File No: LTD/1616

October 2012

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Glycols, 1,2-, C12-16, ethoxylated propoxylated (INCI name: PPG-1-PEG-9 Lauryl Glycol Ether)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Sustainability, Environment, Water, Population and Communities.

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

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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/1616	BASF Australia Ltd	Glycols, 1,2-, C12-16, ethoxylated propoxylated (INCI name: PPG-1-PEG-9 Lauryl Glycol Ether)	Yes	≤ 1 tonne per annum	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 following table.

Hazard classification	*Hazard statement*
Skin Irritation (Category 2)	H315 – Causes skin irritation
Eye Irritation (Category 2A)	H319 – Causes serious 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 phrase(s):
R36: Irritating to eyes
R38: Irritating to skin

The environmental hazard classification according to the *Globally Harmonised System for the 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 Toxicity (Category 2)	H401 - Toxic to aquatic life
Chronic Toxicity (Category 3)	H412 - Harmful to aquatic life with long lasting effects

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

When used at ≤ 2% in leave-on cosmetic products and ≤ 3% in rinse-off cosmetic products, 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 assessed 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:
  - Skin Irritation (Category 2): H315 – Causes skin irritation

- Eye Irritation (Category 2A): H319 – Causes serious eye irritation

The notifier should consider the use of the above hazard statements for products/mixtures containing the notified polymer at ≥ 10% concentration

- The Delegate (and/or the Advisory Committee on Chemicals Scheduling) should consider the notified polymer for listing on the SUSMP.

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 during reformulation processes:
  - Enclosed, automated processes, where possible
  - Adequate ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer during reformulation processes:
  - Avoid contact with skin and eyes
  - Avoid inhalation

- 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 during reformulation processes:
  - Coveralls, goggles, impervious gloves
  - Respiratory protection (if significant inhalation exposure is 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

- The following measures should be taken to minimise public exposure to the notified polymer:
  - The notified polymer should only be used at ≤ 2% in leave-on cosmetic products and ≤ 3% in rinse-off cosmetic products.
  - 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

- The notified polymer should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified 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 importation volume exceeds one tonne per annum notified polymer;
- the concentration of the notified polymer exceeds or is intended to exceed 2% in leave-on cosmetic products or 3% in rinse-off cosmetic products;
- information on the repeated dose toxicity potential of the notified polymer via the inhalation route becomes available;

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 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.

No additional secondary notification conditions are stipulated.

(Material) Safety Data Sheet
The (M)SDSs of the notified polymer and of a product containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDSs remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
BASF Australia Ltd (ABN 62 008 437 867)
Level 12, 28 Freshwater Place
SOUTHBANK VIC 3006

NOTIFICATION CATEGORY
Limited-small volume: Synthetic polymer with Mn <1000 Da (1 tonne or less per year)

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: structural formula, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities and additives/adjuvants.

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
China, Japan

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Eumulgin L
Eumulgin HPS (25% notified polymer)

CAS NUMBER
154248-98-3

CHEMICAL NAME
Glycols, 1,2-, C12-16, ethoxylated propoxylated

OTHER NAME(S)
PPG-1-PEG-9 Lauryl Glycol Ether (INCI name)

MOLECULAR FORMULA
Unspecified

MOLECULAR WEIGHT
> 500 Da

ANALYTICAL DATA
Reference FTIR, MS and GPC spectra were provided

3. COMPOSITION

DEGREE OF PURITY > 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Clear yellowish liquid

Property	Value	Data Source/Justification
Boiling Point	≥ 100 °C	Estimated by the notifier
Density	976-980 kg/m^3 at 70°C	(M)SDS
Vapour Pressure	Not determined	Based on the high molecular weight of the notified polymer, vapour pressure is expected to be low
Water Solubility	Not determined	Reported to have unlimited solubility (Stockhausen, 2003). The notified polymer is a surfactant. It is expected to be dispersible in water.
Hydrolysis as a Function of pH	Not determined	Does not contain any hydrolysable functionality
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to the interface between octanol and water, based on its surfactant properties
Adsorption/Desorption	Not determined	Expected to partition to phase boundaries, based on its surfactant properties
Dissociation Constant	Not determined	Does not contain dissociable functionality
Flash Point	> 100 °C	(M)SDS
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use
Explosive Properties	Not determined	Contains no functions groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functions groups that would imply oxidising properties

DISCUSSION OF PROPERTIES

Reactivity

The notified polymer is expected to be stable under normal conditions of use.

