File No PLC/1097

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

C30-45 Alkyldimethylsilyl Polypropylsilsesquioxane

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:

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Director
NICNAS

May 2013

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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/1097	Dow Corning Australia Pty Ltd and L'Oreal Australia Pty Ltd	C30-45 Alkyldimethylsilyl Polypropylsilsesquioxane	No	≤ 10 tonnes per annum	Component of cosmetic products

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 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

- The notified polymer should be disposed of to landfill.

Storage

- The following precautions should be taken by workers regarding storage of the notified polymer:
  - Store in a segregated and approved area that accounts for the accumulation of flammable hydrogen gas, as per the recommendations on the M(SDS).
  - Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials, as per the recommendations on the M(SDS).

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.

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 a product containing the notified polymer were provided by the applicants. The accuracy of the information on the (M)SDS remains the responsibility of the applicants.

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 are: 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(R) SW-8005 C30 Resin Wax

Other Name(s)
C30-45 Alkyldimethylsilyl Polypropylsilsesquioxane (INCI Name)

Molecular Weight
Number Average Molecular Weight (Mn) is > 1,000 Da

3. PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met*
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	White wax
Melting Point/Glass Transition Temp	63-71 °C
Density	797.63 kg/m^3 at 25 °C
Water Solubility	Not determined. Expected to be low based on the predominantly hydrophobic structure.
Particle Size	Not determined as polymer is a wax
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

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

Use
The notified polymer will be used as a film former in leave-on and rinse-off cosmetic products.

The notified polymer will be imported either at 100% concentration or as a component of finished cosmetic products at ≤ 20% concentration. If imported at 100% concentration, the polymer will be reformulated into cosmetic products at ≤ 20% concentration.

6. HUMAN HEALTH RISK ASSESSMENT

No toxicological data (in English) on the notified polymer were submitted. The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. The risk of the notified polymer to occupational and public health is not considered to be unreasonable given the assumed low hazard and the assessed use pattern.

7. ENVIRONMENTAL RISK ASSESSMENT

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

Release of the notified polymer to the environment may occur from equipment cleaning and accidental leaks or spills during reformulation and transportation. These wastes are expected to be collected 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 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.

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.