

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Polymer in DOW CORNING FA 4002 ID Silicone Acrylate

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

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**

July 2013

Table of Contents

SUMMARY	2
CONCLUSIONS AND REGULATORY OBLIGATIONS.....	2
ASSESSMENT DETAILS.....	3
1. APPLICANT AND NOTIFICATION DETAILS.....	3
2. IDENTITY OF POLYMER	4
3. PLC CRITERIA JUSTIFICATION	4
4. PHYSICAL AND CHEMICAL PROPERTIES.....	4
5. INTRODUCTION AND USE INFORMATION	4
6. HUMAN HEALTH RISK ASSESSMENT.....	5
7. ENVIRONMENTAL RISK ASSESSMENT	6
BIBLIOGRAPHY	6

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/1131	L'Oreal Australia Pty Ltd & Dow Corning Australia Pty Ltd	Polymer in DOW CORNING FA 4002 ID Silicone Acrylate	No	< 10 tonnes per annum	Ingredient in cosmetics

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

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer:
 - Enclosed, automated processes during reformulation processes, where possible.
 - Adequate ventilation during reformulation processes and aerosol applications of products containing the notified polymer.
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure to the notified polymer:
 - Avoid inhalation of aerosol
- 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 during reformulation tasks:
 - Respiratory protection, if ventilation is inadequate.

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.
- Aerosol spray products intended for professional use containing the notified polymer should carry the following safety directions (or similar) on the label:

- Spray only in well ventilated areas
- Avoid inhalation of aerosol

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.

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;
 - information on the inhalation toxicity or potential for lung overloading effects of the notified polymer becomes available;
 - the concentration of the notified polymer exceeds or is intended to exceed 20% in aerosol sprays;
 - the polymer has a number-average molecular weight of greater than 70,000 Da;

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from a component of cosmetic products], 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 notified polymer and products containing the notified polymer were 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)
 Darling Park - Tower 2, Level 20 - 201 Sussex Street
 SYDNEY NSW 2000

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

Exempt Information (Section 75 of the Act)

Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, polymer constituents, residual monomers/impurities, use details and import volume.

2. IDENTITY OF POLYMER**Marketing Name(s)**

DOW CORNING FA 4002 ID Silicone Acrylate (contains the notified polymer at < 50% concentration)

Other Name(s)

Acrylates/Polytrimethylsiloxymethacrylate Copolymer (INCI name)

Molecular Weight

Number Average Molecular Weight (Mn): 10,000 – 70,000 Da

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met</i>
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Not applicable
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	Transparent colourless solid
Melting Point/Glass Transition Temp	132-156 °C
Density	1196.45 kg/m ³ at 25 °C
Water Extractability	< 0.01% at 37 °C, pH 2 and 9; < 0.01% at 20 °C, pH 7, OECD TG 120 (RCC, 2005).
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

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	< 10	< 10	< 10	< 10	< 10

Use

The notified polymer will be imported at < 50% concentration in a solvent based solution for reformulation into cosmetic products. The notified polymer may also be imported in finished cosmetic products. The notified polymer will be used in a range of leave on and rinse off cosmetic products (including sprays) at < 20% concentration.

6. HUMAN HEALTH RISK ASSESSMENT

The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. This is supported by tests submitted on the following toxicological endpoints.

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
1. Rat, acute oral	LD50 > 2000 mg/kg bw	no	OECD TG 423
2. Rat, acute dermal	LD50 > 2000 mg/kg bw	no	OECD TG 402
3. Rabbit, skin irritation	non-irritating	no	OECD TG 404
4. Rabbit, eye irritation	slightly irritating	yes	OECD TG 405
5. Skin sensitisation - non-adjuvant test	no evidence of sensitisation at up to 50% concentration.	no	OECD TG 406 (Buehler test)

All results were indicative of low hazard.

In an eye irritation study in young adult New Zealand White Rabbits, slight to moderate eye irritation was observed at the one hour observation period (redness and chemosis scores of 1 were noted in two of the animals and the remaining animal had a redness score of 2 and iris and chemosis scores of 1). These irritation effects had resolved by the 24-hour observation period with the exception of one animal having a very slight corneal peel (1%) detected during the fluorescein exam. The notified polymer is therefore slightly irritating to the eye but the effects observed do not warrant classification as an eye irritant.