Physical hazard classification

Based on the limited physico-chemical data depicted in the above table, the notified polymer 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 be imported at 100% concentration or at 25% concentration.

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

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

PORT OF ENTRY

Melbourne, Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS

BASF Australia Ltd and/or formulators of cosmetic products

TRANSPORTATION AND PACKAGING

The notified polymer (at 100% or 25% concentration) will be imported in 20 L or 200 L plastic drums, or in 1000 L tanks. The imported and formulated products containing the notified polymer will be transported within Australia by road. The end-use products (up to 10% concentration notified polymer) will be packaged in containers suitable for retail sale.

USE
The notified polymer will be used as a component of cosmetic products at up to 10% concentration (with a typical usage concentration of 2-3%). The notified polymer is intended for use as a fragrance emulsifier and will therefore be used in cosmetic products that require addition of a fragrance.

OPERATION DESCRIPTION
The procedures for incorporating the notified polymer (at 100% or 25% concentration) into end-use products will likely vary depending on the nature of the formulated cosmetic products and may involve both automated and manual transfer steps. However, in general, it is expected that the reformulation processes will involve blending operations that will be highly automated and occur in a fully enclosed environment, followed by automated filling of the reformulated products into containers of various sizes.

The finished products containing the notified polymer (at up to 10% concentration) may be used by consumers and professionals such as hairdressers or beauty salon workers. Depending on the nature of the product, these could be applied in a number of ways, such as by hand, using an applicator or by spray.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration*	*Exposure Frequency*
Transport workers	1.5 hours/day	2-3 days/year
Store persons	0.5-10 hours/week	48 weeks/year
Manufacturing staff	0.5-10 hours/week	48 weeks/year
Laboratory technicians	0.5-10 hours/week	48 weeks/year
Drum recyclers	10 minutes/week	48 weeks/year
Salon workers	8 hours/day	365 days/year

EXPOSURE DETAILS
Transport and storage workers may come into contact with the notified polymer, as a component of the imported products or end-use products, only in the event of an accidental rupture of containers.

During reformulation, dermal, ocular and perhaps inhalation exposure of workers to the notified polymer (at 100% or 25% concentration) may occur during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment. Exposure is expected to be minimised through the use of mechanical ventilation and/or enclosed systems, and through the use of personal protective equipment (PPE) such as coveralls, goggles and impervious gloves.

Exposure to the notified polymer in end-use products (at up to 10% concentration) may occur in professions where the services provided involve the application of cosmetic and personal care products to clients (e.g. hair dressers, beauty salon workers). 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 (at up to 10% concentration).

6.1.2. Public Exposure
There will be widespread and repeated exposure of the public to the notified polymer (at up to 10% concentration) through the use of rinse-off and leave-on cosmetic products. The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible, particularly if products are applied by spray.

Data on typical use patterns of cosmetic product categories in which the notified polymer may be used are shown in the following table (SCCS, 2010; Cadby *et al.*, 2002). For the purposes of the exposure assessment, Australian use patterns for the various product categories are assumed to be similar to those in Europe. Based on the limited dermal absorption data available on analogue polymers, a dermal absorption of 15.6% was assumed for the notified polymer (see Section 6.2. for further details). An adult bodyweight of 60 kg was used

for calculation purposes.

Product type	Amount (mg/day)	C (%)	RF	Daily systemic exposure (mg/kg bw/day)
Body lotion	7820	10	1	2.03
Face cream	1540	10	1	0.40
Hand cream	2160	10	1	0.56
Deodorant	1430	10	1	0.37
Fragrances	750	10	1	0.20
Shower gel	18670	10	0.01	0.05
Hand wash soap	20000	10	0.01	0.05
Shampoo	10460	10	0.01	0.03
Hair conditioner	3920	10	0.01	0.01
Hair styling products	4000	10	0.1	0.10
Total				**3.80**

C - concentration; RF - retention factor.
Daily systemic exposure = Amount × C × RF × dermal absorption/body weight

The worst case scenario estimation using these assumptions is for a person who is a simultaneous user of all products listed in the above tables that contain the notified polymer. This would result in a combined internal dose of 3.80 mg/kg bw/day.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer or analogue polymers are summarised in the table below. Detailed study reports (in English) were only provided for the skin sensitisation and repeated dose oral toxicity endpoints (details of these studies can be found in Appendix A). A summary of the studies was provided for the remaining endpoints (Cognis, 2009).

