File No: LTD/1668

July 2013

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* (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/1668	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*	≤ 0.4 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 for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

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 polymerl 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 a risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- 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

- 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.

Storage

- The handling and storage of 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 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;
- 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 > 0.3%.

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.

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

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

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1000 Da.

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 (exceptions: density, water solubility, partition coefficient, flash point).

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
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 transparent to tan translucent liquid

Property	Value	Data Source/Justification
Boiling Point	Not determined	Estimated to be ≥ 105 ºC
Density	1016 kg/m^3	Measured (full study report not provided)
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	The notified polymer does not contain hydrolysable functionalities and is not expected to hydrolyse 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 is 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 surface activity and potential 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 (full study report not provided)
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

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 a concentration of 0.3%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	0.40	0.11	0.11	0.12	0.12

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 (0.3%) of cleansing wet wipes 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 (at 0.3%) will be used as a softening agent in cleansing wet wipes. The wet wipes are intended to help clean the skin around a baby's diaper area.

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

The imported cleansing wet wipes containing the notified polymer (at 0.3% concentration) may be used by consumers and professionals (such as childcare 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 0.3% 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.

Professionals working in child care facilities may use products containing the notified polymer at 0.3%. 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. Given that potential eye irritation effects of the notified polymer cannot be ruled out, contact with the eyes should be avoided.

6.1.2. Public Exposure

The wet wipes containing the notified polymer at 0.3% are intended to help clean the skin around a baby's diaper area. Young children will therefore have widespread and frequent exposure to these products. The primary route of exposure would be dermal. Eye exposure is not expected from appropriate use of the wipes but given that potential eye irritation cannot be ruled out, contact with the eyes should be avoided. Each baby wipe contains approximately 6.37 g of cleansing liquid, (of which ~19mg will be notified polymer). However, only a small residual amount remains 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 > 2500 mg/kg bw; low toxicity
Rabbit, skin irritation	Not a primary dermal irritant
Guinea pig, skin sensitisation	no evidence of sensitisation
Human, skin sensitisation – RIPT (0.5%) Re-challenge*	evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, metabolism and distribution.

Based on its relatively high molecular weight (> 1000 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 polymer has a small percentage of low molecular weight species (< 500) that may be more likely to be absorbed.

Acute toxicity.

The notified polymer exhibited low acute toxicity in a rat gavage study. There were no deaths or clinical signs of toxicity. All animals showed expected gains in bodyweight over the study period. A hard material present in the stomach was noted at necropsy of three females. No other abnormalities were noted. The acute oral (LD_{50}) of the notified polymer was estimated as being greater than 2500 mg/kg bw.

Irritation

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 edema 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 0.3% cannot be ruled out.

Observations on irritation in 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 0.3%.

Sensitisation
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 sensitization (see appendix B for further details). The original test substance (product A) did induce an edematous reaction indicative of dermal sensitization in 1/219 human subjects. A rechallenge test confirmed dermal sensitisation in this individual using the original test material. 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 2 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 0.3% 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 0.3% are not expected.

Mutagenicity/Genotoxicity.
A reverse mutation assay (AMES test) using *Salmonella Typhimurium* and *Escherichia Coli* was conducted using the notified polymer. No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test material, either with or without metabolic activation. All the positive control polymers 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. Therefore, based on the information provided, the notified polymer is not expected to be mutagenic.

Health hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

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 0.3%.

Repeated dermal exposure (primarily to the hands of child care workers) is possible under the proposed use scenario. The cleansing wet wipes containing the notified polymer will be used directly by hand; however, only a small percentage of liquid from the wet wipe is expected to be left as residual on the skin. While irritation to the skin in sensitive individuals cannot be ruled out, the low use concentration of 0.3% should minimise this risk; any irritation would likely be mild and transient. 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 child care workers, which might accidentally be transferred to the eye, is negligible.

Therefore, provided the manufacturer recommendations on product use are adhered to, the risk to the health or workers from exposure to the notified polymer at 0.3% is not considered to be unreasonable.

6.3.2. Public Health

The notified polymer is proposed for use in cleansing wet wipes at 0.3% 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 (0.3%). Due to the variable sensitivity of baby's skin, some irritation 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 0.3%, 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 0.3% in cleansing wet wipes are not expected. As there is no NOAEL for repeat dose effects, a quantitative risk assessment cannot be conducted.

Therefore providing that the products are used as proposed, the risk to the health of the public from use of the notified polymer at 0.3% 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 softener/softening agent in a skin cleansing solution used in cleansing 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. It is anticipated that some residual amount of the notified polymer in cleansing liquid is likely to remain on the skin, and the rest of it may be retained in the used wipes. It is expected that the residual notified polymer left on the skin will eventually be washed 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 the analogue substance. For the details of the environmental fate studies please refer to Appendix C. Notified polymer remaining on the skin 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 surface activity and potential cationicity. 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 bioavailible 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.

