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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

PUBLIC REPORT

Siloxanes and Silicones, 3-[(2-aminoethyl)amino]propyl Me, di-Me, hydroxy- and methoxy-terminated, polymers with polyethylene-polypropylene glycol bis(2-methyl-2-propen-1-yl) ether (INCI Name: Bis-Isobutyl PEG/PPG-20/35/Amodimethicone Copolymer)

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.

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/1813	Dow Corning Australia Pty Ltd	Siloxanes and Silicones, 3-[(2-aminoethyl)amino]propyl Me, di-Me, hydroxy- and methoxy-terminated, polymers with polyethylene-polypropylene glycol bis(2-methyl-2-propen-1-yl) ether (INCI Name: Bis-Isobutyl PEG/PPG-20/35/Amodimethicone Copolymer)	Yes	≤ 10 tonnes per annum	Component of rinse-off hair care products

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available information, the notified polymer is 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. The recommended hazard classification is presented in the table below.

<i>Hazard classification</i>	<i>Hazard statement</i>
Eye damage (Category 1)	H318 – Causes serious eye damage

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

R41: Risk of serious eye damage

The environmental hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

<i>Hazard classification</i>	<i>Hazard statement</i>
Acute (Category 3)	H402 - Harmful to aquatic life

Human health risk assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

Environmental risk assessment

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

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemical should be classified as follows:
 - Eye damage (Category 1): H318 - Causes serious eye damage

The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present and the intended use/exposure scenario.

- The Delegate (and/or the Advisory Committee on Chemicals Scheduling) should consider the notified polymer for listing on the SUSMP.

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 at $\leq 30\%$ during reformulation processes:
 - 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 at $\leq 30\%$ during reformulation processes:
 - Avoid contact with skin and 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 at $\leq 30\%$ during reformulation processes:
 - Safety glasses
 - Gloves
 - Coveralls

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.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

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 1,000 Da;
 - the notified polymer is intended to be used in products other than rinse-off hair care products;
 - the concentration of the notified polymer exceeds or is intended to exceed 1% in rinse-off hair care products;

or

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

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

(Material) Safety Data Sheet

The (M)SDS of the product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Dow Corning Australia Pty Ltd (ABN: 36 008 444 166)
Locked Bag 2095
NORTH RYDE NSW 1670

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1,000$ Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: molecular and structural formulae, molecular weight, spectral data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Canada

2. IDENTITY OF CHEMICAL

CHEMICAL NAME

Siloxanes and Silicones, 3-[(2-aminoethyl)amino]propyl Me, di-Me, hydroxy- and methoxy-terminated, polymers with polyethylene-polypropylene glycol bis(2-methyl-2-propen-1-yl) ether

OTHER NAME(S)

Amino modified polysiloxane reacted with polyoxyalkylene

Bis-Isobutyl PEG/PPG-20/35/Amodimethicone Copolymer (INCI name)

Dow Corning® Silstyle 101 (containing the notified polymer at 30-50%)

MARKETING NAME(S)

Dow Corning® CE 8401 Emulsion (containing the notified polymer at 10-30%)

CAS NUMBER

921936-12-1

MOLECULAR WEIGHT

> 10,000 Da

ANALYTICAL DATA

IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: amber coloured liquid*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Liquid at room temperature*
Boiling Point	> 35 °C	Product (M)SDS*
Density	910 kg/m ³	Product (M)SDS*
Vapour Pressure	< 1.3 × 10 ⁻⁹ kPa	Estimated based on the NAMW > 1,000 Da (US EPA, 2013)
Water Solubility	Not determined	Expected to be low based on its high molecular weight.
Hydrolysis as a Function of pH	Not determined	Does not contain readily hydrolysable functionalities.
Partition Coefficient	Not determined	Expected to form an emulsion in water and oil mixture.
Adsorption/Desorption	Not determined	Expected to sorb to soil sediment and sludge based on its low water solubility, potential cationicity and high molecular weight
Dissociation Constant	Not determined	The notified polymer contains potential cationic functionality which is expected to be ionised in the environmental pH range (4 - 9).
Flash Point	> 100 °C	Product (M)SDS*
Autoignition Temperature	Not determined	Expected to be relatively high based on the flash point of the product.
Explosive Properties	Predicted negative	Contains no functional groups that would infer explosive properties
Oxidising Properties	Predicted negative	Contains no functional groups that would infer oxidising properties

