

File No PLC/608

2 February 2006

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

FULL PUBLIC REPORT

Z-65

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 | 4 |
| 1. APPLICANT AND NOTIFICATION DETAILS | 4 |
| 2. IDENTITY OF CHEMICAL | 4 |
| 3. COMPOSITION..... | 4 |
| 4. INTRODUCTION AND USE INFORMATION..... | 5 |
| 5. PROCESS AND RELEASE INFORMATION..... | 5 |
| 5.1. Operation Description..... | 5 |
| 6. EXPOSURE INFORMATION | 6 |
| 6.1. Summary of Occupational Exposure | 6 |
| 6.2. Summary of Public Exposure | 6 |
| 6.3. Summary of Environmental Exposure..... | 6 |
| 6.3.1. Environmental Release | 6 |
| 6.3.2. Environmental Fate..... | 6 |
| 7. PHYSICAL AND CHEMICAL PROPERTIES..... | 6 |
| 8. HUMAN HEALTH IMPLICATIONS | 7 |
| 8.1. Toxicology | 7 |
| 8.1.1. Discussion of observed effects..... | 7 |
| 8.2. Human Health Hazard Assessment..... | 7 |
| 9. ENVIRONMENTAL HAZARDS..... | 7 |
| 9.1. Ecotoxicology | 7 |
| 9.2. Environmental Hazard Assessment | 7 |
| 10. RISK ASSESSMENT..... | 8 |
| 10.1. Environment | 8 |
| 10.2. Occupational Health and Safety..... | 8 |
| 10.3. Public Health | 8 |
| 11. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS..... | 8 |
| 11.1. Environmental Risk Assessment..... | 9 |
| 11.2. Human Health Risk Assessment..... | 9 |
| 11.2.1. Occupational health and safety..... | 9 |
| 11.2.2. Public health..... | 9 |
| 12. MATERIAL SAFETY DATA SHEET | 9 |
| 12.1. Material Safety Data Sheet | 9 |
| 13. RECOMMENDATIONS..... | 9 |
| 13.1. Secondary Notification | 9 |

FULL PUBLIC REPORT**Z-65****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, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Manufacture/Import Volume, and Site of Manufacture/Reformulation, Reactive Functional Groups, Purity

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for: Particle size distribution (as notified polymer is a liquid), and Melting point (freezing point provided).

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA TSCA (polymer exemption for personal care products)
EU (complies with Cosmetics Directive 76/766)

2. IDENTITY OF CHEMICAL

OTHER NAME(S)

A-21, A-23, SilSense™ A-21, SilSense™ A-23

MARKETING NAME(S)

Z-65

MOLECULAR WEIGHT (MW)

| | |
|--|-------|
| Number Average Molecular Weight (Mn) | >1000 |
| Weight percentage of polymer species with MW <1000 | <20% |
| Weight percentage of polymer species with MW <500 | <5% |

3. COMPOSITION

PLC CRITERIA JUSTIFICATION

| Functional Group | Category | Equivalent Weight (FGEW) |
|------------------|--------------|--------------------------|
| Amino | High Concern | >5000* |

* Calculation based on maximum nitrogen content of amine-containing monomer.

| <i>Criterion</i> | <i>Criterion met</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 Hazardous 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 will be manufactured outside Australia, and imported to customers in Australia either as a neat liquid polymer or as a component of finished personal care product formulations.

The neat notified polymer will be shipped to Australia in 55 gallon (~208 L) drums or 5 gallon (~19 L) pails. Finished products will be imported in 200-500 ml plastic bottles, shipped in cardboard boxes.

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 | 3-10 | 3-10 | 3-10 |

USE

The notified polymer is used as a cationic conditioner for use in aqueous personal care products (including shampoos, rinse-out conditioners, leave-in conditioners, styling products, body washes, bath gels, liquid soaps and bubble baths). It is typically present in these formulations at 0.5-2.5% by weight.

When the neat notified polymer is imported, the notifier's customers will reformulate it into personal care products. This is expected to take place in New South Wales, Victoria and Queensland.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

Reformulation:

Z-65 will be manufacture and blended outside Australia. It would be shipped as the neat material or as part of finishing product.

