File No: EX/206 (LTD/1676)

December 2016

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Dimethicone/PEG-10/15 Crosspolymer

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.

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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This assessment report is for an extension of the original assessment certificate for dimethicone/PEG- 10/15 crosspolymer. Based on the submission of new information by the extension notifier, the original assessment report has been modified.

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
EX/206 (LTD/1676)	Estee Lauder Pty Ltd	Dimethicone/PEG-10/15 Crosspolymer	ND*	≤ 1 tonne 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 of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Human health risk assessment
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

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 of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- 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 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, 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
Original Application
The (M)SDS of the 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.

Extension Application
The applicant for the extension application has provided a (M)SDS for a product containing the notified polymer. The accuracy of the information on the (M)SDS remains the responsibility of the extension applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Holder of Original Assessment Certificate (LTD/1676)
L'Oreal Australia Pty Ltd (ABN: 40 004 191 673)
564 St Kilda Road
MELBOURNE VIC 3004

Applicant for an Extension of the Original Assessment Certificate
Estee Lauder Pty Ltd (ABN: 63 008 444 719)
165-175 Mitchell Road
ERSKINEVILLE NSW 2043

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, other name, 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/PEG-10/15 Crosspolymer (INCI name)

MOLECULAR WEIGHT
NAMW > 1,000 Da

ANALYTICAL DATA
Reference IR and GC-MS spectra were provided.

3. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Colourless/milky white paste*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	The notified polymer will never be isolated from the liquid commercial mixture
Boiling Point	Not determined	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 Solubility	< 0.1 g/L at 20 °C*	Measured. The notified polymer is expected to be water dispersible based on its amphiphilic structure and use as an emulsifying ingredient.

Hydrolysis as a Function of pH	Not determined	Does not contain readily hydrolysable functionalities.
Partition Coefficient (n-octanol/water)	Not determined	Expected to form an emulsion in water and oil mixture.
Adsorption/Desorption	Not determined	Expected to partition to surfaces from water in the environment based on its surface activity.
Dissociation Constant	Not determined	Does not contain dissociable functionality.
Flash Point	> 94 °C at 101 kPa (closed cup)* 173 °C at 101 kPa (open cup)*	(M)SDS
Flammability	Not determined	Not expected to be flammable
Autoignition Temperature	Not determined	Not expected to undergo autoignition
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative properties

* Data for a product containing < 50% notified polymer in dimethicone.

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 of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

4. 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 (with negligible impurities) for reformulation into cosmetic products in the future.

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

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

Extension Application

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

PORT OF ENTRY
Melbourne and Sydney

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 as a raw material mixture.

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

Extension Application
The notified polymer will be used primarily as a skin conditioning and emulsifying ingredient in cosmetic products at ≤ 2% 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 the neat form for formulation into cosmetic products.

Reformulation
In the case where the notified polymer is imported in the neat form (with negligible impurities), 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.

5. 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 workers may come into contact with the notified polymer in the neat form (negligible impurities) 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 form (negligible impurities) of the notified polymer, dermal, ocular and inhalation exposure of workers to the notified polymer may occur during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment. Exposure is expected to be minimised through the use of mechanical ventilation and/or enclosed systems and through the use of personal protective equipment (PPE) such as overalls, 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 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 a product containing the notified polymer at < 50% concentration in dimethicone 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 > 2000 mg/kg bw; low toxicity
Skin irritation (in vitro)	non-irritating
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration	non genotoxic

Toxicokinetics

Limited data are available on the toxicokinetic properties of the notified polymer. Based on the high molecular weight (> 1,000 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.

The notified polymer is water dispersable and therefore if inhaled at low levels is likely to be cleared from the upper respiratory tract readily through mucociliary action. Small proportions of the notified polymer may reach the lower respiratory tract, but it should still be readily cleared from the lungs unless high levels are inhaled. When high concentrations of the notified polymer are inhaled, it is likely to be cleared from the lungs, but this may be slower and temporary respiratory impairment is possible. The notified polymer will be imported in finished products (< 10% concentration) which are expected to result in minimal inhalation exposure to reformulation workers. Should the notified polymer be imported in a concentrated solid form, the use of dust masks and local exhaust ventilation is recommended to reduce worker inhalation exposure levels and hence lower the risk of temporary lung overloading.

