File No: SN/29

October 2017

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Siloxanes and Silicones, 3-[(2-aminoethyl)amino]propyl Me, di-Me, methoxy-terminated, reaction products with polyethylene glycol Bu glycidyl ether

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 and Energy.

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
SN/29	Kimberly-Clark Australia Pty Ltd	Siloxanes and Silicones, 3-[(2-aminoethyl)amino]propyl Me, di-Me, methoxy-terminated, reaction products with polyethylene glycol Bu glycidyl ether	ND*	≤ 44 tonnes per annum	Component of cleansing wet wipes

*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.

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 1	H400 – Very toxic to aquatic life
Chronic Category 2	H411 – Toxic 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 in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A copy of the 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.

Public Health

- Products containing the notified polymer should be formulated in a manner that addresses the possible irritancy potential of the notified polymer.

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
- further information on the sensitisation potential of the notified polymer becomes available;
- the notified polymer is proposed to be used in cleansing wet wipes at concentration > 0.35%;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from component of cleansing wet wipes, 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.

Safety Data Sheet
The 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 SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Kimberly-Clark Australia Pty Ltd (ABN: 65 000 032 333)
52 Alfred Street
MILSONS POINT NSW 2061

Assessment of the notified polymer was carried out under the *Industrial Chemicals (Notification and Assessment) Act 1989* [the IC(NA) Act], as LTD/1668, with the Public Report of the assessment published in the *Chemical Gazette* of 3 September, 2013.

The Director of NICNAS was informed of an additional use of the notified polymer and also a significant increase in the introduction volume of the notified polymer in excess of the permitted volume under the limited category (1 tonne/annum). Under the IC(NA) Act, the Director declared that a secondary notification was required for the chemical known as Siloxanes and Silicones, 3-[(2-aminoethyl)amino]propyl Me, di-Me, methoxy-terminated, reaction products with polyethylene glycol Bu glycidyl ether.

In accordance with section 65 of the *Industrial Chemical (Notification and Assessment) Act 1989* (the Act), notice requiring the secondary notification of Siloxanes and Silicones, 3-[(2-aminoethyl)amino]propyl Me, di-Me, methoxy-terminated, reaction products with polyethylene glycol Bu glycidyl ether was published in the Chemical Gazette. The notice of 5 May, 2017 stipulated that the following data were required to undertake further assessment of Siloxanes and Silicones, 3-[(2-aminoethyl)amino]propyl Me, di-Me, methoxy-terminated, reaction products with polyethylene glycol Bu glycidyl ether;

- Identity, Properties and Uses

Any changes in the following data items from those submitted in the original notification:

a) Proposed uses of the chemical, including concentration in end-use products
b) Import quantity for each product
c) Transportation, packaging and storage
d) Operation description, including disposal
e) Updated exposure scenarios for the environment, workers and the public
f) Any additional physico-chemical data that is available for the notified polymer

- Toxicity

Human Health
Any additional toxicology data that are available for the notified polymer;

Ecotoxicity
Any additional ecotoxicology data that are available for the notified polymer;

- (M)SDS

Copy of (M)SDS for the products, and for the notified polymer itself (if revised).

The requested data may be provided through the submission of studies (tests conducted on the notified polymer or suitable analogue) or other sources of information.

This report, SN/29, represents the revised assessment for Siloxanes and Silicones, 3-[(2-aminoethyl)amino]propyl Me, di-Me, methoxy-terminated, reaction products with polyethylene glycol Bu glycidyl ether. Where additional data has been provided, it has been incorporated into the report (if necessary) and the implications of the data for the health and environmental risks of the notified polymer considered.

NOTIFICATION CATEGORY
Secondary notification

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

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints (except density, water solubility, partition coefficient, and flash point).

