File No PLC/1395

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Diphenyl Dimethicone/Vinyl Diphenyl Dimethicone/Silsesquioxane Crosspolymer (INCI Name)

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 and Energy.

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:

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Director
NICNAS

March 2017

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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/1395	L'Oreal Australia Pty Ltd	Diphenyl Dimethicone/Vinyl Diphenyl Dimethicone/Silsesquioxane Crosspolymer (INCI Name)	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

- Water insoluble high molecular weight polymers used in the respirable size range (< 10 μm) have the potential to cause lung overloading. Respiratory protection and local exhaust ventilation should be used to prevent inhalation exposure.

- If aerosols are formed during the use of the notified polymer, engineering controls and respiratory protection should be used to prevent inhalation exposure.

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

- In the interest of occupational health and safety, the following precautions should be observed for use of the notified polymer as introduced in powder form:
  - The level of atmospheric nuisance dust should be maintained as low as possible. The Safe Work Australia exposure standard for atmospheric dust is 10 mg/m^3.

- 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;
- the polymer is intended 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

Applicant
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, 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)
Diphenyl Dimethicone/Vinyl Diphenyl Dimethicone/Silsesquioxane Crosspolymer (INCI Name)

Molecular Weight
Number Average Molecular Weight (Mn) is > 70,000 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 powder
Melting Point/Glass Transition Temp	Not determined
Density	1,110 kg/m^3 at 25 °C
Water Solubility	Expected to be insoluble based on hydrophobic cross-linked molecular structure
Dissociation Constant	Not determined. The notified polymer does not contain any functional groups that are expected to dissociate in water
Particle Size	D_{50} = 6.4 µm; D_{95} = 8.1 µm
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 not be manufactured in Australia. It will be imported in formulated finished leave-on and rinse-off cosmetic products at up to 10% concentration as a skin and hair conditioning agent. The notified polymer may at some time in the future be imported as a raw material for reformulation of cosmetic products locally. The notified polymer will not be used in aerosol spray products.

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.

Endpoint	*Result*	*Effects Observed*	*Test Guideline*
Rat, acute oral	LD50 > 5000 mg/kg bw; low toxicity	No	Similar to OECD TG 401
Rabbit, skin irritation	Non-irritating	Yes*	Similar to OECD TG 404
Skin sensitisation – Buehler test	No evidence of sensitisation	No	Similar to OECD TG 406 (Buehler test)
Genotoxicity - bacterial reverse mutation	Non mutagenic	No	Similar to OECD TG 471

* Very slight erythema observed in one test animal at the 24-hour observation.

All results were indicative of low hazard.

Although not considered in this risk assessment, NICNAS notes that the notified polymer contains residual monomers that are classified as hazardous according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

The notified polymer is a high molecular weight (> 70,000 Da), water insoluble polymer with a particle size in the respirable range (< 10 μm). Inhalation 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, 2015). If the notified polymer is inhaled at low levels and/or infrequently, it is assumed that it will be cleared from the lungs.

Occupational Health and Safety Risk Assessment

Reformulation
In the future, the notified polymer may be imported in a powder form for local reformulation into cosmetic products. Control measures including respiratory protection and local ventilation should therefore be in place to prevent inhalation exposure and hence lower the risk of potential lung overloading.

End use
Professional workers (eg. cosmetic service providers) may use pump spray products containing the notified polymer at up to 10% concentration. The risk to such professional workers is expected to be of a similar or lesser extent than that experienced by consumers using the same products (see below).

Given the assumed low hazard of the notified polymer and provided measures are in place to reduce inhalation exposure to the notified polymer, the risk to workers is not considered to be unreasonable.

Public Health and Safety Risk Assessment
Cosmetic products containing the notified polymer at up to 10% concentration will be sold to the public. It has been proposed that the notified polymer may be used in spray products with pump spray

mechanism. Based on a CIR report (CIR, 2012), both pump sprays and propellant sprays (also called "aerosol sprays") produce aerosols, but the aerosols from pump sprays have much smaller fractions of respirable droplets/particles than aerosols from propellant sprays. Typically, the median aerodynamic equivalent diameter (d_{ae}) of the airborne droplets/particles of pump hair sprays range from 60 to 80 µm with < 1% of the droplets/particles having d_{ae} < 10 µm.

Droplets/particles with d_{ae} > 10 µm may enter the nasopharyngeal region through the nose/mouth or pass through the larynx to enter the trachea, bronchi and bronchioles. In these regions of the respiratory tract, mucus-secreting and ciliated cells form a protective mucociliary blanket that carries deposited droplets/particles to the throat to be sneezed or spit out, or swallowed. There is also scientific consensus that healthy people are able to clear particles with d_{ae} > 7 µm from the nasopharyngeal and bronchial regions within 24 hours through mucociliary action (CIR, 2012).

However, droplets/particles with d_{ae} < 10 µm may reach the pulmonary region of the lung. In the pulmonary region, the clearance of water insoluble particles is mediated primarily by alveolar macrophages, and is slow and limited (CIR, 2012). Therefore, to avoid the potential for lung overloading effects, the notified polymer should not be used in spray products that are capable of generating respirable aerosols with d_{ae} < 10 µm during use.

Based on the available information and proposed use scenario, the risk to the public from use of the notified polymer at ≤ 10% in rinse-off and leave-on cosmetics is not considered to be unreasonable.

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 be imported into Australia as a component of finished cosmetic products. The notified polymer may also be imported into Australia as a raw material for local reformulation into a variety of cosmetic products. Release of the notified polymer during reformulation in Australia is expected to be limited to accidental spills or leaks, and residue in import containers. These releases are expected to be collected and disposed of to landfill in accordance with local government regulations.

Based on its use in cosmetic products, the majority of the notified polymer is expected to be released to the aquatic compartment through sewers during use. Under a worst case scenario, it is assumed that 100% of the notified polymer will be washed into sewers. In sewage treatment processes, very little of the notified polymer is expected to partition to the supernatant water as it is insoluble in water and has high molecular weight. Therefore, the notified polymer is not expected to be released to surface waters at ecotoxicologically significant concentrations.

Solid wastes including container residues are expected to be disposed of to landfill. When applied to agricultural soils in biosolids or disposed of to landfill, the notified polymer is expected to be associated with soil and organic matter. Due to its high molecular weight and insolubility in water, the notified polymer is not expected to cross biological membranes, and is therefore not expected to bioaccumulate. In both surface waters, soils and in landfill, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon and silicon.

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

BIBLIOGRAPHY

US EPA (2015) High Molecular Weight Polymers in the New Chemicals Program https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/high-molecular-weight-polymers-new (Accessed on 06 January 2017)

CIR (2012) CIR Precedents - Aerosols (September, 2012) Cosmetic Ingredient Review