File No: LTD/1889

July 2016

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

1-Propanaminium, *N*,*N*,*N*-trimethyl-3-[(1-oxo-2-propen-1-yl)amino]-, chloride (1:1), polymer with 2-hydroxyethyl 2-propenoate

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/1889	Ixom Operations Pty Ltd	1-Propanaminium, *N*,*N*,*N*-trimethyl-3-[(1-oxo-2-propen-1-yl)amino]-, chloride (1:1), polymer with 2-hydroxyethyl 2-propenoate	ND*	< 10 tonnes per annum	Component of cosmetic products

*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

REGULATORY CONTROLS

Hazard Classification and Labelling

- Due to the corrosive properties of the product containing the notified polymer, the notifier should consider their obligations under the Australian Dangerous Goods Code (NTC, 2007).

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:
  - Enclosed, automated processes, where possible
  - Adequate general ventilation and local exhaust ventilation if necessary

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

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during reformulation:
  - Glasses, goggles or face shield
  - Respiratory protection if necessary

  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.

Storage

- The handling and storage of the product containing the notified polymer should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

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 1,000;
- the polymer is proposed to be used in aerosol cosmetic spray products;
- the concentration of the polymer is intended to exceed 3% in cosmetic products;

or

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

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

(Material) Safety Data Sheet
The (M)SDS of a product containing 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)
Ixom Operations Pty Ltd (ABN: 51 600 546 512)
70 Marple Avenue
VILLAWOOD NSW 2163

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

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

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
SIMULQUAT HC 305 (product mixture containing the notified polymer at < 50% concentration)

CAS NUMBER
112783-16-1

CHEMICAL NAME
1-Propanaminium, *N*,*N*,*N*-trimethyl-3-[(1-oxo-2-propen-1-yl)amino]-, chloride (1:1), polymer with 2-hydroxyethyl 2-propenoate

OTHER NAME(S)
Acrylamidopropyltrimonium Chloride/Acrylates Copolymer (INCI name covering the notified polymer)

MOLECULAR WEIGHT
> 10,000 Da

ANALYTICAL DATA
A reference IR spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY
> 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Liquid*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Expected to be high based on structure
Boiling Point	Not determined	Expected to be high based on structure
Density	Not determined	-
Vapour Pressure	Not determined	Expected to be low based on high molecular weight
Water Solubility	Not determined	Expected to be water absorbing based on high molecular weight and molecular structure
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities; however, not expected to rapidly 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 strongly to soil and sediment based on surface activity and cationic properties
Dissociation Constant	Not determined	Expected to be ionised under environmental conditions (pH 4-9)
Flash Point	> 102 °C (closed cup)	Estimated. (M)SDS*
Flammability	Not determined	-
Autoignition Temperature	Not determined	-
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

*For the product mixture SIMULQUAT HC 305 containing the notified polymer at < 50% concentration

DISCUSSION OF PROPERTIES
The notified polymer is formed by radical polymerisation in inverse emulsion and is not isolated from the reaction mixture. The notified polymer is a high molecular weight water swellable polyacrylate.

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.

However, when tested for metal corrosion (Institut de la Corrosion, 2014), SIMULQUAT HC 305 containing the notified polymer at < 50% concentration is consider as a Dangerous Goods of Class 8, Packing group III – Substances and preparations presenting minor danger.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia. The notified polymer will be imported in the product mixture SIMULQUAT HC 305 at < 50% concentration for formulation of cosmetic products. The notified polymer will also be imported as a component of finished cosmetic products at < 3% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 10	< 10	< 10	< 10	< 10

PORT OF ENTRY
Sydney

TRANSPORTATION AND PACKAGING
The product mixture SIMULQUAT HC 305 containing the notified polymer at < 50% concentration will be imported in 30 kg plastic barrels. The notified polymer will also be imported in finished cosmetic products at < 3% concentration in containers suitable for retail sale (≤ 500 mL plastic/HDPE bottles or tubes). SIMULQUAT HC 305 and the finished cosmetic products containing the notified polymer will be transported by road or rail for distribution to industrial customers or retailers.