An analogue substance, modified organopolysiloxane, is considered appropriate to support general assumptions for the notified polymer with regards to biodegradability and bioaccumulation due to their similar generic molecular structure.

7.1.3. Predicted Environmental Concentration (PEC)

The calculation for the Predicted Environmental Concentration (PEC) is summarised in the table below. Based on the reported use in body cleansing solutions, it is assumed as a worst case scenario that 100 % of the total import volume of polymer would be released to sewer on a nationwide basis over 365 days per year. It was as conservatively assumed that 0% of the notified polymer partitions to sludge in STPs although it is a polymer with potential cationicity (Boethling and Nabholz, 1997).

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	120	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	120	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	0.33	kg/day
Water use	200	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:	0.07	µg/L
PEC - Oce□n:	0.007	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 polymer 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 0.07 µg/L may potentially result in a soil concentration of approximately 0.48 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 2.4 µg/kg and 4.8 µg/kg, respectively. However, these are expected to be maximum values as a significant proportion is expected to be disposed of to landfill as sludge or in disposed articles.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on an analogue substance are summarised in the table below. Details of the studies can be found in Appendix C. The analogue substance, modified organopolysiloxane, is used as read across to the notified polymer due to their similar generic molecular structure. However, differences between the analogue substance and the notified polymer include molecular weight and charge density. Since cationic polymers are known to be toxic to aquatic life, ecotoxicological endpoints for the notified polymer were calculated based on Structure Activity Relationships (SARs). SAR equations assume a worst case cationic charge density for the polymer (Boethling and Nabholz, 1997). The toxicity endpoints were predicted based on the tests conducted in standard aquatic toxicity testing media without any mitigation. The results are summarised in the table below.

Endpoint	*Result*	*Assessment Conclusion*
Measured Analogue		
Fish (96 h)	LC50 = 300 mg/L	Not expected to be harmful to fish
Daphnia sp. (48 h)	EC50 = 370 mg/L	Not expected to be harmful to aquatic invertebrates
Algae (72 h)	EC50 = 297 µg/L	Expected to be very toxic to algae
Estimated Notified Polymer		
Fish (96 h)	LC50 = 13.9 mg/L	Predicted to be harmful to fish
Daphnia sp. (48 h)	EC50 = 33.5 mg/L	Predicted to be harmful to aquatic invertebrates
Algae (72 h)	EC50 = 3.2 mg/L	Predicted to be toxic to algae

It can be seen that the endpoints based on the measured toxicity of the analogue polymer and the estimated toxicity of the notified polymer are not compatible. The difference in molecular weight and charge density between the analogue substance and the notified polymer may result in differences in their ecotoxicities in the aquatic environment. The SAR estimation endpoints indicate that the notified polymer is potentially toxic to the freshwater green algae and potentially harmful to fish and aquatic vertebrates. However, the actual toxicity of the notified polymer to aquatic life may be overestimated by SARs estimation used here as surface water tend to have higher total organic content (TOC) and dissolved organic content (DOC) than what is used in standard aquatic toxicity testing media. Classification should be based on actual toxicity endpoints and, therefore, the notified polymer cannot be formally classified 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-Effect Concentration (PNEC) was calculated using the most sensitive toxicity endpoint of the analogue substance among the three test species. The most conservative assessment factor of 1000 was used since ecotoxicological data of the analogue substance was used for the PNEC analysis.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Alga).	0.30	mg/L
Assessment Factor	1,000	
PNEC:	0.30	µg/L

7.3. Environmental Risk Assessment

Risk Ass□ssment	*PEC µg/L*	*PNEC µg/L*	*Q*
Q □ River:	0.07	0.297	0.245
Q - Ocean:	0.007	0.297	0.□2

The Risk Quotients (Q = PEC/PNEC) for a worst case discharge scenario have been calculated to be < 1 for the river and ocean compartments. The notified polymer is not expected to be readily biodegradable or bioaccumulate in the environment. The notified polymer is not likely to significantly bioavailable as it is expected to be removed from the water column due to its strong potential to adsorb on suspended solids and sediments in water. The notified polymer is unlikely to result in ecotoxicologically significant concentrations in aquatic environment for the assessed use pattern. Therefore, there is no unreasonable risk to the aquatic environment from the assessed use scenario.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

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 has surface activity.
Test Facility	Shin-Etsu (2012)

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

Method	OECD TG 107 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 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. The volume administered to each animal was calculated according to the fasted bodyweight as the time of dosing. Necropsy was performed on all animals.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3 F	2000	0/3
II	3 F	2000	0/3