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
LTD/1668 (2013)

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Butoxy PEG-4 PG-Amodimethicone (INCI Name)
Amodimethicone
X-22-86-45
KF889

CAS NUMBER
170274-77-8

CHEMICAL NAME
Siloxanes and Silicones, 3-[(2-aminoethyl)amino]propyl Me, di-Me, methoxy-terminated, reaction products with polyethylene glycol Bu glycidyl ether

MOLECULAR FORMULA
Unspecified

MOLECULAR WEIGHT
> 1,000 Da

ANALYTICAL DATA
Reference NMR and IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: colourless to tan translucent liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Estimated to be > 105 °C
Density	1,016 kg/m^3	Measured*
Vapour Pressure	Not determined	Based on the high molecular weight of the polymer, the vapour pressure is expected to be low
Water Solubility	<1.1 g/L at 20 °C	Measured. The notified polymer is expected to be dispersible in water based on hydrophilic functionalities.
Hydrolysis as a Function of pH	Not determined	Not expected to hydrolyse significantly under environmental conditions (pH=4-9)
Partition Coefficient (n-octanol/water)	log Pow = 4.2 – 4.8.at 20 °C	Analogue data. The notified polymer may be surface active and thus it is expected to

		partition to phase boundaries.
Adsorption/Desorption	Not determined	The notified polymer is expected to sorb to soil sediment and sludge based on its potential surface activity and cationicity.
Dissociation Constant	Not determined	The notified polymer has a potential to ionise under environmental conditions (pH 4-9).
Flash Point	208 °C at 98 kPa (open cup)	Measured*
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use
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

*Full study report not provided

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

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

Physical hazard classification
Based on the limited submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported as a component of cleansing wet wipes at ≤ 0.35% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	28	32	36	40	44

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Kimberly-Clark Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be imported into Australia as a component of cleansing wet wipes (at ≤ 0.35% concentration) in consumer packaging, packed in bulk cartons. The products containing the notified polymer will be transported to distribution centres and/or retail outlets.

USE
The notified polymer will be used as a softening agent in baby wet wipes (at 0.3% concentration) and flushable perineal wet wipes (at 0.35% concentration). The baby wet wipes are intended to help clean the skin around a baby's diaper area. The flushable perineal wet wipes are intended to be used for general skin cleaning of the perineal region after going to the toilet and are targeted for use by adults and children

OPERATION DESCRIPTION
The notified polymer will not be manufactured, reformulated or repackaged in Australia.

The imported cleansing wet wipes containing the notified polymer (at ≤ 0.35% concentration) may be used by consumers and professionals (such as childcare and healthcare workers).

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

The imported finished cleansing wet wipes products containing the notified polymer at ≤ 0.35% will not be manufactured, reformulated or repackaged in Australia. Transport, storage and retail workers may only come into contact with the notified polymer in the unlikely event of an accident involving package rupture.

Professional workers (such as in childcare and healthcare facilities) may use products containing the notified polymer at ≤ 0.35%. The primary route of exposure would be dermal. No specific PPE controls are recommended as the products containing the notified polymer are intended for frequent use on skin.

6.1.2. Public Exposure

Wet wipes containing the notified polymer at ≤ 0.35% are intended to clean the skin around the diaper and perineal area. The primary route of exposure would be dermal. Eye exposure is not expected from appropriate use of the wipes. Each wipe contains approximately 6.37 g of cleansing liquid, (of which ~19 mg will be notified polymer). However, only a small residual amount is expected to remain on the skin surface after use.

6.2. Human Health Effects Assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Guinea pig, skin sensitisation	no evidence of sensitisation
Human, skin sensitisation – RIPT (0.5%)	no evidence of sensitisation*
Mutagenicity – bacterial reverse mutation	non mutagenic

* 1/219 subjects showed evidence of sensitisation to the notified polymer, but this individual also showed evidence of sensitization to products that did not contain the notified polymer.

Toxicokinetics

Based on its relatively high molecular weight (> 1,000 Da) and low water solubility, the notified polymer is not expected to be readily absorbed across biological membranes and thus will have relatively low absorption via the skin and GI tract. However, it is noted that the notified polymer has a small percentage of low molecular weight species (< 500 Da) that may be absorbed.

Acute toxicity

The notified polymer was found to be of low acute oral toxicity in a study conducted in rats.

Irritation and sensitisation

The notified polymer was determined to be slightly irritating to the skin of rabbits in a primary dermal irritation study using the Draize scoring scale. Moderate erythema was noted in all animals at 24 h but recovered in most animals to slight or no erythema at 72 h. Very slight oedema was also noted at one abraded patch at 72 h in one animal. A score of 5 or more on the Draize scale indicates a primary dermal irritant. The results indicate that the primary irritation index was 1.80. While under the conditions of the test, the notified polymer is not considered a primary dermal irritant; the notified polymer is considered mildly irritating to the skin of rabbits at 100% concentration.