Endpoint	*Test Substance*	*Result and Assessment Conclusion*
Rat, acute oral toxicity*	Notified polymer	LD50 2560 mg/kg bw, low toxicity
Rabbit, skin irritation*	Notified polymer (25%)	slightly irritating
Mouse, skin irritation*	Notified polymer (25%)	slightly irritating
Rabbit, eye irritation*	Notified polymer (10%)	slightly irritating
Guinea pig, skin sensitisation – non-adjuvant test.	Notified polymer/Analogue polymer (95:5)	no evidence of sensitisation
Rat, repeat dose oral (gavage) toxicity – 90 days	Analogue polymer	NOAEL 80 mg/kg bw/day
Rat, repeat dose oral (gavage) toxicity – 28 days	Analogue polymer	not determined
Mutagenicity – bacterial reverse mutation*	Notified polymer	non mutagenic
Rat, dermal absorption – leave-on and rinse-off applications*	Analogue polymer	~1% absorption (rinse-off) ~3-5% absorption (leave-on)

*Full study report in English not provided.

Toxicokinetics.
No information on the toxicokinetics of the notified polymer was provided. Based on the surfactant nature of the notified polymer, absorption across the gastrointestinal tract and dermal absorption may occur. However, the extent of absorption may be limited by the relatively high molecular weight (> 500 Da) of the notified polymer. The notified polymer may be absorbed across the respiratory tract. It is also noted that surfactants can enhance the dermal absorption of other compounds.

It is reported that the dermal penetration of an analogue polymer was between 1% (rinse-off application) and 3-5% (leave-on application), based on studies in the rat (Cognis, 1979; note study report in English was not provided - limited details of the results of this study, in English, were provided in Cognis, 2009).

The dermal penetration of an alternate analogue polymer was determined using a mathematical model (two-compartment layer, consisting of a stratum corneum and a viable epidermis; Environ, 2005; discussed in Cognis, 2009). Based on a scenario involving a 1-week continuous exposure to the analogue polymer, the peak concentration of the notified chemical in the stratum corneum was reached after ~24 hours (5.5% absorption after 8 hours; 69.6% absorption after 1-week exposure). Based on a second scenario involving repeated exposure (once per day for 28 days) to formulations containing the analogue polymer (5 and 10% analogue polymer), in which the polymer was washed off following either 8 or 24 hours, the absorption was determined to be 5.5% after 8 hours and 15.6% after 24 hours.

While the notified polymer and the analogue polymers are all nonionic surfactants, based on the structures and expected physico-chemical properties of the polymers, the data derived from the mathematical modeling of the dermal absorption on the analogue polymer is expected to provide a more reasonable estimation of the dermal absorption potential of the notified polymer. Considering that the peak concentration of the analogue polymer in the stratum corneum was reached after ~24 hours, and given the proposed use of the notified chemical in cosmetic products (i.e. repeated exposure to the notified polymer is expected), the dermal absorption value derived from repeated applications (24-hour exposure) was determined to be appropriate for estimating the dermal absorption potential of the notified polymer. Therefore, the dermal absorption was assumed to be 15.6% for the purposes of exposure estimation (see Section 6.1.2. for further details).

Acute toxicity.
The notified polymer was reported to be of low acute toxicity via the oral route in a study conducted in rats (calculated LD50 2560 mg/kg bw; Cognis, 2009). Indisposition, piloerection, dyspnea and spastic walk were reportedly observed in animals treated with the notified polymer at ≥ 1000 mg/kg bw. Acute dermal and inhalation toxicity data were not provided for the notified polymer.

Irritation and Sensitisation.
The dermal irritation potential of the notified polymer (at 25% concentration) was tested in 2 rabbits, with very slight erythema reportedly observed in a single rabbit following repeated application (60 times over 30 minutes; open application; Cognis, 2009). In a cutaneous compatibility study of the notified polymer (at 25% concentration; 5 applications over 5 days) in 5 hairless mice, slight squamous effects were reportedly observed in all animals after the fourth application, and slight erythema noted in 2 animals. Based on the results of these studies, and considering the test conditions employed, the notifier has (precautionary) classified the notified polymer as a skin irritant.

The eye irritation potential of the notified polymer (at 10% concentration) was tested in 4 rabbits, with slight conjunctival erythema reportedly observed in treated rabbits after 24 hours, and no adverse effects observed after 48 hours (study reportedly conducted according to OECD TG 405; Cognis, 2009). Based on the results of these studies, and considering the test conditions employed, the notifier has (precautionary) classified the notified polymer as an eye irritant.

