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June 2016

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, mono(dihydrogen 2-hydroxy-1,2,3-propanetricarboxylate), C_{12-18}-alkyl ethers (INCI name: Laureth-7 citrate)

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	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1580	BASF Australia Ltd	Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, mono(dihydrogen 2-hydroxy-1,2,3-propanetricarboxylate), C_{12-18}-alkyl ethers (INCI name: Laureth-7 citrate)	ND*	≤ 2 tonnes per annum	Component of cosmetics

*ND = 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 for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute Category 3	H402 – Harmful to aquatic life

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

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself. However, these should be selected on the basis of all ingredients in the formulation.

  Guidance in the 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.

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 notified polymer is proposed to be used in cosmetics at concentrations exceeding 5%;
- information on repeated dose toxicity of the notified polymer becomes available;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from component of cosmetics, 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
BASF Australia Ltd (ABN: 62 008 437 867)
Level 12, 28 Freshwater Place
SOUTHBANK VIC 3006

NOTIFICATION CATEGORY
Standard: Synthetic polymer with Mn < 1,000 Da (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, 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 endpoints, acute oral toxicity, acute dermal toxicity, skin irritation, repeated dose toxicity and chromosome damage *in vitro*

NOTIFICATION IN OTHER COUNTRIES
China (2013), Taiwan (2014)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Plantapon LC7 (containing the notified polymer at ≤ 85% concentration)
Uvinul Easy (imported product containing the notified polymer at < 10% concentration)

CAS NUMBER
565429-75-6

CHEMICAL NAME
Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, mono(dihydrogen 2-hydroxy-1,2,3-propanetricarboxylate), C_{12-18}-alkyl ethers

OTHER NAMES
Laureth-7 Citrate (INCI name)
Citric acid, ester with alcohols C12-18, ethoxylated
Citric acid ester of ethoxylated fatty alcohol
Citric (FAEO C12-18 + 7EO)monoE

MOLECULAR WEIGHT
Number Average Molecular Weight (Mn) > 500 Da

ANALYTICAL DATA
Reference GPC and MALDI-MS spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 80%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: yellow viscous liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Liquid at ambient temperature
Boiling Point	Not determined	Expected to be > 100 °C based on

Property	Value	Data Source/Justification
		molecular weight
Density	1,070 – 1,090 kg/m^3 at 20 °C	(M)SDS
Vapour Pressure	Not determined	Based on the molecular weight of the polymer, the vapour pressure is expected to be low
Water Solubility	Not determined	Expected to be dispersible based on molecular structure and surface activity
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities; however, not expected to significantly hydrolyse under environmental conditions (pH 4-9)
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	Expected to be ionised under environmental conditions (pH 4-9)
Flash Point	> 100 °C	(M)SDS
Flammability	Not determined	The notified polymer is not expected to be flammable based on flash point
Autoignition Temperature	Not determined	Not expected to auto-ignite under normal use conditions
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

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 in Australia. It will be imported as a component of a formulation (Uvinul Easy) at < 10% concentration for reformulation into finished cosmetic products. The notified polymer may also be imported as a component of finished cosmetic products at < 5% concentration.

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

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

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
The notified polymer will be imported as a component of a formulation (Uvinul Easy) in 10 kg plastic jerry cans packed in wooden pallets wrapped with plastic shrink. The plastic shrink wrapped pallets containing the containers will be transported to the notifier's warehouse for storage until distribution to end customers. The finished products will be packed in 50 to 200 mL glass containers or plastic pump packs.

USE
The notified polymer will be used as an emulsifier in cosmetic products at < 5% concentration.

OPERATION DESCRIPTION
The notified polymer will be imported as a component of a formulation (Uvinul Easy) at < 10% concentration for reformulation into finished cosmetic products, or as a component of finished cosmetic products at < 5% concentration, which will be sold to the public in the same form in which they are imported.

Reformulation
The procedures for incorporating the formulation *Uvinal Easy* containing the notified polymer at < 10% concentration into end-use products will vary depending on the nature of the cosmetic product being formulated, and both manual and automated steps will likely be involved. However, in general it is expected that the reformulation processes will involve mixing and blending operations that will be highly automated and occur in a fully enclosed systems with good ventilation, followed by filling of the reformulated products into containers of various sizes (50 to 200 mL glass containers or plastic pump packs).

End-use
The finished cosmetic products containing the notified polymer at < 5% concentration will be used by consumers and professionals (such as beauticians). Depending on the nature of the product, application of products could be by hand 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	1-2	30-50
Reformulation	1-3/site	30-50
Retail workers	8-12	240
Professionals	8-12	240

EXPOSURE DETAILS
Transport and storage
Transport and storage workers may come into contact with the notified polymer either at < 10% concentration as a component of Uvinul Easy or at < 5% concentration as a component of finished cosmetic products, only in the event of accidental rupture of containers.

