

File No PLC/618

30 May 2006

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

FULL PUBLIC REPORT

Z-66

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
Australian Safety and Compensation Council
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1162 or email ascc.library@dewr.gov.au

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
NICNAS**

TABLE OF CONTENTS

FULL PUBLIC REPORT	3
1. APPLICANT AND NOTIFICATION DETAILS	3
2. IDENTITY OF CHEMICAL	3
3. COMPOSITION.....	4
4. INTRODUCTION AND USE INFORMATION.....	4
5. PROCESS AND RELEASE INFORMATION.....	4
5.1. Operation Description.....	4
6. EXPOSURE INFORMATION	4
6.1. Summary of Occupational Exposure	4
6.2. Summary of Public Exposure	4
6.3. Summary of Environmental Exposure.....	5
6.3.1. Environmental Release	5
6.3.2. Environmental Fate.....	5
7. PHYSICAL AND CHEMICAL PROPERTIES.....	5
8. HUMAN HEALTH IMPLICATIONS.....	5
8.1. Toxicology	5
8.1.1. Discussion of observed effects.....	6
8.2. Human Health Hazard Assessment.....	6
9. ENVIRONMENTAL HAZARDS.....	6
9.1. Ecotoxicology	6
10. RISK ASSESSMENT.....	6
10.1. Environment	6
10.2. Occupational Health and Safety.....	6
10.3. Public Health	7
11. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS.....	7
11.1. Environmental Risk Assessment.....	7
11.2. Human Health Risk Assessment.....	7
11.2.1. Occupational health and safety.....	7
11.2.2. Public health.....	7
12. MATERIAL SAFETY DATA SHEET	7
12.1. Material Safety Data Sheet	7
13. RECOMMENDATIONS.....	7
13.1. Secondary Notification	8

FULL PUBLIC REPORT**Z-66****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Lubrizol International, Inc (ABN 52 073 495 603)
28 River Street
Silverwater NSW 2128

NOTIFICATION CATEGORY

Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical Name

Other Names

Molecular and structural Formulae

Means of identification

Number Average Molecular Weight

Weight Average Molecular Weight

Weight Percentage of Species MW < 1000 and MW < 500

Polymer Constituents

Residual Monomers/Impurities

Reactive functional groups

Manufacture/Import Volume

Site of Manufacture

Purity

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Particle size distribution

Melting point

Flammability limits

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

No

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

SilSense™ IWIS Silicone, Z-66

CAS NUMBER

None.

MOLECULAR WEIGHT (MW)

% of Low MW Species < 1000 < 10%

% of Low MW Species < 500 < 10%

Number Average Molecular Weight (Mn)

Between 1000 and 10000

3. COMPOSITION

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. INTRODUCTION AND USE INFORMATION

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

The notified polymer is shipped via sealed 208 L drums or in 18.9 L pails if imported neat. It is transported in 200-500 mL plastic bottles or jars in cardboard boxes if imported as part of a finished personal care product.

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>	1-3	1-3	1-3	3-10	3-10

USE

Z-66 is used as a non-ionic silicone emollient ester for use in personal care products such as creams, lotions, hair dressing products and conditioners.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

Z-66 is manufactured outside Australia. The polymer is transported from the dock to customer via truck. Some customers may blend or reformulate the neat polymer with other personal care additives to form the end use product.

A typical operation by customers who plan to repackage or reformulate the neat polymer would involve pumping the notified polymer directly from the 208 L drums or 18.9 L pails to a blend tank where it is blended with organic diluents and other additives. All these operations are expected to be carried out either manually or semi-automatically in a closed system. The finished product being formulated contains about 0.5 to 2.5% by weight of the polymer being notified and the consumer product is generally packaged in 200-500 mL plastic bottles or jars and shipped in cardboard boxes to supermarkets for sale.

6. EXPOSURE INFORMATION

6.1. Summary of 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 in addition to the low concentration of notified polymer in the imported product.

6.2. Summary of Public Exposure

Personal care products containing the notified polymer at 0.5 to 2.5% by weight are for sale to the general public. Members of the public may make dermal contact and possibly accidental ocular

contact with products containing the notified polymer. However, bioavailability is low because the notified polymer has a MW > 1000 therefore it is unlikely to cross biological membrane.

6.3. Summary of Environmental Exposure

6.3.1. Environmental Release

The notifier has indicated that an estimated 1% of product would remain in the imported drums. The residue may be readily flushed using an organic solvent and is then probably incinerated at the reconditioning facility. During reformulation, the polymer is diluted to 0.5 - 2.5% by weight with mineral oil and other additives, in a closed system to form the finished product. Release to the environment would be limited to accidental leakage or spillage of the product and during routine maintenance and cleaning of equipment. The quantities released are expected to be low via this route providing storage, handling and spill procedures are observed.