The notified polymer (100% induction concentration; 75% challenge concentration; 95:5 notified polymer:analogue polymer) was not a skin sensitiser in guinea pigs (Buehler method).

Repeated Dose Toxicity.
Repeated dose toxicity information on the notified polymer was not provided. Upon repeated oral (gavage) exposure of rats (90 day exposure period) to an analogue polymer, the NOAEL was established by the authors as 80 mg/kg bw/day, based on the main findings (at the high dose, 150 mg/kg bw/day) of lesions present in the stomachs at histopathology, reduced weight gain and reduction in food intake, in combination with findings such as nasal respiratory epithelium lesions and organ weight effects (in-particular on the kidneys, thymus and spleen). While effects were noted at lower doses (50 and 80 mg/kg bw/day; especially the effects on the nasal respiratory epithelium), they were considered by the study authors to be due to a local irritant effect of the analogue polymer and/or were not considered to be adverse at the lower dosage levels.

A 28-day repeated dose oral toxicity study of the analogue polymer in rats (treatment at 150 mg/kg bw/day only), was subsequently conducted and was intended to verify the findings of the above mentioned 90-day study, with respect to the findings in the nasal respiratory epithelium. The study authors noted that based on the

unspecified character and widespread distribution of the nasal mucosal changes, the lesions were probably related to a local irritant effect, e.g. from regurgitation of the analogue polymer, however, a direct toxic effect of the analogue polymer on the nasal mucosa via the bloodstream could not be excluded with certainty.

In the absence of repeated dose toxicity information on the notified polymer, the above mentioned repeated dose toxicity data on a suitable analogue polymer, namely the derivation of an NOAEL of 80 mg/kg bw/day, was used to estimate the repeated dose toxicity effects of the notified polymer.

Mutagenicity.
The notified polymer was reportedly not mutagenic in a bacterial reverse mutation test in the presence and absence of metabolic activation (strains TA100, TA1535, TA1537, TA1538 and TA98; 4-2500 µg/plate; Cognis, 2009).

Health 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 following table.

Hazard classification	*Hazard statement*
Skin Irritation (Category 2)	H315 – Causes skin irritation
Eye Irritation (Category 2A)	H319 – Causes serious 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 phrase(s):
R36: Irritating to eyes
R38: Irritating to skin

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Reformulation
Workers may experience dermal and accidental ocular and perhaps inhalation exposure to the notified polymer (at up to 100% concentration) during formulation processes. At such concentrations, there is potential for skin and eye irritation effects. In addition, based on the effects observed in repeated dose toxicity studies on an analogue polymer, regular exposure to the notified chemical should be avoided. The use of enclosed, automated processes and PPE (impervious gloves, goggles, coveralls and respiratory protection, if significant inhalation exposure is expected) should minimise the potential for exposure.

Therefore, provided that adequate control measures are in place to minimise worker exposure, including the use of automated processes and PPE, the risk to workers from use of the notified polymer is not considered to be unreasonable.

End-use
Beauty care professionals will handle the notified polymer at up to 10% concentration, similar to public use. The risk to workers who regularly use products containing the notified polymer is expected to be of a similar or lesser extent than that experienced by members of the public who use such products on a regular basis. For details of the public health risk assessment, see Section 6.3.2.

6.3.2. Public Health
The general public will be repeatedly exposed to the notified polymer during the use of cosmetic products containing the notified polymer (proposed to be used at up to 10% concentration, noting that the typical usage concentration will be 2-3%).

Local effects
Based on the information available, the notified polymer is considered to be a skin and eye irritant. However, as the notified polymer will be present in cosmetic products at concentrations ≤ 10%, skin and eye irritation effects are not expected. Based on the limited available repeated dose toxicity data on an analogue polymer, the risk of adverse nasal irritancy effects cannot be ruled out.

Systemic effects
The potential systemic exposure to the public from the use of the notified polymer in cosmetic products was estimated to be 3.80 mg/kg bw/day (see Section 6.1.2.). Using a NOAEL of 80 mg/kg bw/day, which was derived from a repeated dose toxicity study on an analogue polymer, the margin of exposure (MOE) was estimated to be 21. A MOE value greater than or equal to 100 is considered acceptable to account for intra- and inter-species differences, therefore, the MOE is considered to be unacceptable.