USE
The notified polymer will be used as a component of leave-on and rinse-off cosmetic products at < 3% concentration. It will not be used in aerosol spray products, but may be used in pump sprays.

OPERATION DESCRIPTION
The notified polymer will be imported as a component of the product mixture SIMULQUAT HC 305 at < 50% concentration for formulation of cosmetic products, or as a component of finished cosmetic products at < 3% concentration, which will be sold to the public in the same form in which they are imported.

Reformulation
The procedures for incorporating the product mixture SIMULQUAT HC 305 containing the notified polymer at < 50% 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 for the reformulation process, SIMULQUAT HC 305 will be weighed and added to the mixing tank where it will be blended with additional additives to form the finished cosmetic products. This will be followed by automated filling of the reformulated products into containers of various sizes. The blending operations are expected to be highly automated and use closed systems and/or adequate ventilation. During the formulation process, samples of SIMULQUAT HC 305 and the finished cosmetic products will be taken for quality control testing.

End-use
Finished cosmetic products containing the notified polymer at < 3% 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. The notified polymer will not be used in any aerosol spray products but may potentially be used in hair styling products with pump spray mechanism.

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 workers	4	12
Production compounders	8	12
Chemists	3	12
Packers (for dispensing)	8	12
Store persons	4	12
Professional end users	8	365

EXPOSURE DETAILS
Transport and storage
Transport and storage workers are not expected to come into contact with the notified polymer when handling packaged products containing the notified polymer unless accidental breach of sealed packaging occurs.

Reformulation
During reformulation into cosmetic products, dermal, ocular and inhalation exposure of workers to the notified polymer at < 50% 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 < 3% concentration may occur in professions where the services provided involve the application of cosmetic products to clients (e.g. hair dressers, workers in beauty salons). The principal route of exposure will be dermal. Such professionals may use some PPE to minimise repeated exposure, but this is not expected to occur in all workplaces. However, good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or less extent than that experienced by consumers using the products containing the notified polymer.

6.1.2. Public Exposure
There will be widespread and repeated exposure of the public to the notified polymer at < 3% concentration through the use of cosmetic products. The principal route of exposure will be dermal. Accidental ocular and oral exposure (from the use of lip products) is also possible. Given the high molecular weight of the notified polymer absorption by all exposure routes is not expected, therefore the systemic daily exposure for all products has not been calculated.

The notified polymer is proposed to be used in hair styling spray products. Potential for inhalation exposure to the notified polymer at < 3% concentration may exist. However, the spray mechanism of proposed type of products will be limited to pump spray that does not generate respirable aerosols. Based on the proposed use patterns inhalation exposure that may cause long-term lung effects is not expected (see Section 6.3.2.).

6.2. Human Health Effects Assessment
The results from toxicological investigations conducted on SIMULQUAT HC 305 containing the notified polymer at < 50% concentration are summarised in the following table. For full details of the studies, refer to Appendix A.

Endpoint	*Result and Assessment Conclusion*
Skin irritation (*in vitro* Reconstructed Human *Epidermis* Test)	non-irritating
Skin irritation (Human Volunteer Patch Test)	non-irritating
Eye irritation (*in vitro* BCOP)	not corrosive or severely irritating
Eye irritation (*in vitro* HET-CAM) (up to 5% test substance)	non-irritating
Human, skin sensitisation – RIPT (5% test substance)	no evidence of sensitisation, non-irritating

Given the limited information available for the notified polymer, analogue data is also used to estimate the human health effects of the notified polymer. The analogues (A and B) are polymerised trimonium compounds structurally similar to the notified polymer. Data for the analogues are available from a Cosmetic Ingredient Review (CIR) report (CIR, 2012a).

Toxicokinetics
No toxicokinetic data for the notified polymer was submitted. Based on the high molecular weight of the notified polymer, absorption across biological membranes is not expected.

Acute toxicity
No acute toxicity study reports were provided for the notified polymer.

Based on the CIR report (CIR, 2012a), the oral LD50 of Analogue A in rats was reported to be > 5,000 mg/kg bw. The dermal and oral LD50 of Analogue B in rats were reported as > 4,000 and 16,000 mg/kg bw, respectively.