*For Dow Corning Silstyle 101 (containing the notified polymer at 30-50%)

DISCUSSION OF PROPERTIES

Reactivity

The notified polymer is expected to be stable under normal conditions of use. It has the ability to form emulsions in water/oil mixtures.

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 Dow Corning CE 8401 Emulsion at 10-30%.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	1-5	1-5	5-7	5-7	7-10

PORT OF ENTRY

Sydney

TRANSPORTATION AND PACKAGING

The notified polymer will be packaged in 18 kg cartons or 200 kg steel drums and will be transported by road from the notifier's warehouse to the formulation site.

USE

The notified polymer will be used in rinse off hair care products, such as shampoos and conditioners, at concentrations up to 1%.

OPERATION DESCRIPTION

The procedure for reformulation of the imported product containing the notified polymer (at 10 – 30% concentration) will likely vary depending on the nature of the product formulated and may involve both automated and manual transfer steps. However, in general, it is expected that the formulation process will involve blending operations that will be highly automated and occur in a fully enclosed environment, followed by quality control testing and automated filling of the formulated products into containers of various sizes.

The finished hair care products containing the notified polymer (at $\leq 1\%$ concentration) may be used by consumers and professionals such as hairdressers and workers in beauty salons, either by hand or using an applicator.

6. HUMAN HEALTH IMPLICATIONS**6.1. Exposure Assessment****6.1.1. Occupational Exposure**

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and Storage	4	12
Professional compounder	8	12
Chemist	3	12
Packers (Dispensing & Capping)	8	12
Store Persons	4	12
Salon workers	8	365

EXPOSURE DETAILS

Transport and storage

Transport and storage workers may come into contact with the imported product containing the notified polymer at 10-30% or finished hair care products containing the notified polymer at $\leq 1\%$, only in the event of an accidental rupture of containers.

Reformulation

During reformulation, dermal, ocular and perhaps inhalation exposure of workers to the notified polymer (at up to 30% concentration) may occur during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment. Mixing and dispensing is expected to be carried out in a closed system with machines including contra rotating mixing vessels. Exposure is expected to be minimised through the use of local exhaust ventilation, good general ventilation or forced mechanical ventilation, and through the use of personal protective equipment (PPE) such as safety glasses, gloves and coverall as proposed by the notifier.

End use

Exposure to the notified polymer in end-use products (at up to 1% concentration) may occur in professions where the services provided involve the application of hair care products to clients (e.g. hair dressers, workers in beauty salons). Application of products could be by hand or through the use of an applicator. The principal route of exposure will be dermal, while ocular exposure is also possible. Inhalation exposure is not expected as the notified polymer will only be used in rinse-off hair care products. Such professionals may use some 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 repeated exposure of the public to the notified polymer (at up to 1% concentration) through the use of rinse off hair care products, such as shampoos and conditioners. The principal routes of exposure will be dermal, while ocular and oral exposures are also possible.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on Dow Corning® Silstyle 101 (containing the notified polymer at 30-50%) are summarised in the following table. For full details of the studies, refer to Appendix A.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating (10% of the test substance)
Rabbit, eye irritation	severely irritating
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration test	non genotoxic

Toxicokinetics, metabolism and distribution

Given the high molecular weight of the notified polymer (NAMW >10,000 Da), dermal absorption and passive diffusion of the notified polymer across the gastrointestinal tract (GI tract) is expected to be limited. In addition, absorption of low molecular weight species is not expected as the notified polymer contains negligible proportion < 1,000 Da.

Acute toxicity

In a study conducted in rats Dow Corning® Silstyle 101 (containing the notified polymer at 30-50%) was found to have low acute oral toxicity.

