

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Siloxanes and Silicones, di-Me, Me hydrogen, polymers with polypropylene glycol bis(2-methyl-2-propen-1-yl) ether (INCI Name: Dimethicone/Bis-Isobutyl PPG-20 Crosspolymer)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government 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 Australian Government Department of the Environment.

This Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

**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 SUBSTANCE	INTRODUCTION VOLUME	USE
PLC/1311	Dow Corning Australia Pty Ltd	Siloxanes and Silicones, di-Me, Me hydrogen, polymers with polypropylene glycol bis(2-methyl-2-propen-1-yl) ether (INCI Name: Dimethicone/Bis-Isobutyl PPG-20 Crosspolymer)	No	≤ 3 tonnes per annum	Cosmetic ingredient

CONCLUSIONS AND REGULATORY OBLIGATIONS

Human Health Risk Assessment

Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the health of workers and the public.

Environmental Risk Assessment

Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Health and Safety Recommendations

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself. However, these should be selected on the basis of all ingredients in the formulation.

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

- 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.

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 polymer 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 polymer, 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 notified polymer is introduced in a chemical form that does not meet the PLC criteria;
 - further information becomes available on the sensitisation and/or irritation potential of the notified polymer
 - the notified polymer is proposed to be used in aerosol cosmetic spray products;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from cosmetic ingredient, or is likely to change significantly;
 - the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
 - the notified polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the notified 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 was provided by the applicant. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants

Dow Corning Australia Pty Ltd (ABN: 36 008 444 166)
423 Pennant Hills Rd
Pennant Hills NSW 2120

Exempt Information (Section 75 of the Act)

Data items and details claimed exempt from publication: molecular weight, spectral data, purity, polymer constituents, residual monomers/impurities, use details and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)

Dow Corning® 8042 IDD
Dow Corning® EL-8050 ID Silicone Organic Elastomer Blend
Dow Corning® EL-8051 IN Silicone Organic Elastomer Blend
Dow Corning® EL-8052 IH Silicone Organic Elastomer Blend
(All the above contain the notified polymer)

Chemical Name

Siloxanes and Silicones, di-Me, Me hydrogen, polymers with polypropylene glycol bis(2-methyl-2-propen-1-yl) ether

CAS Number

1043538-34-6

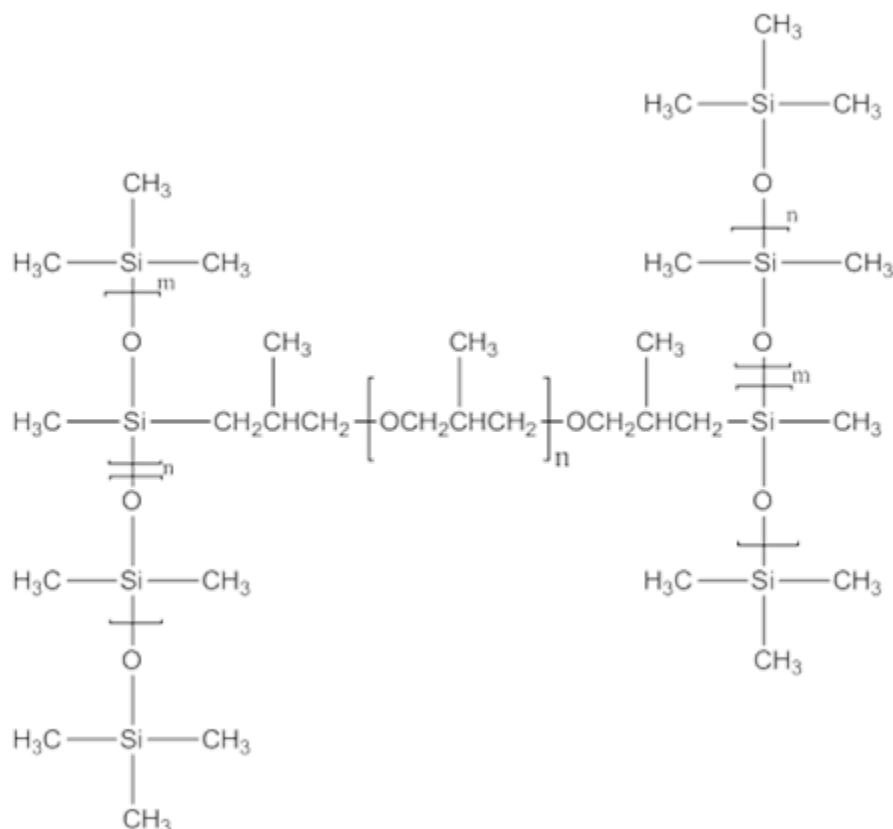
Other Name(s)