Acute toxicity

A product containing the notified polymer as a < 50% solution in dimethicone was found to be of low acute oral toxicity in rats.

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

A product containing the notified polymer as a < 50% solution in dimethicone was slightly irritating to the skin in a study conducted in rabbits. Following treatment at abraded and non-abraded skin sites, very slight to well defined transient erythema was observed in all three test animals that persisted in 1/3 animal (abraded site) after 48 hours and resolved at the end of the observation period (i.e. 72 hours). Very slight transient oedema was observed in 2/3 animals and resolved by 48 hours. However, the notified polymer as a 20-30% solution in dimethicone was found to be non-irritating to skin in a patch test conducted on 45 subjects.

A product containing the notified polymer as a < 50% solution in dimethicone was found to be irritating to the eye in a study conducted in rabbits. Redness of the conjunctivae (Grade 2/3) was observed in all three animals that did not resolve in any of the animals by the end of the 7 day observation period. Chemosis was observed in all three animals after 1 hour and resolved by 24 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 2/3 of the animals. It is also noted that dimethicone is classified as irritating to the eyes (Category 2) under ECHA's CLP; hence there is some uncertainty as to the irritation potential of the notified polymer based on this study. However, in studies conducted on a range of dimethicone crosspolymers either no or mild, transient eye irritancy was observed (CIR, 2012). Although the degree of eye irritancy may be limited based on studies conducted on similar polymers, given available data on the notified polymer, the risk of eye irritation cannot be ruled out.

A product containing the notified polymer as a < 50% solution in dimethicone did not cause skin sensitisation in a guinea pig maximisation study.

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

Mutagenicity/ Genotoxicity
A product containing the notified polymer as a < 50% solution in dimethicone was negative both in a bacterial reverse mutation assay and in an *in vitro* chromosomal aberration study.

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

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
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 (negligible impurities). 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.

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 < 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

Residues of the notified polymer may remain in empty import containers (approximately 1% of the total import volume) or empty end-use containers (up to 3% of the total import volume), 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. 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 expected partitioning to soil and sediment.

The notified polymer is not expected to be readily biodegradable, however, is expected to slowly degrade in the environment based on the data provided by the notifier. 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)

The calculation for the Predicted Environmental Concentration (PEC) is summarised in the table below. Based on the reported use in cosmetics and skin care products, it is assumed that 100% of the total import volume of the chemical is released to sewer on a nationwide basis over 365 days per year. 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 dispersibility and high molecular weight (Boethling and Nabholz, 1997).

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:	41.1	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 81.8 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 chemical may approximate 0.55 mg/kg in applied soil. This assumes that degradation of the notified chemical occurs in the soil within 1 year from application. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated biosolids application, the concentration of notified chemical in the applied soil in 5 and 10 years may approximate 2.73 mg/kg and 5.5 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 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 0.91 µg/L may potentially result in a soil concentration of approximately 6.1µg/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 30.3 µg/kg and 60.6 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. 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 of the notified polymer will be released to water compartments after its use, a significant amount of the notified polymer is expected to be removed from the water column 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 slowly degrade in the environment, 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.

8. RISK ASSESSMENT RELATING TO EXTENSION APPLICATION

The introduction volume will not increase and the proposed use and fate of the notified polymer will not change under the proposed extension. The circumstances in the extension application are not expected to impact on the original human health and environment risk assessment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water extractability < 0.1 g/L

Method	In-house method. Mixtures of test substance and water with the amount of the test substance as 10 g, 1 g, 0.1 g in 1 L of water were prepared, shaken and visually observed right after the shaking and 24 hours later.
Remarks	The water solubility of the test substance was visually determined to be less than 0.1 g/L. In addition, the test substance can form an emulsion with water, but does not uniformly disperse if the concentration is below 10 g/L.
Test Facility	Exempt information (2013)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: A product containing < 50% notified polymer in dimethicone

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 at least once daily for 14 days post-dosing.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3F/2M	2000	0/5

- LD50: 2000 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 > 2000 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 (2002a)