Irritation

Based on studies conducted in rabbits Dow Corning® Silstyle 101 (containing the notified polymer at 30-50%) was severely irritating to eyes and slightly irritating to the skin when tested at 10% concentration.

Sensitisation

No skin sensitisation data were provided for the notified polymer. It is noted the notified polymer does not contain a structural alert for skin sensitisation.

Repeated dose toxicity

No repeated dose toxicity data were provided for the notified polymer.

Mutagenicity/Genotoxicity

Dow Corning® Silstyle 101 (containing the notified polymer at 30-50%) was not mutagenic in a bacterial reverse mutation study and was not clastogenic in an *in vitro* mammalian chromosome aberration test.

Health hazard classification

Based on the available information, the notified polymer is 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. The recommended hazard classification is presented in the following table.

Hazard classification	Hazard statement
Eye damage (Category 1)	H318 – Causes serious eye damage

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):
R41: Risk of serious eye damage

6.3. Human Health Risk Characterisation**6.3.1. Occupational Health and Safety***Reformulation*

Exposure of workers to the notified polymer (at $\leq 30\%$ concentration) may occur during blending operations. The notified polymer is considered to be slightly irritating to the skin and severely irritating to the eyes and the repeated dose toxicity effects of the notified polymer have not been determined. Therefore, caution should be exercised when handling the notified polymer during reformulation processes.

Provided that control measures are in place to minimise worker exposure, including the use of automated processes and PPE, the risk to the health of workers from use of the notified polymer is not considered to be unreasonable.

End-use

Beauty care professionals will handle the notified polymer at up to 1% concentration. If PPE is used, the risk to these professionals who regularly use hair care 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 repeated dose toxicity of the notified polymer has not been determined. However, systemic exposure to the notified polymer is expected to be limited by its high molecular weight and the rinse-off nature of the hair care products. In addition, the potential risk for eye irritation associated with use of the notified polymer at the proposed concentrations $< 1\%$ in rinse-off hair care products is not considered to be unreasonable.

Therefore, based on the information available, the risk to the public associated with the use of the notified polymer at up to 1% concentration in rinse-off hair care products, is not considered to be unreasonable. In the absence of data on the repeated dose toxicity of the notified polymer, use of the notified polymer is supported only under limited exposure conditions for rinse-off hair care products.

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 and will be used as a component for reformulation into rinse off hair care products. Therefore, no release of the notified polymer to the environment is expected from the manufacturing process.

During reformulation activities, the notified polymer will be mixed with other ingredients at the formulation site. Mixing will be done in closed mixers. The formulation equipment will be cleaned by washing with solvent. The equipment wash liquid/solvent waste will be treated as site industrial waste and will be collected by licensed disposal contractors for recycling. Solid waste will be disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The majority of the annual import volume of the notified polymer is expected to be released to the sewer through the consumer use as component in rinse off hair care products.

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 as rinse off hair 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 is expected to associate strongly with the organic compartment based on its cationic properties. It is expected to partition to sludge and 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.

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, nitrogen 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 hair 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).

<i>Predicted Environmental Concentration (PEC) for the Aquatic Compartment</i>		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	10,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	27.40	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	90%	Mitigation

Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.61	µg/L
PEC - Ocean:	0.06	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/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/m³). Using these assumptions, irrigation with a concentration of 0.606 µg/L may potentially result in a soil concentration of approximately 0.004 mg/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 0.02 mg/kg and 0.04 mg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicological data were submitted for the notified polymer. The cationicity of the notified polymer may contribute ecotoxicity to aquatic life. Therefore, the ecotoxicological endpoints for the notified polymer were calculated based on Structure Activity Relationships (SARs) equations for estimating the toxicity of polycationic polymers (Boethling and Nabholz, 1997). The endpoints are summarised in the table below. As a worst case scenario, the toxicity values predicted by SARs have not been modified by mitigation factors to reflect the actual toxicity in the natural aquatic environments to account for the anticipated binding of the polymer with organic carbon in surface waters.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity	LC50 (96 h) = 10.92 mg/L	Predicted to be harmful to fish
Daphnia Toxicity	EC50 (48 h) = 249.59 mg/L	Predicted to be not harmful to aquatic invertebrates
Algal Toxicity	EC50 (96 h) = 16.22 mg/L	Predicted to be harmful to algae

