File No: LTD/1763

August 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Poly(oxy-1,2-ethanediyl), α-isohexadecyl-ω-hydroxy- (INCI Name: Isoceteth-20)

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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also 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

TABLE OF CONTENTS

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/1763	L'Oreal Australia Pty Ltd	Poly(oxy-1,2-ethanediyl), α-isohexadecyl-ω-hydroxy- (INCI Name: Isoceteth-20)	Yes	< 5 tonnes per annum	A component of cosmetic products

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the table below.

Hazard classification	*Hazard statement*
Eye irritation (Category 2B)	H320 - Causes eye irritation

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrases:

- R36: Irritating to eyes

Human health risk assessment
Provided that the recommended controls are being adhered to, 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 PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified polymer should be classified as follows:
  - Eye irritation (Category 2B): H320 - Causes eye irritation

- The above should be used for products/mixtures containing the notified polymer, if applicable, based on the concentration of the notified polymer present and the intended use/exposure scenario.

(Material) Safety Data Sheet
- The MSDS provided by the notifier should be amended to include relevant hazard classification and personal protection information.

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 polymer:
  - Enclosed and automated system
  - Adequate general ventilation and local exhaust ventilation if necessary

- 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:
  - Avoid contact with eyes
  - Avoid formation of dusts/aerosols

- 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:
  - Gloves
  - Goggles
  - Face shields
  - Coveralls
  - Respiratory protection if dust/aerosol formations are expected

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

- A copy of the (M)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 for the 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

- Product formulators should exercise due care when using the notified polymer in cosmetic products given its potential ability to enhance the dermal penetration of other chemicals in the formulation.

- Formulators should take into account the potential for the notified polymer to cause eye irritation when manufacturing cosmetic products containing the notified polymer.

Disposal

- Where reuse or recycling are unavailable or impracticable, dispose of the 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 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 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 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 Da;
- the concentration of the notified polymer is intended to exceed 25% in hair styling products, 12% in rinse off cosmetics, 10% in aerosol sprays, 6% in deodorants (non-spray), 5% in hair dyes and make-up products, and 2% in other leave on cosmetics.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a component of cosmetic products, 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.

(Material) Safety Data Sheet
The (M)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 (M)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 Rd
MELBOURNE VIC 3004

NOTIFICATION CATEGORY
Limited (Reduced fee notification): Synthetic polymer with Mn ≥ 1,000 Da – NICNAS previously assessed similar chemical

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: degree of purity, polymer constituents, impurities, 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: all physico-chemical properties except water solubility.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2013), China (2010), Korea (2013) and New Zealand (2012)

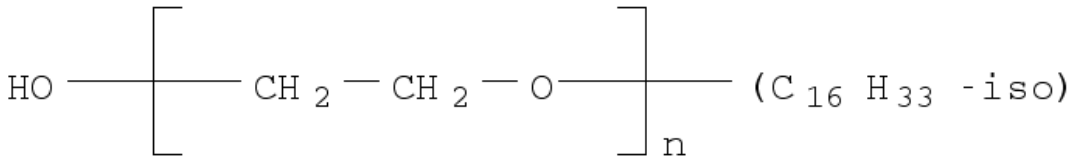
2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Isoceteth-20
Tego Alkanol IC 20 J
Tego Alkanol IC 20
Ceteth

CHEMICAL NAME
Poly(oxy-1,2-ethanediyl), α-isohexadecyl-ω-hydroxy-

CAS NUMBER
69364-63-2

STRUCTURAL FORMULA



Where n = 20

MOLECULAR FORMULA
$(C_2H_4O)_nC_{16}H_{34}O$ (where n = 20)

MOLECULAR WEIGHT
> 1,000 Da

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: white soft waxy solid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	> 40 °C	Analogue data (for ethoxylates)
Boiling Point	1,037 °C at 101.3 kPa	Calculated by QSAR
Density	1,020 kg/m^3 at 45 °C	Analogue data (for ceteth-20)
Vapour Pressure	1.34 × 10^{-32} kPa at 25 °C	Calculated by QSAR
Water Solubility	524 – 1,048 g/L at 20 °C (water solubility) Extractability 0.95 g/L at 19.7 °C (1 g/L loading rate) 9.26 g/L at 19.7 °C (10 g/L loading rate)	Measured. The notified polymer is expected to be water dispersible based on its amphiphilic structure and use as an emulsifier.
Hydrolysis as a Function of pH	Not determined	The notified polymer is not expected to be hydrolysed over the environmental pH range (4–9) based on the absence of readily hydrolysable functional groups
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is an emulsifier and will tend to accumulate at the phase interface of octanol and water and/or form emulsions.
Adsorption/Desorption	Not determined	The notified polymer is expected to partition to surfaces from water in the environment based on its surface activity.
Dissociation Constant	Not determined	The notified polymer does not contain dissociable functionalities
Particle Size	Not Determined	The notified polymer is a waxy solid.
Flash Point	> 110 °C	SDS
Flammability	Not Determined	
Explosive Properties	Not Determined	Not expected to be explosive based on structure
Oxidising Properties	Not Determined	Not expected to be an oxidiser based on structure

