File No PLC/1110

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Polymer in Xiameter MEM-1997 Emulsion
(INCI name: Divinyldimethicone/Dimethicone Copolymer)

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 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.

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

July 2014

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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/1110	Dow Corning Australia Pty Ltd L'Oreal Australia Pty Ltd	Polymer in Xiameter MEM-1997 Emulsion (INCI name: Divinyldimethicone/dimethicone copolymer)	No	≤10 tonnes per annum	Component of 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

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following controls to minimise occupational exposure during reformulation of cosmetic products, where aerosols may be generated:
  - Ventilation system
  - Avoid inhalation of aerosols
  - Use respiratory protection if ventilation is inadequate

- 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.

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

Disposal
- The notified polymer should be disposed 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;
- 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 a component of cosmetics, 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 Road
MELBOURNE VIC 3004

Exempt Information (Section 75 of the Act)
Data items and details claimed exempt from publication: chemical name, CAS number, molecular weight, reactive functional groups, polymer constituents, residual monomers, use details, import volume, and site of reformulation.

2. IDENTITY OF POLYMER

Marketing Name(s)
Xiameter MEM 1997 Emulsion (product containing the notified polymer)

Other Name(s)
Divinyldimethicone/Dimethicone copolymer (INCI)

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

Reactive Functional Groups
The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met*
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	White liquid (product)
Melting Point/Glass Transition Temp	Not determined
Density	990 kg/m^3 at 25 °C
Water Solubility	Expected to be very low based on its high molecular weight and hydrophobic functionalities
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

5. INTRODUCTION AND USE INFORMATION

Mode of Introduction
The notified polymer will not be manufactured in Australia. It will be imported by ship, as a component of cosmetic products (< 5% concentration) in bottles, jars or tubes up to 400 mL in size. Products will be packed in cardboard containers and transported within Australia by road. The polymer may also be imported as the commercial product (emulsion) for reformulation in Australia.

Maximum Introduction Volume of Notified Chemical (100%) Over Next 5 Years

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 10	< 10	< 10	< 10	< 10

Use
The notified polymer will be used as a film forming component of cosmetics. It is proposed for use as an ingredient of cosmetic products in leave-on and rinse-off applications. It will not be used in aerosol spray products, but may be used in pump sprays.

The notified polymer will be imported for reformulation of cosmetic products in Australia, or imported as an ingredient in finished cosmetic products manufactured overseas.

Finished cosmetic products both reformulated in Australia and imported from overseas will contain the notified polymer at < 5%.

6. HUMAN HEALTH RISK ASSESSMENT

No toxicological data were submitted. As the notified polymer meets the PLC criteria it would generally be considered to be of low hazard. However, the notified polymer has low water solubility and a high molecular weight with a majority of particles > 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.

The particle size of the spray is important in determining whether it will reach the deep sections of the lung. It is not expected that particles from pump spray products will reach the alveolar region; therefore lung overloading associated with use of pump spray products containing the notified polymer (< 5% concentration) is not expected to occur.

Occupational Health and Safety Risk Assessment
Worker exposure to the notified polymer during the importation, transport and storage is not expected, except in the event of an accident where packaging may be breached. During reformulation and quality assurance (QA) processes, workers may experience dermal, accidental ocular and perhaps inhalation exposure to the notified polymer up to 90%. The use of enclosed, automated processes and appropriate PPE (impervious gloves, goggles, coveralls and respiratory protection, if significant inhalation exposure is expected) should minimise the potential for exposure. Salon workers may experience dermal, ocular and inhalation exposure to products containing the notified polymer at concentrations of < 5%.

Based on the assumed low hazard of the notified polymer and the expected pattern of exposure, the risk to workers is not considered unreasonable.

Public Health and Safety Risk Assessment
There will be widespread and repeated exposure of the public to the notified polymer up to 5% through the proposed use of rinse-off and leave-on cosmetic products. The principal route of exposure will be dermal, although incidental ocular and inhalation exposure may also occur. Oral (ingestion) exposure is possible if products are applied to the lips. The high molecular weight and expected low water solubility of the polymer are expected to limit absorption by all routes.

Based on the assumed low hazard of the polymer and the expected pattern of exposure, the health risk to the public is not considered to be unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

The majority of the notified polymer will be released to sewer as a result of its use in personal care and cosmetic products that will be washed off the hair and skin. 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 (10,000 kg/365 = 27.4 kg) is diluted by the daily effluent production (200 L/person/day × 22.613 million people = 4,523 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.

Release of the notified polymer to the environment may come from washes for equipment cleaning during reformulation and accidental spills during transportation. These wastes are expected to be collected and disposed of by licensed waste disposal contractors. Some of the notified polymer may remain as residues in empty import containers (approximate 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.

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

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/newchems/pubs/hmwtpoly.htm (Accessed 1 October 2013)