Based on the results from analogue studies, the notified polymer is likely to be of low acute oral and dermal toxicity.

Irritation and sensitisation
The product mixture (SIMULQUAT HC 305) containing the notified polymer at < 50% concentration was non-irritating to skin when tested in an *in vitro* skin irritation study or patch test on human volunteers.

Two *in vitro* ocular studies have been conducted with the product mixture (SIMULQUAT HC 305) containing the notified polymer at < 50% concentration. In an *in vitro* eye irritation study using the HET-CAM model, SIMULQUAT HC 305 at up to 5% concentration (< 2.5% notified polymer) did not cause an irritation response. SIMULQUAT HC 305 was also found not to be corrosive or severely irritating to the eyes in a bovine corneal opacity and permeability (BCOP) test. However, the study could not conclude whether SIMULQUAT HC 305

was an irritant or non-irritant. Based on the CIR report (CIR, 2012a), Analogue B was non-irritating in rabbits at 5% concentration but produced trace eye irritation in one eye at 10% concentration. Based on the available information, the notified polymer is not expected to be irritating to the eyes at up to 5% concentration; however, eye irritation at higher concentrations cannot be ruled out.

A repeated insult patch test (RIPT) using 5% SIMULQUAT HC 305 (< 2.5% notified polymer) did not reveal any evidence of skin sensitisation.

Repeated dose toxicity
No repeated dose toxicity study report was provided for the notified polymer. The CIR report (CIR, 2012a) indicated that Analogue B demonstrated no toxicity to rabbits when tested at 1% concentration for 21 days via the dermal route.

Mutagenicity/Genotoxicity
No study reports on mutagenicity/genotoxicity of the notified polymer were provided. Based on the CIR report (CIR, 2012a), Analogue A at 20% concentration was negative in a reverse mutation assay using *Salmonella typhimurium* with or without metabolic activation. In a micronucleus assay using the bone marrow cells of mice, Analogue A did not induce an increase in bone marrow polychromatic erythrocytes. Analogue B was also negative in genotoxicity tests using *S. typhimurium* or Chinese hamster ovary cells with or without metabolic activation. There was no increase in micronucleated polychromatic erythrocytes when mice were treated with Analogue B up to 400 mg/kg bw.

Based on the results from analogue studies, the notified polymer is likely to be of low genotoxicity.

Potential for long-term lung effects
The notified polymer is a high molecular weight water absorbing polymer. This category of polymers have concern for long-term adverse lung effects, including fibrosis and cancer, based on data showing that cancer was observed in a two-year inhalation study in rats on a high molecular weight water-absorbing polyacrylate polymer (US EPA, 2015).

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
Based on the available information, the notified polymer may have potential to cause long-term adverse lung effects, including fibrosis and cancer, if inhaled. In addition, the potential to cause eye irritation at high concentrations cannot be ruled out.

Reformulation
Ocular exposure of the compounders and chemists to SIMULQUAT HC 305 with < 50% concentration of the notified polymer may occur during formulation of cosmetics. Packers may come into contact with cosmetics containing the notified polymer at < 3% concentration. However, significant inhalation exposure of workers to the notified polymer is not expected unless aerosols and mists are formed in the workplaces. As stated by the notifier, the use of PPE such as safety glasses and engineering controls including automated and enclosed blending processes and local exhaust ventilation should minimise the risk for workers. Provided that the protective measures and engineering controls proposed are implemented, the use of the notified polymer is not expected to pose an unreasonable risk to workers under the occupational conditions described.

End use
Store persons and professional end users may come into contact with cosmetic products containing the notified polymer at < 3% concentration. These products will also be available to the public. The risk to workers who regularly handle these products is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified polymer (for details of the public health risk assessment, see Section 6.3.2).

6.3.2. Public Health

Cosmetic products containing the notified polymer at < 3% concentration will be sold to the public. The main route of exposure is expected to be dermal with some potential for ocular or oral exposure. The notified polymer has potential for eye irritation at high concentration; however at the end use concentrations eye irritation effects are not expected. Systemic toxicity is not expected given the high molecular weight of the notified polymer.