Reducing the concentration of the notified chemical in leave-on cosmetic products to 2% and in rinse-off products to 3% gives a recalculated combined internal dose of 0.78 mg/kg bw/day. An acceptable MOE of 102 is then estimated.

As the notified polymer may also increase the dermal absorption of other components of cosmetic products, care should be taken when reformulating the notified chemical into the end-use products.

Therefore, based on the information available, the risk to the public associated with the use of the notified polymer at ≤ 2% in leave-on cosmetic products and ≤ 3% in rinse-off 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 into Australia at 100% or 25% concentration in 20 L or 200 L plastic drums, or in 1000 L tanks. The notified polymer will be reformulated at cosmetic manufacturing sites. Transfer and pumping of the notified polymer into blending vessels, and packing the mixture into end-use containers will be automated. Any spills will be contained using an absorbent material and, along with wastes, will be transported to an offsite industrial disposal facility and disposed of according to state regulations. Transfer hoses and pipes will be washed to the sewer. It is expected that < 0.5% of the annual import volume of the notified polymer will be discharged to the sewer during washout procedures. The notifier estimates that approximately 0.5% of the notified polymer will remain in empty import containers. These containers are expected to be sent for recycling at registered drum recyclers.

RELEASE OF CHEMICAL FROM USE
The notified polymer will be used in the manufacture of personal care products in concentrations up to 10%. The personal care products will be sold to a variety of users, mostly domestic. These products will be used undiluted and any residues will usually be released directly to the sewer.

RELEASE OF CHEMICAL FROM DISPOSAL
The majority of waste containing the notified polymer generated during the manufacture of personal care products will be released to sewer as industrial effluent. As part of the end-use products, the notified polymer is expected to be released to the domestic sewer. Residues of the notified polymer in empty end-use containers are expected to be disposed of to landfill.

7.1.2. Environmental Fate
The notified polymer is expected to be biodegradable (89% biodegradation after 28 days), however, as the notified polymer failed the 10-day biodegradation window, it cannot be classified as readily biodegradable. For the details of the environmental fate studies please refer to Appendix B. The majority of the notified polymer is expected to be released to the sewage system. During waste water treatment processes in sewage treatment plants (STPs), a proportion of the notified polymer is expected to be removed from waste waters due to its likelihood to partition to phase boundaries. The notified polymer that partitions to sludge will be removed with the sludge 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.

If released to surface waters, the notified polymer is expected to partition to suspended solids and organic matter, disperse and eventually degrade. Based on its surface activity and potential to biodegrade, the notified polymer is not expected to bioaccumulate.

7.1.3. Predicted Environmental Concentration (PEC)

With the assumption that all of the notified polymer will be washed into the sewer, the predicted environmental concentration (PEC) was calculated on a nationwide basis. For the worst case scenario it is assumed that there is no removal of the notified polymer during the sewage treatment process.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of polymer released to sewer	1000	kg/year
Days per year where release occurs	365	days/year
Daily polymer release:	2.74	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:	0.61	µg/L
PEC – Ocean:	0.06	µg□L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.61 µg/L may potentially result in a soil concentration of approximately 4.04 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 20.2 µg/kg and 40.4 µg/kg, respectively.

7.2. Environmental Effects Assessment

Full study reports were provided for acute algal toxicity and chronic daphnia toxicity endpoints. Only summary reports were provided for the acute fish and acute daphnia toxicity endpoints. The acute toxicity endpoints were determined for an analogue polymer. The results from ecotoxicological investigations conducted on the notified polymer and the analogue polymer are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	*Result*	*Assessment Conclusion*
Acute Toxicity		
Fish Toxicity (48 hours)	LC50 = 21 mg/L*	Harmful
Daphnia Toxicity (24 hours)	EC50 = 63 mg/L*	Harmful
Algal Toxicity (72 hours)	E_rC50 = 4.7 mg/L*	Toxic
Chronic Toxicity		
Daphnia Toxicity	NOEC = 1.5 mg/L	Not harmful
Algal Toxicity	NOEC = 1.0 mg/L*	Harmful

*Determined for an analogue polymer

Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) the notified polymer is classified as acutely harmful to fish and aquatic invertebrates, and toxic to algae. Based on the acute toxicity to algae, the notified polymer is formally classified under the GHS as "Acute Category 2: Toxic to aquatic life". Two adequate chronic toxicity endpoints were available (daphnia and algae). Therefore, the long-term classification for the notified polymer was determined based on the most stringent outcome by comparing the long-term hazard classification using either the acute or chronic data. The most stringent outcome resulted from classification based on the chronic endpoint for algae. The notified polymer is therefore formally classified under the GHS as "Chronic category 3; Harmful to aquatic life with long lasting effects".