B.2. Irritation – skin

TEST SUBSTANCE: A Product containing < 50% notified polymer in dimethicone

METHOD
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 3
- Vehicle: None
- Observation Period: 72
- Type of Dressing: Occlusive
- Remarks - Method: Three male 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, 48 and 72 hours.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar (Intact)	0.7	0.3	0.7	2	< 48 hour	0
Erythema/Eschar (Abraded)	1	0.3	0.7	2	< 72 hour	0
Oedema (Intact)	0.3	0	0.3	1	< 48 hour	0
Oedema (Abraded)	0.3	0	0.3		< 48 hour	0

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

- Remarks - Results: Slight to well-defined erythema was observed in all 3 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 48-hour observation period and resolved in one of the animals at the 72-hour observation. Irritation scores were similar for the abraded and unabraded test sites.

CONCLUSION The test substance is slightly irritating to the skin.

TEST FACILITY CPT (2002b)

B.3. Skin irritation – human volunteers

TEST SUBSTANCE A product containing < 50% notified polymer in dimethicone

METHOD Patch test
Study Design Induction Procedure: Patches containing 0.01 g test substance were applied using a Finn Chamber. Patches were removed after 24 h and graded after an additional 1 h and 24 h.
Study Group 28 F, 17 M; age range 23-53 years
Vehicle None
Remarks - Method Occluded

RESULTS
Remarks - Results 45/45 subjects completed the study. No adverse responses were noted 1 h or 24 h after the removal of the test substance.

CONCLUSION The test substance was non-sensitising under the conditions of the test.

TEST FACILITY Japan Hair Science (2002)

B.4. Irritation – eye

TEST SUBSTANCE A product containing < 50% notified polymer in dimethicone

METHOD Modified Draize test
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Observation Period 7 days
Remarks - Method 0.1 mL of test substance was placed in one eye of each rabbit. The upper and lower lids were held together for 1 second to prevent the loss of test substance. If any of the test substance remained in the eye after 24 hours, the eye was washed out with distilled water after the 24 hour observations. Observations were made at 1, 24, 48 and 72 hours and 4 and 7 days.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	2	2	2	2	> 7 days	2
Conjunctiva: chemosis	0	0	0	1 (1 hr)	-	0
Conjunctiva: discharge	0	0	0	0	-	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results Redness of the conjunctivae (Grade 2) 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 2/3 animals the degree of irritation decreased over the observation period indicating that the irritation would likely resolve.

Chemosis was observed in all animals at the end of 1 hour observation period with the effects clearing by 24 hours. Discharge was not observed in all animals. There were no iridial or corneal effects.

CONCLUSION The test substance is irritating to the eye.

TEST FACILITY CPT (2002c)

B.5. Skin sensitisation

TEST SUBSTANCE A product containing < 50% notified polymer in dimethicone

METHOD Similar to OECD TG 406 skin sensitisation – maximisation test in guinea pigs

Species/Strain Guinea pig/ Hartley Albino

PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: 100%
topical: 100%

MAIN STUDY

Number of Animals Test Group: 5 Control Group: 5

INDUCTION PHASE Induction Concentration:
intradermal: 100%
topical: 100%

Signs of Irritation Not reported.

CHALLENGE PHASE

1st challenge topical: 100%

Remarks - Method Only 5 animals were used in the treatment group. At Day 6 the test animals were treated with 10% sodium lauryl sulfate.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	100%	0/5	0/5
Control Group	100%	0/5	0/5

Remarks - Results Only questionable erythema was noted in one animal in the test group.

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

TEST FACILITY CPT (2002d)

B.6. Genotoxicity – bacteria

TEST SUBSTANCE A product containing < 50% notified polymer in dimethicone

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Plate incorporation procedure

Species/Strain *S. typhimurium*: TA1535, TA1537, TA98, TA100
E. coli: WP2uvrA

Metabolic Activation System S9 mix from phenobarbitone/β-naphthoflavone induced rat livers

Concentration Range in Main Test a) With metabolic activation: 50-5000 µg/plate
b) Without metabolic activation: 50-5000 µg/plate

Vehicle Ethanol

Remarks - Method A preliminary toxicity test (0-5000 µg/plate) was performed to determine

the toxicity of the test substance (TA100 or WP2uvrA).

