

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

POLYMER OF LOW CONCERN PUBLIC REPORT

Siloxanes and Silicones, di-Me, Me hydrogen, polymers with 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane-hexamethyldisiloxane-silicic acid (H₄SiO₄) tetra-Et ester hydrolysis products (INCI Name: Vinyltrimethyl/ Trimethylsiloxysilicate/Dimethicone Crosspolymer)

This Self Assessment has been compiled by the applicant and adopted by NICNAS in accordance with the provisions of the Industrial Chemicals (Notification and Assessment) Act 1989 (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS), administered by the Department of Health and the Department of the Environment, has screened this assessment report. The data supporting this assessment will be subject to audit by NICNAS.

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**

March 2014

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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
SAPLC/159	Wacker Chemie Ag	Siloxanes and Silicones, di-Me, Me hydrogen, polymers with 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane-hexamethyldisiloxane-silicic acid (H ₄ SiO ₄) tetra-Et ester hydrolysis products (INCI Name: Vinyltrimethyl/Trimethylsiloxysilicate/Dimethicone Crosspolymer)	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.

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

- 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.

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**

Wacker Chemie Ag (ABN: 11 607 113 062)
1/35 Dunlop Road
MULGRAVE VIC 3170

Exempt Information (Section 75 of the Act)

Data items and details claimed exempt from publication: structural formulae, molecular weight, polymer constituents, residual monomers/impurities, and import volume.

2. IDENTITY OF POLYMER

Chemical Name

Siloxanes and Silicones, di-Me, Me hydrogen, polymers with 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane-hexamethyldisiloxane-silicic acid (H₄SiO₄) tetra-Et ester hydrolysis products

CAS Number

909791-34-0

Molecular Formula

Unspecified

Marketing Name(s)

BELSIL® REG 1100 (contains the notified polymer at < 16% concentration)

Other Name(s)

Vinyldimethyl/Trimethylsiloxysilicate/Dimethicone Crosspolymer (INCI name)

Molecular Weight

Number Average Molecular Weight (Mn) is > 10,000 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	Solid
Melting Point/Glass Transition Temp	Not applicable
Density	930 kg/m ³ at 20 °C (for the product BELSIL® REG 1100)
Water Solubility	Insoluble in water
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	≤ 10	≤ 10	≤ 10	≤ 10	≤ 10

Use and Mode of Introduction

The notified polymer will be imported into Australia in formulated products only. Those products will be imported at > 95% by sea in steel drums of 180 kg and in polyethylene pails of 18 kg and transported from the wharf by truck to customer sites. The notified polymer is manufactured in

Germany. Customers in Australia will only receive the notified polymer in formulated products containing the notified polymer at less than 16%. Formulations containing the notified polymer will be used to manufacture cosmetic products.

6. HUMAN HEALTH RISK ASSESSMENT

No toxicological data were submitted. The notified polymer meets the PLC criteria and can therefore be considered 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

7.1. Exposure Assessment

The notified polymer is intended for cosmetic application to be used on the human skin. Most of it will end up in the waste-water system, going to the waste water treatment plant. The notified polymer is expected to be stable under normal environmental conditions. Due to its low water solubility and low vapour pressure, the notified polymer in solid wastes is expected to remain bound within the soils and sediments of landfills and eventually degrade through biotic and abiotic processes. When used in cosmetic applications, the final fate of the product is the waste-water system. The notified polymer is insoluble in water and will be eliminated from the waste water in treatment plants by adsorption to the sewage sludge, which is expected to be disposed of to landfill. The notified polymer is not expected to be readily biodegradable but due to its high molecular weight, it is not expected to bioaccumulate. Thermal decomposition of the notified polymer will result in the formation of water vapour, carbon dioxide and silicone oxide.

7.2. Environmental Hazard Characterisation

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

7.3. Environmental Risk Assessment

The notified polymer will mainly end up in the waste water system and be carried out of the water compartment via the sewage sludge. Based on its assumed low hazard and assessed use pattern, and its properties (non-hazardous, low vapour pressure, high molecular weight), the notified polymer is not considered to pose an unreasonable risk to the environment.