File No: LTD/1660

July 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Dimethicone/Polyglycerin-3 Crosspolymer

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/1660	L'Oreal Australia Pty Ltd	Dimethicone/Polyglycerin-3 Crosspolymer	ND*	< 15 tonnes per annum	Ingredient in cosmetic products

*ND = Not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System 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 polymer is not considered to pose an unreasonable risk to public health.

Environmental risk assessment
On the basis of the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

(Material) Safety Data Sheet

- The (M)SDS provided by the notifier should be amended as follows:
  - Revision to reflect the hazard identification as an eye irritant where applicable

CONTROL MEASURES
Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer during reformulation:
  - Enclosed, automated processes, where possible.

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

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Goggles

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Public Health

- Cosmetic products containing the notified polymer should be formulated in a manner that addresses the potential for the notified polymer to cause eye irritation effects.

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

- Spills and/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 chemical/polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
- the polymer has a number-average molecular weight of less than 1000;
- additional information becomes available on the eye irritancy potential of the notified polymer;

or

(2) Under Section 64(2) of the Act; if
- the function or use of polymer has changed from an ingredient in cosmetic products, or is likely to change significantly;
- the amount of polymer being introduced has increased from 15 tonnes per annum, 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.

No additional secondary notification conditions are stipulated.

(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)
L'Oreal Australia Pty Ltd (ABN: 40 004 191 673)
564 St Kilda Rd
MELBOURNE VIC 3004

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, import volume, site of manufacture and identity of manufacturer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physicochemical data.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Dimethicone/Polyglycerin-3 Crosspolymer (INCI name)

MOLECULAR WEIGHT
NAMW > 4000 Da

ANALYTICAL DATA
Reference IR, and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Colourless translucent paste

Property	Value	Data Source/Justification
Melting Point	Not determined	The notified polymer will never be isolated from the liquid commercial mixture.
Boiling Point	Not determined	The notified polymer is expected to degrade before boiling.
Density	930 kg/m^3 at 25 °C	(M)SDS
Vapour Pressure	Not determined	High MW polymer expected to have low vapour pressure
Water Extractability	≤ 0.024%	Measured
Hydrolysis as a Function of pH	Not determined	No readily hydrolysable functionalities
Partition Coefficient (n-octanol/water)	Not determined	Expected to form an emulsion in water and oil solution
Adsorption/Desorption	Not determined	Expected to sorb to soil sediment and sludge based on its low water solubility and high molecular weight

Dissociation Constant	Not determined	The notified polymer has very low water solubility and lacks readily dissociable groups.
Flash Point	173 °C at 101 kPa	(M)SDS
Flammability	Not determined	Not expected to be flammable
Autoignition Temperature	Not determined	Not expected to autoignite.
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that 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 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 in finished cosmetic products at ≤ 10% concentration. The notified polymer may be introduced in the neat form (i.e. > 95% concentration) for reformulation into cosmetic products in the future.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 15	< 15	< 15	< 15	< 15

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in finished products generally by sea in HDPE bottles or tubes in sizes up to 500 mL.

There is no information available in the case when the notified polymer is imported in the neat form.

USE
The notified polymer will be used primarily as a skin conditioning and emulsifying ingredient in cosmetic products at ≤ 10% concentration.

OPERATION DESCRIPTION

The notified polymer will be imported into Australia as part of cosmetic products (≤ 10% concentration), which will be sold to end-users in the same form in which they are imported.

The notified polymer may at some point in the future be imported in neat form for formulation into cosmetic products.

Reformulation
In the case where the notified polymer is imported in the neat form (> 95% concentration), it will be weighed and added directly into flame-proof mixing tanks. Mixing will occur in a closed system. The finished formulation will be dispensed via dedicated pumps and lines. During the formulation process, samples of the notified polymer and the finished cosmetic products will be taken for quality control testing.

