No: LTD/1910

May 2016

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

2-Propenoic acid, 2-ethyl-2-[[(1-oxo-2-propenyl)oxy]methyl]-1,3-propanediyl ester, polymers with 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid monoammonium salt and polyethylene glycol methacrylate $C_{16\text{-}18}$-alkyl ethers

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.

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/1910	Clariant (Australia) Pty Ltd	2-Propenoic acid, 2-ethyl-2-[[(1-oxo-2-propenyl)oxy]methyl]-1,3-propanediyl ester, polymers with 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid monoammonium salt and polyethylene glycol methacrylate C_{16-18}-alkyl ethers	ND*	< 15 tonnes per annum	Cosmetic ingredient

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer 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, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

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

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, automated processes, where possible
  - Exhaust ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling the notified polymer:
  - Avoid contact with eyes
  - Avoid generating dust

- 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:
  - Safety glasses, coveralls, impervious gloves

- Respirator (where dust may be generated)

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 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 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 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;

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.

(Material) Safety Data Sheet
The (M)SDS of the notified polymer provided by the notifier was 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)
Clariant (Australia) Pty Ltd (ABN: 30 069 435 552)
Level 3, 3 Acacia Place
296-324 Ferntree Gully Road
NOTTING HILL VIC 3168

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1,000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Aristoflex HMS

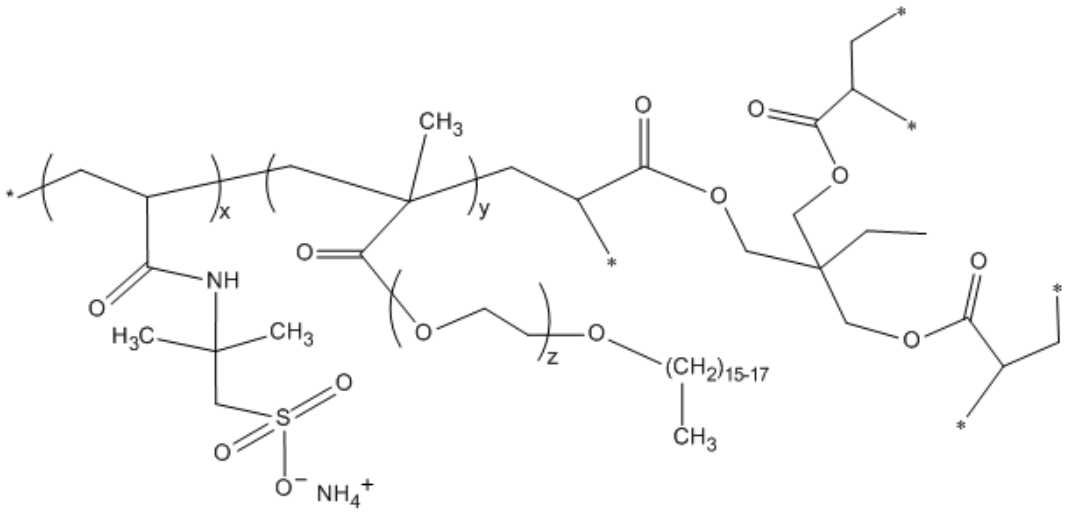
CAS NUMBER
683748-06-3

CHEMICAL NAME
2-Propenoic acid, 2-ethyl-2-[[(1-oxo-2-propenyl)oxy]methyl]-1,3-propanediyl ester, polymers with 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid monoammonium salt and polyethylene glycol methacrylate C_{16-18}-alkyl ethers

OTHER NAME(S)
Hydrophobically modified sulfonic acid copolymer, partially neutralised
Ammonium acryloyldimethyltaurate/Steareth-25 methacrylate cross polymer

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA



MOLECULAR WEIGHT

Number Average Molecular Weight (Mn)	892,000 Da*
Weight Average Molecular Weight (Mw)	12,100,000 Da*
Polydispersity Index (Mw/Mn)	13.6*
% of Low MW Species < 1,000 Da	< 1%*
% of Low MW Species < 500 Da	< 1%*

*Read-across from a similar polymer 2-Propenoic acid, 2-ethyl-2- [[(1-oxo-2-propenyl) oxy] methyl] -1, 3-propanediyl ester, polymers with 2-methyl-2- [(1-oxo-2-propenyl) amino] -1-propanesulfonic acid monoammonium salt and polyethylene glycol methacrylate C_{18-22}-alkyl ethers (CAS No. 683748-12-1; Marketing name: Aristoflex HMB). Molecular weight distribution of Aristoflex HMB was determined using a non-cross-linked polymer synthesised using the same polymerisation technique as that for Aristoflex HMS but without inherent crosslinking and the molecular weights for both polymers are comparable.

