

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

POLYMER OF LOW CONCERN PUBLIC REPORT

PEG-9 Polydimethylsiloxylethyl Dimethicone

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:

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/1119	L'Oreal Australia Pty Ltd	PEG-9 Polydimethylsiloxyethyl Dimethicone	No	≤ 5 tonnes per annum	Component of personal care and 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 MSDS should be easily accessible to employees.
- When formulating cosmetic and personal care products containing the notified polymer, formulators should take into account its irritation potential.
- 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 to landfill.

Storage

- The following precautions should be taken by workers regarding storage of the notified polymer:
 - Store in a segregated and approved area.

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 personal care and 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 MSDS of the notified polymer and products containing the notified polymer were provided by the applicant. The accuracy of the information on the MSDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants

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, polymer constituents, residual monomers/impurities, import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)

KF-6028

Other Name(s)

PEG-9 Polydimethylsiloxylethyl Dimethicone (INCI Name)

Molecular Formula

Unspecified

Molecular Weight

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

Reactive Functional Groups

The notified polymer contains only low concern functional groups.

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	Colourless to light brown liquid
Melting Point/Glass Transition Temp	Not Determined
Density	990-1010 kg/m ³ at 25 °C
Water Solubility	< 1x10 ⁻³ g/L at 20 °C. Test substance (0.1mg) dispersed in water (100 mL) was observed to be turbid after shaking for 96 hours (Shin-Etsu, 2012).
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	≤ 5	≤ 5	≤ 5	≤ 5	≤ 5

Use

The notified polymer will be used as a component of cosmetics. The expected product types are foundation, leave-on creams and lotions, and rinse-off surfactants. Some product types may be applied by spray.

The notified polymer will not be manufactured in Australia. The notified polymer will be imported in end-use products at a concentration of ≤ 4%. The notified polymer may be imported into Australia at a concentration of 100% and reformulated into products containing the notified polymer at ≤ 4% 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 toxicological endpoints detailed below. The notified polymer is expected to have slight irritation potential, that does not meet the criteria for classification under the GHS. Worker exposure is likely to be controlled through use of personal protective equipment. Dermal exposure of the public to the notified polymer at ≤ 4% is expected to be widespread and frequent through daily use of personal care and cosmetic products. However, given the assumed low hazard and relatively low concentration of use by consumers, the risk posed by exposure to the notified polymer is not considered unreasonable.

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
Rat, acute oral	LD50 > 5000 mg/kg bw	No	Similar to OECD TG 401
EpiSkin Primary Cutaneous Tolerance, skin irritation	Potentially non-irritating		ECVAM Episkin Skin Irritation Test Version 1.2
Rabbit, skin irritation	Slightly irritating	Yes	Similar to OECD TG 404
Rabbit, cumulative skin irritation	Slightly irritating	Yes	In-house method
Isolated Calf Cornea, eye irritation	Slightly irritating	Yes	Isolated Calf Cornea Method (BCOP)
Rabbit, eye irritation	Slightly irritating	Yes	Similar to OECD TG 405
Hen's Egg Test – Chorio-allantoic membrane (HET-CAM)	Slightly irritating	Yes	HET-CAM
Guinea pig, skin sensitisation	No evidence of sensitisation (Challenge at 50% conc.)	No	Similar to OECD TG 406 (Buehler)
Genotoxicity - bacterial reverse mutation	Non mutagenic	No	Similar to OECD TG 471

Toxicokinetics

The notified polymer has a high molecular weight (> 1000 Da) with a moderate proportion of low molecular weight species (< 10% with molecular weight < 1000 Da) and limited water solubility (< 1 mg/L). These characteristics are expected to limit absorption in the gastrointestinal tract, or following dermal or inhalation exposure.

Acute toxicity

The notified polymer was of low acute oral toxicity in rats with a LD50 > 5000 mg/kg bw in a study similar to OECD TG 401. No mortalities or signs of systemic toxicity were observed. The treated animals displayed expected weight gains during the study.

Skin Irritation

After a single dose, the notified polymer was considered to be a slight irritant to the intact and abraded skin of rabbits at concentrations of 100% and 20%.

A cumulative dermal irritation was conducted in rabbits, with each rabbit receiving a dermal application of 0.5 mL of the notified polymer at 5% in corn oil, 5 days/week for 2 weeks. Under the conditions of this test, the notified polymer elicited a very slight to well-defined erythema, with some scaling.

An *in vitro* evaluation of skin irritation was performed on reconstructed human epidermis model using the EpiSkin small model. The results suggest that the notified polymer is potentially non-irritant.

Eye irritation

The notified polymer was predicted to be slightly irritating to the eye in two *in vitro* studies, the HET-CAM (Hen's Egg Test Chorioallantoic Membrane) test and the isolated Calf Cornea (BCOP) test. It is noted that the HET-CAM assay has not yet been fully validated as a replacement test for the *in vivo* Draize test.

Skin sensitisation

In a study similar to OECD TG 406 the notified polymer was not a skin sensitizer in guinea pigs under the conditions of the test.

Mutagenicity

In a study similar to OECD TG 471 the notified polymer no genotoxicity was observed.

7. ENVIRONMENTAL RISK ASSESSMENT

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

It is estimated by the notifier that up to 4% of the total import volume of the notified polymer may be released to the environment as a result of waste produced during reformulation processes, accidental spills during transportation or residues in empty containers. These 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 that will be washed off the 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 assumption that 100% of the total annual import volume is released to sewer nationwide with the removal of 90% notified polymer during sewage treatment plant (STP) processes (Boethling RS & Nabholz J, 1997). The PEC_{river} is 0.3 µg/L if the daily chemical release ($10\% \times 5000 \text{ kg}/365 = 1.37 \text{ kg}$) is diluted by the daily effluent production ($200 \text{ L/person/day} \times 22.613 \text{ million people} = 4,523 \text{ ML}$). Therefore, the notified polymer is unlikely to reach ecotoxicologically significant concentrations in surface waters. The notified polymer is not expected to cross biological membranes due to its high molecular weight and is therefore not expected to bioaccumulate. The remainder of the notified polymer partitions to biosolids with an estimated concentration of 27.3 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 based on its low water

solubility. In landfill and soil, the notified polymer is expected to eventually degrade to form water and oxides of carbon and silica.

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.

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