DISCUSSION OF PROPERTIES
For full details of water solubility test on the notified polymer, which has not been assessed previously, refer to Appendix A.

Reactivity
The notified polymer is stable under normal conditions of use and compatible with other cosmetic substances under normal usage conditions. The notified polymer is surface active and used as an emulsifier and solubiliser.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System for the 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 within Australia. The notified polymer will be imported into Australia either in neat form (100%) for reformulation or in finished cosmetic products at up to 25% concentration.

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

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

PORT OF ENTRY
Melbourne and Sydney

IDENTITY OF RECIPIENTS
L'Oreal Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer or products containing the notified polymer at concentrations up to 25% will be imported into Australia by sea in containers. The products are packed in dozens inside a shipper, with multiple shippers per pallet and multiple pallets per containers. The European standard pallet size is usually 1200 × 800 × 160 mm. The containers will be transported from the wharf to distribution centres then to retailer warehouses.

USE
The notified polymer will be used as an emulsifier or as a solubiliser in cosmetic products at up to 25% concentration. The product types in which the polymer will be used include leave on and rinse off cosmetics, make-ups and spray products.

OPERATION DESCRIPTION
The notified polymer will not be manufactured in Australia. It will be imported into Australia in neat form (100%) for reformulation or in finished cosmetic products.

Dockside and warehouse workers will transport the raw and finished products from the wharf to the central distribution centres and place the pallets of products into the warehouse. Warehouse workers will be involved in transferring pallets in the central warehouse and operating picking operations for stock to distributors at the retailer's central distribution depots.

Reformulation of the notified polymer into finished cosmetic products will also occur in Australia. During the formulation process, quantities of the notified polymer and finished products containing it will be sampled and tested by a chemist for QA purposes. Production compounders will weigh an appropriate amount of the notified polymer into a separate container then add the amount directly into a flame proof mixing tank. Mixing and dispensing will be carried out in an enclosed system with flame proof mixers and pumps designed not to create aerosols or dust hazard. The systems are earthed to prevent the processes from static discharges. The end use containers for finished products will be available as bottles or tubes and will be made mainly from plastics/HDPE with size up to 500 mL.

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 and Capping)	8	12
Store persons	4	12
Professional end users	8	365

EXPOSURE DETAILS

Transport and storage

Dockside and warehouse workers are not expected to come into contact with the notified polymer, which is contained in sealed packages, except in the case of spills.

Reformulation

During the formulation process, the chemists may come into skin or eye contact with the neat form of the notified polymer during sampling and testing for QA purposes. Workers involved in mixing and dispensing (compounders) may experience dermal, ocular and inhalation exposure to the neat form of the notified polymer from drips, spills, splashes, dusts, aerosols and vapour when weighing the material and adding to mixing tanks. The notifier stated that workers are expected to use personal protective equipment (PPE) including safety glasses with shields, gloves, apron or coverall during formulation process. Adequate ventilation and appropriate local exhaust hoods will be also used in the workplace.

End-use

Exposure to the notified polymer in end-use products (at ≤ 25% concentration) may occur in professions where the services provided involve the application of cosmetic and personal care products to clients (e.g. hair dressers, workers in beauty salons). The principal route of exposure will be dermal, while ocular and inhalation 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 less 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 up to 25% concentration) through the use of a wide range of cosmetic products. The principal route of exposure will be dermal, while oral, ocular and inhalation exposures are also possible, if products are applied by spray or are applied to the lips.

A combined internal dose of 1.206 mg/kg bw/day was estimated using data on typical use patterns for cosmetic product categories in which the notified polymer will be used (SCCS, 2012; Cadby *et al.*, 2002; ACI, 2010; Loretz *et al.,* 2006; specific use details of the notified polymer are considered as exempt information). This estimation assumed a worst case scenario and is for a person who is a simultaneous user of a selection of cosmetic products that may contain the notified polymer.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer and the analogue chemicals are summarised in the following table. The information has been previously assessed by NICNAS.