The notified polymer is a high molecular weight water swellable polyacrylate that may be a concern to cause long-term adverse lung effects if inhaled. It has been proposed that the notified polymer may be used in hair styling spray products with pump spray mechanism. Based on a CIR article (CIR, 2012b), both pump sprays and propellant sprays (also called "aerosol sprays") produce aerosols, but the aerosols from pump sprays have much smaller fractions of respirable droplets/particles than aerosols from propellant sprays. Typically, the median aerodynamic equivalent diameter (d_{ae}) of the airborne droplets/particles of pump hair sprays range from 60 to 80 µm with < 1% of the droplets/particles having d_{ae} < 10 µm.

Droplets/particles with d_{ae} > 10 µm may enter the nasopharyngeal region through the nose/mouth or pass through the larynx to enter the trachea, bronchi and bronchioles. In these regions of the respiratory tract, mucus-secreting and ciliated cells form a protective mucociliary blanket that carries deposited droplets/particles to the throat to be sneezed or spit out or swallowed. There is also scientific consensus that healthy people are able to clear particles with d_{ae} > 7 µm from the nasopharyngeal and bronchial regions within 24 hours through mucociliary action (CIR, 2012b).

However, droplets/particles with d_{ae} < 10 µm may reach pulmonary region of the lung. In the pulmonary region, the clearance of inert particles is mediated primarily by alveolar macrophages, and is slow and limited (CIR, 2012b). Therefore, to avoid the potential for long-term adverse lung effects, the notified polymer should not be used in spray products that are capable of generating respirable aerosols with d_{ae} < 10 µm during use.

Based on the available information and proposed use scenario, the risk to the public from use of the notified polymer at < 3% in rinse-off and leave-on cosmetics 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 not be manufactured in Australia. The notified polymer will be imported in the product mixture SIMULQUAT HC 305 at < 50% concentration for formulation of cosmetic products, or as a component of finished cosmetic formulations. Release of the notified polymer to the environment from transport and storage is unlikely, except in the case of accidental spills and leaks. 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 may be collected and released to sewers or disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The notified polymer is a component of rinse-off and leave-on cosmetic 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

It is estimated that a maximum of 4% (or up to 400 kg) of the notified polymer may remain in import containers after reformulation and 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 cosmetic formulations, the majority of the notified polymer is expected to enter the sewer system, before potential release to surface waters nationwide. Based on the results of a ready biodegradability study, the notified polymer is not considered readily biodegradable (3.53% in 28 days). For details of the environmental fate study, please refer to Appendix B. Based on its high molecular weight and cationic properties, up to 90% of the notified polymer is expected to adsorb to sludge and sediment during sewage treatment plant (STP) processes (Boethling and Nabholz, 1997). 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 and nitrogen.

The majority of the notified polymer will be released to sewer after use. A 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, or disposed of 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 and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated to assume a worst case scenario, with 100% release of the notified polymer into sewer systems nationwide and no removal within sewage treatment plants (STPs).

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	10,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	27.40	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:	6.058	µg/L
PEC - Ocean:	0.606	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 6.06 µg/L may potentially result in a soil concentration of approximately 40.39 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 201.9 µg/kg and 403.9 µg/kg respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted for the notified polymer. Ecotoxicological endpoints for aquatic organisms for the notified polymer were calculated based on structure-activity relationship (SAR) equations, assuming a worst case cationic charge density for the polymer (Boethling and Nabholz, 1997). The endpoints are summarised in the table below.

