File No PLC/773

May 2008

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Plioway Ultra 200

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, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also 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

Plioway Ultra 200

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
International Sales & Marketing Pty Ltd (ABN 36 467 259 314)
262 Highett Road
HIGHETT VIC 3190

Akzo Nobel Pty Ltd (59 000 119 424)
115 Hyde Road
YERONGA QLD 4103

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, Manufacture/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)
No

NOTIFICATION IN OTHER COUNTRIES
USA, Europe, China, Korea, New Zealand

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Plioway Ultra 200

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) > 10000 Da

REACTIVE FUNCTIONAL GROUPS
The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met*
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. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	White, friable fine granules
Melting Point/Glass Transition Temp	52-62°C
Density	1030 kg/m^3 at 25°C
Water Solubility	Based on the structure of the notified polymer, no solubility in water is expected
Particle Size	< 0.13 mm 10%; < 0.49 mm 50%; < 1.19 mm 90%
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	1-10	1-10	1-10	5-15	5-15

USE

The notified polymer will be used as a component of coatings for steel at concentrations of 10-12% (w/w).

Mode of Introduction and Disposal

The notified polymer will be imported as the pure product in 25 kg polyethylene bags and as a component of formulated products (containing 10-12% w/w of the notified polymer) in 20 L pails. The notified polymer will not be manufactured in Australia.

6. HUMAN HEALTH IMPLICATIONS

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by toxicological endpoints observed in testing conducted on the notified polymer.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
Rat, acute oral	LD50 > 2000 mg/kg bw	no	OECD TG 401
Rabbit, skin irritation	slightly irritating	yes	OECD TG 404
Skin sensitisation - adjuvant test	no evidence of sensitisation.	no	OECD TG 406 (Maximisation test)

All toxicological study results were supportive of the assumption of low hazard.

Skin irritation
Very slight erythema was observed in 2 of the 3 rabbits tested one hour after application. This was resolved after 48 hours. Similar irritation was observed with the application of the vehicle only (mineral oil).

Occupational Health and Safety Risk Assessment
The notified polymer meets the PLC criteria. Thus, it is expected to be generally a low health hazard to workers, following oral, dermal or ocular exposure. However, as the notified polymer may contain a small fraction of particulates in the respirable range (<10 µm), there is a potential health risk to workers when handling the notified polymer in resin form.

The health effects of inhalation exposure to the notified polymer are unknown. The notified polymer is unlikely to be absorbed from the lung, so deposition in the deep lung is probable, combined with an inability of the lungs to dislodge the particles. Inhaled particulates are known to interfere with cell function in the airways, causing inflammatory-like reactions[*]. Therefore, bronchial or pulmonary irritation is possible following inhalation exposure to particles containing the notified polymer, arising from deposition of water-insoluble particles in the lung. The US EPA have similarly expressed concern regarding high molecular weight (70,000 Da or greater) insoluble polymer particles of respirable size, as they can potentially result in irreversible lung damage. However, there is a data gap for polymers with MW between 10,000 and 70,000 Da. The notified polymer falls within this range. The Australian recommended exposure standard for dust is 10 mg/m^3 [NOHSC 3008:(1995)], but a recommended exposure limit of 3 mg/m^3 has been suggested by the American Conference of Governmental Industrial Hygienists (ACGIH) for "respirable (insoluble) particulates (not otherwise regulated)".

Appropriate control measures (e.g. local exhaust ventilation, dusk masks) to mitigate inhalation exposure to respirable particles of the notified polymer should be implemented when the level of atmospheric dust is above the ASGIH exposure standard of 3 mg/m^3.

Inhalation exposure to the notified polymer could occur during opening of the 25 kg polyethylene bags containing the notified polymer, weighing, manually transferring the contents to a hopper and when cleaning up spills. When the amount of handling and the import volume is taken into account together with the low expected amount of respirable particles, a low risk to worker safety is presented from the notified polymer.

[*] R.C. Rylander (1997) Organic dusts. In: Roth RA, ed. *Comprehensive Toxicology, Volume 8: Toxicology of the Resipratory System*. Elsevier Science Ltd., pp 415-424.

Public Health Risk Assessment
The notified polymer is intended for use by professional spray painters only, and will not be sold to the public. There is potential to inhalation exposure to the notified polymer on the rare occasions when spray applications are conducted in the open air. Given the assumed intrinsic low hazard of the notified polymer, the infrequency of the event and expected low exposure, the risk to the public is not considered to be unacceptable.

Following application, the notified polymer will become trapped within a film and will be unavailable for exposure.

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation
No ecotoxicological data were submitted. PLCs without significant ionic functionality are of low concern to the aquatic environment.

Environmental Risk Assessment
As release to the aquatic environment is not expected at any stage of the notified polymer's lifecycle within Australia, the notified polymer is not expected to pose an unacceptable risk to the aquatic environment based on its reported use pattern.

8. CONCLUSIONS AND RECOMMENDATIONS

Human health risk assessment
Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to public health.

Environmental risk assessment
Based on the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer during spray application:
  - Use of spray paints containing the notified polymer should be in accordance with the NOHSC National Guidance Material for Spray Painting (NOHSC 1999)

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical in resin form:
  - Avoid the formation of airborne dusts

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during the application where dust may be generated:
  - Use of a dust mask (adequate for respirable particle sizes) as needed.

- In the interest of occupational health and safety, the following guidelines and precautions should be observed for use of the notified polymer as introduced in powder form
  - The level of atmospheric dust should be maintained as low as possible. The ACGIH exposure standard for atmospheric dust is 3 mg/m^3.

  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 *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

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

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the polymer under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified polymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 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 Section 64(2) of the Act; if
- the function or use of the notified polymer has changed from use as a component of coatings for steel, or is likely to change significantly;
- the amount of notified polymer being introduced has increased from 15 tonnes per annum, or is likely to increase, significantly;
- if the notified polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet
The MSDS of the notified polymer and products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.