LD50	> 2500 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 hours, the patches were removed and 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 hrs after application and this remained at abraded skin sites in all animals after 72 hrs. Recovery was noted at some intact skin sites with slight or no erythema noted at 72 hrs in 4/6 animals. No edema was noted in any animals at 24 hrs. Very slight adema was noted in 1/6 animals at the abraded site after 72

hrs.
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 Similar to OECD TG 406 Skin Sensitisation – Buehler test method.
Species/Strain Guinea pig/Hartley albino
PRELIMINARY STUDY Maximum Non-irritating Concentration: 100% (topical)

MAIN STUDY
Number of Animals Test Group: 12 Control Group: 10
INDUCTION PHASE Induction Concentration: 100% (topical)
Signs of Irritation Very faint erythema was observed in all but one treated animals 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, edema 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

	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 at 0.5% concentration

METHOD Human repeated insult patch test with challenge
Study Design For studies 1, 2 and 3:
Induction Procedure: Patches containing 1cm^2 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 naïve 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: Re challenge
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. One subject was discontinued due to a significant number of insect bites on his back. One subject was discontinued due to medication he was taking and one subject was discontinued because she was having surgery during the challenge phase. 18 subjects discontinued due to personal reasons. No subject discontinued due to test material.
7 subjects reported who returned for 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 a erythema and edema (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 edematous reaction. Dermal sensitisation to the original test material was sustained. The subject was also challenged with 5 additional formulations 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*	*Challange*	*Reaction*	*Re Challenge (n=1)*	*Reaction*
Study 1 (n= 219)	Product A	Product A	1/219 Sensitization (edema)	Product A [1]	Sensitisation Reaction sustained
				Product B [2]	No reaction
				Product C [2]	No reaction
				Product D [3]	Sensitization (edema)
				Product E [2]	Sensitization (edema)
				Product F [2]	Sensitization (edema)
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 (2011a)

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
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 µg/plate	> 5000 µg/plate	No precipitation	Negative
Test 2		> 5000 µg/plate	No precipitation	Negative
Present				
Test 1	> 5000 µg/plate	> 5000 µg/plate	No precipitation	Negative
Test 2		> 5000 µg/plate	No precipitation	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, with any dose of the test material, 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 polymerl 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 chemical 2
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 (required by guideline) showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the test substance after the cultivation period was 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 chemical 2
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	Analogue chemical 2
METHOD	Static Acute Toxicity Test with Feathead Minnows following TSCA 797-1400 for Premature Notice 021689/PMN797-1400FM-SA
Species	Feathead Minnows (*Pimephales promelas*)
Exposure Period	96 hours
Auxiliary Solvent	Acetone (0.1%)
Water Hardness	42 mg $CaCO_3$/L
Analytical Monitoring	None reported
Remarks – Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. The above stated test guideline is very similar to OECD TG 203.

RESULTS

Nominal Concentration (mg/L)	*Number of Fish*	*Mortality(96 h)*
Control	*20*	0
130	20	0
220	20	0
360	20	90
600	20	100
1000	20	100

LC50	300 (220 – 360) mg/L at 96 hours.
NOEC	130 mg/L at 96 hours.
Remarks – Results	All validity criteria for the test were satisfied. All the exposure solutions containing the test substance were observed to have a surface film of undissolved test materials. The 96-hour LC_{50} was calculated by nonlinear interpolation method.
CONCLUSION	The analogue and, by inference, the notified polymer are not harmful to fish
TEST FACILITY	Springborn (1990a)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Analogue chemical 2
METHOD	Static Protocol for Conducting a Static Acute Toxicity Test with *Daphnia magna* for Premature Notice 013189/PMN DM-SA, Appendix 1, 1989 and Protocol Amendment #1, 1990
Species	*Daphnia pulex*

Exposure Period	48 hours
Auxiliary Solvent	Acetone (0.1%)
Water Hardness	56 mg $CaCO_3$/L
Analytical Monitoring	None reported
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported.

RESULTS

Nominal Concentration (mg/L)	*Number of D. magna*	*Cummulative % Immobilised 48 h*
Control	20	5
81	20	5
130	20	20
220	20	55
360	20	55
600	20	50
1000	20	95

EC50	370 (290 – 500) mg/L at 48 hours
NOEC	81 mg/L at 48 hours
Remarks - Results	All validity criteria for the test were satisfied. At 24 and 48 hours, precipitation of the test substance was observed on the bottom of all exposure vessels containing the treatment solutions. The amount of precipitate increased with the nominal test concentrations. The 48 hour EC_{50} was calculated by probit analysis.
CONCLUSION	The analogue and, by inference, the notified polymer are not harmful to aquatic invertebrates
TEST FACILITY	Springborn (1990b)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Analogue chemical 2
METHOD	TSCA Guideline 797.1050
Species	Freshwater green algae (*Selenastrum capricornutum*)
Exposure Period	96 hours
Concentration Range	Nominal: 63, 130, 250, 500, and 1000 µg/L
Auxiliary Solvent	Acetone (0.01%)
Analytical Monitoring	None reported
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. The above stated test guideline is very similar to OECD TG 201.