ANALYTICAL DATA

Reference ^{1}H-NMR, IR and UV-Vis spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 92%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name	2-Propenoic acid, 2-methyl-		
CAS No.	79-41-4	*Weight %*	< 0.001
Hazardous Properties	Xn; R21/22 C; R35 Conc. ≥ 25%: C; R21/22; R35 10% ≤ Conc. < 25%: C; R35 5% ≤ Conc. < 10%: C; R34 1% ≤ Conc. < 5%: Xi; R36/37/38		
Chemical Name	2-Propanol, 2-methyl-		
CAS No.	75-65-0	*Weight %*	2.1

Hazardous Properties	F; R11 Xn; R20 Xi; R37-41 Conc. ≥ 25%: Xn; R20; R37; R41 20% ≤ Conc. < 25%: Xi; R37; R41 10% ≤ Conc. < 20%: Xi; R41 5% ≤ Conc. < 10%: Xi; R36

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% BY WEIGHT)

Chemical Name	Water		
CAS No.	7732-18-5	*Weight %*	3.1

ADDITIVES/ADJUVANTS

Chemical Name	Ammonia		
CAS No.	7664-41-7	*Weight %*	6.00
Hazardous Properties	R10 T; R23 C; R34 N; R50 Conc. ≥ 5%: T; R23; R34		

Chemical Name	Peroxide, bis(1-oxododecyl)		
CAS No.	105-74-8	*Weight %*	2.00
Hazardous Properties	O; R7		

POLYMER CONSTITUENTS

Chemical Name	*CAS No.*	*Weight % starting*	*Weight % residual*
1-Propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-yl)amino]-	15214-89-8	72.7	0.012
Poly(oxy-1,2-ethanediyl), α-(2-methyl-1-oxo-2-propen-1-yl)-ω-hydroxy-, C_{16-18}-alkyl ethers	70879-51-5	18.3	0.0084
Ammonia	7664-41-7	6	0
Peroxide, bis(1-oxododecyl)*	105-74-8	1.93	0
2-Propenoic acid, 1,1'-[2-ethyl-2-[[(1-oxo-2-propen-1-yl)oxy]methyl]-1,3-propanediyl] ester#	15625-89-5	1	0.008

*It is not included in the chemical name as it is present at < 2%.
#It is not included in the structure as it is present at < 2%; however, it is included in the chemical name.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: white powder

Property	**Value**	**Data Source/Justification**
Melting Point/Freezing Point	> 150 °C	(M)SDS
Boiling Point	> 250 °C	(M)SDS
Density	1,287.5 kg/m^3 at 25.7 °C	Measured
Vapour Pressure	< 1 × 10^{-6} kPa at 20 °C	(M)SDS
Water Solubility	Miscible	Measured; the notified polymer forms strongly viscous solutions in water.
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 and anionic properties

Dissociation Constant	$pKa_1 = 1.09 \pm 0.50$ $pKa_2 = 8.62 \pm 0.48$	Calculated using ACD/I-Lab v12.1.0.50374
Particle Size	Not determined	Low concentration in primarily solid/liquid end use products
Autoignition Temperature	280 °C	(M)SDS
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that imply oxidising properties.

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity
The notified polymer 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 polymer is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

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 the neat form as a powder for formulation of cosmetic products or as a component of finished cosmetic products at 0.3-1.2% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 15	< 15	< 15	< 15	< 15

PORT OF ENTRY
Melbourne and Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Manufacturer: Clariant SE (Germany)
Recipient: Clariant Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be imported either as a powder in a 25 kg fibreboard box within a sealed inner polyethylene bag or as a component of finished cosmetic products in containers suitable for retail sale.