The neat notified polymer will be transported from the dock to the customers by truck. These customers will use the neat notified polymer in the formulation of personal care products. A typical process would involve pumping the liquid notified polymer from the import container directly to a blending tank, where it would be mixed with water and other additives. Typical components of formulations might include (but are not limited to) diluents, moisturisers, neutralisers, conditioners, preservatives, and fragrances. Reformulation processes will be carried out manually or semi-automatically in a closed system. Drums and pails will be disposed of to a reconditioning facility after flushing with water to remove residual notified polymer (~1%).

End use:

Finished products containing the notified polymer (in plastic bottles) are packed into cardboard boxes for transport to customers. These products will be sold to retailers, who would store them in their storerooms until needed. The individual bottles of personal care products will then be placed on supermarket shelves for sale to the public.

6. EXPOSURE INFORMATION

6.1. Summary of Occupational Exposure

Reformulation workers:

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 and personal protective equipment worn by workers. Safety glasses, protective aprons, boots and gloves are recommended by the MSDS, with face shields recommended if the potential for splashing or mists exists. Inhalation exposure is not expected due to the non-volatile nature of the polymer.

Occupational exposure to finished products:

Intermittent, wide-dispersive occupational use of finished products containing the notified polymer is likely to occur among workers such as hairdressers and beauticians. Dermal exposure to products containing up to 2.5% of the notified polymer is likely.

6.2. Summary of Public Exposure

The neat liquid notified polymer is intended only for use in industry, to be reformulated into Personal care products. The public will not be exposed to the neat liquid polymer.

Personal care products containing the notified polymer will be sold to the general public. Members of the public will primarily make dermal contact with products containing the notified polymer, but accidental ocular contact or ingestion is possible. However, exposure will be low because the notified polymer is present at low concentrations.

6.3. Summary of Environmental Exposure

6.3.1. Environmental Release

During manufacture of the polymer, there will be only small volumes released from rinsing the empty containers (1%). Otherwise, there will be no need to dispose of the notified polymer in any way apart from use as a component of personal care products. As the products will be applied to the skin or hair, the majority of the notified polymer can be expected to ultimately make its way into the sewer. The remainder of the notified polymer will be disposed to landfill as residues of personal care products in plastic containers.

6.3.2. Environmental Fate

Potentially, up to the maximum import volume (10 tonnes) will end up in wastewater that passes into sewer systems across Australia. Due to its high water solubility, any polymer entering receiving waters at a sewage treatment plant is likely to stay in the water column with minimal degradation. However, it could be expected to become associated with the sediment compartment due to its cationic charge.

7. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|---|--|
| Appearance at 20°C and 101.3 kPa | Pale yellow slightly viscous liquid |
| Freezing Point | -14.0 ± 0.5°C Freezing point was determined using the crystallizing point method, Method 102 of the OECD test guidelines. |
| Boiling Point | Decomposition occurred from approximately 208.85°C at 100.65 kPa, as determined by differential scanning calorimetry, Method 103 of the OECD test guidelines, so no value for boiling temperature could be determined. A calculated value of 496.85°C was determined for boiling temperature, using an adaptation of the Stein and Brown Method (MPBP for Windows v1.41). |
| Density | 1080 kg/m ³ at 20.0 ± 0.5°C Density was determined using the pycnometer method, Method 109 of the OECD test guidelines. |
| Water Solubility | The test material was observed to be miscible in all portions with water at 20 ± 0.5°C, using a procedure based on the flask method (OECD TG 105). Mixtures of test material and glass double distilled water were added to a separate flask, swirled gently by hand, and the contents of the flask were visually |

| | |
|---------------------------------|--|
| Dissociation Constant | observed. Not determined. There are two potential cationic groups in the environmental pH range of 4 to 9. |
| Reactivity | Stable under normal environmental conditions. |
| Autoignition temperature | 382 ± 5°C |
| Degradation Products | Not determined |

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 LD50 >2500 mg/kg bw | low toxicity | no | no |
| Rabbit, skin irritation | non-irritating | no | no |
| Rabbit, eye irritation | slightly irritating | no | yes |
| Mouse, Local Lymph Node Assay | no evidence of sensitisation | no | yes |

All results were indicative of low hazard.