No *in vivo* data or data tested on the notified polymer alone was provided for eye irritation. An EpiOcular™ Reconstructed Human Corneal Epithelium Model *in vitro* test was conducted on a product containing a combination of chemical ingredients in solution, including the notified polymer at 0.5% concentration; however, this is not currently a validated test method for eye irritation. ET_{50} scores were calculated, which represent the time at which the EpiOcular™ tissue viability was reduced to 50% compared to control tissues. The ET_{50} scores were then converted to an irritancy classification. The product containing the notified polymer at 0.5% was considered as a mild irritant using this system. Therefore, in the absence of any further information on the notified polymer, eye irritation from exposure to the notified polymer at 0.35% cannot be ruled out.

A guinea pig sensitisation (Buehler) test was carried out using 100% notified polymer. Faint erythema was noted during the induction phase in treated animals but no adverse effects or sensitisation was observed on challenge. The test article was found not to be a sensitiser in guinea pigs under the conditions of the test.

A human repeated insult patch test (HRIPT) was conducted on a range of products containing the notified polymer (0.5%) to evaluate sensitisation (see Appendix B for further details). The original test substance (product A) did induce an oedematous reaction indicative of dermal sensitization in 1/219 human subjects. A rechallenge test confirmed dermal sensitisation in this individual. This individual also exhibited dermal sensitisation to three other otherwise identical products that were missing one ingredient. This included a formulation that did not contain the notified polymer (product E). A further two HRIPT studies were conducted, each with 57 individuals. Product C, containing the notified polymer but missing one other ingredient, and a further test with the original test material, product A, showed no sensitisation reactions on challenge with the test substances.

While sensitisation from exposure to the notified polymer cannot be ruled out, based on a weight of evidence approach the notified polymer is not expected to cause sensitisation at 0.35% concentration in cleansing wet wipes.

Repeated dose toxicity
No repeat dose toxicity data were provided for the notified polymer. However, given the low acute toxicity and low expected absorption, particularly via the dermal route, significant adverse effects from repeated use of the notified polymer at 0.35% are not expected.

Mutagenicity/Genotoxicity
The notified polymer tested negative in a bacterial reverse mutation assay.

Observations on human exposure
Cumulative skin irritation tests were carried out using the notified polymer on 30 subjects (28 completed the test). Test materials (4 products; 3 containing the notified polymer at 0.5%) elicited negligible cumulative irritation in these subjects.

A facial sting test was carried out on 10 subjects, to evaluate the potential of the notified polymer to induce a burning, itching, stinging, tightness, tingling and/or warming sensation on the faces of pre-assessed facially sensitive human subjects. Both the test material and the control did not induce any irritation in any of the subjects.

It is noted that all tests have been conducted on adult skin and the irritancy potential in contact with sensitive baby skin has not been evaluated. However, 10 adult subjects with sensitive skin were used in the facial sting test which may be considered similar to the sensitivity of baby skin. Therefore, based on a weight of evidence of animal and human data, the notified polymer is not expected to be irritating to the skin at the use concentration of 0.35%.

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.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified polymer is of low toxicity by the oral route and is not expected to be a skin irritant or sensitiser at the low use concentration of ≤ 0.35%.

Professional workers (such as in childcare and healthcare facilities) may use cleansing wipes containing the notified polymer at ≤ 0.35%. The primary route of exposure would be dermal. While sensitisation to the skin in sensitive individuals cannot be ruled out, the low use concentration of ≤ 0.35% should minimise this risk.

There is uncertainty regarding the potential for eye irritation of the notified polymer; however, given the proposed use of the notified polymer, the risk of eye irritation from the residual concentration of the notified

polymer left on the hands of professional workers, which might accidentally be transferred to the eye, is negligible.

Therefore the risk to the health of workers from exposure to the notified polymer at ≤ 0.35% concentration is not considered to be unreasonable.