End-use
The finished cosmetic products containing the notified polymer at ≤ 10% concentration will be used by consumers and professionals (such as workers in beauty salons). Application of products could be by hand or through the use of an applicator.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	4	12
Professional compounder	8	12
Chemist	3	12
Packers (Dispensing and capping)	8	12
Store persons	4	12
End users	8	365

EXPOSURE DETAILS
Transport and storage
Transport and storage workers may come into contact with the notified polymer in the neat form (> 95% concentration) or as a component of cosmetic products (≤ 10% concentration) only in the event of accidental rupture of containers.

Formulation of cosmetic products
During formulation of cosmetic products from the neat notified polymer, dermal, ocular and inhalation exposure of workers to the notified chemical (at > 95% concentration) may occur during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment. Exposure is expected to be minimised through the use of mechanical ventilation and/or enclosed systems and through the use of personal protective equipment such as coveralls, safety glasses and impervious gloves. The use of respirators should also be considered, if appropriate ventilation is not available.

End-use
Exposure to the notified polymer (at ≤ 10% concentration) in end-use products may occur in professions where the services provided involve the application of cosmetic and personal care products to clients (e.g. workers in beauty salons). Such professionals may use personal protective equipment (PPE) to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified polymer.

6.1.2. Public Exposure

There will be widespread and repeated exposure of the public to the notified polymer (at ≤ 10% concentration) through the use of the cosmetic and personal care products. The principal routes of exposure will be dermal and oral (through the use of lip products), and inhalation exposure (through the use of spray products).

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 > 5000 mg/kg bw; low toxicity[1]
Skin irritation (in vitro)	non-irritating[2]
Rabbit, skin irritation	slightly irritating[1]
Rabbit, eye irritation	irritating[1]
Guinea pig, skin sensitisation –non-adjuvant test.	no evidence of sensitisation[1]
Mutagenicity – bacterial reverse mutation	non mutagenic[1]

[1] Test substance notified polymer in 40% dimethicone (CAS No. 63148-62-9)
[2] Test substance notified polymer in ~24% dimethicone

Toxicokinetics, metabolism and distribution.
Limited data are available on the toxicokinetic properties of the notified polymer. Based on the high molecular weight (> 4000 Da) of the notified polymer, the potential to cross the gastrointestinal (GI) tract by passive diffusion or to be dermally absorbed after exposure is limited. The notified polymer is predicted to have a low vapour pressure based on its high molecular weight. Thus, inhalation exposure would only be expected if aerosols are formed during spray applications.

Acute toxicity.
The notified polymer as a 40% solution in dimethicone was found to be of low acute oral toxicity in rats (LD50 > 5000 mg/kg bw.

There are no acute dermal toxicity studies available for the notified polymer. The notified polymer is not expected to be readily absorbed through the skin based on its high molecular weight.

There are no acute inhalation data available for the notified polymer. The notified polymer is predicted to have a low vapour pressure based on its high molecular weight. Inhalation exposure to the notified chemical may occur in cases where aerosols are formed during spray applications. However, the notified polymer is expected to be cleared from the lungs.

Irritation and sensitisation.
The notified polymer as a 40% solution in dimethicone was slightly irritating to the skin in a rat study. Slight to well defined erythema was observed in all six test animals that persisted in 4/6 animals at the end of the observation period (i.e. 72 hours). The study was not extended to determine if the irritation resolved. However, an *in vitro* reconstituted human epidermis model found the notified polymer to be non-irritating to skin.

The notified polymer as a 40% solution in dimethicone was found to be irritating to the eye. Redness of the conjunctivae (Grade 2/3) was observed in all animals that did not resolve in any of the animals by the end of the 7 day observation period. Chemosis was observed in one animal after 24 hours with the effects clearing by 48 hours. There were no corneal or iridial effects. Although the observation period was not extended to determine if the irritations effects observed would resolve, there were signs that the degree of irritation was decreasing for 5/6 of the animals. It is also noted that dimethicone is classified as irritating to the eyes (Category 2) under ECHA's CLP. Based on uncertainty as to the irritation potential of the notified polymer, given available data, the risk of eye irritation cannot be ruled out. the

Repeated Dose Toxicity.
There are no repeat dose toxicity data available for the notified polymer.