USE
The notified polymer will be used as an ingredient in cosmetic products at 0.3-1.2% concentration.

OPERATION DESCRIPTION
The notified polymer will be imported into Australia either in the neat form for formulation of cosmetic products or as a component of finished cosmetic products at 0.3-1.2% concentration.

Reformulation
When reformulated, the notified polymer will be blended into end-use consumer products at customer sites. Procedures will vary depending on the nature of the cosmetic product being formulated. Both manual and automated steps will likely be involved. For example, a chemist will sample and test the notified polymer for QA purposes manually; a compounder will weigh an appropriate amount of the notified polymer into a container then add the amount directly into a mixing tank, with periodic sampling being carried out during the reformulation process for quality control purposes. Automated processes may include mixing and filling of end-use containers with end use products.

End-use
Finished products containing the notified polymer at 0.3-1.2% concentration will be used by the public and may also be used by professionals such as hairdressers and workers in beauty salons. Depending on the nature of the product, these could be applied by hand or by using 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)*
Stevedores	2-3	10-15
Transport	6	260
Warehousing	6	262
Reformulation process	4	260
Quality assurance	4	260
Maintenance and cleaning	1	260
End users (workers)	8	365

EXPOSURE DETAILS
Transport and storage
Transport and storage workers may come into contact with the notified polymer either in neat form or at various concentrations in cosmetic products (0.3-1.2%), only in the event of an unlikely accidental rupture of containers.

Reformulation
During reformulation into cosmetic products, dermal, ocular and inhalation exposure of workers to the notified polymer at ≤ 100% concentration may occur. Exposure is expected to be minimised through the use of exhaust ventilation and/or automated/enclosed systems as well as through the use of personal protective equipment (PPE) such as coveralls, eye protection, impervious gloves and respiratory protection (as appropriate).

End use
Exposure to the notified polymer in end-use products at 0.3-1.2% concentration may occur in professions where the services provided involve the application of cosmetic products to clients (e.g. hair dressers and workers in beauty salons). The principal route of exposure will be dermal, while ocular exposure is also possible. Inhalation exposure is not expected given the low vapour pressure of the notified polymer. 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
Public exposure to the notified polymer is expected to be widespread and frequent through daily use of cosmetic products containing the notified polymer at 0.3-1.2% concentration. The principal route of exposure will be dermal, while ocular and inhalation exposures (e.g. through the use of spray products) are also possible.

6.2. Human Health Effects Assessment
The results from toxicological investigations conducted on the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – non-adjuvant test	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic

The notified polymer is a dialkyl polyethylene glycol (PEG) ether consisting of hydrophobic cetyl/stearyl (ceteareth) alcohols substituted at the ends of a hydrophilic PEG group. The notified polymer is structurally related to other polyethylene glycols substituted with long chain aliphatic alcohols. Therefore, in addition to studies conducted on the notified polymer, information on other polyethylene glycol compounds (for example, from the safety assessments of cetearyl alcohol PEG ethers (CIR, 1999), and alkyl PEG ethers (CIR, 2012) is briefly discussed below and is considered to support the health hazard conclusions for the notified polymer. The available data are for PEG ethers substituted with one aliphatic alkyl chain.

Toxicokinetics.
No information on the toxicokinetics of the notified polymer was provided.

No percutaneous absorption data is available for the notified polymer. The notified polymer has a molecular weight > 10,000 Da, which suggests a limited dermal absorption potential. The absorption potential is dependent on the length of the alkyl chain and the number of ethoxylate units (of the PEG), where increasing chain length and/or number of units leads to a decrease in dermal absorption (CIR, 2012). Some PEG derivatives have the potential to enhance the dermal penetration of other chemicals after topical application (CIR, 2012). Dermal penetration of the notified polymer is expected to be enhanced where skin is severely damaged (similar to other PEG derivatives) (CIR, 2012).

Acute toxicity.
The notified polymer was found to have low acute toxicity via the oral route in a study conducted in rats.

No acute dermal toxicity data was provided for the notified polymer. Acute dermal toxicity studies performed with alkyl PEG ethers were of low toxicity (no systemic effects or mortalities reported) via this route (CIR 1999, 2012).