7.2.1. Predicted No-Effect Concentration

The endpoint for the most sensitive species from the reported results was used to calculate the predicted no-effect concentration (PNEC). An assessment factor of 500 was used as full study reports were available on the acute and chronic toxicity endpoints for algae, but no full study reports were provided for acute toxicity to fish or aquatic invertebrates. The acute endpoint for algae was used because it provides the lowest, most conservative PNEC value. Furthermore, the endpoints are for an analogue polymer.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
E_rC50 (Algae)	4.7	mg/L
Assessment Factor	500	
PNEC:	9.4	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.61	9.4	0.065
Q - Ocean	0.061	9.4	0.0065

The Risk Quotients (Q = PEC/PNEC) for the worst case discharge scenario have been calculated to be < 1 for the river and ocean compartments. The notified polymer is not expected to persist or bioaccumulate in the environment, therefore the notified polymer is not expected to pose an unreasonable risk to the aquatic environment based on its assessed use pattern.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Skin sensitisation

TEST SUBSTANCE	95:5 Notified polymer: analogue polymer
METHOD	OECD TG 406 Skin Sensitisation - Buehler Test.
Species/Strain	Guinea pig/SPF Albino
PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical: 100% (v/v)
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 10
INDUCTION PHASE	Induction Concentration: topical: 100% (v/v)
Signs of Irritation	No signs of irritation were observed
CHALLENGE PHASE	
1st challenge	topical: 75% (v/v)
Remarks - Method	The vehicle was water. While no irritation was noted from application of the test substance at any concentration (25-100%) in the preliminary study, 75% was selected as the challenge dose concentration.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	75%	0	0
Control Group	75%	0	0

Remarks - Results	No signs of skin reactions were noted in either the control group or test group following challange.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the mixture containing the notified polymer under the conditions of the test.
TEST FACILITY	Frey-Tox (2005)

A.2. Repeat dose toxicity

TEST SUBSTANCE	Analogue polymer
METHOD	OECD TG 408 Repeated Dose 90-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.26 Repeated Dose (90 Days) Toxicity (Oral).
Species/Strain	Rat/HSDBrl:WH Wistar
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 90 days Dose regimen: 7 days per week
Vehicle	Water
Remarks - Method	No significant protocol deviations. Individual animal data were not provided.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	10 male, 10 female	0	0
low dose	10 male, 10 female	50	0
Medium dose	10 male, 10 female	80	0
high dose	10 male, 10 female	150	0

Clinical Observations

The main clinical observation was salivation, which was observed in animals of the high dose group of both sexes. Statistically significantly reduced mean body weight gain was observed in all male dose groups and was assumed by the study authors to be test-substance related for the high dose group. While there were no statistically significant reductions in mean body weights in females, an apparent decrease was noted for females of the high dose group (especially in the final month of treatment). Mean food consumption was statistically significantly reduced in high dose males (and statistically significantly increased in low-dose females.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

In general, any findings were considered by the study authors to not be toxicologically significant.

Statistically significantly decreased mean cholesterol levels were noted in high dose males, which were assumed by the study authors to be treatment-related.

Individual high platelet determinations were noted in animals of the high and mid-dose groups, with the mean value being statistically significant in mid-dose males. The study authors indicate that as slight decreases in clotting values were also found, there may be an influence on the intrinsic clotting system.

Effects in Organs

At necropsy, isolated observations were made (e.g. cyst on the kidney of a single high dose male), but related histopathological findings were not found and/or the findings were not considered by the study authors to be of toxicological relevance or a treatment association could not be concluded.

Treatment related lesions in the nasal respiratory epithelium were noted in the animals of all treated dosage groups and in the keratinised stomachs of the high dose males (mild gastric acanthosis; not significant in high-dose females).

The study authors note that there was an increased incidence in a mild degree of renal globular eosinophilic cytoplasmic inclusions (male rats only), with a suggested trend towards a treatment relationship, however, it was not considered numerically significant.

