cosmetic products (dermal exposure)

Product Type	Amount (mg/day)	C (%)	RF (unitless)	Daily Systemic Exposure (mg/kg bw/day)
Body lotion	7820	15	1.000	18.3281
Face cream	1540	15	1.000	3.6094
Hand cream	2160	15	1.000	5.0625
Fine fragrances	750	15	1.000	1.7578
Deodorant (non-spray)	1500	15	1.000	3.5156
Shampoo	10460	15	0.010	0.2452
Conditioner	3920	15	0.010	0.0919
Shower gel	18670	15	0.010	0.4376
Hand wash soap	20000	15	0.010	0.4688
Hair styling products	4000	15	0.100	0.9375
Total				**34.4543**

C = maximum intended combined concentration of the notified chemicals; RF = retention factor
Daily systemic exposure = (Amount × C × RF × Dermal Absorption) / Body Weight

Hairspray (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)
Hairspray	9.89	20	20	1	20	50	1	10	0.6439
Total									**0.6439**

C = maximum intended combined concentration of the notified chemicals
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 polymer at the maximum intended combined concentration as specified by the notifier in various product types. This would result in a combined internal dose of 35.0982 mg/kg bw/day.

It is acknowledged that inhalation exposure to the notified polymer from use of other cosmetic products (in addition to hair spray) may occur. However, it is considered that the combination of the conservative hair spray inhalation exposure assessment parameters, and the aggregate exposure from use of the dermally applied products, which assumes a conservative 100% absorption rate, is sufficiently protective to cover additional inhalation exposure to the notified polymer from use of other spray cosmetic products with low exposures (e.g. deodorants).

6.2. Human Health Effects Assessment

The results from skin sensitisation studies conducted on two products containing the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix A.

Endpoint	*Result and Assessment Conclusion*
Human, skin sensitisation – RIPT (10.8%)	no evidence of sensitisation
Human, skin sensitisation – RIPT (0.1%)	no evidence of sensitisation

Sensitisation

In human repeat insult patch tests, there was no evidence of sensitisation to the notified polymer at 10.8% and 0.1% concentration. Furthermore, the notified polymer does not contain structural alerts associated with skin sensitisation.

Skin Irritation

No studies were provided for skin irritation of the notified polymer. The notified polymer has been classified on the supplied SDS as a skin irritant (H315 – Causes skin irritation). This is consistent with the notified polymer being surface active.

The supplied SDS states the following results:

- Guinea pig, undiluted, 5 hour closed patch test: slight erythema was observed in 3/5 animals
- Guinea pig, undiluted, 4 times repeated application test: Final mean score = 2.8 (max. 4)
- Human, undiluted, 24 hour closed patch test: non-irritating

The data is reported by the notifier to be on the notified polymer but using animal derived oleic acid.

The irritation potential of the notified polymer is further supported from studies conducted on analogues (CIR, 2015) (see below for more details). However, the results of these studies, as with the results on the supplied SDS, are conflicting.

Analogue data

The following toxicological information was obtained from the Cosmetic Ingredient Review report, “Safety Assessment of Polysorbates as Used in Cosmetics” (CIR, 2015). This document is a safety assessment of 80 polysorbates used in cosmetics, including the notified polymer. The polysorbates were grouped based on their common core structure of sorbitan or sorbitol etherified with PEG chains and esterified with fatty acids.

The authors of this document noted the lack of systemic toxicity in acute and repeated-dose oral exposure studies, little or no irritation or sensitisation in multiple tests of dermal and ocular exposure, a lack of reproductive toxicity and the absence of genotoxicity. The authors of this document concluded that the polysorbates assessed in the report are safe in cosmetics when formulated to be non-irritating.

Acute Toxicity

The oral LD50 of polysorbate 81 was reported to be > 20,000 mg/kg in rats. No toxic effects were observed in human subjects when sorbitan monostearate, ethoxylated was orally administered. The acute dermal LD50 of sorbitan monostearate, ethoxylated in rats was > 2000 mg/kg. The inhalation LC50 of sorbitan monostearate, ethoxylated was 5.1 mg/L air after administration to rats for 4 hours (CIR, 2015).

Skin Irritation

In a 30-day study of polysorbate 60 in rabbits, moderate irritation and skin necrosis were observed at 5% and 10% concentration, respectively. Similar observations were observed in a separate study with sorbitan monostearate, ethoxylated. However, administration of sorbitan monostearate, ethoxylated at 100% concentration for 60 days was found not to cause irritation in rabbits. Mild dermal irritation was noted when polysorbate 60 was administered undiluted for 60 days but was not an irritant at 15% concentration. When

undiluted polysorbate 60 was applied to mice over a long-term period (time not specified), local inflammation occurred (CIR, 2015).
In human irritation studies, polysorbate 60 (at 100%), polysorbate 80 (at 100%) and sorbitan monostearate, ethoxylated (at 25%) were not dermally irritating (CIR, 2015).