No acute inhalation toxicity data was provided for the notified polymer. The CIR safety assessment report indicated that some alkyl PEG ethers (or their fatty alcohol precursors) used in products that may be inhaled (e.g. aerosols) may irritate the respiratory tract (CIR, 2012). However, the report also stated that in the absence of inhalation toxicity data, alkyl PEG ethers can be used safely in aerosol products, because the aerosol particle size consists of a low fraction of respirable particles (CIR, 2012).

Irritation
The notified polymer is non-irritating to skin and slightly irritating to eyes based on studies conducted in rabbits.

Sensitisation.
A Buehler guinea pig maximisation test was conducted for the notified polymer to determine its skin sensitisation potential. Under the conditions of the study, the notified polymer (at 100% induction and challenge concentrations) was found to be a non-sensitiser, with no responses noted in any animals at both the 24 and 48 hour observations after challenge patch removal.

Repeated dose toxicity.
No data was provided on the repeated dose toxicity of the notified polymer.

Repeated dose toxicity studies performed with alkyl PEG ethers generally indicated the absence of toxicologically adverse effects at doses ≤ 100 mg/kg bw/day (CIR 2006, 2012). However, the notified polymer is likely to have some differences in physiological action due to the differences in structure (dialkyl PEG ether compared with alkyl PEG ethers, alkyl chain length, number of ethoxylate units) and dermal penetration potential. There were also a wide range of NOAELs reported for the chemicals in this category. Therefore, there is some uncertainty in the evidence supporting the low toxicity of the notified polymer from repeated exposure.

Mutagenicity/Genotoxicity.
The notified polymer was non-mutagenic in an in vitro bacterial reverse mutation study. No further in vitro or in vivo genotoxicity data were provided for the notified polymer.

Reproductive and developmental toxicity
No data was provided on the reproductive and/or developmental toxicity of the notified polymer.

It is generally recognised that the PEG monomer, ethylene glycol, and certain of its monoalkyl ethers, are reproductive and developmental toxins (CIR, 2012). There is a possibility that PEG-derived cosmetic ingredients

could present similar concerns (CIR, 1999). However, in general, the metabolites of concern are not expected to be formed in cosmetic formulations that contain polymers of ethylene glycol (CIR, 2012). From the data discussed, the safety assessment report also concluded that the toxicity of the monoalkyl ethers is inversely proportional to the length of the alkyl chain (CIR, 1996). Therefore, long alkyl chains, such as those in ceteareth compounds, similar to the notified polymer, were found by the CIR Expert Panel to not be a reproductive or developmental hazard (CIR, 1999).

Health hazard classification
Based on the available information, the notified polymer 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, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Reformulation
During reformulation, dermal, ocular and perhaps inhalation exposure of workers to the notified polymer (≤ 100%) may occur during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment.

Based on information available, the notified polymer is considered to be non-irritating to the skin and slightly irritating to eyes. It is uncertain whether the notified polymer, like some alkyl PEG ethers, may irritate the respiratory tract following inhalation exposure. If the notified polymer is inhaled at low levels and/or infrequently, it is assumed that it will be cleared from the lungs. Therefore, caution should be exercised when handling the notified polymer during reformulation and quality control processes.

The notified polymer will be handled in the powder form during reformulation. Although the notified polymer has a high molecular weight (> 70,000 Da), it has high water solubility. Therefore, lung overloading effects are not expected.

The use of enclosed, automated processes and PPE (e.g. impervious gloves, coveralls, eye protection and respiratory protection) should minimise the potential for exposure. Therefore, provided that adequate control measures are in place to minimise worker exposure, the risk to workers from use of the notified polymer is not considered to be unreasonable.

End-use
Workers involved in professions where the services provided involve the application of cosmetic products containing the notified polymer to clients (e.g., hairdressers and beauty salon workers) may be exposed to the notified polymer (at 0.3-1.2% concentration). The risk to these workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified polymer. Such professionals may use PPE (i.e., gloves and glasses) to minimise repeated exposure, and good general hygiene measures are expected to be in place to minimise the potential for exposure. Based on the information available, the risk to workers associated with use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health
Members of the public will experience widespread and frequent exposure to the notified polymer through daily use of cosmetic products at 0.3-1.2% concentration.