Dimethicone/Bis-Isobutyl PPG-20 Crosspolymer (INCI Name)
Dimethyl, Methyhydrogen Siloxane with Polypropylene Glycol Silicone Elastomer Organic Blend

Molecular Formula

Unspecified

Structural Formula



Idealised structure - The polymer prior to crosslinking is a methicone / dimethicone copolymer (methicone has one methyl and one hydrogen on each silicon in the polymer backbone).

Molecular Weight

Number Average Molecular Weight (Mn) is > 10,000 Da

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met</i>
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
Stable Under Normal Conditions of Use	Yes
Not Water Absorbing	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20 °C and 101.3 kPa*	Viscous liquid
Melting Point/Glass Transition Temp	Not determined
Density*	793.6 kg/m ³
Water Solubility	Not determined. Expected to be low since the notified polymer is mainly composed of hydrophobic components and

	has a high molecular weight.
Dissociation Constant	Not determined. The notified polymer does not contain any functional groups that are expected to dissociate in water.
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use
*For product containing the notified polymer at < 20% concentration in organic solvent	

5. INTRODUCTION AND USE INFORMATION

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>
Tonnes	1-2	1-3	1-3	1-3	1-3

Use

The notified polymer will be imported as an ingredient in cosmetic products at < 10% concentration, or at < 20% concentration in organic solvent for formulation of cosmetic products in Australia. The notified polymer is not expected to be used in spray products.

6. HUMAN HEALTH RISK ASSESSMENT

The notified polymer meets the PLC criteria and is therefore expected to be of low hazard. Several skin sensitisation studies carried out on mixtures containing the notified polymer were submitted and are summarised in the following table:

<i>Material Tested</i>	<i>Result</i>	<i>Year of testing</i>	<i>Test Guideline/ Method</i>
1. 10-30% notified polymer in isodecyl neodecanoate	positive	2010	OECD TG 406 Magnusson and Kligman Method
2. 10-30% notified polymer in isodecyl neodecanoate	positive	2010	OECD TG 406 Buehler Method
3. 10-30% notified polymer in isodecyl neodecanoate	negative	2010	OECD TG 406 Buehler Method
4. 10-30% notified polymer in isodecyl neodecanoate	positive	2010	OECD TG 406 Magnusson and Kligman Method
5. 10-30% notified polymer in isodecyl neodecanoate	positive on first challenge but negative in rechallenges at lower concentration	2010	OECD TG 406 Magnusson and Kligman Method
6. 10-30% and 7-21% notified polymer in isodecyl neodecanoate	negative	2011	Repeat insult patch test in human volunteers (HRIPT)
7. 7.5-22.5% notified polymer in isododecane	negative	2015	OECD TG 406 Buehler Method

The results of the different guinea pig sensitisation tests on the blends were inconsistent, with some studies showing negative results (including the most recent study) and some studies indicating that the test materials showed irritation and/or sensitising potential. In a recent well-conducted human skin sensitisation (HRIPT) study on a blend containing up to 10-30% of the notified polymer, the results were negative for both irritation and sensitisation. No Local Lymph Node Assays (LLNA) studies were available.