6.3.2. Public Health

The notified polymer is proposed for use in cleansing wet wipes at ≤ 0.35% concentration. The notified polymer is of low toxicity by the oral route and is not expected to be a skin irritant or sensitiser at the low use concentration (≤ 0.35%). Due to the variable sensitivity of baby's skin, some sensitisation may occur in sensitive individuals. However, this effect should be mild and transient.

Eye irritation from exposure to the notified polymer cannot be ruled out. A product containing a combination of chemical ingredients in solution, including the notified polymer at 0.5%, was considered mildly irritating to the eyes in a non-validated test. Given the low use concentration of ≤ 0.35%, and the type of products containing the notified polymer, adverse effects are not anticipated; however, contact with eyes should be avoided as a precaution.

In addition, formulators should consider the possible irritation potential of the notified polymer in formulating cleansing wet wipe products.

The repeat dose toxicity effects of the notified polymer have not been determined. However, given the low acute toxicity, low expected dermal absorption, and low use concentration, significant adverse effects from repeated use of the notified polymer at ≤ 0.35% in cleansing wet wipes are not expected.

Therefore, the risk to the health of the public from use of the notified polymer at ≤ 0.35% concentration in cleansing wet wipes is not considered to be unreasonable. Eye contact with wet wipes should be avoided, as a precaution.

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 as a softening agent in a skin cleansing solution used in baby wet wipes and flushable perineal wet wipes. The notified polymer will not be manufactured or reformulated in Australia; therefore, there will be no release from this activity.

RELEASE OF CHEMICAL FROM USE

The notified polymer will be applied to the skin of consumers as a component in a skin cleansing solution used in wet wipes. For baby wet wipes, which are not flushable, some residual amount of the notified polymer in the cleansing solution is likely to remain on the skin, and the rest of it likely retained on the used wipes disposed to landfill.

For flushable perineal wet wipes, it is anticipated that some residual amount of the notified polymer in the cleansing solution is likely to remain on the skin, and the rest of it retained on the used wipes flushed to the sewers. It is expected that the residual notified polymer on the skin will eventually be rinsed off to sewers.

RELEASE OF CHEMICAL FROM DISPOSAL

Any residue of the notified polymer in empty end-use containers is likely either to share the fate of the container or be disposed of to landfill. The used wipes are expected to be collected in waste bins and to be disposed of to landfill.

7.1.2. Environmental Fate

The notified polymer is not expected to be readily biodegradable or bioaccumulate based on the environmental fate studies for an analogue. The analogue provided by the notifier, modified organopolysiloxane, was considered appropriate to support general assumptions for the notified polymer with regards to biodegradability and bioaccumulation due to their similar generic molecular structure. For the details of the environmental fate

studies please refer to Appendix C. For baby wet wipes, the notified polymer remaining on the skin is expected to be released to sewers. For flushable perineal wipes, the notified polymer remaining on the skin or on the wipe is expected to be released to sewers. During waste water treatment processes in sewage treatment plants (STPs), most of the notified polymer is expected to be removed from waste waters to sludge due to its tendency to sorb to surface boundaries based on its potential surface activity, cationicity and high molecular weight. The notified polymer that partitions and/or adsorbs to sludge will be removed with the sludge for disposal to landfill or used in soil remediation. Small amounts of the notified polymer remaining in the effluent from STP may be released to surface waters. The notified polymer that is released to surface waters is expected to partition to suspended solids and disperse. Hence, it is not anticipated to be significantly bioavailable to aquatic organisms. Since it has a high molecular weight, it is too large to cross the biological membranes. In landfill, the notified polymer will be associated with the disposed article or sludge, and is unlikely to be mobile due to its high molecular weight, surface activity, and tendency to bind to soil/sediments. Ultimately, the notified polymer is expected to degrade in soil or water via abiotic and biotic pathways to form water, oxides of carbon, nitrogen and silica.

