File No PLC/733

October 2007

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Desmopan 786 E

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 Water Resources.

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:

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Bayer Australia Limited (ABN 22 000 138 714)
391 Tooronga Road, Hawthon East
VIC 3123

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 Formula, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Use Details, Manufacture/Import Volume, and Site of Manufacture/Reformulation

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)
Desmopan 786 E

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) >10,000

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 Yellowish transparent granules

Melting Point / Softening Temperature 170-200°C

Density 1150 kg/m^3

Water Solubility

pH	Condition	%
1.2	40°C, 1 day	0.09
7	40°C, 2 weeks	0.21
9	40°C, 2 weeks	0.37

Water solubility was determined by total organic content in accordance with OECD TG 120.

Dissociation Constant No dissociable groups present.

Particle Size Up to 3x5mm

Reactivity The notified polymer is stable under normal environmental conditions.

Degradation Products None under normal conditions of use. There was no change over time in TOC of GPC trace in the above water solubility test. Temperatures above 230°C cause thermal decomposition producing toxic fumes consisting of carbon monoxide and carbon dioxide. Formation of traces of aliphatic hydrocarbons, aldehydes, acids, hydrogen cyanide, and isocyanates may occur.

5. INTRODUCTION AND USE INFORMATION

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-30	10-30	10-30	10-30	10-30

Use
The notified polymer will be imported as a component of plastic moulding granules. The granules will be used in injection moulding equipment to produce plastic articles.

Mode of Introduction and Operation description
The notified polymer will not be manufactured in Australia. It will be imported by sea at a neat concentration as yellowish transparent granules in 25 kg bags. Upon arrival at Melbourne port, the notified polymer will be transported by road to a warehouse where it will be stored until such time that it is transported to the injection moulding site for conversion to plastic articles.

The injection moulding process occurs in Australia. Prior to moulding, the granules containing the notified polymer will be manually transferred from the bags in which they were imported in to a hopper adjacent to the injection moulder. During the moulding process, the granules are gravity-fed from the hopper to the injection moulder. Injection moulding consists of the following steps: compressing the granules, heating the granule to the processing point (190-210°C), and moulding the plastic. The moulded article is cooled, trimmed and stored until such time that it is shipped to industries.

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

OCCUPATIONAL HEALTH AND SAFETY
Transport workers should not be exposed to the notified polymer, as they will be handling closed containers. Exposure will only be possible in the event of an accident where the packaging is breached.

Before and during the injection moulding process, workers may have dermal, ocular and inhalation exposure to the notified polymer. However, since the moulding processes are largely enclosed and automated, worker exposure is expected to be limited. The moulding process is supplied with local ventilation and workers will wear suitable personal protective equipment (PPE) such as overalls, protective gloves, and safety glasses.

It is very important to note that the heating process occurs at a range of 190-210°C and the thermal decomposition of the notified polymer begins at 230°C. If the processing temperatures are exceeded, there will be a significant increase in the amount of isocyanate vapour generated. Over exposure entails a risk of respiratory irritation and/or sensitisation. Precautions should be taken and additional controls should be in place. With these additional controls against exposure to the by-products of overheating, the risk to workers is considered acceptable.

After moulding, workers will only be exposed to the notified polymer bound within a plastic matrix and therefore experience negligible risk. Likewise, a negligible risk also applies to end-users of the plastic articles containing the notified polymer.

The OHS risk presented by the notified polymer is expected to be low, given the expected low hazard of the polymer, the engineering controls, the good work practices and safety measures including the use of appropriate personal protective equipment by workers.

Public Health Risk Assessment
The notified polymer will not be sold to the public. The injection-moulded finished products will be used in industries and as such, public exposure is not expected. The public may be exposed in the unlikely event of a transport accident where the transport containers are breached and product is spilled. The public will be potentially exposed to the notified polymer within manufactured plastic articles. However, the risk to public health will be negligible because the notified polymer is of low hazard, and is bound within a matrix. Therefore, the introduction of the notified polymer is unlikely to present any risk to public health for the notified uses.

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
Release to the environment during shipping, transport and warehousing will only occur through accidental spills or leaks from bags. Spills will be taken up mechanically and re-used where possible. Other waste will be sent to a licensed waste landfill site.

It is expected that <1% of the notified polymer will be lost to spills and a further <2% will remain as residue in paper bags. A further 2% waste will be generated from trimming of components. Total waste is expected to be less than 5% per annum. All waste and "empty" bags will be disposed of as inert solid waste to a licensed waste landfill site. The vast majority of the notified polymer (>95%) will be bound within the polymer matrix of the moulded components and will share the fate of these components. Majority of the components will go to landfill.

The notified polymer is expected to be hydrolytically stable and to not be readily biodegradable. Due to its hydrophobic nature, it is expected that the notified polymer in landfill will associate with sediments and organic phases of soil and sediments, and slowly degrade to simple carbon compounds and water vapour.

No aquatic exposure is anticipated during manufacture of plastic components and end use of the notified polymer. It is envisaged that <5% waste would be generated from the moulding process. These wastes would be collected by licensed waste contractors and be disposed of in approved landfills as inert solid waste. In landfill, the solid wastes will not be mobile and will degrade slowly and not pose a significant environmental risk.

8. CONCLUSIONS AND RECOMMENDATIONS

Human health risk assessment
Under the conditions of the occupational settings described, the risk to workers is considered to be acceptable.

When used in the proposed manner the risk to the public is considered to be acceptable.

Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following precautionary measures in the injection moulding equipment to minimise sensitisation and inhalation exposure of workers to isocyanates in the event that the processing temperatures are exceeded:
  - Local exhaust ventilation should be used.
  - Process temperatures should be monitored.
  - Workers who become sensitised to the isocyanate vapour should be transferred to another workplace and not continue to handle the injection moulding equipment.
  - The MSDS should be provided to the authorised medical practitioner responsible for health surveillance in the workplace.
  - Respiratory protection should be available to workers.

  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.

Storage

- The following precautions should be taken by workers regarding storage of the notified polymer:
  - Protect from moisture and do not expose to temperatures above 40°C.
  - Keep container tightly closed.

Emergency procedures

- Spills and/or accidental release of the notified polymer should be collected by sweeping disposing with, if appropriate, other combustible waste materials. Avoid dust formation.

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 chemical 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 chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical 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 chemical has changed from a component of plastic moulding granules, or is likely to change significantly;
- the amount of chemical being introduced has increased from 30 tonnes, or is likely to increase, significantly;
- if the chemical 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 chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.