Endpoint	*Result and Assessment Conclusion*	*Source*
Rat, acute oral toxicity	LD50 = 9,700 mg/kg bw; low toxicity	Notified polymer
Rat, acute dermal toxicity	LD50 > 800 mg/kg bw	Analogue data ($C_{15\text{-}16}$EO10)#
	LD50 > 2,000 mg/kg bw; low toxicity	Analogue data (Laureth-9) **
Rat, acute inhalation toxicity	LC50 1.5 to 20.7 mg/L (1 or 4 hour exposure)	Analogue data (Alcohol Ethoxylates) **
Rabbit, skin irritation	Mild to moderately irritating	Notified polymer*
Rabbit, eye irritation	Moderately irritating	Notified polymer (50 & 100% concentration).*
Human skin patch tests	No evidence of irritation or sensitisation	Notified polymer*
Human skin sensitisation	No evidence of sensitisation	Analogue data (Steareths, $C_{12\text{-}15}$EO3 &C_{18}EO21)#

Rat, repeat dose (oral gavage) toxicity – 90 days.	NOAEL – 100 mg/kg bw/day	Analogue data (C_{16-18} EO10)#
Mutagenicity – bacterial reverse mutation	non mutagenic	Analogue data (Ceteth-20)#
Genotoxicity – *in vitro* chromosomal damage in Chinese hamster bone marrow cells	non genotoxic	Analogue data (C_{12-13} EO6.5 & C_{14-15}EO7)#

*Full studies were not available.
** HERA, 2009
# CIR, 1999

Use of analogue data in human health effects assessment
Only limited toxicological data were provided for the notified polymer. Therefore, analogue data were used for human health effects assessment. As all toxicology information was not available for the closest analogue (C_{16} branched chain), a range of analogues were chosen for human health effects assessment, such as Ceteths (linear C_{16}), Ceteareths (C_{16}-C_{18}), Steareths (C_{18}) and Laureths (C_{12}) and others:

Chemical	CAS Number	Structure	Analogue Alkyl chain carbon number
Ceteths	9004-95-9	HO—[—CH_2—CH_2—O—]$_n$— $(CH_2)_{15}$-CH_3	C_{16}
Ceteareths	68439-49-6	HO—[—CH_2—CH_2—O—]$_n$— $(CH_2)_{15-17}$-CH_3	C_{16-18}
C_{15-16}	Not available	HO—[—CH_2—CH_2—O—]$_n$— $(CH_2)_{14-15}$-CH_3	C_{15-16}
C_{14-15}EO7	Not available	HO—[—CH_2—CH_2—O—]$_n$— $(CH_2)_{13-14}$-CH_3	C_{14-15}
Steareths	9005-00-9	HO—[—CH_2—CH_2—O—]$_n$— $(CH_2)_{17}$-CH_3	C_{18}
C_{18}EO21	9005-00-9	HO—[—CH_2—CH_2—O—]$_{21}$— $(CH_2)_{17}$-CH_3	C_{18}
C_{12-15}	68131-39-5	HO—[—CH_2—CH_2—O—]$_n$— $(CH_2)_{11-14}$-CH_3	C_{12-15}
Laureths	9002-92-0	HO—[—CH_2—CH_2—O—]$_n$— $(CH_2)_{11}$-CH_3	C_{12}

EO: Ethylene Oxide

The notified polymer (with an alkyl chain of C_{16} – iso) and its analogues are Alcohol Ethoxylates (AEs) and also called polyethylene glycol ethers (PEGs). These are manufactured by the ethoxylation of the corresponding alcohol with a number of moles of ethylene oxide (EO) to the average polyethylene glycol chain length desired.

The PEGs in the table above are close analogues to the notified polymer. Ceteths are the closest analogue to the isoceteths (notified polymer), as both have same chain carbon number of $C_{16.}$ The difference is that C_{16} for ceteths are linear while those for isoceteths are branched. The closest analogues after the Ceteths are provided in the above table according to their order of similarity to the notified polymer.

Toxicokinetics, metabolism and distribution
Data is not available on toxicokinetic properties of the notified polymer. The notified polymer has an average molecular weight > 1,000 Da and a very low vapour pressure (1.34×10^{-32} kPa). These indicate a low absorption following ingestion, dermal exposure or inhalation.