The notified polymer is expected to be harmful to fish and algae and not harmful to aquatic invertebrates in environmental waters with typical levels of total organic carbon. The QSAR estimation procedure used here is a standard approach and is considered reliable to provide general indications of the likely environmental effects of the polymer. However, this method is not considered sufficient to formally classify the long term hazard of the notified polymer to aquatic life under the Globally Harmonised System for the Classification and Labelling of Chemicals (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The most sensitive endpoint from the ecotoxicity calculations on the notified polymer is for fish and this was selected for the calculation of the predicted no-effect concentration (PNEC) below. A more conservative assessment factor of 1000 is appropriate, in this case, as although acute endpoints for three trophic levels are available as a general indication of potential toxicity, these endpoints are predicted by SARs calculations.

<i>Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment</i>		
LC0 (Fish).	10.92	mg/L
Assessment Factor	1,000	
PNEC:	10.92	µg/L

7.3. Environmental Risk Assessment

Based on the above PEC and PNEC, the following Risk Quotient ($Q = \text{PEC}/\text{PNEC}$) has been calculated:

<i>Risk Assessment</i>	<i>PEC µg/L</i>	<i>PNEC µg/L</i>	<i>Q</i>
Q - River:	0.61	10.92	0.055
Q - Ocean:	0.06	10.92	0.006

The risk quotient for discharge of effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations based on its annual importation quantity. Although the majority quantity of the notified polymer will be released to water compartments after its use, due to cationicity and higher molecular weight it is not expected to bioaccumulate.

Therefore, on the basis of the PEC/PNEC ratio, the maximum annual importation volume and assessed use pattern as a component in rinse off hair care products, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Acute toxicity – oral

TEST SUBSTANCE	Dow Corning® Silstyle 101 (containing the notified polymer at 30-50%)
METHOD	Similar to OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Rat/albino
Vehicle	None
Remarks - Method	No significant protocol deviations. Characterisation of the test article was not performed.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	3 M 2 F	2,000	0/5

LD50	> 2,000 mg/kg bw
Signs of Toxicity	The animals appeared normal during the study.
Effects in Organs	No gross changes were observed.

CONCLUSION The test substance is of low toxicity via the oral route.

TEST FACILITY Consumer Product Testing Co. (2001a)

A.2. Irritation – skin

TEST SUBSTANCE	Dow Corning® Silstyle 101 (containing the notified polymer at 30-50%)
METHOD	Similar to OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 F
Vehicle	Unspecified Diluent
Observation Period	72 hours
Type of Dressing	Occlusive
Remarks - Method	The test article was used as a 10% suspension in the vehicle. Characterisation of the test article was not performed. The test was conducted for both intact and abraded skin.

RESULTS

<i>Lesion</i>	<i>Mean Score* Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
Intact skin						
Erythema/Eschar	0.3	0.7	0.3	1	< 72 hours	0
Oedema	0	0	0	0	-	0
Abraded skin						
Erythema/Eschar	0	0.7	0.7	2	< 72 hours	0
Oedema	0	0	0	0	-	0

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

Remarks - Results	No oedema was observed. Twenty-four hours after treatment, well-defined erythema was observed on the abraded skin in one animal and very slight erythema was noted on the abraded skin in one animal and on the intact skin in three animals. Very slight erythema was noted on the abraded skin and on the intact skin in the same animal 48 hours after treatment. All effects were completely reversed 72 hours after treatment.
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CONCLUSION The test substance is slightly irritating to the skin under the test condition.

TEST FACILITY Consumer Product Testing Co. (2001b)

A.3. Irritation – eye

TEST SUBSTANCE Dow Corning® Silstyle 101 (containing the notified polymer at 30-50%)

METHOD Similar to OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain Rabbit/New Zealand White

Number of Animals 3 M

Observation Period 7 days

Remarks - Method No significant protocol deviations. Characterisation of the test article was not performed.