Eye and skin irritation effects are not expected from use of the notified polymer at the proposed concentration.

Inhalation exposure may occur from use of the notified polymer at 0.3-1.2% in spray products, including aerosols. However, due to the nature of the final products, airborne particle size distributions and concentrations in the breathing zone, inhalation under normal use conditions is not expected to lead to local respiratory effects or systemic effects.

The repeated dose toxicity effects of the notified polymer have not been determined. However, exposure is expected to be limited by the dermal absorption. In addition, limited data on alkyl PEG ethers generally indicate low repeated dose toxicity. Therefore, based on the information available, the risk to the public associated with the use of the notified polymer at 0.3-1.2% 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 cosmetic and personal care formulations, or as a component of finished cosmetic and personal care products. There is unlikely to be any significant release to the environment from transport and storage. In the event of spills, the notified polymer and products containing the notified polymer are expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations.

The reformulation process will involve blending operations that will be highly automated, and is expected to occur within a fully enclosed environment. Therefore, significant release of the notified polymer from this process to the environment is not expected. The process will be followed by automated filling of the formulated products into containers of various sizes suitable for retail. Wastes containing the notified polymer generated during reformulation include equipment wash water, empty import containers, and spilt materials. Wastes may be collected and released to sewers in a worst case scenario, or disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The notified polymer is a component of cosmetic and personal care formulations. The formulated products will be applied to the body, and will be washed off the body with ultimate release to the sewer.

RELEASE OF CHEMICAL FROM DISPOSAL

Wastes and residue of the notified polymer in empty end-use containers are likely either to share the fate of the container and be disposed of to landfill, or to be released to sewer when containers are rinsed before recycling through an approved waste management facility.

7.1.2. Environmental Fate

Following its use in Australia, the majority of the notified polymer is expected to enter the sewer system through its use in cosmetic and personal care formulations, before potential release to surface waters nationwide. Based on the results of a ready biodegradability study, the notified polymer is not considered to be readily biodegradable (33% in 28 days). For details of the environmental fate study, please refer to Appendix C. The lack of ready biodegradability of the notified polymer may also be due to a slight inhibitory effect of the notified polymer to microbial activity. This is supported by the results of a microbial activity inhibition study which indicated some inhibition of microbial respiration at all test concentrations (Clariant, 2001). Based on its surfactant properties, release to surface waters is unlikely as partitioning to sludge and sediment is expected under environmental pH (4-9). The notified polymer is not expected to bioaccumulate due to its high molecular weight and surfactant properties. 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, sulphur and nitrogen.

The majority of the notified polymer will be released to sewer after use. 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. A proportion of the notified polymer may also be applied to land through disposal to landfill as collected spills and empty container residue. The notified polymer residues in landfill, soil and sludge are expected to eventually degrade through biotic and abiotic processes to form water and oxides of carbon, sulphur and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The calculation for the predicted environmental concentration (PEC) is summarised in the table below. Based on the reported use in cosmetics and household 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 0% of the notified polymer will be removed during sewage treatment processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	15,000	kg/year
Proportion expected to be released to sewer	100%	

Annual quantity of chemical released to sewer	15,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	41.10	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	9.087	µg/L
PEC - Ocean:	0.909	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 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 9.09 µg/L may potentially result in a soil concentration of approximately 60.58 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of the notified polymer in the applied soil in 5 and 10 years may be approximately 302.9 µg/kg and 605.8 µg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 > 100 mg/L	Not harmful to fish
Inhibition of Bacterial Respiration	0.5 h IC50 = 120 mg/L	May be inhibitory to bacterial respiration

Based on the above ecotoxicological endpoint for the notified polymer, it is not expected to be harmful to aquatic life. Therefore, the notified polymer is not formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009) for acute and chronic toxicities.