8.1.1. Discussion of observed effects

- The test report for eye irritation in the rabbit describes conjunctival redness, chemosis and discharge, all of which had completely resolved within 72 hours after administration. Iridal irritation (grade 1) was observed after 1 hour in one animal only.
- The test report for skin sensitisation in the mouse, by local lymph node assay, showed irritation score values in the treated animals to range between 0.59 and 2.86, indicating that some minor effects were observed in some animals (however, an average value of ≥ 3 is required for classification). Positive control-treated animals averaged an irritation score of only 2.3, indicating that perhaps the test was not sufficiently sensitive. Slight erythema was noted among the animals of the 35-50% dose group.

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 for the notified polymer indicated low acute toxicity, slight eye irritation, and no skin irritation or potential for sensitisation.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

No toxicological data were submitted.

9.2. Environmental Hazard Assessment

While the polymer is potentially cationic and thus toxic to the aquatic organisms, its FGEW is >5000, which indicates low toxicity.

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. In a worst-case scenario, based on the entire imported volume (maximum of 10,000 kg) being washed out into the sewer, and assuming no sorption or degradation of the notified polymer during the treatment, the Predicted Environmental Concentration (PEC) in the aquatic compartment can be estimated as shown below:

| | |
|--|--------------------------------|
| Amount entering STP per year | 10000 kg |
| Population of Australia | 20 million |
| Amount of water used per person per day | 200 L |
| Number of days used per year | 365 days |
| National water use per day for total population | 4000 ML |
| Chemical concentration in Australian sewerage network: | 6.85×10^{-3} mg/L/day |
| (i.e. $10000 \times 10^6 \text{ mg} \div 365 \text{ days/year} \div 4000 \times 10^6 \text{ L} = 6.85 \times 10^{-3} \text{ mg/L/day}$) | |

Based on dilution factors of 1 and 10 for inland and ocean discharge of STP treated effluent (respectively), the PEC of the notified chemical in fresh water and marine water may be approximated as follows:

The following PECs are determined:

| | |
|----------------------|-----------|
| PEC _{Sewer} | 6.85 µg/L |
| PEC _{Ocean} | 0.68 µg/L |
| PEC _{River} | 6.85 µg/L |

Although no data have been provided, the polymer is not likely to be hazardous to the aquatic environment. Therefore, the PNEC can be predicted accordingly to be high. The resulting PEC/PNEC ratio will be very low. Therefore, the risk arising from the use of the notified polymer is expected to be acceptable.

10.2. Occupational Health and Safety

The OHS risk presented by the notified polymer is expected to be low. Workers who are engaged in the formulation of personal care products will be exposed to the greatest concentration of the notified polymer (i.e., the neat liquid polymer). This presents some risk in terms of the potential of the notified polymer to induce slight eye irritation. However, the appropriate use of PPE during handling should ensure that the risk to these workers is low.

Workers such as hairdressers and beauticians are likely to be intermittently exposed to finished products containing up to 2.5% notified polymer, primarily through dermal exposure. However, due to the low toxicity of the notified polymer, the low concentrations present in finished products and the properties of the notified polymer (as a Polymer of Low Concern), this level of exposure is unlikely to present a significant risk.

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 public will be directly exposed to the notified polymer, as it will be formulated into personal care products. There is a slight concern arising from the slight eye irritant potential of the notified polymer. However, it is unlikely to cause eye irritation during use, as it is only present at low concentrations in personal care products.

In addition, the notified polymer will often be used in formulations that contain higher concentrations of irritating ingredients (eg sodium lauryl sulfate). Therefore, as shampoos etc. often contain such ingredients, consumers will be expected to avoid eye contact.

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

11.1. Environmental Risk Assessment

The notified polymer is not considered to pose a risk to the environment based on its reported use pattern and low cationic charge.

11.2. Human Health Risk Assessment**11.2.1. Occupational health and safety**

There is No 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**

- 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

- Waste notified polymer should be disposed of by incineration when in a liquid form in appropriate incineration facilities in accordance with Federal, State and Local government regulations. Liquids cannot be disposed in landfill.

Emergency procedures

- Spills/release of the notified polymer should be handled as specified by MSDS: Soak up spills with an inert adsorbent, such as sand, earth or other non-combustible material. Place into labelled, closed container; store in a safe location to await 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.