Cosmetic Ingredient Review (CIR, 1999) states that, in both oral and intravenous studies, no metabolism was observed and the PEGs were rapidly eliminated unchanged in the urine and faeces. In a study with human burn patients, Andersen (1993) showed that PEGs appear to be readily absorbed mainly through damaged skin.

^{14}C-labelled C_{12-15}EO6 and C_{12-15}EO7 were applied orally and dermally to rats to evaluate the intake (absorption) and excretion in rats. The label was either in the hydroxyl-bearing carbon or the carbon of the alkyl group. The orally dosed material was absorbed quickly and extensively (> 75% of the dose). The percutaneous doses were absorbed slowly and incompletely (about 50% in 72 hours). In most of the experiments about half of the ^{14}C that was absorbed by either route was excreted promptly in the urine; smaller amounts appeared in the faeces and expired air. Much of the ^{14}C in the faeces probably resulted from biliary excretion. The greatest amount of radioactivity was found in faeces, urine and expired air, whereas very little radioactivity remained in tissues. The alkyl chain length appears to have an impact on the fate of the chemicals. AEs with longer alkyl chains are excreted at a higher proportion into expired air and less in urine (HERA, 2009).

The Human & Environmental Risk Assessment report (HERA, 2009) also showed studies in rats that the factor influencing the adsorption, distribution and excretion of the AEs was the length of the ethoxy chain and not the

degree of branching. The data showed that more AEs were excreted via the faeces and expired in air as the ethoxy chain length increased, suggesting that the length of the ethoxy chain may determine how the AEs are distributed.

The same trends were observed when AEs were administered dermally, with the only difference being that adsorption was slower and less of the total administered compound was absorbed.

Dermal absorption
No dermal absorption study is available for the notified polymer.

However, the skin penetration of a range of AEs which were applied in 1% solutions was evaluated after a series of washing and rinsing procedures (HERA 2009). Considerable proportions of the administered dose penetrated the skin. Shorter chained ethoxylates were absorbed more readily than longer ones.

For risk assessment purposes, when dermal absorption data are not available for the notified polymer, under the Scientific Committee on Consumer Products' (SCCP's) Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation (SCCP, 2006), a dermal absorption value of 100% is recommended as a worst case scenario. However, AE analogues have shown approximately 50% dermal absorption based on the HERA report (HERA, 2009).

In a later CIR report provided by the notifier ("Tentative Amended Report" Alkyl PEG Ethers as Used in Cosmetics, 10 September 2010), some specific information on dermal absorption of analogues was noted. A percutaneous absorption trend data for 4 hour measurements on series of Laureths in hairless mice, showed a decrease of dermal absorptions from 22.9 % to 2.1% with the increase of ethylene oxide units in Laureths from 1 to 10. The report includes a number of other animal and human dermal absorption studies. A study in rats with C_{12-15} PEG ethers containing 6 to 7 ethylene oxide units showed approximately 50% absorption by 72 hours. Human absorption data on Laureth-9 showed 5.3 – 17.6% absorption up to 24 hours. The report states that the short chain ethoxylates were absorbed more readily than the long chain ethoxylates.

As Isoceteth-20 (the notified polymer) has longer chain length than Laureths, a 10% dermal absorption was conservatively assumed for quantitative risk assessment purposes.

Acute toxicity
The notified polymer has low acute oral toxicity, with LD50 value of 9,700 mg/kg bw (7,800 – 12,000 mg/kg bw in male and female rats).

As no acute dermal or inhalation toxicity studies were provided for the notified polymer, analogue data were used for these endpoints.

Endpoints	Analogues		
	Alcohol Ethoxylates	**Laureths (**Laureth -9)	**Alcohol Ethoxylate (C_{15-16})**
Acute dermal (Rats)	-	**LD50 > 2,000 mg/kg bw**; **low toxicity**	The acute LD50 value of a 10% w/v solution in water as a single dose was **greater than 800 mg/kg bw in rats.** There were no deaths or signs of toxicity observed at this low concentration.
Acute inhalation	LC50 values ranged from 1.5 to 20.7 mg/L.	-	-

Reference: HERA, 2009

AEs were shown to have a low order of acute dermal toxicity in rat and rabbit (LD50 > 800 in rat or > 2,000 mg/kg bw in rabbits). There was no relationship between compound structure and dermal toxicity. Therefore, based on the analogue data, the notified polymer is likely to have low dermal toxicity.

