File No PLC/422

16 December 2003

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Silicon polyamide

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.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
National Occupational Health and Safety Commission
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1161 or + 61 2 6279 1163.

This Full 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:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, 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
Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT

Silicon polyamide

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Dow Corning Australia Pty Ltd of Macquarie University Research Park, 3 Innovation Road, North Ryde, NSW 2113 (ABN 36 008 444 166).

NOTIFICATION CATEGORY
Synthetic Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

- Chemical name
- Other names
- CAS number
- Molecular formula
- Structural formula
- Molecular weight
- Polymer constituents

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)
No

NOTIFICATION IN OTHER COUNTRIES
No

2. IDENTITY OF CHEMICAL

Exempted

PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met (yes/no/not applicable)*
Meets Molecular Weight Requirements	Yes
Meets Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
No Substantial Degradability	Yes
Not a Water Absorbing Polymer	Yes
Low Concentrations of Residual Monomers	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. INTRODUCTION AND USE INFORMATION

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1	1	1	1	1

USE
Will be used in colour cosmetics, skin care (facial moisturize & nourishing), sun care and hair care (conditioning, colourants & styling).

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

The notified polymer will be imported in the solid product 2-8178 Gellant at a concentration > 60% in 10 kg pails or 100 kg drums. It will be reformulated in Australia by manufacturers of cosmetics, hair care, and skin care products. at concentrations less than 30%.

Following stevedoring, the product containing the notified polymer will be transported to reformulation sites where it is heat melted and poured into either an open or closed mixer. Following blending, the reformulated product will be automatically packaged for consumer use and transported to retail outlets for sale.

6. EXPOSURE INFORMATION

6.1. Summary of Environmental Exposure

The notifier indicates that the majority of the polymer will be used in the formulation of personal care products. A small amount of the notified polymer may be washed off from formulation machinery during the normal cleaning process. This normally should be treated as site industrial waste and dealt with by licensed disposal contractor. Some will be ultimately released into the sewer. Empty import containers with any remaining residual material will be disposed of to landfill.

The formulated product will be applied to hair or skin. Therefore, the majority of the polymer is expected to be washed off and enter the sewer, with the remainder disposed of in landfill as residues in product containers. It is expected that waste polymer that enters the sewer will adsorb onto sediments due to its low water solubility. Sludge is expected to be landfilled.

6.2. Summary of Occupational Exposure

Reformulation

Dermal and ocular exposure may occur during the pouring of the melted product containing the notified polymer into the mixer. However, exposure to significant amounts of the notified polymer is limited because of the engineering controls and the personal protective equipment worn by workers. Inhalation exposure is not likely to occur due to the non-volatility of the polymer solution. Following quality control procedures, the formulation containing the notified polymer is packaged into consumer sized packaging. Exposure to the notified polymer is not expected during this highly automated process except in the event of leaking or malfunctioning filling equipment or transfer lines.

Transport & Storage

Exposure to the notified polymer as it occurs in either the imported product or the reformulated consumer articles, is not expected except in the unlikely event of an accident where the containers may be breached.

Retail

Retail workers involved in the shelf filling and sale of the final consumer product are not expected to be exposed to the notified polymer except in cases of an accident where the packaging may be breached

End-Use
Intermittent, wide-dispersive use with direct handling is expected to occur among hairdressers, cosmeticians, and beauticians. According to EASE (1997) modelling of this work environment, exposure in the range of 1-5mg/cm^2.day of products containing up to 30% of the notified polymer could result. Dermal exposure is expected during application of certain products and accidental ocular exposure may also occur. The notified polymer is non-volatile, however, if it is present in product applied as a mist or aerosol, inadvertent inhalation of the notified polymer may also occur.

6.3. Summary of Public Exposure
Cosmetic products containing the notified polymer at concentrations of up to 30% are for sale to the general public. Members of the public will make dermal contact and possibly accidental ocular contact with products containing the notified polymer. In most cases exposure is expected to be limited to 1-10 grams of product, 1-2 times per day.

7. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20^{o}C and 101.3 kPa	Straw-coloured wax-like solid
Melting Point/Glass Transition Temp	Not determined
Density	1 g/mL
Water solubility	Silicones are typically classed as having low water solubility (Hamelink 1992). A review of a related high molecular weight PDMS has indicated that solubility decreases with increase in molecular weight (Kuo 1996). At a MW of 56,000, a solubility of 0.076 ppm was obtained for PDMS. Silicone polyamide is a solid gel particle which has a highly-linked insoluble 3-D matrix. Its molecular weight is greater than 56,000. Therefore, its solubility in water is expected to be <0.076 ppm.
Flammability Limits	Not flammable
Reactivity	None
Explosive properties	None

Considering the likely low solubility, the polymer is unlikely to hydrolyse in the environmental pH range of 4-9 (despite the presence of amide groups) and should associate with the octanol or soil/sediment phases. There are no dissociable groups.

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology
No toxicological data were submitted.

