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

FULL PUBLIC REPORT

**Siloxanes and Silicones, di-Me, 3-hydroxypropyl Me, ethers with polyethylene-
polypropylene glycol monobenzoate**

This Assessment has been compiled 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) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Heritage.

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**Director
NICNAS**

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FULL PUBLIC REPORT**Siloxanes and Silicones, di-Me, 3-hydroxypropyl Me, ethers with polyethylene-polypropylene glycol monobenzoate****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

A.S. Harrison & Co. Pty Ltd (ABN 89 000 030 437)
75 Old Pittwater Road
Brookvale NSW 2100

NOTIFICATION CATEGORY

Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

CHEMICAL NAME

Siloxanes and Silicones, di-Me, 3-hydroxypropyl Me, ethers with polyethylene-polypropylene glycol monobenzoate

OTHER NAME(S)

Dimethicone PEG/PPG-20/23 Benzoate

MARKETING NAME(S)

Finsolv SLB-101

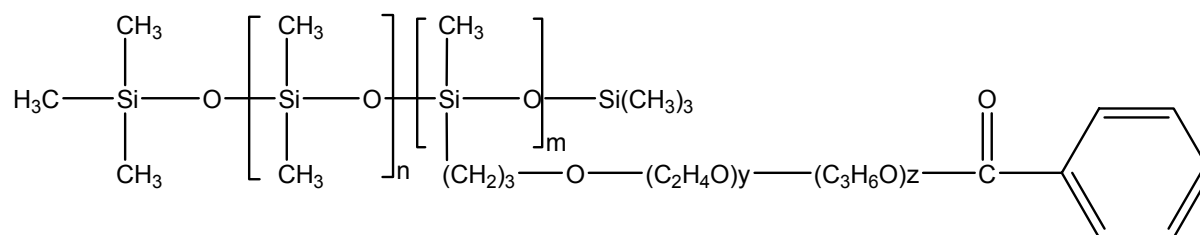
CAS NUMBER

337966-38-8

MOLECULAR FORMULA

$C_3H_9SiO(C_2H_6OSi)_n[C_4H_9SiO_2(C_2H_4O)_y(C_3H_6O)_zC_7O]_mC_3H_9Si$

STRUCTURAL FORMULA



MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn)	6449
Weight Average Molecular Weight (Mw)	14048
Polydispersity Index (Mw/Mn)	2.18
% of Low MW Species < 1000	0
% of Low MW Species < 500	0

POLYMER CONSTITUENTS

<i>Chemical Name</i>	<i>CAS No.</i>	<i>Weight % starting</i>	<i>Weight % residual</i>
Poly(oxy-1,2-ethanediyl), α -hydro- ω -hydroxy-	25322-68-3	6	0
Poly[oxy(methyl-1,2-ethanediyl)], α -hydro- ω -hydroxy-	25322-69-4	9	0
Benzoic acid	65-85-0	1	0
Dimethicone	9006-65-9	84	0
Oxirane	75-21-8		< 0.01
Oxirane, methyl-	75-56-9		< 0.10

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met (yes/no/not applicable)</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	Clear to hazy liquid
Melting Point/Glass Transition Temp	Freezing point < -10 °C
Density	~1000 kg/m ³ at 25 °C
Water Solubility	> 400 g/L at 20°C. A clear solution was observed, after incremental amounts of test substance were added to deionised water. However, silicones are generally insoluble so the polymer may actually be present as a

micro-emulsion rather than in solution.

**Dissociation Constant
Reactivity**

No acid or base groups are present
Stable under normal environmental conditions. Contains hydrolysable groups but unlikely to undergo hydrolysis except under extreme pH and temperature 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>
<i>Tonnes</i>	0.6	0.8	1.0	1.5	3.0

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

Imported in sealed 204.15 kg drums at approximately 100%.

Reformulation/manufacture processes

This product will be reformulated in a batch process with other ingredients. It is added at the end of the process at a maximum temperature of 35°C. It will be then filled into aerosol cans, pressurised and distributed to the consumer market. The end use will be into a range of shaving foams.