7.1.3. Predicted Environmental Concentration (PEC)

The calculation for the Predicted Environmental Concentration (PEC) is summarised in the table below. The submitted study by the notifier indicated that 5% of the annual import volume of the notified polymer used in baby wet wipes (2050 kg/year) transfers to the skin with product usage and subsequently washed into sewer. It is also assumed that 100% of the annual import volume of the notified polymer used in flushable perineal wet wipes (3000 kg/year) and will be released to sewer on a nationwide basis over 365 days per year. The exposure scenario was calculated assuming 90% of the notified polymer was to partition to sludge in STPs based on its high molecular weight and potential cationicity (Boethling and Nabholz, 1997). The results of the calculation with the mitigation are shown in the table below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	5,050	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	5,050	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	13.84	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	90%	**Mitigation**
Daily effluent production:	4,877	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.28	µg/L
PEC - Ocean:	0.03	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 0.284 µg/L may potentially result in a soil concentration of approximately 1.89 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 9.46 µg/kg and 18.91 mg/kg, respectively.

7.2. Environmental Effects Assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Acute toxicity		
Fish Toxicity	96 h LC50 =17.2 mg/L	Harmful to fish
Daphnia Toxicity	48 h EC50 = 0.36 mg/L	Very toxic to aquatic invertebrates
Algal Toxicity	72 h EC50 = 3.89 mg/L	Toxic to algae
Chronic toxicity		
Daphnia Toxicity	21 d NOEC = 0.11 mg/L	Toxic to aquatic invertebrates

Based on the acute ecotoxicological endpoints, the notified polymer is expected to be very toxic to aquatic invertebrates. Therefore, the notified polymer is classified as "Acute Category 1: Very toxic to aquatic life" according to the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations 2009). On the basis of not ready biodegradable and NOEC values, the notified polymer is formally classified as 'Chronic Category 2: Toxic to aquatic life with long-lasting effects".

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentrations (PNEC) for the notified polymer was calculated using the most sensitive chronic endpoint (NOEC) for daphnia and an assessment factor 100 was used since three acute and one chronic endpoints are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
NOEC (Invertebrates).	0.11	mg/L
Assessment Factor	100	
Mitigation Factor	1.0	
PNEC:	1.1	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	*PEC µg/L*	*PNEC µg/L*	*Q*
Q - River:	0.28	1.1	0.258
Q - Ocean:	0.03	1.1	0.026

The Risk Quotients (Q = PEC/PNEC) for discharge of effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations based on its annual importation quantity. Due to potential cationicity and high molecular weight of the notified polymer it is not expected to be bioavailable and bioaccumulative in the environment. Therefore, there is no unreasonable risk to the aquatic environment from the assessed use scenario.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility < 1.1 g/L at 20 °C

Method	OECD TG 105 Water Solubility.
Remarks	Preliminary determination by step-wise procedure. The mixture of water and the notified polymer appeared milky white suspensions in the solubility test. This is an indication that the notified polymer may have surface activity.
Test Facility	Shin-Etsu (2012)

Partition Coefficient (n-octanol/water) log Pow = 4.2 – 4.8 at 20 °C

Method	OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks	The study report indicated that two phases were visually confirmed to be separated completely, however, the study was conducted using the analogue chemical 1. As the notified polymer is suggested to have surface activity due to the formation of milky white suspension in the mixture during the water solubility test, the result of this study may not reflect the true partition coefficient.
Test Facility	Shin-Etsu (1995)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
- Species/Strain: Rat
- Vehicle: None
- Remarks - Method: No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
I	3 F	2,000	0/3
II	3 F	2,000	0/3

- LD50: > 2,000 mg/kg bw
- Signs of Toxicity: None
- Effects in Organs: A hard material present in the stomach was noted at necropsy of three females. No other abnormalities were noted.
- Remarks - Results: No mortalities or clinical signs were observed following dosing with the test substance. The animals displayed expected body weight gains during the study.

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

TEST FACILITY: Safepharm (2002a)

B.2. Irritation – skin

TEST SUBSTANCE: Notified polymer

METHOD: Similar to OECD TG 404 Acute Dermal Irritation/Corrosion.
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 6
- Vehicle: None
- Observation Period: 72 h
- Type of Dressing: Occlusive.
- Remarks - Method: Non-GLP study.

0.5 mL of the test substance was applied to intact and abraded sites on the backs of the rabbits. The treated sites were covered in an impermeable plastic occlusive wrapping fixed in place with porous tape. After 24 h, the patches were removed and the remaining substance removed with water. Observations were recorded on patch removal and 48 hours post-patch removal using the Draize scoring system.