The product is to be used domestically in personal care products containing 0.5 - 2.5% by weight of the polymer. Although no estimate of residue has been given for the finished product remaining in the final packaging, it is expected that this would also be approximately 1%. Consequently the vast majority is released into the sewer system. Assuming that the maximum value of 5 tonnes is imported each year it is expected that approximately 4.9 tonnes (98%) is disposed via the sewer with minor amounts being disposed of as domestic waste or incinerated. Being hydrophobic the polymer may deposit to the sewage sludge. The collected sludge is disposed of either by authorised landfill or incineration.

6.3.2. Environmental Fate

The sewage sludge containing the polymer is disposed of by either incineration or authorised landfill. Incineration of the sludge decomposes the polymer to water vapour, oxides of carbon and silicates.

The notified polymer contains ester linkages that could be expected to undergo hydrolysis under extreme pH. However, in the environmental pH range of 4 to 9, significant hydrolysis is unlikely to occur. The hydrophobic nature of the molecule would render such hydrolysis even more unlikely. The landfilled polymer is immobilised due to its hydrophobicity.

No tests were submitted for biodegradation or bioaccumulation on the basis that the notified polymer has low water solubility and high molecular weight and is therefore unlikely to biodegrade or bioaccumulate.

7. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Clear to yellow liquid
Melting Point/Glass Transition Temp	<-20 ± 0.5°C
Density	966 kg/m ³ at 20 ± 0.5°C
Water Solubility	Estimations only: 1) < 1.30 × 10 ⁻³ g/L at 20 ± 0.5 °C (visual estimation) 2) < 1.60 × 10 ⁻⁶ mg/L (atom/fragment contribution method)
Auto-ignition Temperature	> 400°C
Reactivity	Stable under normal environmental conditions.
Degradation Products	None under normal conditions of use.

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

The following toxicological end-points were submitted for the notified polymer.

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>
Rabbit, skin irritation	non-irritating	no	no
Rabbit, eye irritation	slightly irritating	no	yes
Rat, skin sensitization	non-sensitizing	no	no

All tests were performed in accordance with OECD guidelines for testing of chemicals. All test reports included a statement of GLP compliance.

All results were indicative of low hazard.

8.1.1. Discussion of observed effects

Rabbit, eye irritation: Instillation of 0.1 mL notified polymer into one eye of each of the three rabbits resulted in irritation of the conjunctivae, which was seen as redness and discharge in all animals. The irritation had completely resolved within 24 hours in all animals. No iridial irritation or corneal opacity was observed, and treatment of the eyes with 2% fluorescein, 24 hours after test substance instillation revealed no corneal epithelial damage in any of the animals. The test material produced a maximum mean score of 4 out of 110 and was classified as minimally irritating.

Test Facility: NOTOX 2003

Based on the available data the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

8.2. Human Health Hazard Assessment

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

No ecotoxicological data were submitted. However, this is not required for polymers of NAMW > 1000 according to the Act. The polymer has a high molecular weight and is unlikely to cross biological membranes. It is not surface active so it is unlikely to affect outer membranes of aquatic creatures. The functional groups are unlikely to chelate essential nutrients and the polymer is practically inert and insoluble in water. This polymer is therefore expected to be non toxic.

10. RISK ASSESSMENT

10.1. Environment

The notified polymer is used in personal care products, with the vast majority being released via the sewer system. Under a worst case scenario with no removal of the notified polymer in the sewage plant the resultant predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated to be 3.41 µg/L.

Amount entering sewer annually:	5000kg
Population of Australia:	20.1 million
Amount of water used per person per day:	200 L
Number of days in a year:	365

Based on dilution factors of 1 and 10 for inland and ocean discharges of STP- treated effluents, the PECs of the notified polymer in freshwater and marine water may be approximately 3.41 or 0.34 µg/L, respectively.

However, being hydrophobic the polymer deposits to the sludge with only negligible amounts being released to the aquatic environment. Consequently the PEC is expected to be much lower than 3.41 µg/L in sewage effluent. Although no data have been provided, the polymer meets the PLC criteria and is likely to be of non hazardous nature to the aquatic environment, with the PNEC being accordingly high. The resulting PEC/PNEC ratio is very low. The risk of use of this notified polymer is therefore expected to be acceptable.

10.2. Occupational Health and Safety

The OHS risk presented by the notified polymer is expected to be low. 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.

10.3. Public Health

The notified polymer 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 (0.5-2.5%).

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

12. MATERIAL SAFETY DATA SHEET

12.1. 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.

13. 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.

Environment

Disposal

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

Emergency procedures

- Spills/accidental release of the notified polymer should be handled by physical containment, followed by collection and safe disposal.

13.1. 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.