RESULTS

Growth EC50 µg/L at 72 h
297.1 (95% confidence limits: 94.1 - 1162.1)

Remarks - Results	The 72-hour EC50 was calculated to be 297 µg/L. Bonferroni's statiscal comparison test indicated that the 130, 500 and 1000 µg/L treatment

	levels were significantly different from that of the polled controls cell densities at 96 hours. However, due to the lack of a clear concentration-response relations at 96 hours, combined with the fact that no concentration tested resulted in growth reduction of less than 50%, no EC values were calculated for this interval.
CONCLUSION	Under the conditions of the test, the analogue and, by inference, the notified polymer are very toxic to algae
TEST FACILITY	Springborn (1990c)

BIBLIOGRAPHY

Boethling RS & Nabholz JV (1997) Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act. In: Hamilton JD & Sutcliffe R, ed. Ecological Assessment of Polymers; Strategies for product stewardship and regulatory programs. New York, Van Nostrand Reinhold.

CRT (2004) Primary dermal irritation in rabbits and guinea pig sensitisation (Buehler) (Study No. T04-0172, December, 2004). Fairfield NJ USA, Consumer Product Testing Co. (Unpublished report submitted by the notifier).

Kurume (1987) Test on Biodegradability of [Analogue 2] by Microorganisms (May 1987). Japan, Kurume Research Laboratory, Chemicals Inspection and Testing Institute (Unpublished report submitted by the notifier).

Kurume (1989) Test on Bioaccumulation of [Analogue 2] in Carp (April 1989). Japan, Kurume research Laboratory, Chemicals Inspection and Testing Institute (Unpublished report submitted by the notifier).

Harrison (2011). Human repeated insult patch test (Study No. 11-105, March, 2011). Union NJ USA, Harrison Research Laboratories Inc (unpublished report submitted by the notifier).

Harrison (2011). Cumulative irritation test (Study No. 11-3506S, March, 2011). Union NJ USA, Harrison Research Laboratories Inc (unpublished report submitted by the notifier).

Harrison (2011). Facial sting test (Study No. 11-2152, March, 2011). Union NJ USA, Harrison Research Laboratories Inc (unpublished report submitted by the notifier).

MB (2011). MatTek EpiOcular MTT viability assay (Study No. MB 11-19813.19). Spinnerstown, PA USA, MB Research Laboratories (unpublished report submitted by the notifier).

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia

SafePharm (2002a) [Notified Polymer]: Acute oral toxicity in the rat – acute toxic class method, (Study No. 763/245, November, 2002) Derbyshire, UK, SafePharm Laboratories Limited (unpublished report submitted by the notifier).

SafePharm (2002b) [Notified Polymer]: Reverse mutation assay 'ames test' using *salmonella typhimurium* and *eschericha coli*, (Study No. 763/243, October, 2002) Derbyshire, UK, SafePharm Laboratories Limited (unpublished report submitted by the notifier).

Shin-Etsu (1995) Determination of the Partition Coefficient (n-Octanol/Water) of [Analogue 1] (October, 1995). Tokyo, Japan, Analytical Laboratory, Shin-Etsu Chemical Co., Ltd (Unpublished report submitted by the notifier).

Shin-Etsu (2012) Preliminary Determination of the Water Solubility of Shin-Etsu Silicone [Notified Polymer] (August 2012). Gunma Prefecture, Japan, Silicone-Electronics Materials Research Center Shin-Etsu Chemical Co., Ltd (Unpublished report submitted by the notifier).

Springborn (1990a) – [Analogue 2] Acute Toxicity to Fathead Minnows (*Pimephales promelas*) Under Static Conditions (August 1990). Massachusetts, Springborn Laboratories (Unpublished report submitted by the notifier).

Springborn (1990b) – [Analogue 2] Acute Toxicity to Daphnids (*Daphnia pulex*) Under Static Conditions (August 1990). Massachusetts, Springborn Laboratories (Unpublished report submitted by the notifier).

Springborn (1990c) – [Analogue 2] Acute Toxicity to the Freshwater Green Alga *Selenastrum capricornutum* (August 1990). Massachusetts, Springborn Laboratories (Unpublished report submitted by the notifier).

SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/managing-risks-of-hazardous-chemicals-in-the-workplace.

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >..