File No PLC/1304

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Stearate ester of modified silicone polymer

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.

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

August 2016

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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/1304	L'Oreal Australia Pty Ltd	Stearate ester of modified silicone polymer	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

- 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 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.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the notified polymer has changed from 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 a product containing the notified polymer was 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
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
Dimethiconol Stearate (name used on cosmetic products)

Other Name
Stearate ester of modified silicone polymer (generic 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	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	Soft creamy off white paste with fatty odour
Melting Point/Glass Transition Temp	10-40 °C
Density	940 kg/m^3 at 25 °C
Water Solubility	Expected to be low based on predominantly hydrophobic molecular structure
Dissociation Constant	Contains no dissociable functionalities
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 to Australia in end-use leave on and rinse off cosmetic products, including aerosol products. It may also be imported as a raw material for reformulation into cosmetic 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*
1. Rat, acute oral*	LD50 > 2,000 mg/kg bw	no	OECD TG 401
2. Rat, acute dermal*	LD50 > 2,000 mg/kg bw	no	OECD TG 402
4. Rabbit, skin irritation*	Slightly irritating	yes	OECD TG 404
5. Rabbit, eye irritation*	Slightly irritating	yes	OECD TG 405
6. Skin sensitisation - adjuvant test**	no evidence of sensitisation.	no	OECD TG 406 (Magnusson and Kligman Maximisation test)

* Notified polymer, translated summary submitted.
** Analogue polymer, study report submitted. The presence of a crust 24 h after challenge was attributed to injuries at the dressing site. No crust was seen at the 48 h 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. These are not present in the notified polymer as introduced above the cut off concentrations for classification.

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. 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, due to its high molecular weight and expected low water solubility. Therefore, the notified polymer is not expected to be released to surface waters at ecotoxicologically significant concentrations. Based on its high molecular weight and expected low water solubility, the notified polymer is not expected to cross biological membranes, and is therefore unlikely to bioaccumulate.

All wastes including container residues are expected to be disposed of to landfill. Based on the results of an ultimate biodegradability study on an analogue, the notified polymer is not expected to be readily biodegradable (20% in 28 days). In both surface waters 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.