Based on the HERA report (HERA, 2009), a few studies evaluated the inhalation toxicity of AEs in rats. None of these studies followed the principles of OECD guideline nor were they GLP compliant. In one study, rats of each sex were exposed for 4 hours to C_{9-11}AE5 generated as a mist. The acute LC50 was determined to be greater than 0.22 mg/L/4 hour. There were no mortalities or signs of toxicity observed during the study. LC50 values for AEs ranged from 1.5 to 20.7 mg/L were also reported in the HERA report. Some studies reported no mortalities (1-

hour LC50-study) occurred at concentrations as high as 52 mg/L. Treatment-related effects were observed in acutely exposed animals including laboured breathing, inactivity and bloody nasal discharge. Gross necropsies revealed corneal opacities, congestion and mottling of the lungs, and in some cases, paleness or congestion of the liver, kidneys, and adrenals. Necropsy findings in surviving animals were typical of healthy animals. No details on methodology and time point of observations were provided. The HERA report concludes that AEs are considered to be of low acute inhalation toxicity to rats with LC50 values exceeding the saturated vapour concentration in air. Acute toxic thresholds were reached only when animals were exposed to the undiluted test chemical in form of a respirable mist or aerosol.

Irritation and sensitisation

Skin irritation
Brief summary of a skin irritation study (April 1970) with 100% notified polymer, evaluated according to a Draize classification, was provided. According to this summary, the notified polymer is a mild to moderate skin irritant to the rabbit. The full study was not provided.

Brief summary of a report on a skin irritation study conducted on 204 people in a closed patch test with 100% notified polymer was provided (dated 6 April 1977). A patch was applied for 72 hours over an unstated amount of notified polymer and then the skin was observed daily for 10 days. At 10-14 days, a second application was made. According to the brief summary provided, the notified polymer is unlikely to cause skin irritation or skin sensitisation in humans. The full study was not provided.

In a 90-day repeat dose dermal toxicity study of $C_{9\text{-}11}$EO6, dry and flaky skin was noted at the 10% and 25% concentrations (HERA 2009).

Neat applications of a range AEs in a 4 h human patch test did not warrant these chemicals to be classified as skin irritants (HERA 2009).

Based on the available information, there is insufficient evidence to warrant classification of the notified polymer as a skin irritant.

Eye Irritation
Brief summary of an eye irritation study (April 1970) with 100% notified polymer, evaluated according to the method of Kay & Calandra, was provided. According to this study, the notified polymer is a moderate irritant to the rabbit eye. The full study was not provided.

Brief summary of an eye irritation study (April 1977) with 50% notified polymer in water, evaluated according to the method of Kay & Calandra, was also provided. According to this study, the notified polymer is a moderate irritant to the rabbit eye. The full study was not provided.

Based on the available information, the notified polymer is expected to be a moderate eye irritant at 50% and 100% concentrations; however, the severity of the irritation effects cannot be established from the brief summaries provided.

Skin Sensitisation
Brief summary of a report on a skin irritation study conducted on 204 people in a closed patch test with 100% notified polymer was provided (dated 6 April 1977). The report concluded that the notified polymer was unlikely to cause skin irritation or skin sensitisation in humans. The full study was not provided.

Analogue data on Steareths and other AEs are available.

Endpoint	Analogues		
	Steareths	**$C_{12\text{-}15}$EO3**	**C_{18}EO21**
Skin sensitisation	Steareth-20 at up to 60% in water and in cosmetic formulations was neither an irritant nor a sensitizer and was not phototoxic to human skin. Steareths-20 at 60% in water SIPT test with 200 subjects did not cause skin	2% of the test substance did not cause skin sensitization in guinea pigs in Magnusson-Kligman test (HERA 2009).	10% w/v emulsion of the test sample in de-ionized water did not elicit any sensitization response in guinea pigs in Magnusson-Kligman test (HERA

	irritation, not a primary irritant or a skin sensitiser. At 1.5% in moisture lotion (RIPT) test with 189 subjects was not an allergic contact sensitiser (CIR 1999).	2009)

The notified polymer is unlikely to be a skin irritant or sensitizer, based on the above data.

Repeated dose toxicity
No repeat dose toxicity data for the notified polymer was provided.

A 90 day repeat dose dermal toxicity study of C_{9-11}EO6, 10 rats per sex per group were treated with 1%, 10% and 25% of the test substance. Treated animals showed no significant treatment related effects. However, dry and flaky skin was noted at the 10% and 25% concentrations. Relative kidney weights were increased in both sexes at 25% treatment level, but there were no histological lesions. The NOAEL was determined to be 10% concentration, which reflects a dose of approximately 80 mg/kg bw/day (HERA, 2009). HERA report states that shorter chain AEs are absorbed via the dermal route more readily than long chain AEs and therefore 80 mg/kg bw/day dermal NOAEL for C_{16} branched AEs may be a conservative value.

