File No PLC/624

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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Y-14849

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
GE Silicones Australia Pty Ltd
175 Hammond Rd
DANDENONG VIC 3175

NOTIFICATION CATEGORY
Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name, CAS Number, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Import Volume.

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
Canada, September 2005.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Y-14980 (30% notified polymer polydimethylsiloxane (PDMS); Y-14849 (18% notified polymer in PDMS).

MOLECULAR WEIGHT

Number Average Molecular Weight (Mn)	> 10000
Weight Average Molecular Weight (Mw)	> 10000
% of Low MW Species < 1000	< 1%
% of Low MW Species < 500	< 1%

REACTIVE FUNCTIONAL GROUPS
The notified polymer contains high concern functional groups but still meets the PLC criteria.

3. PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met (yes/no/not applicable)*
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

4. PHYSICAL AND CHEMICAL PROPERTIES

The notified polymer is made as a solution in polydimethylsiloxane (Y-14849) and is never isolated. The water solubility and density tests were performed with this solution.

Appearance at 20°C and 101.3 kPa	White gel.
Melting Point/Glass Transition Temp	Not determined.
Density	960 kg/m^3
Water Solubility	0.54 mg/L at 25°C
Particle Size	Not applicable
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	< 1	< 1	1 - 3	< 1	< 1

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The notified polymer will be imported as a component of skin care and cosmetic formulations in typical containers for these products. Y-14849 will be present in emulsions (4 – 25%), anhydrous gels (25 – 90%), cleansing products (1 – 5%), shower conditioners (5 – 40%) and hair care products (1 – 5%).

Reformulation/manufacture processes

No reformulation will occur in Australia.

Use

The notified polymer will be used in skin care and cosmetic formulations by consumers.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Occupational exposure will be limited to transport workers and retail staff handling consumer containers and no exposure is likely except in the event of accidental rupture of the containers.

PUBLIC EXPOSURE

Since the notified polymer will be in products sold to the general public, widespread public exposure is expected.

6.2. Toxicological Hazard Characterisation

Summaries of toxicological data for an analogue chemical were provided.

Endpoint	*Result*	*Classified?*	*Effects Observed?*	*Test Guideline*
1. Rat, acute oral	LD50 > 2000 mg/kg bw	no	no	Not stated
2. Rat, acute dermal	LD50 > 2000 mg/kg bw	no	no	"

3. Rabbit, skin irritation	non-irritating	no	no	“
4. Rabbit, eye irritation	slightly irritating	no	no	“
5. Skin sensitisation - LLNA.	no evidence of sensitisation.	no	no	“
6. Genotoxicity - bacterial reverse mutation	non-mutagenic	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, based on the low intrinsic hazard of the polymer, the fact that exposure to workers is unlikely and the fact that the concentration of the polymer in products handled by workers is < 20%.

PUBLIC HEALTH

Although the public will be exposed to the notified polymer during use the risk to public health is considered to be low due to the predicted low hazard coupled with a maximum concentration of the notified polymer in imported products of < 20%. The slight eye irritancy identified for an analogue would not be expected to occur during use as it is insufficient for the analogue to be classified as an eye irritant on the basis of the NOHSC criteria, there is uncertainty the same result would be found with the notified polymer itself, there is a low concentration of polymer in imported products and it is likely there would be infrequent accidental ocular exposure given the way in which the products are designed to be used.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

The notified polymer is imported into Australia in epoxy lined steel containers. It is then reformulated into cosmetic and skin care products. During reformulation import drums will be rinsed with the polymer being added to the reformulation process. Batches will be scheduled to minimise the requirement for rinsing of equipment, and rinsings from maintenance and cleaning will be recycled to the reformulation process to the extent practicable. Minimal release of the polymer is therefore expected during reformulation of the product.

The cosmetic and skin care products may be viscous resulting in up to 5% of the notified chemical remaining in packaging. This packaging will be disposed as household waste. The majority of the chemical will be released to sewer during use of the product.

ENVIRONMENTAL FATE

No environmental fate data were submitted. The majority of the notified polymer will be released to sewer where it is expected to adsorb to the sludge. The sludge may be incinerated where the polymer will decompose to silica, oxides of carbon and water vapour or be used as fertiliser for agricultural use. Any remaining in the aqueous compartment is likely to be persistent.

The notified polymer is slightly soluble in water and contains functional groups that may further bind to soil. It is therefore unlikely to be mobile and will undergo eventual in-situ degradation to silica; landfill gases including oxides of carbon and methane and water vapour by biotic and abiotic processes.

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 majority of the notified polymer will be released to sewer during its normal use. Assuming that

95% is released in this manner then up to 950 kg will be released throughout Australia. Assuming a worse case scenario where no polymer is adsorbed to sludge then the Predicated Environmental Concentration (PEC) is calculated as 0.635 µg/L on the assumption that 20.5 million persons use 200 L of water per day. Although no Predicted No Effect Concentration (PNEC) is calculated, the polymer is unlikely to show any toxicity up to the limits of its solubility.

Although the polymer is likely to be persistent in the aquatic environment it is unlikely to be bioavailable or bioaccumulate due to its high molecular weight.

8. CONCLUSIONS

8.1. Level of Concern for Occupational Health and Safety

There is No Concern to occupational health and safety under the conditions of the occupational settings described.

8.2. Level of Concern for Public Health

There is Negligible 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

- 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 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 wiping, scraping or adsorption to inert material (diatomaceous earth, vermiculite, sand etc). Place in proper container for disposal.

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.