Eye Irritation
In studies conducted in rabbits, polysorbate 20 (at 10%), polysorbate 81 (at up to 100%) and sorbitan monolaurate, ethoxylated (at 100%) were not eye irritants (CIR, 2015).

Skin sensitisation
Polysorbate 81 at up to 4% concentration was not sensitizing in guinea pigs. Polysorbate 81 at 100% concentration was also not sensitising in human patch tests (CIR, 2015).

In a local lymph node assay of sorbitan monolaurates, ethoxylated (at 25%, 50% and 100% concentration) the stimulation indexes (SI) were calculated to be 1.9, 6.0 and 5.0, respectively. As such, the test substance was considered sensitizing in this study; however, a dose response relationship was not observed (CIR, 2015).

Repeat Dose Toxicity
There were no adverse effects or mortalities related to oral administration of polysorbate 80 in rats at up to 0.15 g/kg for 5 days or in rats at up to 3,700 mg/kg/day for 28 days. No adverse effects were observed in mice orally administered polysorbate 80 at up to 6,400 mg/kg/day, or polysorbate 20, polysorbate 40, or polysorbate 60 at 1,600 mg/kg/day for 28 days (CIR, 2015).

Genotoxicity
Polysorbate 80 was not genotoxic to S. *typhimurium*, and E. *coli* at up to 10,000 µg/plate and 5,000 µg/plate, respectively. Sorbitan monolaurate, ethoxylated was not mutagenic in S. *typhimurium* at up to 5,000 µg/plate. In a chromosomal aberration assay using human lymphocytes, sorbitan monolaurate, ethoxylated was not genotoxic at up to 100 µg/mL. In two mammalian cell gene mutation assays using mouse lymphoma L5178Y cells, sorbitan monolaurate, ethoxylated was not found to be genotoxic at up to 275 µg/mL without metabolic activation and at up to 300 µg/mL with metabolic activation. Sorbitan monooleate, ethoxylated was not genotoxic in a chromosome aberration assay using CHO cells (CIR, 2015).

Reproductive and Developmental Toxicity
The teratogenic and reproductive No Observed Adverse Effect Level (NOAEL) of polysorbate 60 was reported to be 7,693 mg/kg/day (highest study dose) when administered in the diet to pregnant rats on gestation days 7-14. When polysorbate 80 was administered by oral gavage to rats on gestation days 6-15, the maternal and the developmental NOAELs were reported to be > 5,000 mg/kg/day (highest study dose) (CIR, 2015).

Health hazard classification
Based on the available information, the notified polymer cannot be classified 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 available information the notified polymer is expected to be of low hazard but may present as a skin irritant.

Reformulation
During reformulation, workers may be at risk of skin irritation effects when handling the notified polymer neat as introduced. It is anticipated by the notifier that engineering controls such as enclosed and automated processes and local ventilation will be implemented where possible and appropriate PPE (coveralls, imperious gloves, eye protection and respiratory protection) will be used to limit worker exposure.

End-Use
Workers involved in professions which involve the application of cosmetic products containing the notified polymer to clients (*e.g.* beauty salon workers) may be exposed to the notified polymer at ≤ 20% concentration. Dermal, and to a lesser extent, ocular and inhalation exposure may occur. PPE may be employed by workers 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 for consumers using the various products containing the notified polymer.
Overall, under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

6.3.2. Public Health

Members of the public will experience widespread and frequent exposure to the notified polymer at ≤ 20% concentration through daily use of cosmetic products. The main route of exposure is expected to be dermal, while ocular and inhalation exposure are also possible, particularly if products are applied by spray.

Based on the toxicological information provided, the notified polymer is expected to be of low hazard but may present as a skin irritant. However, there is uncertainty on the magnitude of potential skin irritation effects, since full skin irritation studies were not provided by the notifier. This risk assessment recommends that formulators of cosmetic products containing the notified polymer take into account the potential for the notified polymer to cause skin irritation when formulating cosmetic products.

Therefore, provided the skin irritation potential of the notified polymer is considered when formulating cosmetic products containing the notified polymer, the risk to the public associated with use of the notified polymer at ≤ 20% concentration in cosmetic products 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 polymer will be imported neat into Australia for reformulation into finished cosmetic products. There is unlikely to be any significant release to the environment from transport and storage, except in the case of accidental spills and leaks. In the event of spills, the notified polymer is expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations.