RESULTS

- Remarks - Results: There was moderate erythema noted in all animals at all sites 24 h after application and this remained at abraded skin sites in all animals after 72 h. Recovery was noted at some intact skin sites with slight or no erythema noted at 72 h in 4/6 animals. No oedema was noted in any animals at 24 h. Very slight oedema was noted in 1/6 animals at the abraded site after 72 h.

The primary irritation index was determined to be 1.80 out of a possible 8, which indicates the test substance is mildly irritating to the intact and abraded skin of rabbits at 100% concentration.

CONCLUSION The notified polymer is slightly irritating to the skin.

TEST FACILITY CPT (2004)

B.3. Skin sensitisation

TEST SUBSTANCE Notified polymer

METHOD OECD TG 406 Skin Sensitisation – Buehler test method.
Species/Strain Guinea pig/Hartley albino
PRELIMINARY STUDY Maximum Non-irritating Concentration: 100%

MAIN STUDY
Number of Animals Test Group: 12 Control Group: 10
Vehicle None
INDUCTION PHASE Induction Concentration: 100% (topical)
Signs of Irritation Very faint erythema was observed in all but one treated animal following the first and second inductions.

CHALLENGE PHASE
1st challenge topical: 100%
Remarks - Method Following 3 induction applications over 3 weeks, a dorsal virgin site on each animal was treated 2 weeks later with 0.4 mL test substance at the highest non-irritating concentration of 100%. Control animals who had not received any induction applications, were also treated with identical challenge treatment. The test sites were scored for erythema, oedema and other effects at 7 h and 24 h after the induction application and 7, 24 and 48 h after challenge application. The concentration causing mild irritation was used for the induction phase.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*		
		7 h	*24 h*	*48 h*
Test Group	100%	0/12	0/12	0/12
Negative Control Group	100%	0/10	0/10	0/10

Remarks - Results No sensitisation was observed upon challenge with the test substance at 100% concentration.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.

TEST FACILITY CPT (2004)

B.4. Skin sensitisation – human volunteers

TEST SUBSTANCE Formulations containing the notified polymer (0.5% concentration)

METHOD Repeated insult patch test with challenge
Study Design For studies 1, 2 and 3:
Induction Procedure: Patches containing 1 cm^2 of test substance were applied 3 times per week (Monday, Wednesday and Friday) for a total of 9 applications. Patches were removed by the applicants after 24 h and graded after an additional 24 h (or 48 h for patches applied on Friday).

Rest Period: ~14 days

Challenge Procedure: A patch was applied to a naive site. Patches remained in place for 24 h. Sites were graded at patch removal and 48 h,

72 h and 96 h post-patch removal.

Additional design for study 1: Rechallenge
A naive site was tested for sensitisation potential in 1 individual.

Study Group: Study 1: 160 F, 80 M; age range 18 – 79 years
Study 2: 41 F, 16 M; age range 19-69
Study 3: 41 F, 16 M; age range 19-69

Vehicle: None

Remarks - Method: Occluded

RESULTS

Remarks - Results

Study 1:
A total of 240 subjects were enrolled and 219 subjects completed the test. No subject discontinued due to test material.
7 subjects at the 24 h post challenge grading had patches missing at which time the patch was reinstated.
14 subjects who missed the 96 h post challenge grading reported no adverse reaction on a follow up visit 2 months later.

During the challenge phase one subject exhibited oedema noted 72 and 96 h after challenge. Three other subjects exhibited faint erythema reaction that was noted at each grading but was not considered an adverse reaction by the study authors.

A rechallenge was conducted on the one subject that exhibited an oedematous reaction. Dermal sensitisation was sustained. The subject was also challenged with 5 additional formulations (B-F), all containing the notified polymer except product D, which are noted in the table below.

Study 2 and 3:
Two further HRIPT studies were conducted as shown in the table below that showed no sensitisation.