A substantial number of AEs of different structures with regard to the length of the alkyl chain and the degree of ethoxylation were evaluated in oral and dermal repeated dose toxicity studies (HERA 2009). The NOAEL of AEs for systemic toxicity was established to be 50 mg/kg bw/day on the basis of a scientifically sound and well conducted 2-year oral feeding study in rats with C_{12-13}EO6.5. Effects observed at the lowest observed adverse effect level (LOAEL) which was established as 0.75% of dietary intake were related to significantly elevated organ-to-body weight ratios for liver, kidney and heart. No adverse histopathological changes were observed at the LOAEL. Therefore, the established NOAEL is consistent with the outcome of the majority of existing chronic and subchronic studies determined for further AEs most commonly used in consumer products. Only one 90-day study revealed some minor effects at a dose level of 50 mg/kg bw/day. The study investigators did not consider these effects to be of toxicological significance and also suggested a NOAEL of 50 mg/kg bw/day. However, for assessing the risk associated with human exposure to AEs in context of its use in laundry and cleaning products, a NOAEL of 37.5 mg/kg bw/day has been considered, adjusting for the GI tract absorption (HERA 2009).

Studies which established oral NOAELs for AEs are listed below:

Test Material	**C_{14-15}EO7**	**C_{12-15}EO7**	**C_{16-18}EO10**
Study summary	90 days oral feeding at dosage level of 0, 300, 1,000, 3,000, 10,000 ppm. No adverse effects were reported at 1,000 ppm (equivalent to ca. 50 mg/kg bw/day). Increased relative liver weight in both sexes at 3,000 and 10,000 ppm and haematology effects in both sexes at 10,000 ppm and in males at 3,000 ppm.	90 days oral feeding at dosage level of 0, 0.03, 0.063, **0.125**, 0.25, 0.5, 1.0%. The NOAELs were established on the basis of hepatic histology at the 0.125% level, corresponding to a daily intake of 102 mg/kg bw/day.	90 days oral gavage feeding at dosage level of 0, 20, 100, 500 mg/kg bw/day in an application volume of 10 mL/kg bw. According to the findings, the limit of systemic compatibility was 100 mg/kg bw/day for male rats. On the basis of the observations made in this study (delayed growth of the males and damage to forestomach and kidneys in both male and female rats) a NOAEL of 100 mg/kg bw/day can be established.
Estimated NOAEL	50 mg/kg bw/day	102 mg/kg bw/day	100 mg/kg bw/day

Reference: HERA 2009

The notified polymer is a C_{16} alkyl alcohol ethoxylate. Considering the dermal and oral NOAELs available for AEs and similarity of these analogues to the notified polymer, a NOAEL of 100 mg/kg bw/day established in the 90 days oral study for C_{16-18}EO10 was considered appropriate to be used in the risk assessment.

Mutagenicity/Genotoxicity
A mutagenicity study for the notified polymer is not provided.

Various mutagenicity assays on PEGs and cetyl alcohol were negative. However, Cosmetic Ingredient Report for analogue Ceteths (CIR, 1999) states that Ceteth-20 was found in a spot test to enhance transposition of Tn9 in *Escherichia coli*. Phage λ::Tn9-infected cells were plated on chloramphenicol media and one to two drops of ceteth-20 (0.1%) were placed on the plate. Chloramphenicol-resistant colonies were attributed to the transposition of Tn9 to the bacterial chromosome. This effect was not observed when palmitic acid was also added suggesting that lipid or membrane was involved in the transposition process.

Based on the above information, the notified polymer is unlikely to induce reverse gene mutations in *Salmonella typhimurium* but could enhance transposition of Tn9 in *Escherichia coli* test systems.

Health hazard classification
Based on the available information and previous assessment, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	***Hazard statement***
Eye irritation (Category 2B)	H320 - Causes eye irritation

Based on the available information and previous assessment, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):

- R36: Irritating to eyes

The notified polymer has been listed in *Hazardous Substances Information System (HSIS), Safe Work Australia* with the above risk phrase (http://hsis.safeworkaustralia.gov.au/).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The main acute risk of the notified polymer is moderate eye irritation. In addition, there is uncertainty if the notified polymer is also a skin irritant.

