File No PLC/906

April 2010

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Makrolon 2600

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

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Bayer Material Science Pty Ltd (ABN 18 086 237 765)
17-19 Wangara Road, Cheltenham, VIC 3192

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, CAS Number, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Use Details and 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
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Makrolon 2600

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) > 10,000 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:	Clear nearly colourless 3 mm solid pellets
Glass Transition Temp	150-238°C determined by differential scanning analysis
Density	1120-1200 kg/m^3 at 20°C determined by Pyknometer method
Water Solubility	< 0.2 mg/g determined by OECD TG 120
Dissociation Constant	Not determined. The notifier estimates a pKa between 9.59 and 11.30 based on the notified polymer's terminal groups
Particle Size	3 mm beads
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	100-300	100-300	100-300	100-300	300-1000

Use
Thermoplastic for moulding of high compression parts for general machinery and automobiles.

Mode of Introduction and Disposal
The notified polymer will be introduced in the form of clear colourless 3 mm pellets, packaged in 25 kg poly bags, and 500 kg and 1,000 kg Octabins with a waterproof liner, depending on each specific customer's equipment and specifications. It will be imported by sea through the ports of Melbourne and Sydney.

6. HUMAN HEALTH IMPLICATIONS

Hazard Characterisation
No toxicological data were submitted. The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard.

Occupational Health and Safety Risk Assessment
Dermal exposure may potentially occur during certain processes involving the notified polymer. However, exposure to significant amounts of the notified polymer is limited due to the largely automated processes, and the engineering controls and personal protective equipment likely to be used during such operations. In addition, the notified polymer is not expected to be bioavailable from the imported pellets and finished articles and thus exposure is unlikely.

Inhalation exposure to the notified polymer is unlikely to occur, given the relatively large size of the imported pellets and the fact that dust is not expected to be generated. However, toxic gases may be released due to thermal degradation of the notified polymer during the high-temperature moulding process. The expected use of local exhaust ventilation should minimise inhalation exposure to these toxic gases.

Overall, the OHS risk presented by the notified polymer is expected to be low, based on the anticipated low exposure to workers and the low intrinsic hazard of the polymer.

Public Health Risk Assessment
Members of the public may make dermal contact with a range of articles containing the notified polymer. However, exposure is not expected because the notified polymer will be bound within a matrix and is unlikely to be bioavailable. Therefore, the risk to public health will be low, given the low exposure and the assumed low hazard of the notified polymer.

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

The estimated environmental release from accidental spillage and residue remaining in empty containers is less than 1% of the total imported notified polymer. Materials and/or empty containers will be disposed of in accordance with all local and national regulations. Scrap from extrusion and injection moulding will be recycled within the process or treated within all local and national regulations for handling industrial wastes. The polymer is expected to be completely incorporated into products so there should be no release from use or disposal of products. Based on the proposed use pattern, the release of the notified polymer to the environment is expected to be very low. Notified polymer that is disposed to landfill is expected to be immobile, due to its low solubility in water. Eventually, the notified polymer is expected to degrade via biotic and abiotic mechanisms to simple organic compounds and water. While no ecotoxicity data are available, due to limited release to water it is unlikely that the polymer would be present at levels which could pose a risk to aquatic organisms. The high molecular weight and low water solubility indicates a low potential for bioaccumulation. Based on the reported exposure levels and use pattern, the notified polymer is not expected to pose a risk to the environment when it is stored, transported and used in the proposed manner.

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 expected to pose a risk to the environment.

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 *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 a thermoplastic for moulding of high compression parts for general machinery and automobiles, or is likely to change significantly;
- the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
- 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.

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