Formulation of end use products
During reformulation, dermal, ocular and perhaps inhalation exposure of workers to the notified polymer (at < 10% concentration) may occur during weighing and transfer stages, dilution, blending, quality control, packaging of the finished products, and cleaning and maintenance of equipment. The notifier states that exposure is expected to be minimised through the use of automated enclosed systems and/or engineering controls (local exhaust ventilation), and through the use of appropriate PPE such as safety glasses, impervious gloves and coveralls.

End-use
Exposure to the notified polymer in end-use products may occur in professions where the services provided involve the application of cosmetic products (at < 5% concentration) to clients (e.g. workers in beauty salons). The principal route of exposure will be dermal, while ocular exposure is also possible. Good hygiene practices are expected to be in place. 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 < 5% concentration. The principal route of exposure will be dermal, while ocular exposure is also possible. As the notified polymer is not proposed to be used in spray products, inhalation exposure is not anticipated.

Data on typical use patterns of cosmetic product categories in which the notified polymer may be used are shown in the following table (SCCS, 2012). For the purposes of the exposure assessment via the dermal route, Australian use patterns for the various product categories are assumed to be similar to those in Europe. A dermal absorption of 10% was assumed for the notified polymer based on dermal absorption studies on an analogue (see Section 6.2, Toxicokinetics). An adult bodyweight of 64 kg was used for calculation purposes.

Product type	Amount (mg/day)	C (%)	Retention Factor (RF) (unitless)	Daily systemic exposure (mg/kg bw/day)
Body lotion	7820	5	1	0.6109
Face cream	1540	5	1	0.1203
Foundation	510	5	1	0.0398
Shampoo	10460	5	0.01	0.0082
Total				0.7792

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

The worst case scenario estimation using these assumptions is for a person who is a simultaneous user of all products listed in the above table that contain the notified polymer. This would result in a combined internal dose of 0.7792 mg/kg bw/day.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer and an analogue 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: 500-2000 mg/kg bw, harmful (analogue)
Eye irritation (in vitro) (HET-CAM Assay)	none to slightly irritating
Human, skin sensitisation – RIPT (10%)	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic

Use of analogue data in human health effects assessment

The notified polymer is expected to hydrolyse in the stomach to citric acid and alcohol ethoxylates (AEs) ($C_{12}AE_7$ on average) prior to absorption. Therefore information on alcohol ethoxylates was considered to support the health hazard conclusions for the notified polymer. Citric acid is a GRAS direct food additive and is therefore not expected to contribute to toxicity. For acute oral toxicity, the notifier provided data for an alcohol ethoxylate similar to that used for the manufacture of the notified polymer.

Toxicokinetics

No data on the toxicokinetics of the notified polymer was provided. The notified polymer is an ionic surfactant with a moderately high molecular weight (NAMW > 500 Da); therefore dermal absorption is expected to be limited. This is supported by the low skin penetration (< 2%) observed for Laureth-6 ($C_{12}AE_6$) in a dermal penetration study on two human volunteers using radiolabelling (HERA, 2009). Laureth-6 is considered acceptable to estimate the dermal absorption of the notified polymer as it is of lower molecular weight and has a similar structure but without the ionic functionality present in the notified polymer which is expected to further limit absorption. While there is uncertainty about the dermal absorption potential of the notified polymer, a value of 10% dermal absorption was assumed for quantitative risk assessment purposes. Given the surfactant properties of the notified polymer it may enhance the dermal absorption of other chemicals.

The notified polymer is expected to hydrolyse in the stomach to citric acid and AEs ($C_{12}AE_7$ on average). Oral absorption studies on AEs found that these chemicals were absorbed in the GI tract and extensively and rapidly excreted in the urine. A small amount was excreted in faeces and expired air (as CO_2) (HERA, 2009). Orally administered citric acid is largely absorbed and metabolised, and is an intermediate in the Krebs cycle (CIR. 2012).

Acute toxicity

Acute toxicity data on the notified polymer was not provided.

A study on an AE similar to that used for the manufacture of the notified polymer (i.e. $C_{12}AE_7$ on average) in rats indicated low to moderate acute oral toxicity. An apparent sex difference was observed in the study; with females being more susceptible to the acute oral toxicity (LD50: 500 to 2000 mg/kg) than males (LD50: > 2000

mg/kg). However it has been suggested that this is not a sex specific phenomenon, but an effect related to body weight; lighter animals being more susceptible than heavier animals (HERA 2009).