The reformulation process will involve transfer of the notified polymer into blending vessels, followed by blending operations that will be highly automated and expected to occur within a fully enclosed environment.
Therefore, significant release of the notified polymer from this process to the environment is not expected (< 1% of the import volume). The reformulation process will be followed by automated filling of the reformulated products into end-use containers of various sizes. Wastes containing the notified polymer that were generated during reformulation include equipment wash water, residues in import containers and spilt materials. These, along with empty import containers, are expected to be collected for disposal by licensed waste management services, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The notified polymer is expected to be released to the aquatic compartment through sewers during its use in various cosmetic products.

RELEASE OF CHEMICAL FROM DISPOSAL

A small proportion (approximately 3%) of the notified polymer may remain in end-use containers once the cosmetic products are used up. Wastes and residue of the notified polymer 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.

7.1.2. Environmental Fate

Following its use in cosmetic products in Australia, the majority of the notified polymer is expected to enter the sewer system, before potential release to surface waters nationwide. Based on its surfactant properties, release to surface waters is unlikely to occur as partitioning to sludge and sediment is expected under environmental pH. The notified polymer is not expected to bioaccumulate, due to its surfactant properties, and is expected to be biodegradable. Therefore, in surface waters the notified polymer is expected to disperse and degrade through biotic and abiotic processes to form water and oxides of carbon.

A small proportion of the notified polymer may be applied to land when effluent is used for irrigation, or when sewage sludge is used for soil remediation. The notified polymer may also be applied to land when disposed of to landfill as collected spills and empty container residue. Residues of the notified polymer in landfill, soil and sludge are expected to eventually degrade through biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

Based on the reported use in cosmetic products, it is assumed that 100% of the total import volume of the notified polymer will be released to the sewer. The release is assumed to be nationwide over 365 days per year. It is conservatively assumed that none of the notified polymer will be removed during sewage treatment plant (STP) processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	6,000	kg/year
Proportion expected to be released to sewer	100	%
Annual quantity of chemical released to sewer	6,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	16.4	kg/day
Water use	200.0	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:	3.36	µg/L
PEC - Ocean:	0.34	µg/L

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 polymer 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 3.36 µg/L may potentially result in a soil concentration of approximately 0.022 mg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 0.11 mg/kg and 0.22 mg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted.

7.2.1. Predicted No-Effect Concentration

A PNEC cannot be calculated as no ecotoxicity data were submitted.

7.3. Environmental Risk Assessment

A risk quotient cannot be calculated as the ecotoxicity data required to determine the PNEC are not available. Based on its surface active properties the notified polymer is expected to partition to sludge during waste treatment process. The notified polymer is expected to be biodegradable, and is expected to have a low potential for bioaccumulation. On the basis of the reported use pattern and import volume, the notified polymer is not considered to pose an unreasonable risk to the aquatic environment.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Skin sensitisation – human volunteers

TEST SUBSTANCE	Cosmetic product containing the notified polymer at 10.8% concentration
METHOD	Repeated insult patch test with challenge
Study Design	Induction Procedure: Patches containing the test substance (volume not provided) were applied for a total of 10 applications. Patches were removed after 48 hours and graded immediately after patch removal and 1-2 hours later before the next patch was applied. Rest Period: 2 weeks Challenge Procedure: Two challenges were conducted. The second challenge was conducted one week after the first. Patches were removed after 48 hours and graded immediately after patch removal and 1-2 hours after patch removal.
Study Group	600 subjects
Remarks - Method	Occluded. The test substance was spread on a ½ inch × ½ inch patch.
RESULTS	
Remarks - Results	600/600 subjects completed the study. No visible skin reaction was observed on any of the subjects during the induction or challenge phases.
CONCLUSION	The test substance was non-sensitising under the conditions of the test.
TEST FACILITY	Confidential

A.2. Skin sensitisation – human volunteers

TEST SUBSTANCE	Cosmetic product containing the notified polymer at 0.1% concentration
METHOD	Repeated insult patch test with challenge
Study Design	Induction Procedure: Patches containing 0.2 mL test substance were applied 3 times per week (Monday, Wednesday and Friday) for a total of 9 applications. Patches were removed by the applicants after 24 hours and graded after an additional 24 hours (or 48 hours for patches applied on Friday). Rest Period: 10-15 days Challenge Procedure: Patches were applied to previously untreated test sites. Patches were removed after 24 hours and sites were graded 24 and 48 hours after patch removal.
Study Group	100 F, 15 M; age range 19-70 years
Remarks - Method	Occluded. The test substance was applied to a 2cm × 2cm patch.
RESULTS	
Remarks - Results	103/115 subjects completed the study. The remaining subjects discontinued their participation for reasons unrelated to the application of the test material. No visible skin reaction was observed on any of the subjects during the induction or challenge phases.
CONCLUSION	The test substance was non-sensitising under the conditions of the test.
TEST FACILITY	Confidential

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