

File No PLC/613

7 March 2006

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

FULL PUBLIC REPORT

Z-64

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	5
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.....	6
8.1. Toxicology	6
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.....	7
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-64****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Lubrizol International, INC (ABN 52 073 495 603)
28 River Street, P.O.Box 6445
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 Formula

Structural Formula

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

Intended Use

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

None.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Z-64, SilSense™ DW-18

CAS NUMBER

133448-16-5

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn)

% of Low MW Species < 1000

Between 1000 and 10000

< 20%

% of Low MW Species < 500

< 10%

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 MW Polyester Manufactured from Allowable Reactants	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

Z-64 is manufactured and blended outside Australia. It is shipped to Australia either as the neat polymer or as a product in sealed containers such as 208 L drums or 18.9 L pails.

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-64 is used as a water-dispersible liquid wax to impart the conditioning benefits of silicone to personal care products.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

Z-64 is manufactured and blended outside Australia. It is shipped to Australia as the neat polymer. Z-64 is used as a conditioning silicone for use in hair and skin products including creams, body lotions, after-shave balms and gels, shampoos and conditioners. Z-64 is combined with other components to form these products. Z-64 is present in these products typically at less than 2 weight percent.

A typical operation by customers involves pumping the Z-64 containing product directly from the 208 L drums or 18.9 L pails to a blend tank where it is blended with water and other additives. All these operations are expected to be carried out manually or semi-automatically in a closed system. The finished product contains about 0.25 to 2% by weight of the chemical being notified. Water could be used to flush the container or drum. Residual product remaining in the container is expected to be minimal (approximately 1%) and easily removed by washing with water and properly disposed of at the reconditioning facility.

The finished consumer products containing Z-64 is packaged in 200 to 500 mL plastic bottles. The bottles are shipped in cardboard boxes.

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.

During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached.

6.2. Summary of Public Exposure

The general public is not exposed to the neat Z-64. 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 (0.25 to 2% by weight).

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 import drums. The residue may be readily flushed using water or mineral oil. In some cases the rinsing will take place at the site of reformulation and the rinsings will be used in subsequent batches. However, the majority is expected to occur at drum reconditioning facilities and the solvents containing the notified polymer are then probably incinerated. During reformulation, the polymer is diluted to 0.25 - 2% by weight with water and other additives, in a closed system to form the finished product packed in 200-500 mL plastic bottles. 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 0.25 - 2% by weight of the polymer. Residues in the personal care product containers are expected to be less than 1%. Consequently the vast majority will be released into the sewer system. Assuming that the maximum value of 10 tonnes is imported each year it is expected that approximately 9.8 tonnes (98%) will be disposed via the sewer with minor amounts being disposed of as domestic waste or incinerated. Being hydrophobic the polymer will report to the sewage sludge. The collected sludge will be disposed of either by authorised landfill or incineration.

6.3.2. Environmental Fate

The sewage sludge containing the notified polymer will be disposed of either by incineration or in authorised landfill. Incineration of the sludge will decompose 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 polymer would render such hydrolysis even more unlikely. As with all polymers of this class the notified polymer is expected to be persistent if released to the aquatic environment.

The landfilled polymer will be immobilised due to its hydrophobicity. Clay surfaces in soils especially when dry are known to catalyse the degradation of polymers of this class to form low-molecular weight water soluble products, with eventual production of silicates and landfill gases such as methane and oxides of carbon.

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	Yellow liquid
Melting Point/Glass Transition Temp	-2 ± 3°C
Density	1.04 × 10 ³ kg/m ³ at 20.0 ± 0.5°C
Water Solubility	0.221-0.231 g/L at 20.0 ± 0.5°C (Shake flask method with visual estimation. Considered unreliable due to dispersion/emulsification issues.)

Auto-ignition Temperature**Reactivity****Degradation Products**

3.77×10^{-9} g/L (Calculated using an atom fragment contribution method with WATERNT™ estimation software).

$370 \pm 5^\circ\text{C}$

Stable under normal environmental conditions.

None under normal conditions of use.

8. HUMAN HEALTH IMPLICATIONS**8.1. Toxicology**

The following toxicological end-points were submitted:

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>
Rat, acute oral	> 5000 mg/kg bw	no	no
Rabbit, eye irritation	non-irritating	no	no
Rabbit, skin irritation	non-irritating	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

Rat, acute oral: No signs of toxicity were observed.

Test Facility: AMA Laboratories, NY, USA.

Rabbit, eye irritation: The Maximum Mean Total Score was determined to be 0.00. Base on these results the test polymer was considered to be non-irritating.

Test Facility: AMA Laboratories, NY, USA.

Rabbit, skin irritation: The Primary Irritation Index was determined to be 0.00. Base on these results the test polymer was not considered to be a primary skin irritant.

Test Facility: AMA Laboratories, NY, USA.

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. The toxicological data submitted support this view and provide evidence for low acute oral toxicity in rats as well as no evidence of skin or eye irritation in rabbits.

9. ENVIRONMENTAL HAZARDS**9.1. Ecotoxicology**

No ecotoxicological data were submitted. Non-ionic polymers with NAMW >1000 are generally of low concern to the aquatic environment.

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 7 µg/L.

Amount entering sewer annually:

10000kg

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 for inland and 10 for ocean discharges of STP- treated effluents, the PECs of the notified chemical in freshwater and marine water may approximate 7 or 0.7 µg/L, respectively.

However, being hydrophobic the polymer will report to the sludge with only negligible amounts being released to the aquatic environment. Consequently the PEC will be expected to be much lower than 7 µg/L in sewage effluent. Although no data have been provided, the polymer is likely not to be of hazardous in the aquatic environment, with the PNEC being accordingly high. The resulting PEC/PNEC ratio will be 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 general public is not exposed to the neat Z-64. However, since Z-64 is for use in the personal care market, the general public comes into contact with products containing Z-64 at 0.25 to 2% by weight. Z-64 is currently used in other countries throughout the world in the personal care market and no adverse public health impact has been observed. Therefore it is anticipated that Z-64 presents a low risk to public health in Australia.

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/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.