Use

To improve skin feel in a shaving cream formulation. Used at ~0.1% by weight.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Dermal and ocular exposure can occur during certain formulation processes. However, exposure to significant amounts of the notified polymer is limited because of the engineering controls (local exhaust ventilation) and personal protective equipment worn by workers.

PUBLIC EXPOSURE

The general public is not exposed to the neat notified polymer. Personal care products containing the notified polymer are for sale to the general public. Members of the public make dermal contact and possibly accidental ocular contact with products containing the notified polymer. However, exposure is low because the notified polymer is present at low concentrations (appropriately 0.1% by weight).

6.2. Toxicological Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by toxicological endpoints observed in testing conducted on the notified polymer.

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>
MatTek Corporation EpiDerm™ Skin Model <i>In Vitro</i> Toxicity Testing System, skin irritation	Non irritating	no	no

MatTek Corporation EpiOcular™ Tissue Model *In Vitro* Toxicity Testing System, eye irritation

Non irritating

no

no

All results were indicative of low hazard.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

The OHS risk presented by the notified polymer is expected to be low given its likely low hazard and predicted low exposure to workers involved in formulating personal care products due to a mostly automated system coupled with the use of PPE. The notified polymer may be present in formulations containing hazardous ingredients. If these formulations are classified as hazardous to health in accordance with the NOHSC Approved Criteria for Classifying Hazardous Substances, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

PUBLIC HEALTH

The notified polymer as imported is not available to the public. Members of the public may make dermal contact with products containing the notified polymer. However, the risk to public health is negligible because the notified polymer meets the PLC criteria and the concentration of the polymer in personal care products is low (~ 0.1%).

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

The notified polymer is not manufactured in Australia but is reformulated and packaged into aerosol cans for personal care products. It is estimated that a maximum of 1% (< 30 kg per annum) of the notified polymer will remain in the import packaging. Currently approximately 50% of this packaging (tin plate cans) undergoes metal recycling. The remaining packaging is likely to be disposed of to landfill. A small amount (< 1%; < 30 kg per annum) may require disposal from cleaning of equipment and spills. This is likely to be disposed of to landfill. Approximately 3-5% (< 150 kg per annum) of the notified polymer is expected to remain in the empty aerosol cans. These are likely to be disposed of as domestic waste. The remainder is likely to enter the sewer during use (e.g. from washing of skin and razor after shaving and washing of towels used to dry skin).

ENVIRONMENTAL FATE

Most of the notified polymer (~95%; < 2850 kg per annum) is expected to enter the sewer during use. The remainder as residue in packaging will share the fate of the packaging. Most of this will be landfilled with the polymer eventually undergoing abiotic and biotic degradation to landfill gases including methane and oxides of carbon and silicon and water vapour. During metal recycling the notified polymer is expected to undergo thermal decomposition to oxides of carbon, silicon and water vapour.

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

Most of the notified polymer will be disposed of to sewer throughout Australia during use. A worst case predicted environmental concentration (PEC) assuming no adsorption of the polymer in the sewage treatment plant (STP) may therefore be calculated as 1.9 µg/L at sewage outfall (2850 kg per

annum ÷ (20.5 million persons × 200 L per day per person × 365 days).

As no toxicity data were provided a predicted no effect concentration (PNEC) and risk quotient (RQ) cannot be calculated. However, non-toxic PLCs are of low concern to the aquatic environment. Therefore the notified polymer is likely to pose an acceptable risk to the environment.

8. CONCLUSIONS

8.1. Level of Concern for Occupational Health and Safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

8.2. Level of Concern for Public Health

There is No Significant Concern to public health when used in the proposed manner.

8.3. Level of Concern for the Environment

The polymer is not considered to pose a risk to the environment based on its reported use pattern.

9. MATERIAL SAFETY DATA SHEET

9.1. Material Safety Data Sheet

The notifier has provided MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

10. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- 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.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of by authorised landfill.

Emergency procedures

- Spills and/or accidental release of the notified polymer should be handled by physical containment with subsequent adsorption with compatible material (sand, vermiculite etc). Transfer to suitable containers for disposal or reclamation.

10.1. Secondary Notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under subsection 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 subsection 64(2) of the Act:
- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.