In general AEs have been shown to be of low to moderate acute oral toxicity, and of low acute dermal and inhalation toxicity (HERA 2009). For acute oral toxicity there is an apparent relationship with the degree of ethoxylation of the AE, with ethoxylate chains between 5 and 14 being more toxic than those with less than 4 or more than 21 ethoxy units. The notified polymer has on average 7 ethoxy units. Therefore, based on the available information, the notified polymer may be harmful by the oral route.

Irritation and sensitisation
No skin irritation data on the notified polymer was available. An *in vitro* eye irritation study on the notified polymer using the HET-CAM model showed that the notified polymer at a concentration of 5% did not cause an irritation response. According to the classification criteria provided in the study report, the notified polymer at 5% concentration has none to slight eye irritation potential.

A human repeated insult patch test using the notified polymer at 10% concentration did not reveal any signs of irritation or sensitisation.

AEs with varying carbon chain lengths and degree of ethoxylation were found to be slightly to severely irritating to skin and eye in rabbits and rats (HERA 2009). Therefore, in the absence of skin and eye irritation data for undiluted notified polymer, potential skin and eye irritation effects of the notified polymer cannot be ruled out on the basis of data for AEs (HERA 2009)

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

A number of AEs have been evaluated in oral and dermal repeated dose toxicity studies. 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 $C_{12\text{-}13}AE_{6.5}$ (HERA, 2009). Effects observed at the LOAEL were related to significantly elevated organ-to-body weight ratios for liver, kidney and heart. No adverse histopathological changes were observed at the LOAEL. This NOAEL is consistent with the outcome of the majority of existing chronic and subchronic studies determined for AEs. Only one 90-day study revealed some minor effects at a dose level of 50 mg/kg bw/day which were not considered be of toxicological significance.

A NOAEL of 50 mg/kg bw/day is therefore considered for the notified polymer for quantitative risk assessment purposes.

Mutagenicity/Genotoxicity
The notified polymer was negative in a bacterial reverse mutation study. No further genotoxicity data is available for the notified polymer.

Based on a number of *in vitro* and *in vivo* studies, there is no evidence that AEs are either mutagenic or genotoxic (HERA, 2009).

Therefore, based on the available information, the notified polymer is not expected to be genotoxic.

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, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified polymer may be irritating to the skin and eyes, and may be harmful by the oral route.

Reformulation
Reformulation workers may be exposed to the notified polymer at < 10% concentration. However at the proposed use concentration acute toxicity effects are not expected. Furthermore, the proposed use of PPE and enclosed, automated processes should minimise the potential for exposure.

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 < 5% concentration. The risk to these workers is expected to be of 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.

Overall, 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 < 5% concentration. The notified polymer may be irritating to the skin and eyes, and may be harmful by the oral route. However at the proposed use concentration acute toxicity effects are not expected.

The potential systemic exposure to the public from the use of the notified polymer in cosmetic products was estimated to be 0.7792 mg/kg bw/day based on a dermal absorption of 10%. Using a NOAEL of 50 mg/kg bw/day based on a 2-year oral feeding study with an analogue, the margin of exposure (MOE) was estimated to be 64. A MOE value greater than or equal to 100 is considered acceptable to account for intra- and inter-species differences. However, given a dermal absorption of 2% has been determined in a dermal absorption study for an acceptable analogue, a dermal absorption of 10% for the notified polymer is likely to represent a conservative value. Using a dermal absorption of 2%, the MOE was estimated to be 320.

As the notified polymer may have the potential to enhance dermal absorption of other chemicals due to its surfactant activity, care should be taken in formulating end-use products containing it.

Based on the available information, the risk to the public associated with the proposed use of the notified polymer in cosmetic products at < 5% concentration 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 into Australia as a component of raw material for reformulation into finished cosmetic products, or as a component of 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 product containing 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 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 end-use 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 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 of the notified polymer may remain in end-use containers once the consumer products are used up. Wastes and residues of the notified polymer in empty 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 products, before potential release to surface waters nationwide. Based on the results of a ready biodegradability study, the notified polymer is considered to be readily biodegradable (61.1% in 28 days). The results of an anaerobic biodegradability study indicated the notified polymer is anaerobically biodegradable (> 80% in 60 days). For details of the environmental fate studies, please refer to Appendix C. Based on its surfactant properties, release to surface waters is unlikely 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 ready biodegradability. 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.

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. The notified polymer may also be 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 cosmetics 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 (STP).