Endpoint	*Result*	*Assessment Conclusion*
Acute Toxicity		
Fish	96 h LC50 = 34.11 mg/L	Predicted to be harmful to fish
Daphnia	48 h EC50 = 15.08 mg/L	Predicted to be harmful to *Daphnia*
Algae	96 h EC50 = 3.28 mg/L	Predicted to be toxic to algae

Endpoint	*Result*	*Assessment Conclusion*
Chronic Toxicity		
Fish	ChV = 1.90 mg/L	Not predicted to be harmful to fish in the long term
Daphnia	ChV = 0.84 mg/L	Predicted to be toxic to *Daphnia* in the long term
Algae	ChV = 0.84 mg/L	Predicted to be toxic to algae in the long term

Based on the above worst case SAR estimations, the notified polymer is potentially acutely toxic to algae and acutely harmful to fish and aquatic invertebrates, and is potentially chronically toxic to aquatic invertebrates and algae. The SAR estimation procedure used here is a standard approach, and is considered reliable to provide general indications of the likely environmental effects of the polymer for the purposes of risk assessment. However, this method is not considered sufficient to formally classify the acute and chronic hazards of the notified polymer to aquatic life under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated from the most sensitive endpoint for *Daphnia*. A safety factor of 10 was used given acute and chronic endpoints for three trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
NOEC (*Daphnia*, ChV)	0.84	mg/L
Assessment Factor	10	
Mitigation Factor	1.00	
PNEC:	84	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	6.058	84	**0.072**
Q – Ocean	0.606	84	**0.007**

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 readily biodegradable, it is expected to have a low potential for bioaccumulation. On the basis of the PEC/PNEC ratio, maximum annual importation volume and assessed use pattern in cosmetic formulations, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Irritation – skin (*in vitro*)

TEST SUBSTANCE	SIMULQUAT HC 305 (product mixture containing < 50% notified polymer)
METHOD	OECD TG 439 *In vitro* Skin Irritation: Reconstructed Human *Epidermis* Test Method EC Commission Regulation No 761/2009 B.46 *In Vitro* Skin Irritation: Reconstructed Human Epidermis Model Test
Vehicle	None. The test substance was directly applied to Epidermis model.
Remarks - Method	No significant deviations of protocol were noted. Sodium dodecyl sulphate (SDS) aqueous solution at 5% (w/v) was used as a positive control and Dulbecco's phosphate-buffered saline (D-PBS) was used as a negative control.

RESULTS

Test material	*Mean OD_{570} of triplicate tissues*	*Relative mean Viability (%)*	*SD of relative mean viability*
Negative control	0.941	100	3
Test substance	0.878	93	15
Positive control	0.064	7	1

OD = optical density; SD = standard deviation

Remarks - Results	In a preliminary test the test substance did not have any direct MTT reducing properties. As the mean relative viability was > 50%, the test substance is considered a non-irritant to skin.
CONCLUSION	The notified polymer was considered non-irritating to the skin under the conditions of the test.
TEST FACILITY	Exempt information (2014a)

A.2. Irritation – skin (patch test)

TEST SUBSTANCE	SIMULQUAT HC 305 (product mixture containing < 50% notified polymer)
METHOD	Occlusive patch test on scapular part of the back
Volunteers	22 (16 F/6 M) volunteers aged 20 to 36 years participated.
Vehicle	None
Application Period	48 hours
Type of Dressing	Occlusive
Remarks - Method	Single application of 25 µL of the test substance was applied with Finn Chambers® 8 mm (50 mm^2) occlusive patch to the test area and maintained for 48 hours. The macroscopic skin examinations were carried out 30 minutes and 24 hours after the patch removal.
RESULTS	Very slight erythema (score of 0.5) was observed in two female participants at the 30 minute reading that was resolved after 24 hours. No other skin reactions were recorded. Mean cumulative irritation index (MCII) was determined to be 0.02, below the interpretation criteria for an irritant.
Remarks - Results	All volunteers completed the test.

CONCLUSION The notified polymer is non-irritating to the skin under the conditions of the test.

TEST FACILITY Exempt information (2014b)

A.3. Irritation – eye (*in vitro* BCOP)

TEST SUBSTANCE SIMULQUAT HC 305 (product mixture containing < 50% notified polymer)

METHOD OECD TG 437 Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants

Vehicle None

Remarks - Method No significant deviations of protocol were noted. Sodium hydroxide solution (10%) was used as a positive control and sodium chloride solution (0.9%) was used as a negative control.