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

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 a potential eye irritant. Exposure via inhalation is not expected given the low estimated vapour pressure of the notified polymer. Based on the molecular weight of the notified polymer, the possibility of dermal absorption following exposure is limited.

Reformulation
Compounders and laboratory staff involved in the formulation of cosmetic products may come in contact with the neat notified chemical (> 95% purity). Exposure is expected to be limited during product formulation by the engineering controls, the use of PPE, and the use of enclosed and automated processes. Given the control measures in place to limit exposure, the notified polymer is not considered to pose an unreasonable risk to reformulation workers.

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

Based on the information available, the risk to workers associated with use of the notified polymer at ≤ 10% concentration in cosmetic products is not considered to be unreasonable.

6.3.2. Public Health
The general public will be repeatedly exposed to the notified polymer during the use of cosmetic products containing the notified polymer at up to 10% concentration.

Local effects
Based on the information available, the notified polymer may be an eye irritant. However, the potential for eye irritation is further reduced by the relatively low concentration (≤ 10%) of the notified polymer in cosmetic products.

Systemic effects
There are no repeat dose toxicity data available for the notified polymer. However, given the high molecular weight of the notified polymer dermal absorption is not expected.

Therefore, based on the information available, the risk to the public associated with the use of the notified polymer at ≤ 10% concentration in cosmetic products is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified polymer will be imported into Australia as finished products or in the neat form for reformulation into cosmetic products. Release of the notified polymer to the aquatic environment is negligible during reformulation, transportation, handling and storage as any leaks and spills are expected to be collected and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE
The notified polymer will be applied to the skin of consumers as a component in skin care and cosmetic products. The majority of the annual import volume of the notified polymer is expected to be released to the sewer through the consumer use as an ingredient in cosmetics.

RELEASE OF CHEMICAL FROM DISPOSAL
Small amounts of the notified polymer may remain as residues in empty import containers (approximately 1% of the total annual import volume) or empty end-use containers (3%), which are expected to be disposed of to landfill along with the empty containers.

7.1.2. Environmental Fate
No environmental fate data were submitted for the notified polymer.

The majority of the notified polymer is expected to be released to sewer during use in skin care products. During waste water treatment processes in sewage treatment plants (STPs), 90% of notified polymer is expected to be removed from waste waters due to its low water solubility and high molecular weight (Boethling and Nabholz, 1997). The notified polymer that partitions to sludge will be removed with the sludge for disposal to landfill or used on land for soil remediation. The notified polymer that is released to surface waters is expected to partition to suspended solids and organic matter, and disperse. Notified polymer disposed of to landfill is expected to associate with soil and organic matter and be largely immobile based on its low water solubility.

The notified polymer in water is not readily biodegradable based on the MSDS data provided by the notifier. However, significant degradation in soil was observed for the similar polymers belonging to the same chemical category as the notified polymer (Dow Corning, 1998). Bioaccumulation of the notified polymer is unlikely due to its high molecular weight. In the aquatic and soil compartments, the notified polymer is expected to slowly degrade through biotic and abiotic processes to form water and oxides of carbon and silicon.

7.1.3. Predicted Environmental Concentration (PEC)
Since most the notified polymer will be applied to the skin in cosmetic products, the Predicted Environmental Concentration (PEC) is calculated, under a worst case scenario, assuming that the total import volume (15 tonnes/year) is washed off the skin to sewers with 90% removal of the notified polymer to sludge during sewerage treatment plant (STP) processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	15,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	15,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	41.10	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	90%	**Mitigation**
Daily effluent production:	4,523	ML
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River:	0.91	µg/L
PEC - Ocean:	0.09	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 81.78 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1500 kg/m^3 and a soil-mixing zone of 10 cm, the concentration of the notified polymer may approximate 0.545 mg/kg in applied soil. This assumes that degradation of the notified polymer occurs in the soil within 1 year from application. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated biosolids application, the concentration of notified polymer in the applied soil in 5 and 10 years may approximate 2.725 mg/kg and 5.45 mg/kg, respectively.