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	2,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	2,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	5.48	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:	1.212	µg/L
PEC - Ocean:	0.121	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 1.21 µg/L may potentially result in a soil concentration of approximately 8.08 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 40.39 µg/kg and 80.77 µg/kg, respectively.

7.2. Environmental Effects Assessment

The results from an ecotoxicological investigation conducted on the notified polymer are summarised in the table below. Details of this study can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Algal Toxicity	72 h E_rC50 = 57 mg/L	Harmful to algae

Based on the above ecotoxicological endpoints for the notified polymer, it is expected to be acutely harmful to algae. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS)

(United Nations, 2009) the notified polymer is formally classified as "Acute Category 3; Harmful to aquatic life". Based on the above acute toxicity, ready biodegradability and low bioaccumulation potential of the notified polymer, it is not formally classified under the GHS for chronic toxicity.

7.2.1. Predicted No-Effect Concentration

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

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
E_rC50 (Algae, 72 h)	57	mg/L
Assessment Factor	1,000	
Mitigation Factor	1.00	
PNEC:	57	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	1.212	57	**0.021**
Q – Ocean	0.121	57	**0.002**

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. The notified polymer is readily biodegradable, and is not expected to be bioaccumulative. On the basis of the PEC/PNEC ratio, maximum annual importation volume and assessed use pattern in cosmetic products, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Analogue A
METHOD	OECD TG 401 Acute Oral Toxicity.
Species/Strain	Rat/Bor:WISW (SPF) Cpb
Vehicle	Arachidis oil, DAB 9

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5M/5F	2000	4F
2	5F	500	0

LD50	> 500 to < 2000 mg/kg bw
Signs of Toxicity	4 female rats died within 48 hours post administration in the first group. Clinical signs of toxicity observed in the first group of animals included diarrhea, piloerection, reduced activity, emaciation, crusted snout, hunched postures (female only), disponea (female only), vocalisation(female only), discolouration of nose (female only) and salivation (female only) No clinical signs of toxicity were observed in group 2. Bodyweight loss was noted in the sacrificed female animal in Group I. All surviving male animals in group 1 and female animals in group 2 showed bodyweight gain over the observation period.
Effects in Organs	Macroscopic effects consisted of: Group I: Male: There were no remarkable necropsy findings except left liver lobe adhesive to peritoneum and stomach, slight splenic enlargement in 1 male only Female: black discolouration of the forestomach, ulcerations, gas-accumulation in the stomach, hydrothorax, ascites, autolysis Group 2: There were no remarkable necropsy findings.
Remarks - Results	

CONCLUSION	The test substance is harmful *via* the oral route.
TEST FACILITY	Henkel (1992)

B.2. Irritation – eye (in vitro)

TEST SUBSTANCE	Notified polymer (5%)
METHOD	Hen's egg test - chorio-allantoic membrane (HET-CAM) test: Reaction Time Method
Vehicle	Water
Remarks - Method	Not a validated method.

RESULTS

Test material	*Q (SD)*
Test substance	0.00 (±0)
Positive control	1.00 (±0.06)

SD = Standard deviation; Q = in vitro irritation value

Remarks - Results	The notified polymer did not exhibit eye irritation potential under the conditions of the test.

CONCLUSION	According to the classification criteria provided in the study report, the test substance is none to slightly irritating.
TEST FACILITY	Henkel (2002)

B.3. Skin sensitisation – human volunteers

TEST SUBSTANCE	Notified polymer (10% in water)
METHOD	Repeated insult patch test with challenge –In-house method.
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 after 24 h of each application and the test sites were evaluated prior to each re-application. Rest Period: approximately 2 weeks Challenge Procedure: A challenge patch was applied to a naïve site adjacent to the original induction site. The patch was removed after 24 h and the site was evaluated 24 h and 72 h post-application.
Study Group	113 subjects, 86 F, 27 M; 100 subjects completed the test Age group: 18-69 years
Vehicle	Water with pH adjustment to 5.5
Remarks - Method	Occluded. The test substance was spread on a 1.9 cm × 1.9 cm absorbent pad portion of an adhesive dressing.
RESULTS	
Remarks - Results	Thirteen (13) subjects discontinued participation for non-test substance related reasons. There was no evidence of irritation during the study in any test subject.
CONCLUSION	The test substance was non-sensitising and non-irritating under the conditions of the test.
TEST FACILITY	Consumer Product Testing (2003)

B.4. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA98, TA100
Metabolic Activation System	S9 fractions from phenobarbitone/ β-naphthoflavone induced rat liver
Concentration Range in Main Test	3, 10, 33, 100, 333, 1000, 2500 and 5000 µg/plate (with/without metabolic activation)
Vehicle	Deionised water
Remarks - Method	No preliminary toxicity test was carried out to determine the toxicity of the test material. The test material formulations and vehicle control were dosed using the plate incorporation method. This procedure was repeated, in triplicate, for each bacterial strain and for each concentration of test material both with and without S9-mix. The positive and untreated controls were dosed using the standard plate incorporation method. The study was performed with TA 98 and TA100 only.
RESULTS	

Metabolic Activation	*Test Substance Concentration (μg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	N/A	> 5000	> 5000	Negative
Present				
Test 1	N/A	> 5000	> 5000	Negative

Remarks - Results

No toxicity or precipitation was observed in the mutation tests. The test substance did not cause a marked increase in the number of revertants per plate of any of the tester strains either in the presence or absence of S9. Negative controls were within historical limits. Positive controls confirmed the sensitivity of the test system.

CONCLUSION

The notified polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

RCC (2003)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Inoculum	Activated sewage sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Theoretical Oxygen Demand (ThOD)
Remarks - Method	The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

Test substance		*Sodium acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
8	38.0-43.5	8	67.3-78.2
16	51.9-54.6	16	67.4-78.2
20	55.6-58.3	20	68.6-82.9
28	61.1	28	65.0-82.9

Remarks - Results	All validity criteria for the test were satisfied. The percentage degradation of the reference compound surpassed the threshold level of 60% by 4 days (≥ 60.2%). Therefore, the tests indicate the suitability of the inoculums. The degree of degradation of the test substance after 28 days was 61.1%. As the test substance is surface active, the 10-day window is not applicable. Therefore, the test substance is considered to be readily biodegradable according to the OECD (301 F) guideline.
CONCLUSION	The notified polymer is readily biodegradable.
TEST FACILITY	Hydrotox (2003)

C.1.2. Anaerobic biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 311 Anaerobic Biodegradability of Organic Compounds in Digested Sludge: By Measurement of Gas Production
Inoculum	Digested sewage sludge
Exposure Period	60 days
Auxiliary Solvent	None
Analytical Monitoring	Theoretical Organic Carbon (ThOC)
Remarks – Method	The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported. The first incubation was 28 days, and the second incubation period ran from day 28 to day 60.

RESULTS

Test substance		*Glucose*	
Day	*% Degradation*	*Day*	*% Degradation*
0	0	0	0
14	67.3	14	> 95
28	81.2	28	100
28*	0	28*	0
32	43.8	32	> 70

46	77.7	46	> 85
60	87.4	60	90

* Second addition of test substance for second incubation

Remarks – Results	All validity criteria for the test were satisfied. The percentage degradation of the reference compound surpassed the threshold level of 60% by 2 days (75%) and achieved a degradation plateau. Therefore, the tests indicate the suitability of the inoculums. The degree of degradation of the test substance after 28 days was > 80%. Therefore, the test substance is considered to be anaerobically biodegradable according to the OECD (311) guideline.
CONCLUSION	The notified polymer is anaerobically biodegradable.
TEST FACILITY	Landeshauptstadt Düsseldorf (2015)

C.2. Ecotoxicological Investigations

C.2.1. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 201 Freshwater Alga and Cyanobacteria, Growth Inhibition Test.
Species	*Desmodesmus subspicatus* (green alga)
Exposure Period	72 hours
Concentration Range	Nominal: 5-160 mg/L Actual: 4.35-164.04 mg/L
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Measured according to the method described in DIN 38412, part 23
Remarks - Method	The concentration of $NaHCO_3$ was increased to be twice of that indicated in OECD TG 201. This concentration has been found to be optimal. The initial concentration of algae at time t_0 is higher than given by OECD TG 201. This deviation is not considered to have impacted on the integrity or validity of the test results. The definitive test was conducted at nominal concentrations of 5, 10, 20, 40, 80, and 160 mg/L of the test substance. The test was conducted in accordance with the test guideline above.

RESULTS

Biomass		*Growth*	
E_bC50 mg/L at 72 h	*NOE_bC mg/L*	*E_rC50 mg/L at 72 h*	*NOE_rC mg/L*
22	4.1	57	8.7

Remarks - Results	All validity criteria for the test were satisfied. The test solutions were not renewed during the 72 h test period. The actual concentrations of the test substance were measured at the start and end of the 72 h test period. The 72 h E_bC50 and E_rC50 were determined to be 22 mg/L and 57 mg/L, respectively, based on nominal concentrations.
CONCLUSION	The notified polymer is considered to be harmful to algae.
TEST FACILITY	Institut Fresenius (2004)

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