RESULTS

Test material	*Mean opacity of triplicate tissues (SD)*	*Mean permeability of triplicate tissues (SD)*	*IVIS (SD)*
Negative control	0.7 (±0.6)	0.004 (±0.006)	-
*Test substance**	9.3 (±5.6)	0.008 (±0.002)	9 (±5.6)
*Positive control**	175.0 (±57.6)	5.466 (±1.662)	257 (±65.0)

SD = Standard deviation; IVIS = *in vitro* irritancy score
*Corrected for background values

Remarks - Results The test substance induced an IVIS between 3 and 55, and was not identified as an ocular corrosive or severe irritant, but no prediction could be made on the irritant properties of the test substance to the eye.

CONCLUSION The notified polymer was not corrosive or a severe eye irritant under the conditions of the test.

TEST FACILITY Exempt information (2014c)

A.4. Irritation – eye (*in vitro* HET-CAM)

TEST SUBSTANCE SIMULQUAT HC 305 (product mixture containing < 50% notified polymer)

METHOD HET-CAM Test - Official Journal of the Republic France (#302, 26 December 1996)

Vehicle Water

Remarks - Method No GLP compliance statement was present.

3 doses of the test substance were tested:

- 1%
- 3% with 0.5% NaCl
- 5% with 0.5% NaCl

0.3 mL of the prepared sample was spread over the chorio-allantoïc membrane and rinsed off with 10 mL of water after 20 seconds. The treated membranes were observed for 301 seconds to record signs of hyperaemia (Hy), haemorrhage (Ha) and coagulation (Co).

Total score was calculated as:

$$Total\ score = 5 \times (301 - T_{Hy}) + 7 \times (301 - T_{Ha}) + 9 \times (301 - T_{Co})$$

(Where T represents average time in seconds from 4 to 6 samples when the reaction signs were observed)

RESULTS

Dose (% w/w)	*Average time (second)*			*Total score*
	Hyperaemia	Haemorrhage	Coagulation	
1	301	301	301	0
3	301	301	301	0
5	301	301	301	0

Remarks - Results: Based on the interpretation criteria, score < 1 was considered as non-irritant.

CONCLUSION: The test substance was considered to be non-irritating to the eye under the conditions of the test.

TEST FACILITY: Exempt information (2014d)

A.5. Skin sensitisation – human volunteers

TEST SUBSTANCE: Cosmetic product containing 5% SIMULQUAT HC 305 (< 2.5% notified polymer)

METHOD: Repeated insult patch test with challenge (Marzulli-Maibach Method)

Study Design: Induction Procedure: 25 µL test substance was applied to homolateral scapular zone of the skin for 48 hours. The applications were repeated 3 times a week for 3 weeks.

Rest Period: 2 weeks

Challenge Procedure: 25 µL test substance was applied to contralateral scapular zone of the skin for 48 hours. Skin reactions were observed for 1 week.

Study Group: 84 F, 16 M; age range 18 to 70 years

Vehicle: None

Remarks - Method: Occluded. The test substance was spread on Finn Champers on Scanpor® (with an unspecified patch size).

RESULTS

Remarks - Results: No significant skin reactions were observed during the study.

CONCLUSION: The test substance containing < 2.5% notified polymer was considered non-irritating and non-sensitising under the conditions of the test.

TEST FACILITY: Exempt information (2014e)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Environmental Fate

B.1.1. Ready biodegradability

TEST SUBSTANCE	SIMULQUAT HC 305 (product mixture containing < 50% notified polymer)
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test
Inoculum	Aerated activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Theoretical Oxygen Demand (ThOD)
Remarks - Method	No significant deviation in protocol was reported.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	2.32	7	80.11
14	2.76	14	87.90
21	2.50	21	91.49
28	3.53	28	94.65

Remarks - Results

All validity criteria for the test were satisfied. The percentage degradation of the reference compound surpassed the threshold level of 60% by 7 days (80.11%) and reached 94.65% degradation by 28 days. Therefore, the test indicates the suitability of the inoculums.

The test substance attained 3.53% degradation by 28 days. Therefore, the test substance is not considered to be readily biodegradable according to the OECD (301 F) guideline.

CONCLUSION: The test substance is not readily biodegradable.

TEST FACILITY: Exempt information (2015)

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