RESULTS

Lesion	Mean Score*			Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period
	1	2	3			
<i>Conjunctiva: redness</i>	2.7	3	2.7	3	> 7 days	2
<i>Conjunctiva: chemosis</i>	0.3	0.3	0.3	1	< 2 days	0
<i>Conjunctiva: discharge</i>	0	0.3	0	1	< 2 days	0
<i>Corneal opacity</i>	0	0	0	0	-	0
<i>Iridial inflammation</i>	0	0	0.3	1	< 2 days	0

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

Remarks - Results No effects were observed for cornea opacity.

Scores of 1 were observed for conjunctivae chemosis in two animals 1 hour after treatment and in all animals 24 hours after treatment. Scores of 1 (any swelling above normal, including nictitating membrane) were observed for conjunctivae discharge in one animal 1 hour after treatment and in one animal 24 hours after treatment. Score of 1 was observed for iris in one animal 24 hours after treatment. These effects were completely reversed 48 hours after the treatment.

Scores of 3 (diffuse beef red) or 2 (more diffuse, crimson red, individual vessels not easily discernible) were observed for conjunctivae redness in all three animals and these effects remained at end of 7-day observation period.

CONCLUSION The test substance is severely irritating to the eye.

TEST FACILITY Consumer Product Testing Co. (2001b)

A.4. Genotoxicity – bacteria

TEST SUBSTANCE Dow Corning® Silstyle 101 (containing the notified polymer at 30-50%)

METHOD Similar to OECD TG 471 Bacterial Reverse Mutation Test.

Pre incubation procedure

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

Metabolic Activation System S9 fraction from phenobarbital/5,6-benzoflavone induced rat liver

Concentration Range in Main Test a) With metabolic activation: 0, 156, 313, 625, 1,250, 2,500, 5,000 µg/plate
b) Without metabolic activation: 0, 156, 313, 625, 1,250, 2,500, 5,000 µg/plate in TA1535, TA100 and WP2uvrA and 0, 19.5, 39.1, 78.1, 156, 313, 625 µg/plate in TA1537 and TA98

Vehicle
Remarks - Method

Acetone
No significant protocol deviations. There was only one main test.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>	> 5,000	≥ 313	≥ 5,000	negative
<i>Present</i>	> 5,000	> 5,000	≥ 2,500	negative

Remarks - Results

As the number of revertant colonies was less than a two-fold increase compared with the negative controls in all five test strains used with or without metabolic activation, in the dose finding test and the main test, the test substance was considered not to induce gene mutation.

The positive controls produced satisfactory responses, 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

Shin Nippon Biomedical Laboratories Ltd (2002a)

A.5. Genotoxicity – in vitro

TEST SUBSTANCE

Dow Corning® Silstyle 101 (containing the notified polymer at 30-50%)

METHOD

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

Cell Type/Cell Line

Chinese hamster lung (CHL) cells

Metabolic Activation System

S9 fraction from phenobarbital/5,6-benzoflavone induced rat liver

Vehicle

Carboxy methylcellulose sodium (CMC-Na) solution of 0.5 w/v% in water

Remarks - Method

No significant protocol deviations.

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL)</i>	<i>Exposure Period</i>	<i>Harvest Time</i>
<i>Absent</i>			
Test 1	1250, 2500, 5000	6 h	18 h
Test 2	1250, 2500, 5000	24 h	24 h
Test 3	1250, 2500, 5000	48 h	48 h
<i>Present</i>			
Test 1	1250, 2500, 5000	6 h	18 h

All cultures were selected for metaphase analysis.

RESULTS

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

Remarks - Results

The positive and vehicle controls gave satisfactory responses confirming the validity of the test system.

CONCLUSION	The test substance was not clastogenic to CHL cells treated in vitro under the conditions of the test.
TEST FACILITY	Shin Nippon Biomedical Laboratories Ltd (2002b)

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