Statistically significant changes in mean organ weights were observed for the liver (male high dose group: decreased absolute weight; female high dose group: increased absolute and relative weights, with statistical significance for the relative weight), spleen (male high dose group: decreased absolute weight), thymus (mean and absolute values lower for all treated groups; statistical significance in low- and high dose males), kidney (decreased absolute and relative weights in low- and mid-dose females), brain (decreased relative weight in treated male groups), testes (increased relative weight in treated male groups) and epididymides (decreased absolute weight in high dose males. Due to the decreased body weights in males (resulting in increased relative weights of certain organs) and/or lack of apparent dose-response relationships and/or lack of associated histopathological findings, the study authors considered the most relevant findings to be to the spleen, thymus and kidneys (although it is noted that overall, the effects at the low- and mid- dose levels were not considered by the study authors to be adverse).

Remarks – Results

The study authors indicate that the reduced weight gain (and reduced feed consumption of the high dose males) corresponded with the histopathological assessment regarding gastric acanthosis, and may have been due to local irritation. Furthermore, the authors note that while no regurgitation was observed in the study, it cannot be ruled out that the nasal epithelium effects were caused by local irritation (and hence is not representative of a systemic effect). This was investigated further in a follow-up study (see A.3. Repeat dose toxicity).

The study authors concluded that the effects that were observed were not clearly dose related or may be attributed to local effects (with the recommendation that further studies be conducted). The NOAEL was established by the authors based on the main findings (high dose) of lesions present in the stomachs at histopathology, reduced weight gain and reduction in food intake, in combination with the findings such as the nasal respiratory epithelium lesions and the organ weight results (kidneys, thymus and spleen).

CONCLUSION
The No Observed (Adverse) Effect Level (NO(A)EL) was established by the study authors as 80 mg/kg bw/day in this study.

TEST FACILITY BSL Bioservice (2004)

A.3. Repeat dose toxicity

TEST SUBSTANCE Analogue polymer

METHOD

Species/Strain	Rat/HsdRccHan-WIST
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week
Vehicle	Water
Remarks - Method	Study was undertaken to verify the findings in the nasal respiratory epithelium in a 90-day repeated dose toxicity study (see A.2. Repeat dose toxicity) – with a focus on the organs at the portal route of entry. - Animals were housed in metabolic cages to avoid ingestion of faeces. - Single dosage level: 150 mg/kg bw/day (application volume 10 mL/kg bw/day). - Body weight measurements (weekly) and clinical observations (≥ 1/day) were conducted during the treatment period. -At necropsy, the weights of the kidney and thymus were recorded and histopathological evaluation performed on preserved tissues (nose and any with gross lesions). Individual animal data were not provided.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5 male, 5 female	0	0
treatment	5 male, 5 female	150	0

Clinical Observations
Salivation was observed in treated animals in weeks 3 and 4. In a single treated male animal, slightly blood stained, foamy discharge from the nose was noted on days 16-18. In a single treated female animal, respiratory sounds were noted on day 26.

Statistically significantly reduced mean weight gain was noted in treated males.

Effects in Organs
There were no statistically significant effects of treatment on the mean relative and absolute kidney weights. The mean absolute and relative thymus weights of treated males were decreased relative to the control animals, but the effect was not statistically significant.

Histopathological findings in the nasal cavities of the treated animals were noted. The noted effects included widespread luminal neutrophilic exudate, degenerative, inflammatory and reparative lesions of the olfactory and respiratory epithelium and inflammation and hyperplasia of the transitional epithelium. In addition, the squamous epithelium was infiltrated with neutrophilic granulocytes (minor amounts and in 2 males only).

CONCLUSION
The No Observed (Adverse) Effect Level (NO(A)EL) was not established in this study. Based on the effects observed, the study authors noted that based on the unspecified character and widespread distribution of the nasal mucosal changes, the nasal lesions were probably related to a local irritant effect, e.g. from regurgitation of the test substance. However, a direct toxic effect of the test substance on the nasal mucosa via the bloodstream could not be excluded with certainty.