Dermal and ocular exposure to transport and storage workers could only occur in the event of an accident of breakage or spillage of sealed containers containing the notified polymer at up to 100% concentration.

Dermal, ocular and potentially inhalation exposure of the compounders and chemists to the raw material containing up to 100% concentration of the notified polymer could occur during formulation of cosmetics. As stated by the notifier, the use of PPE such as protective clothing, gloves and safety glasses and engineering controls including automated and enclosed blending processes and local exhaust ventilation will minimise the risk for formulation workers.

Employees in hair and beauty salons may experience dermal, ocular and inhalation exposure during application of products containing the notified polymer (up to 25% concentration) to clients. The exposure of these employees is expected to be similar or less to that of consumers if PPE is used. Good hygiene practices in place would further minimise the exposure. Therefore, the risk of irritation effects is not anticipated to be unreasonable.

Overall, provided that the protective measures and engineering controls proposed are implemented, the use of the notified polymer is not expected to pose an unreasonable risk to workers under the occupational conditions described.

6.3.2. Public Health

As stated above, the main acute risk associated with the notified polymer is its potential to cause eye irritation. As the maximum concentration proposed by notifier for use in hair styling products is 25%, which exceeds 20% cut-off concentration for classification, there is a risk for consumers using the products to experience eye irritation. However, there is uncertainty on the magnitude of potential eye irritation effects, since full eye irritation studies were not provided by the notifier. The risk assessment recommends that formulators of cosmetic products containing the notified polymer take into account the potential for the notified polymer to cause eye irritation in the cosmetics manufacturing process. In addition, based on the limited data provided for the notified polymer, the risk of skin irritation cannot be ruled out.

Members of the public may experience repeated exposure to the notified polymer (up to 25% concentration) through the use of a range of cosmetic products.

Based on the available information, acute toxicity effects are not expected from use of the notified polymer. The repeated dose toxicity potential to the notified polymer using the worst case exposure scenario from use of multiple products would result in a combined internal dose of 1.206 mg/kg bw/day (see Section 6.1.2). Using a NOAEL of 100 mg/kg bw/day, which was established in the 90 days oral repeat dose toxicity study for a close analogue (see Section 6.2), the margin of exposure (MoE) was estimated to be 82. In general, a MoE value greater than or equal to 100 is considered acceptable to account for intra- and inter-species differences. However, considering the conservative assumptions employed in the calculations (e.g., dermal absorption, inhalation exposure factors, assumed daily use of a large number of leave on, rinse off and make up products), the MoE is not considered to indicate unreasonable risk.

Therefore, based on the available information, the risk to the public from use of the notified polymer at ≤ 25% in hair styling products, ≤ 12% in rinse off cosmetics, ≤ 10% in aerosol sprays, ≤ 6% in deodorants (non-spray), ≤ 5% in hair dyes and make ups, and ≤ 2% in other leave on 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 manufactured overseas and imported to Australia either in neat form or already blended in finished cosmetic hair and skin products. Release of the notified polymer to the environment is unlikely except in the event of a transport accident or an accidental spill during handling. Accidental spills of formulated products containing the notified polymer are expected to be physically contained and then absorbed into inert material (e.g. sand or vermiculite). The absorbed notified polymer is expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

As the notified polymer is used in cosmetics and personal care products such as shampoos, facial and body cleansers, skin creams etc, it is expected that effectively the entire annual import volume will be released to sewer through consumer use. A small proportion (estimated to be ≤ 3%) may remain as residues within the end-use containers.

RELEASE OF CHEMICAL FROM DISPOSAL

Expired wastes and residue of the notified polymer in the empty containers (≤ 3%) are likely either to share the fate of the container and be disposed of to landfill, or to be washed to sewer when containers are rinsed before recycling.

7.1.2. Environmental Fate

No environmental fate data were supplied. The majority of the notified polymer is expected to be released to the sewerage system. In waste water treatment processes in sewage treatment plants (STPs), a high proportion (≥ 90%) of the notified polymer is expected to be removed from influent based on several fate studies of AEs in STPs (Madsen et al., 2001). Moreover, since the notified polymer is a high molecular weight, non-ionic polymer, 90% removal of the notified polymer to sludge is expected during sewerage treatment plant (STP) processes (Boethling and Nabholz, 1997).

Therefore, the high removal efficiency will be due to a combination of relatively rapid biodegradation and partitioning of the notified polymer to sludge and suspended solids. The notified polymer that partitions to sludge will be removed for disposal to landfill or used on land for soil remediation. In soil, the notified polymer is expected to be degraded by abiotic and biotic processes to form water and oxides of carbon.