Number	*Induction*	*Challenge*	*Reaction*	*Re Challenge (n=1)*	*Reaction*
Study 1 (n= 219)	Product A	Product A	1/219 Sensitisation (oedema)	Product A [1]	Sensitisation Reaction sustained
				Product B [2]	No reaction
				Product C [2]	No reaction
				Product D [3]	Sensitisation (oedema)
				Product E [2]	Sensitisation (oedema)
				Product F [2]	Sensitisation (oedema)
Study 2 (n=57)	Product C	Product C	No reaction		
Study 3 (n=57)	Product A	Product A	No reaction		

[1]Original test substance containing the notified polymer at 0.5% and nine other ingredients
[2]Products identical to A, each minus one ingredient but all containing the notified polymer at 0.5%
[3]Product identical to A but minus notified polymer

CONCLUSION: Based on a weight of evidence approach, the notified polymer was not sensitising at 0.5% under the conditions of the tests.

TEST FACILITY: Harrison (2011)

B.5. 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*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA$^-$
Metabolic Activation System	Rat S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 50-5000 µg/plate b) Without metabolic activation: 50-5000µg/plate
Vehicle	Dimethyl sulphoxide
Physical Form	Gas/vapour
Remarks - Method	In order to select appropriate dose levels for use in the main study, a preliminary test was carried out to determine the toxicity of the test material Five concentrations (50-5000 µg/plate) were assayed in triplicate against each tester strain, using the direct plate incorporation method (Test 1). During the replicate assay the exposure conditions were the same as for test 1. Positive and negative controls were run in parallel.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5000	> 5000	> 5000	Negative
Test 2		> 5000	> 5000	Negative
Present				
Test 1	> 5000	> 5000	> 5000	Negative
Test 2		> 5000	> 5000	Negative

Remarks - Results	No precipitation was observed at any dose level either with or without metabolic activation. The test material caused no visible reduction in the growth of the bacterial background lawn at any dose level. The test material was tested up to the maximum recommended dose level of 5000 µg/plate. No significant increases in the frequency of revertant colonies were recorded for any bacterial strains either with or without metabolic activation. All of the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	SafePharm (2002b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Analogue
METHOD	OECD TG 301 C Ready Biodegradability: Modified MITI Test (I)
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	Aniline
Analytical Monitoring	Measured of biochemical oxygen demand (BOD). The test substance was analysed by HPLC
Remarks - Method	The test was conducted in Japan according to the "Basic Standards to be Observed by Testing Facilities Conducting Test Stipulated in the Order Prescribing Those Items of the Test Relating to the New Chemical Substances, 1984". No significant deviations from the test guidelines were reported.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
28	0 (BOD)	7	69
		14	90

Remarks - Results	All validity criteria for the test were satisfied. The toxicity control exceeded 25% biodegradation showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the test substance 0%. Therefore, the test substance cannot be classified as readily biodegradable according to the OECD (301 C) guideline.
CONCLUSION	The analogue and, by inference, the notified polymer are not readily biodegradable
TEST FACILITY	Kurume (1987)

C.1.2. Bioaccumulation

TEST SUBSTANCE	Analogue
METHOD	OECD TG 305 Bioconcentration: Flow-through Fish Test - Continuous flow
Species	Carp (*Cyprinus carpio*)
Exposure Period	Exposure: 56 days
Auxiliary Solvent	None reported
Concentration Range	Level 1: 3 mg/L Level:2: 0.3 mg/L
Analytical Monitoring	Atomic absorption spectrometry
Remarks - Method	The test was conducted in Japan according to the "Basic Standards to be Observed by Testing Facilities Conducting Test Stipulated in the Order Prescribing Those Items of the Test Relating to the New Chemical Substances, 1984". No significant deviations from the test guidelines were reported.
RESULTS	
Bioconcentration Factor (BCF)	Level 1: 5.5 to 14 Level:2: 18 to 30

Remarks - Results	All validity criteria for the test were satisfied. BCFs of the test substance were found to have reached equilibrium after 8 weeks. No significant differences among the BCFs were observed at the two levels.
CONCLUSION	The analogue and, by inference, the notified polymer are not expected to bioaccumulate in fish.
TEST FACILITY	Kurume (1989)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test –Static.
Species	*Branchydanio rerio*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	230 mg $CaCO_3$/L
Analytical Monitoring	Total organic carbon analyser
Remarks – Method	The test substance was weighted directly into the test flask at 1 g/L and stirred for 48 hours. The stock solution was diluted further to prepare five different concentrations.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual**		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control		7	0	0	0	0	0
50.00		7	6	7	7	7	7
33.33		7	1	7	7	7	7
22.22		7	0	6	6	6	6
14.81		7	0	0	5	5	5
9.88		7	0	0	0	0	0

