

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

POLYMER OF LOW CONCERN PUBLIC REPORT

Siloxanes and Silicones, di-Me, 3-hydroxypropyl Me, lauryl Me, Me 2-[3,3,3-trimethyl-1,1-bis[(trimethylsilyl)oxy]-1-disiloxanyl]ethyl, ethoxylated (INCI Name: Lauryl PEG-10 Tris(trimethylsiloxy)silylethyl 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**

June 2014

Table of Contents

SUMMARY	2
CONCLUSIONS AND REGULATORY OBLIGATIONS.....	2
ASSESSMENT DETAILS.....	3
1. APPLICANT AND NOTIFICATION DETAILS	3
2. IDENTITY OF POLYMER	3
3. PLC CRITERIA JUSTIFICATION	4
4. PHYSICAL AND CHEMICAL PROPERTIES.....	4
5. INTRODUCTION AND USE INFORMATION	4
6. HUMAN HEALTH RISK ASSESSMENT.....	5
7. ENVIRONMENTAL RISK ASSESSMENT	5

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/1199	Dow Corning Australia Pty Ltd	Siloxanes and Silicones, di- Me, 3-hydroxypropyl Me, lauryl Me, Me 2-[3,3,3- trimethyl-1,1- bis[(trimethylsilyl)oxy]-1- disiloxanyl]ethyl, ethoxylated (INCI Name: Lauryl PEG-10 Tris(trimethylsiloxy)silylethyl Dimethicone)	No	≤ 30 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 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 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 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

Dow Corning Australia Pty Ltd (ABN: 36 008 444 166)
Locked Bag 2095
NORTH RYDE NSW 1670

Exempt Information (Section 75 of the Act)

Data items and details claimed exempt from publication: structural formulae, molecular weight, polymer constituents, use details.

2. IDENTITY OF POLYMER

Marketing Name(s)

ES-5300 Formulation Aid

Chemical Name

Siloxanes and Silicones, di-Me, 3-hydroxypropyl Me, lauryl Me, Me 2-[3,3,3-trimethyl-1,1-bis[(trimethylsilyl)oxy]-1-disiloxanyl]ethyl, ethoxylated

CAS Number

1365118-01-9

Other Name(s)

Lauryl PEG-10 Tris(trimethylsiloxy)silylethyl Dimethicone (INCI Name)
Dimethyl, methyl(dodecyl), methyl(propyl(polyethylene oxide)), methyl
(tris(trimethylsiloxy)silylethyl) siloxane, trimethyl terminated
Organo functional silicone

Molecular Formula

Unspecified

Molecular Weight

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

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met</i>
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	Light brown liquid
Melting Point/Glass Transition Temp	Not applicable
Density	960.8 kg/m ³ at 25 °C
Water Solubility	Expected to be low since the notified polymer is mainly composed of hydrophobic components and has a high molecular weight.
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	1-30	1-30	1-30	1-30	1-30

Use

The notified polymer will be imported into Australia in 18 kg or 190 kg drums or 100 g bottles at 100% concentration. The notified polymer will be reformulated in Australia and used as a cosmetic additive at an end-use concentration of approximately 2%.

6. HUMAN HEALTH RISK ASSESSMENT

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

The notified polymer will not be manufactured in Australia. Release of the notified polymer to the aquatic environment is not expected during reformulation as mixing of notified polymer with other ingredients will be done in closed mixers. The formulation equipment is expected to be cleaned by washing with solvent. The solvent waste is expected to be treated as site industrial waste and collected by licensed disposal contractors for recycling. Solid 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 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 1.82 $\mu\text{g/L}$ if the daily chemical release ($30000 \text{ kg}/365 \times 10\% = 8.2 \text{ kg}$) is diluted by the daily effluent production ($200 \text{ L/person/day} \times 22.613 \text{ million people} = 4,523 \text{ ML}$). The remainder of the notified polymer partitions to biosolids with an estimated concentration of 163.6 mg/kg (dry wt), and is expected to be disposed of to landfill or applied to agricultural soils for soil remediation. Notified polymer released to surface waters is not expected to reach ecotoxicologically significant concentrations.

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.