TEST FACILITY BSL Bioservice (2006)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Environmental Fate

B.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Activated sludge, non-adapted
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Dissolved organic carbon (DOC) and total inorganic carbon (TIC) were measured with a TC Analyser (Shimadzu TOC-5050A)
Remarks - Method	The method was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
4	10	14	100
14	50.4		
28	89.3		

Remarks - Results	The difference of extremes of replicate values of the removal of the test item at the end of the test was 20.4%, which is just outside the 20% difference required by the test guideline. However, all other test validity criteria were met. The test substance was found to degrade over 28 days, however, as it failed to pass the 10-day window under the chosen test conditions, it cannot be classified as readily biodegradable. No inhibitory effects of the test item were observed in the toxicity control.
CONCLUSION	The notified polymer cannot be considered as readily biodegradable as it failed the 10-day window under the chosen test conditions.
TEST FACILITY	Fraunhofer- IME (2007)

B.2. Ecotoxicological Investigations

B.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue polymer
METHOD	German standard methods corresponding to OECD TG 203 Fish, Acute Toxicity Test - Static.
Species	*Leuciscus idus* (Golden orfe)
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Visual
Remarks – Method	A full study report was not provided. No deviations to the protocol were reported in the study summary.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*3 h*	*6 h*	*24 h*	*48 h*
15*	-	10	NR	NR	NR	0
30*	-	10	NR	NR	NR	10

* Various concentrations and control but not recorded. LC0 and LC100 recorded.

LC50	22 mg/L at 48 hours. A calculation of the geometric mean, produces a more conservative value of 21 mg/L.
NOEC	15 mg/L at 48 hours.
Remarks – Results	A full study report was not provided. As the test was not confirmed to have met the validity criteria, the toxicological data should be used with caution.

CONCLUSION The notified polymer is harmful to fish.

TEST FACILITY Henkel (1997a)

B.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Analogue polymer

METHOD German standard method corresponding to OECD TG 202 *Daphnia*, Acute Toxicity Test – 24 hour, Static Test.

Species	*Daphnia magna*
Exposure Period	24 hours
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Visual
Remarks - Method	A full study report was not provided. No deviations to the protocol were reported in the study summary.

RESULTS

Concentration mg/L		*Number of Daphnids*	*Mortality*		
Nominal	*Actual*		*3 h*	*12 h*	*24 h*
40*	-	20	NR	NR	0
100*	-	20	NR	NR	20

* Various concentrations and control but not recorded. LC0 and LC100 recorded.

EC50	70 mg/L at 24 hours. A calculation of the geometric mean, produces a more conservative value of 63 mg/L.
NOEC	40 mg/L at 24 hours
Remarks - Results	A full study report was not provided. As the test was not confirmed to have met the validity criteria, the toxicological data should be used with caution.

CONCLUSION The notified polymer is harmful to aquatic invertebrates when exposed for 24 hours.

TEST FACILITY Henkel (1997b)

B.2.3. Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Notified polymer

METHOD OECD TG 211 *Daphnia magna*, Reproduction test (1998) – semi-static

Species	*Daphnia magna*
Exposure Period	21 days

Auxiliary Solvent	None
Water Hardness	Total hardness 2.2 - 3.2 mmol/L
Analytical Monitoring	Total carbon content measured using Carbon analyser (DIMATOC 100 (Fa. Dimatec Essen))
Remarks - Method	The method was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations.

RESULTS

Test Day 21			
Concentration (mg/L)	Mean Number of Offspring Released	Number of Adult Daphnids Immobilized	Percent parental survival (%)
Control	80 ± 13	0	100
0.15	82 ± 15	0	100
0.47	80 ± 9	0	100
1.5	75 ± 14	0	100
4.8	37 ± 17	5	75
15.4	-	20	0

EC50 (reproduction)	4.3 mg/L at 21 days
NOEC (reproduction)	1.5 mg/L at 21 days
Remarks - Results	All relevant test validity criteria were met.

CONCLUSION The notified polymer does not have long lasting harmful effects on aquatic invertebrates.

TEST FACILITY Stockhausen (2003)

B.2.4. Algal growth inhibition test

TEST SUBSTANCE Analogue polymer

METHOD DIN 38412 (part 9) understood to be equivalent to OECD TG 201

Species	*Scenedesmus subspicatus* now known as *Desmodesmus subspicatus* (Green algae)
Exposure Period	72 hours
Concentration Range	Nominal: 1, 3, 10, 30, 100, 300 and 1000 mg/L Actual: Not Measured
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Cell densities were determined using a Coulter counter
Remarks - Method	The method was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations.

RESULTS

Biomass		*Growth*	
E_bC50	*NOEC*	*E_rC50*	*NOEC*
mg/L at 72 h	*mg/L*	*mg/L 72 h*	*mg/L*
2.5	1.0	4.7	Not Determined

Remarks - Results	All relevant test validity criteria were met. Water hardness was not reported in the study report and this may affect algal growth.

CONCLUSION The notified polymer is toxic to algae

TEST FACILITY Henkel (1995)

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