In the mutation studies, aliquots of 0.1 mL of either test substance, positive, or negative control solution was used at five concentrations up to 5000 µg/plate. The negative control was ethanol and positive controls were N-ethyl-N'-nitro-N-nitrosoguanidine, 9-aminoacridine, and 4-nitroquinoline-1-oxide 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	> 1500	Negative
Test 2		> 5000	> 1500	Negative
Present				
Test 1	> 5000	> 5000	> 1500	Negative
Test 2		> 5000	> 1500	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

Safepharm (2002)

B.7. Genotoxicity – in vitro

TEST SUBSTANCE

A product containing < 50% notified polymer in dimethicone

METHOD

Similar to OECD TG 473 In vitro Mammalian Chromosome Aberration Test.

Species/Strain: Hamster

Cell Type/Cell Line: Chinese hamster lung cell line (CHL/IU)

Metabolic Activation System: Phenobarbital/5,6-benzoflavone induced, rat liver S9

Vehicle: Ethanol

Remarks - Method: Doses up to 5000 µg/mL were chosen in a dose-finding study (using short-time treatment method and continuous treatment method) on the basis that no cytotoxicity was shown at the highest dose.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	1250*, 2500*, 5000*	6	24
Test 2	1250*, 2500*, 5000*	24	24
Test 3	1250*, 2500*, 5000*	48	48
Present			
Test 1	1250*, 2500*, 5000*	6	24

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5000	> 5000	> 5000	Negative
Test 2	> 5000	> 5000	> 5000	Negative
Test 3	> 5000	> 5000	> 5000	Negative
Present				
Test 1	> 5000	> 5000	> 5000	Negative

Remarks - Results

The maximum dose level selected for the main experiments was based on the results of the preliminary study, and was up to the recommended dose of 5000 μg/mL.

The test substance did not induce significant increase in the incidence of cells with structural and numerical chromosomal aberrations, irrespective of the presence or absence of a metabolic activation system and the length of treatment duration in any of the exposure groups. Deposition of the test substance was observed at incubation at all doses in the continuous treatment method.

CONCLUSION

The test substance was not clastogenic to CHL cells treated in vitro under the conditions of the test.

TEST FACILITY

Shin Nippon (2002)

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.

CIR (2012) Safety assessment of dimethicone crosspolymers as used in cosmetics. Cosmetic Ingredient Review (28 September 2012).

CPT (2002a) Acute Oral Toxicity in Rats (Study No. T01-0272-3, February, 2002). New Jersey, USA, Consumer Product Testing Co. (Unpublished report submitted by the notifier).

CPT (2002b) Primary Dermal Irritation in Rabbits (Study No. T01-0272-1, February, 2002). New Jersey, USA, Consumer Product Testing Co. (Unpublished report submitted by the notifier).

CPT (2002c) Primary Ocular Irritation in Rabbits (Study No. T01-0272-2, February, 2002). New Jersey, USA, Consumer Product Testing Co. (Unpublished report submitted by the notifier).

CPT (2002d) Guinea Pig Maximisation Test (Study No. T01-0272-5, February, 2002). New Jersey, USA, Consumer Product Testing Co. (Unpublished report submitted by the notifier).

Japan Hair Science (2002) Patch Test of Cosmetic Raw Material on Human Skin (Study No. 13068-(1), January, 2002). Japan, Japan Hair Science Association (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.

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 >.

Safepharm (2002) Dimethicone, mixture with PEG-10/Dimethicone Crosspolymer and PEG-15/Dimethicone Crosspolymer: Reverse Mutation Assay “AMES Test” using *Salmonella typhimurmium* and *Escherichia coli* (Project No. 763/234, April, 2002). Derby, U.K., Safepharm Laboratories Limited (Unpublished report submitted by the notifier).

Shin Nippon (2002) Chromosomal Aberration Test of <Test Substance> Using Cultured Mammalian Cells (Study No. SBL 34-43, March, 2002), Kagoshima, Japan, Shin Nippon Biomedical Laboratories, Ltd. (Unpublished report submitted by the notifier).