The notifier advised that the reason for some positive sensitisation results with mixtures containing the notified polymer is not known. The notifier is not aware of positive results with similar polymers, or

of lower molecular weight components / impurities that may produce sensitising effects. The Cosmetic Ingredient Review (CIR) 2014 report on “Safety Assessment of Dimethicone Crosspolymers as Used in Cosmetics” covers a number of ingredients, including the notified polymer. Skin sensitisation studies reported in this document on other dimethicone crosspolymers were negative. Based on the available information, the notified polymer cannot be classified for skin sensitisation, however due to the conflicting results the possibility of sensitising effects cannot be ruled out.

There is also uncertainty about the irritation potential of the notified polymer. Based on data in the animal and human sensitisation studies, the polymer may cause mild irritation effects, however the available information is not sufficient for classification. At the concentration of the polymer in imported mixtures (<20%) and cosmetic products (<10%), any irritation potential is likely to be further reduced.

The notified polymer has low water solubility and a high molecular weight, with a majority of particles expected to be > 70,000 Da. Inhalation of respirable particles of polymers with MW > 70,000 Da has been linked with irreversible lung damage due to lung overloading and impaired clearance of particles from the lung, particularly following repeated exposure (US EPA, 2013). It is also noted (SEHSC, 2001) that some silicone polymers and emulsions demonstrate acute toxicity to the lungs in experimental animals, when inhaled as an aerosol. However, as the notified polymer is not expected to be used in spray products, inhalation exposure is not likely to occur.

Overall the risk of the notified polymer to occupational and public health is not considered to be unreasonable, noting that there is uncertainty regarding the polymer’s potential to cause skin sensitisation.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. Polymers without significant ionic functionality are generally of low concern to the environment.

The notified polymer will not be manufactured in Australia. Release of the notified polymer to the aquatic environment is not expected during blending as mixing of the notified polymer with other ingredients will be done in closed mixers. The blending equipment is expected to be cleaned by washing with solvent. The solvent waste is expected to be collected by licensed disposal contractors for recycling. Solid wastes are expected to be disposed of to landfill.

The majority of the notified polymer will be released to sewer as a result of its use in cosmetic products. Release is assumed to occur daily, and to be diffuse in nature. In sewage treatment plants, most of the notified polymer is expected to partition to sludge and sediments as it has high molecular weight. However, using a conservative assumption that none of the notified polymer will be removed *via* absorption to sludge in the STP, the resultant predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated as 1.82 µg/L [$\text{PEC}_{\text{river}} = 8.22 \text{ kg notified polymer/day} \div (200 \text{ L/person/day} \times 22.613 \text{ million people}) \times 1 \text{ (dilution factor)}$]. The PEC is below the EC50 for algae of the most toxic polymers ($\text{EC}_{50} > 1 \text{ mg/L}$). Notified polymer released to surface waters is not expected to reach ecotoxicologically significant concentrations.

The notified polymer is not expected to be readily biodegradable, as an acceptable analogue has reported a ready biodegradation of 15.60%. When applied to agricultural soils in biosolids or disposed of to landfill, the notified polymer is expected to associate with soil and organic matter and be largely immobile. The notified polymer is not expected to cross biological membranes due to its high molecular weight and is therefore not expected to bioaccumulate. Therefore, the notified polymer is expected to eventually degrade to form water and oxides of carbon and silicon.

Therefore, based on its assumed low hazard and assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

BIBLIOGRAPHY

- CIR (2014) Safety Assessment of Dimethicone Crosspolymers as Used in Cosmetics. International Journal of Toxicology, 2014. Vol. 3(Supplement 2), pp 655-1155.
- SEHSC (2001) Guidance for Aerosol Applications of Silicone-Based Materials, Reston USA, Silicones Environmental, Health and Safety Council, North America
- US EPA (2013) High Molecular Weight Polymers in the New Chemicals Program.
<http://www.epa.gov/oppt/newchemicals/pubs/hmwtpoly.htm> (Accessed 1 October 2013)