In surface waters, the notified polymer will partition to suspended solids and organic matter and is expected to rapidly biodegrade. Based on its surface activity, the notified polymer is not expected to bioaccumulate.

7.1.3. Predicted Environmental Concentration (PEC)

A PEC for discharge of the notified polymer to surface waters has been calculated, under a worst case scenario, assuming that the total import volume of the polymer is discharged to sewers nationwide. It is expected that 90% removal of the notified polymer to sludge during sewerage treatment plant (STP) processes (Boethling and Nabholz, 1997). The details of the calculation are as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	5,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	5,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	13.70	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	90%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.30	µg/L
PEC - Ocean:	0.03	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 27.261 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1,500 kg/m^3 and a soil-mixing zone of 10 cm, the concentration of the notified polymer may approximate 0.182 mg/kg in applied soil. This assumes that degradation of the notified polymer occurs in the soil within 1 year from application. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated biosolids application, the concentration of notified polymer in the applied soil in 5 and 10 years may approximate 0.91 mg/kg and 1.82 mg/kg, respectively. The latter soil concentrations are likely to be a conservative overestimate as AEs are known to be ultimately degraded under aerobic conditions (Madsen et al., 2001).

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 polymer 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 0.303 µg/L may potentially result in a soil concentration of approximately 2.02 µg/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 10.1 µg/kg and 20.2 µg/kg, respectively.

7.2. Environmental Effects Assessment

No experimental ecotoxicity data were submitted. Algae are the aquatic organisms which appear to be most sensitive to AEs with EC50 endpoints ranging from 0.05 to 50 mg/L being reported in the literature (Madsen et al., 2001). The closest analogue chemical to the notified polymer in the structures considered by Madsen et al. is a linear primary AE composed of a C_{15} hydrophobe and 7 to 8 ethoxylate units. (i.e. C_{15}EO7-8). The 72 h EC50 for *Scenedesmus subspicatus* (now known as *Desmodesmus subspicatus*) is 0.05 mg/L (Madsen et al., 2001, p55). Hence this endpoint was used as a lower limit for the calculation of the Predicted No-Effect Concentration below. This is a conservative estimate for the notified polymer since ecotoxicity of AEs is known to decrease with branching in the hydrocarbon chain and increasing ethylene oxide chain length. The higher molecular

weight components of the notified polymer would therefore be expected to have lower aquatic toxicity than this analogue chemical.

The notified polymer is a mixture of homologous compounds. As there are no specific ecotoxicity endpoints for this mixture of compounds, it is not appropriate, in this case, to classify the notified polymer for acute or long-term aquatic hazards under the *Globally Harmonised System of Classification and Labelling of Chemicals* (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) for the notified polymer has been calculated and is presented in the table below. An assessment factor of 100 has been used to derive the PNEC as the notified polymer belongs to a class of compounds that have been thoroughly investigated for ecotoxicity in aquatic species at three trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Alga)	0.05	mg/L
Assessment Factor	100	
PNEC:	0.50	µg/L

7.3. Environmental Risk Assessment

Based on the above PEC and PNEC values, the following Risk Quotient (Q) has been calculated:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.3	0.5	0.61
Q - Ocean	0.03	0.5	0.061

The Risk Quotients (Q = PEC/PNEC) have been calculated to be < 1 for both river and ocean compartments.

The notified polymer is not expected to bioaccumulate and is unlikely to persist in surface waters or soils. Therefore, on the basis of the PEC/PNEC ratio, maximum annual import volume and assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility 524 – 1,048 g/L at 20 °C

Method	OECD TG 105 Water Solubility. EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks	Flask Method. The test substance was mixed with double distilled water at several nominal concentrations. After mixing, the test samples were checked visually for any undissolved material. The pH of the water mixture at a nominal concentration of 103.8 g/L was determined.
Test Facility	WIL (2013)

Solution/Extraction Behaviour 0.95 g/L at 19.7 °C (1 g/L loading rate)
9.26 g/L at 19.7 °C (10 g/L loading rate)

Method	OECD TG 120: Solution/Extraction behaviour of Polymers in Water
Remarks	The solubility/extractivity of the test substance in water at neutral pH at 19.7 ± 0.3 °C was determined by TOC analysis. The solubility/extractivity of the test substance in the aqueous phases is given as the actual concentration observed and as the units of mass per weight of the initial weight sample.
Test Facility	WIL (2013)

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