The notified polymer is a high molecular weight (10,000-70,000 Da) polymer with low water solubility. Inhalation of respirable particles of polymers with molecular weights > 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). While there is also a concern for polymers with molecular weights between 10,000 and 70,000 Da, it is acknowledged that there is a data gap for this range. Therefore, there is uncertainty for the potential for lung overloading effects with respect to the notified polymer. If the notified polymer is inhaled at low levels and/or infrequently, it is assumed that it will be cleared from the lungs. However, high level and/or frequent exposure may result in lung overloading effects, though the level of exposure in humans that would result in any effects, as well as the severity of the effect(s), are uncertain. The level of exposure is influenced by the particle size distribution of aerosol products containing the notified polymer. No data to characterise the spray products in view of the potential for aerosol inhalation exposure was supplied by the notifier for the polymer.

Occupational Health and Safety Risk Assessment

The primary risk to human health associated with use of products containing the notified polymer will be due to the potential for lung overloading effects following repeated inhalation of aerosols.

Reformulation

Although reformulation workers will handle the notified polymer frequently at concentrations of < 50%, inhalation exposure is expected to be minimised given the proposed use of PPE and largely enclosed, automated processes used in reformulation facilities. The risk to the health of reformulation workers is therefore not considered to be unreasonable, provided control measures are in place to minimise inhalation exposure (including the use of respiratory protection if ventilation is inadequate).

End users

The potential for lung overloading effects may be of specific concern to hairdressers who regularly use spray products containing the notified polymer (at < 20% concentration), although the degree of exposure is likely to vary greatly depending on the amount and frequency of application and the spray environment (e.g. type of aerosol spray product, room size and degree of ventilation). As there is the potential for lung overloading effects, with uncertainty regarding the level of exposure that would lead to any potential effects, it is recommended that hairdressers avoid inhalation of aerosols and use products in well ventilated areas to minimise exposure. Therefore, provided inhalation exposure of workers to aerosol spray products containing the notified polymer is limited through the use of control measures (e.g. users directed to only apply spray products in well ventilated areas and to avoid inhalation of the spray contents), the risk to the health of workers is not considered to be unreasonable.

Public Health and Safety Risk Assessment

The risk to public health from use of the notified polymer in aerosol spray products (at < 20% concentration) is not considered to be unreasonable, based on infrequent and short-term exposure. Therefore, the risk to public health is not considered to be unreasonable under the proposed use of the notified polymer.

7. ENVIRONMENTAL RISK ASSESSMENT

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

Release of the notified polymer to the aquatic environment is not expected during reformulation as any accidental spills are expected to be collected by inert material and disposed of according to local regulations. Some of the notified polymer may remain as residue in empty import containers (approximately 1% of the total annual import volume) or empty end-use containers (3%), which is expected to be disposed of to landfill along with the empty containers.

The majority of the notified polymer will be released to sewer as a result of its use in hair and skin care products. Release is assumed to occur daily, and to be diffuse in nature. A predicted environmental concentration in rivers (PEC_{river}) can be calculated on the assumptions that 100% of the total annual import volume is released to sewer nationwide but that 90% of the notified polymer is removed by sewage treatment plant (STP) processes. The PEC_{river} is 0.61 µg/L if the daily chemical release ($10000 \text{ kg}/365 \times 10\% = 2.74 \text{ kg}$) is diluted by the daily effluent production ($200 \text{ L/person/day} \times 22.613 \text{ million people} = 4,523 \text{ ML}$). The remainder of the notified polymer partitions to biosolids with an estimated concentration of 54.52 mg/kg (dry wt), and is expected to be disposed of to landfill or applied to agricultural soils for soil remediation. Notified polymer released to surface waters is not expected to reach ecotoxicologically significant concentration.

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. 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

US EPA (2013) High Molecular Weight Polymers in the New Chemicals Program, <www.epa.gov/oppt/newchemicals/pubs/hmwtpoly.htm>.

RCC (2005) Determination of the solution/extraction behaviour of ZMAT number 4047663 (Study number, 2005-I0000-55246, June 2005) Zelgliweg, Switzerland, RCC Ltd, Dow Corning Corporation (Unpublished report submitted by the notifier).