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated from the endpoint for fish. A safety factor of 1,000 was used given only one acute endpoint is available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish, 96 h)	> 100	mg/L
Assessment Factor	1,000	
Mitigation Factor	1.00	
PNEC:	> 100	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has been calculated based on the predicted PEC and PNEC.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q – River	9.087	> 100	< 0.091
Q – Ocean	0.909	> 100	< 0.009

The risk quotient for discharge of treated effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. Although the notified polymer is not considered to be readily biodegradable, it is not expected to bioaccumulate. On the basis of the PEC/PNEC ratio, maximum annual importation volume and assessed use pattern in cosmetic and personal care formulations, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Density 1,287.5 kg/m^3 at 25.7 °C

Method	Not reported
Remarks	Determined using AccuPyc 1330 V2.04M
Test Facility	Clariant (2014a)

Water Solubility Miscible

Method	OECD TG 105 Water Solubility.
Remarks	Shake Flask Method. The notified polymer forms strongly viscous solutions in water which cannot be stirred or filtered.
Test Facility	Clariant (2014b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
- Species/Strain: Rat/Hsd:Sprague Dawley
- Vehicle: Sesame oil
- Remarks - Method: No protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 per sex	2000	1 F/6

- LD50: > 2000 mg/kg bw
- Signs of Toxicity: Mortality as indicated in the table above occurred 10-30 minutes post-dose. Clinical signs including hypoactivity, stilted and uncoordinated gait, squatting posture, prone position, ataxia, irregular respiration, gasping and stupor were noted on day 1 post-dose. The symptoms discontinued from day 2 for all surviving animals.
- Effects in Organs: No macroscopically visible changes were noted in the female animal found dead or the animals terminated at the end of the observation period.
- Remarks - Results: Body weight development of surviving animals was unaffected.

CONCLUSION: The notified polymer is of low toxicity via the oral route.

TEST FACILITY: Aventis (2002a)

B.2. Irritation – skin

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 404 Acute Dermal Irritation/Corrosion.
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 3 F
- Vehicle: Sesame oil
- Observation Period: 72 hours
- Type of Dressing: Semi-occlusive
- Remarks - Method: No protocol deviations

RESULTS

- Remarks - Results: One animal showed well-defined erythema 30-60 minutes post-dose, which disappeared at 24 hours. The scores at 24, 48, and 72 hours for each animal were 0.

CONCLUSION: The notified polymer is non-irritating to the skin.

TEST FACILITY: Aventis (2002b)

B.3. Irritation – eye

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 405 Acute Eye Irritation/Corrosion.
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 3 F

Observation Period	72 Hours
Remarks - Method	No protocol deviations

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	1.3	1.3	1.3	2	< 72 hours	0
Conjunctiva: chemosis	0.3	0.7	0.7	2	< 72 hours	0
Conjunctiva: discharge	0.3	0	0	1	< 48 hours	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

* Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results	The conjunctive of the animals showed some definitely hyperaemic blood vessels up to diffuse crimson colour so the individual vessels were not easily discernible from 1 hour up to 48 hours post-dose. During the same period, the lids of the animals showed slight up to obvious swelling with partial eversion of lids. Colourless serous eye discharge was also noted. The irritation had disappeared 72 hours post-dose.
CONCLUSION	The notified polymer is slightly irritating to the eye.
TEST FACILITY	Aventis (2002c)

B.4. Skin sensitisation

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 406 Skin Sensitisation - Buehler test.
Species/Strain	Guinea pig/Mol:DH (Moellegaard)
PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical: 100%
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 10
Vehicle	Sesame oil
Positive control	Not conducted in parallel with the test substance, but had been conducted previously in the test laboratory using α-hexylcinnamaldehyde (25% in PEG 400).
INDUCTION PHASE	Induction Concentration: topical: 100%
Signs of Irritation	None
CHALLENGE PHASE	
challenge	topical: 100%
Remarks - Method	No protocol deviations

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: challenge*	
		24 h	*48 h*
Test Group	100%	0/20	0/20
Control Group	100%	0/10	0/10

Remarks - Results	No signs of irritation were noted in any animal following induction or challenge. Body weight development of animals was unaffected. No adverse clinical signs were noted during the study.

CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.
TEST FACILITY	Aventis (2002d)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA97a, TA98, TA100, TA102, TA1535
Metabolic Activation System	S9 fraction from phenobarbital/β-naphthoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 5-500 µg/plate b) Without metabolic activation: 5-500 µg/plate
Vehicle	Water
Remarks - Method	Due to the solubility the test substance and the formation of gel at concentrations > 500 µg/plate the highest concentration level was set at 500 µg/plate. No preliminary study was conducted. E. coli strain was not tested. Vehicle and positive controls were used in parallel with the test material. Positive controls: i) without S9: ICR 191 acridine mutagen dihydrochloride (TA97a), 4-nitro-1,2-phenylenediamine (TA98), nitrofurantoine (TA100), cumene hydroperoxide (TA102) and sodium-azide (TA1535); ii) with S9: 2-aminoanthracene (TA97a, TA98, TA100, TA1535) and danthron (TA102).

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:* *Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	> 500	> 500	negative
Test 2		> 500	negative
	> 500		
Present			
Test 1	> 500	> 500	negative
Test 2		> 500	negative
	> 500		

Remarks - Results	The test substance did not cause a visible reduction in the growth of the bacterial background lawn or a substantial reduction in the frequency of revertant colonies at ≤ 500 µg/plate both in the presence and absence of metabolic activation The controls produced satisfactory responses, thus confirming the activity of the metabolic activation and the sensitivity of the bacterial strains.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Dr U Noack (2002a)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 B Ready Biodegradability: CO2 Evolution Test.
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Theoretical Carbon Dioxide ($ThCO_2$)
Remarks - Method	The test was conducted in accordance with the test guideline above with no significant deviation from the protocol reported..

RESULTS

Test substance		*Toxicity control*		*Sodium acetate*	
Day	*% Degradation*	*Day*	*% Degradation*	*Day*	*% Degradation*
6	8	6	21	6	54
14	22	14	35	14	89
21	30	21	41	21	100
28	33	28	49	28	100

Remarks - Results	All validity criteria for the test were satisfied. The percentage degradation of the reference compound surpassed the threshold level of 60% by 14 days (89%) and reached 100% degradation by 28 days. Therefore, the test indicates the suitability of the inoculums. The percentage degradation of the toxicity control surpassed the threshold level of 25% by 14 days (35%); however, the toxicity control reached 49% degradation by 28 days, showing that toxicity may be an inhibiting factor to the biodegradability of the test substance. The test substance attained 33% degradation by 28 days. Therefore, the test substance is not considered to be readily biodegradable according to the OECD (301 B) guideline.
CONCLUSION	The notified polymer is not readily biodegradable.
TEST FACILITY	Dr U Noack (2002b)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static.
Species	*Danio rerio* (zebrafish)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	40-180 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks – Method	The test was conducted in accordance with the test guideline above with no significant deviation from the protocol reported.

RESULTS

Nominal Concentration mg/L	*Number of Fish*	*Mortality (%)*

		24 h	*48 h*	*72 h*	*96 h*
Control	7	0	0	0	0
100	7	0	0	0	0

LC50	> 100 mg/L at 96 hours.
NOEC	100 mg/L at 96 hours.
Remarks – Results	All validity criteria for the test were satisfied. The test solutions were not renewed during the 96 h test period. The actual concentrations of the test substance were not measured as no effects were observed at the highest concentration tested. The 96 h LC50 and NOEC for fish were determined to be > 100 mg/L and 100 mg/L, respectively, based on nominal concentrations.
CONCLUSION	The notified polymer is not considered to be harmful to fish.
TEST FACILITY	Dr U Noack (2001)

C.2.2. Inhibition of microbial activity

TEST SUBSTANCE	Notified polymer
METHOD	DIN EN ISO 11348-2
Inoculum	Not reported
Exposure Period	0.5 hours
Concentration Range	Nominal: 4-1,000 mg/L Actual: Not determined
Remarks – Method	The test was conducted in accordance with the test guideline above with no significant deviation from the protocol reported. The inhibitory effect of the test substance was determined as the inhibition of luminescence after 0.5 h exposure compared to the control.
RESULTS	
IC50	120 mg/L at 0.5 hours.
NOEC	Not determined
Remarks – Results	All validity criteria for the test were satisfied. Inhibition of luminescence was observed at all concentrations tested. The 0.5 h IC50 was determined to be 120 mg/L based on nominal concentrations.
CONCLUSION	The notified polymer may be inhibitory to microbial activity.
TEST FACILITY	Clariant (2001)

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