8.2. Human Health Hazard Assessment
The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. The MSDS for the imported product 2-8178 Gellant indicates that direct contact with the eyes may cause mild irritation.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology
No toxicological data were submitted for the notified polymer. However, ecotoxicity data based on a related polymer to support the application of another polymer were used to support this notification. The following results of the toxicological studies were submitted:

Endpoint	*Result and Conclusion*
Ready Biodegradability	not biodegradable

Bioaccumulation	not bioaccumulative
Fish Toxicity	Not determined
Daphnia Toxicity (*Daphnia magna*)	No mortalities experienced at a nominal loading of 11.5 g/L after 48 h exposure
Algal Toxicity	Not determined
Inhibition of Bacterial Respiration	EC50>100 mg/L
Microtox testing	5 and 15 min EC50>90 mg/L

All results were indicative of low hazard.

9.2. Environmental Hazard Assessment

Waste generated from the cleaning of the formulation machinery and from use of the product will be released into the sewer. It is expected that the notified polymer will adsorb onto sediments due to its expected low water solubility. Some sludge containing the notified polymer and residues from empty import drums and product containers will be disposed of to landfill. Any notified polymer released in landfill will not leach due to its low water solubility. Siloxanes are degraded in soils. Polydimethylsiloxanes (PDMS) are unstable under dry conditions in landfill situations as clay minerals catalyse their hydrolytic decomposition to smaller molecules. (Hamelink 1992; Lehmann *et al* 1994a and 1994b). Therefore, in landfill the notified polymer, like PDMS, would eventually degrade.

The ecotoxicity data from a related polymer indicate that the notified polymer is expected to be non-toxic to *Daphnia magnia.* The hydrophobic nature of the notified polymer indicates that most would be adsorbed onto sediments and sludge and would not remain in the water compartment and be available for consumption by the aquatic organisms. A Literature report (Henry et al 2001) suggests that PDMS may accumulate in aquatic sediments. However, sediment toxicity tests with amphipod *Hyalella azteca* and *Chironomous tentans* indicate that PDMS has no toxic effects on these organisms. Due to its high molecular weight and the expected very low water solubility, the notified polymer has little potential for bioaccumulation (Connell 1990).

10. RISK ASSESSMENT

10.1. Environment

On the basis of the low volume used and the nationwide and diffuse use of the notified polymer, it is not considered to pose an unacceptable risk to the health of the aquatic life based on its reported use pattern.

Wastes generated from the formulation process would be disposed of by licenced waste contractors. Wastes released into sewer from the formulation process and from use of the formulated products are likely to be adsorbed to sludge and be landfilled ultimately. The amount remaining in the water compartment is likely to be low and of low toxicity to aquatic organisms.

In landfill the notified polymer is unlikely to leach and will degrade over time, posing minimal hazard to the environment.

10.2. Occupational health and safety

The greatest potential for occupational exposure occurs in those professions, such as hairdressing and beauty therapy, where workers may apply the product containing the notified polymer several times each working day. Dermal exposure is the main route of exposure although inadvertent ocular exposure may also occur. However, the notified polymer is of low hazard and high molecular weight, therefore the risk to these workers is considered low.

The OHS risk presented by the notified polymer during transport, storage, and reformulation is also expected to be low due to its expected low hazard and low potential for worker exposure.

10.3. Public health

The products containing the notified polymer will be used by the general public applying the

products themselves, and also by those having products applied during professional hairdressing or cosmetic applications. The notified polymer has a MW > 1000, and thus will be unable to cross biological membranes. Despite the potential widespread use, the risk to public health is considered low due to the non-hazardous nature of the notified polymer.

11. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

11.1. Environmental risk assessment

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

11.2. Human health risk assessment

11.2.1. Occupational health and safety

There is low concern to occupational health and safety under the conditions of the occupational settings described.

11.2.2 Public health

There is low concern to public health when used in the intended manner.

12. MATERIAL SAFETY DATA SHEET

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.

13. RECOMMENDATIONS

CONTROL MEASURES

- 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.

Environment

Disposal

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

Emergency procedures

- The MSDS indicates that if diked material can be pumped, stored recovered material in appropriate container. Wipe up or scrape up and contain for salvage or disposal.

Materials in contact with water, moisture, acids or bases have the potential to generate hydrogen gas. Recovered material should be stored in vented container. Clean area as appropriate since some silicone material, even in small quantities, may present a slip hazard. Final cleaning may require the use of steam, solvent or detergents. Dispose of saturated absorbent or cleaning materials appropriately, since spontaneous heating may occur.

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.

No additional secondary notification conditions are stipulated.

14. BIBLIOGRAPHY

Connell DW (1989). General characteristics of organic compounds which exhibit bioaccumulation. In: Connell DW ed. Bioaccumulation of xenobiotic compounds. Boca Raton, USA, CRC Press, pp 47-57.

Hamelink J (1992). Silicones. In The Handbook of Environmental Chemistry, Vol. 3: Detergents, N. T. de Oude (ed).

Henry K S (2001). Laboratory analysis of the potential toxicity of sediment-associated polydimethylsiloxane to benthic macroinvertebrates. Environ. Toxicol. Chem., 20 (11), 2611-2616.

Kuo C M (1996). Polydimethylsiloxane data. Report No. 1996-10000-42713, Dow Corning Proprietary, Midland Michigan.

Lehmann *et al* (1994a). Degradation of silicone polymers in soil, *Environ. Toxicol. Chem*., 13 (7) 1061-1064.

Lehmann *et al* (1994b). Fate of silicone degradation products (Silanols) in soil. *Environ. Toxicol. Chem*., 13 (11) 1753-1759.