* Actual concentrations were determined based on TOC measurements

LC50	17.15 mg/L at 96 hours.
Remarks – Results	All validity criteria for the test were satisfied. The recovery rates of the test substance were in the range of ±20 % of the nominal concentrations based on TOC measurements. The 96-hour LC_{50} was calculated to be 17.15 mg/L.
CONCLUSION	The notified polymer is harmful to fish
TEST FACILITY	Eurofins Biolab SRL (2016a)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	≤ 250 mg $CaCO_3$/L
Analytical Monitoring	Total organic carbon analyser
Remarks - Method	The test substance was weighted directly into the test flask at 100 mg/L and stirred for 48 hours. The stock solution was diluted further to prepare

five different concentrations.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual**		*24 h*	*48 h*
Control		20	0	0
0.04		20	0	0
0.09		20	1	3
0.21		20	2	5
0.45		20	5	9
1.00		20	16	19

* Actual concentrations were determined based on TOC measurements

EC50 0.36 mg/L at 48 hours

Remarks - Results All validity criteria for the test were satisfied except the recovery rates of the test substance were not in the range of ±20 % of the nominal concentrations at low concentrations based on TOC measurements. The 48-hour EC_{50} was calculated to be 0.36 mg/L.

CONCLUSION The notified polymer is very toxic to aquatic invertebrates

TEST FACILITY Eurofins Biolab SRL (2016b)

C.2.3. Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Notified polymer

METHOD OECD TG 211 *Daphnia* sp. Reproduction test –Semi-static.
Species *Daphnia magna*
Exposure Period 21 d
Auxiliary Solvent None
Water Hardness 250 mg $CaCO_3$/L
Analytical Monitoring Total organic carbon analyser
Remarks - Method The test substance was added directly into the test flask at 100 mg/L and was diluted to obtain 10.00 mg/L solution. The 10 mg/L solution was diluted further to prepare five different concentrations.

Concentration tested, total number of offspring released, number of offspring released per female daphnid (*Daphnia magna*) and number of immobilised parental daphnids.

	Concentration (mg/L)					
Test Day 21	*Control*	*0.01*	*0.04*	*0.11*	*0.33*	*1.00*
Total no. of offspring released by survived *Daphnia*	1163	1065	1044	902	459	348
Total no. of offspring released per survived daphnid	116	107	104	90	77	70
No. of adult daphnids Immobilised	0	0	0	0	1	4

21 day NOEC 0.11 mg/L
21 day LOEC 0.33 mg/L

Remarks - Results All validity criteria for the test were satisfied. The recovery rates of the test substance were in the range of ±20 % of the nominal concentrations at high concentrations based on TOC measurements. The lowest tested concentration at which the substance was observed to have a statistically significant effect on reproduction (LOEC) was determined to be 0.33 mg/L. The NOEC was determined to be 0.11 mg/L.

CONCLUSION The notified polymer is toxic to daphnids on a chronic basis.

TEST FACILITY Eurofins Biolab SRL (2017)

C.2.4. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 0.26, 0.64, 1.60, 4.00 and 10.00 mg/L Actual concentrations were determined based on TOC measurements
Auxiliary Solvent	None
Water Hardness	Not determined
Analytical Monitoring	Total organic carbon analyser
Remarks - Method	The test substance was weighted directly into the test flask at 100 mg/L and stirred for 48 hours. The stock solution was diluted further to prepare five different concentrations.

RESULTS

Biomass		*Growth*	
EC50 *mg/L at 72 h*	*NOEC* *mg/L*	*EC50* *mg/L at 72 h*	*NOEC* *mg/L*
Not determined	Not determined	3.89	Not determined

Remarks - Results	All validity criteria for the test were satisfied. The recovery rates of the test substance were in the range of ±20% of the nominal concentrations based on TOC measurements. The 72-hour EC_{50} was determined to be 3.89 mg/L based on growth rate.
CONCLUSION	The notified polymer is toxic to algae.
TEST FACILITY	Eurofins Biolab SRL (2016c)

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