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 0.909 µg/L may potentially result in a soil concentration of approximately 6.058 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer the applied soil in 5 and 10 years may be approximately 30.29 µg/kg and 60.58 µg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data for the notified polymer were submitted. The notified polymer is a non-ionic polymer which is generally of low concern to the environment. The notified polymer is not expected to be bioaccumulative, due to its high molecular weight, nor readily bioavailable to aquatic organisms due to its limited solubility in water. Therefore, the notified polymer has not been formally classified for its acute and long-term hazard under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS, United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

A Predicted No Effect Concentration (PNEC) has not been calculated as the notified polymer is not expected to be readily bioavailable and is predicted to have no effect on aquatic biota.

7.3. Environmental Risk Assessment

A risk quotient (PEC/PNEC) for the notified polymer was not calculated as a PNEC was not derived.

Although the majority quantity of the notified polymer will be released to water compartments after its use, the majority is expected to be removed from the receiving waters by partitioning to sludge during waste water treatment processes. Therefore, notified polymer released to surface waters is not expected to reach ecotoxicologically significant concentrations. The notified polymer is expected to degrade significantly in soil, although it is not expected to be readily biodegradable in water nor be bioaccumulative. Based on the assumed low hazard and the assessed use pattern of the notified polymer, it is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water extractability ≤ 0.024%

Method In-house method.

Remarks A preliminary water solubility test was carried out for the test product (containing 24% of the notified polymer) at the concentration of 10%, 1% and 0.1%. For each test concentration, insoluble material was observed in the solutions. At the lowest concentration of 0.1%, it was observed that the polymer adhered to the inner wall of the glass bottle. Therefore, it concluded that water extractability of the notified polymer is less than 0.024% (= 0.1% × 24%).

As the notified polymer is designed as a water/oil emulsifier, it only swells in water but is not soluble in water. Therefore, water extractability is used in this report to describe the notified polymer's behaviour in water.

Test Facility Shi-Etsu (2012)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer (40% in dimethicone)
METHOD	In house method.
Species/Strain	Rat/Wistar albino
Vehicle	None
Remarks - Method	After 18 hours of fasting, test animals were dosed via oral gavage. Water and feed were available ad libitum. Animals were observed for sign of pharmacological activity and toxicity at 1, 3, 6 and 24 hours post-dosing. Observations were made once daily for 14 days post-dosing.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5F/5M	5000	0/10

LD50	> 5000 mg/kg bw
Signs of Toxicity	No signs of toxicity were noted following gross necropsy.
Effects in Organs	No effects were noted in the organs
Remarks - Results	The oral LD50 value of the test substance was estimated to be > 5000 mg/kg. Overall limited data was provided and the methods used were not fully described.
CONCLUSION	The test substance is of low toxicity via the oral route.
TEST FACILITY	CPT (2003)

B.2. Irritation – skin (in vitro)

TEST SUBSTANCE	Notified polymer (~24% in dimethicone)
METHOD	OECD TG 431 In vitro Skin Corrosion - Human Skin Model Test - EpiSkin™ Reconstituted Human Epidermis Model
Vehicle	None
Remarks - Method	The full study report was not available and so the methods could not be confirmed. No significant protocol deviations were apparent. The positive control was a 5% aqueous solution of sodium dodecyl sulfate.

RESULTS

Test material	*Relative mean Viability (%)*	*SD of relative mean viability*
Negative control	Not provided	Not provided
Test substance	98	2.8
Positive control	≤ 35	< 18

SD = standard deviation

Remarks - Results	The results suggest that the test substance is a non-irritant. The detailed results for the positive and negative control were not available.
CONCLUSION	The test substance was non-irritating to the skin under the conditions of the test.
TEST FACILITY	Episkin (2007)

B.3. Irritation – skin

TEST SUBSTANCE	Notified polymer (40% in dimethicone)
METHOD	In-house method
Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Vehicle	None
Observation Period	72 hours
Type of Dressing	Occlusive
Remarks - Method	Six test animals received a single dose of 0.5 mL at two test sites- one abraded and one non-abraded. The sites were occluded for 24 hours and observations made at 24 and 72 hours.

RESULTS

Lesion	*Mean Score**		*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	Abraded	*Unabraded*			
Erythema/Eschar	1.3	1.3	2	> 72 h	2
Oedema	0	0	0	-	0

*Calculated on the basis of the scores at 24 and 72 hours for EACH animal.

Remarks - Results	Slight to well-defined erythema was observed in all six test animals at the 24-hour observation period at both the abraded and unabraded test sites that resolved in two of the animals at the 72-hour observation period. Irritation scores were similar for the abraded and unabraded test sites. The observation period was not extended past the 72-hour observation period to determine if the irritation observed in the remaining 4 animals would resolve.
CONCLUSION	The test substance is slightly irritating to the skin.
TEST FACILITY	CPT (2003)

B.4. Irritation – eye

TEST SUBSTANCE	Notified polymer (40% in dimethicone)
METHOD	Modified Draize test
Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Observation Period	7 days
Remarks - Method	0.1 mL of test material was placed on one eye of each rabbit. The upper and lower lids were held together for 1 second to prevent the loss of material. If any of the test article remained in the eye after 24 hours, the eye was washed out with distilled water after the 24 hour observations. Observations were made at 24, 48, and 72 hours and 4, and 7 days.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	2.8	3	> 7 days	3
Conjunctiva: chemosis	0	0	-	-
Conjunctiva: discharge	0	0	-	-
Corneal opacity	0	0	-	-
Iridial inflammation	0	0	-	-

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks - Results	Redness of the conjunctivae (Grade 2/3) was observed in all animals that did not resolve in any of the animals by the end of the 7 day observation period. However, for 5/6 animals the degree of irritation decreased over the observation period indicating that the irritation would likely resolve. Chemosis was observed in one animal after 24 hours with the effects clearing by 48 hours. There were no iridial or corneal effects.
CONCLUSION	The test substance is severely irritating to the eye.
TEST FACILITY	CPT (2003)

B.5. Skin sensitisation

TEST SUBSTANCE	Notified polymer (40% in dimethicone)
METHOD	Similar to OECD TG 406 Skin Sensitisation – Buehler test
Species/Strain	Guinea pig/ Hartley Albino
PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical: 100%
MAIN STUDY	
Number of Animals	Test Group: 12 Control Group: 10
INDUCTION PHASE	Induction Concentration: topical: 100%
Signs of Irritation	Very faint erythema
CHALLENGE PHASE	
1st challenge	topical: 100%
Remarks - Method	Only 12 animals were used in the treatment group and the induction phase involved applications made once a week for three consecutive weeks.

RESULTS

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

Remarks - Results	Only very fainit erythema was noted in some animals with no signs of irritation remaining 24 hours after the challenge phase.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test.
TEST FACILITY	CPT (2003)

B.6. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer (40% in dimethicone)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test.

	Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA100, TA98 *E. coli*: WP2uvrA
Metabolic Activation System	Liver preparations (S9 mix) from rats treated with phenobarbital and 5,6-benzoflavone
Concentration Range in Main Test	a) With metabolic activation: 313-5000 µg/plate b) Without metabolic activation: 313-5000 µg/plate
Vehicle	acetone
Remarks - Method	Aliquots of 0.05 mL of either test substance, positive, or negative control solution was used at five concentrations up to 5000 µg/plate. The negative control was acetone and positive controls were sodium azide, 9-aminoacridine, and 2-(2-furyl)-3-(5-nitro-2-furyl)acrylamide in the absence of S9 mix and 2-aminoanthracene and benzo[a]pyrene in the presence of S9 mix.

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 toxicologically significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test substance, either with or without metabolic activation. All 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 test substance was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Genetic Laboratory (2003)

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