File No PLC/936

December 2010

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

NYLON 66/6T

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government 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 Australian Government Department of Sustainability, Environment, Water, Population and Communities.

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 Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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)
DuPont (Australia) Ltd (ABN 59 000 716 469)
7 Eden Park Drive
Macquarie Park NSW 2113

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, 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
Canada (1997) and the USA (1997)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Zytel HTN52 (contains 65% notified polymer)

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) > 1,000 Da

REACTIVE FUNCTIONAL GROUPS

Functional Group	Category	Equivalent Weight (FGEW)
Primary amine	High Concern	4,232

3. PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met*
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	No*
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 contains a primary amine reactive functional group which is a structural alert for irritation/corrosion. The presence of the primary amine group also implies that the polymer is potentially cationic which is a concern for the environment. However, the calculated FGEW of > 4,000 is closer to the allowable criteria of 5,000 and the polymer is insoluble and imported and used in the solid phase with minimal environmental release. In addition, the polymer will be used for the manufacture of articles in which the notified polymer will be bound within a polymer matrix and not bioavailable. Given this NICNAS has allowed for this polymer to be considered as a PLC.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Solid
Melting Point/Glass Transition Temp	270-285°C
Density	1134 kg/m^3
Water Solubility	≤ 1.5 × 10^{-3} g/L at 20°C Modification of OECD TG 120 – Gravimetric determination. Samples of notified polymer (50 mg) in water (1 L) were shaken at 30°C. After 72 h, undissolved polymer was filtered from the cooled solution, dried and weighed. Difficulty was reported in recovering all polymer particles from the test vessel walls during filtration.
Dissociation Constant	Residual end groups with a pK_a ~ 4 and/or pK_a ~ 9 are not expected to be ionised in the environment due to the water insolubility of the notified polymer.
Particle Size	Pellets of approximately 3 × 2.5 mm (composite containing > 50% notified polymer)
Reactivity	Stable under normal environmental conditions. The notified chemical contains hydrolysable functionality, however, due to its water insolubility, it is expected to be hydrolytically stable in the environmental pH range (4-9) at ambient temperature.
Degradation Products	None under normal conditions of use

5. INTRODUCTION AND USE INFORMATION

Mode of Introduction
The notified polymer will be imported in the product Zytel HTN52 (contains 65% notified polymer).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 500	≤ 500	≤ 500	≤ 500	≤ 500

Use
Component used in the manufacture of plastic articles.

The notified polymer will be imported as part of a pre-mixed composite that will not undergo further reformulation but will be loaded directly into thermoplastic extrusion equipment for manufacture of moulded parts for automobiles.

6. HUMAN HEALTH IMPLICATIONS

Hazard Characterisation
No toxicological data were submitted. The notified polymer is considered a PLC and can therefore be assumed to be of low hazard.

Occupational Health and Safety Risk Assessment
Dermal and ocular exposure may potentially occur during transfer of the notified polymer (65% concentration) from the imported containers into the thermoplastic extrusion equipment, and during the cleaning and maintenance of equipment. However, exposure to significant amounts of the notified polymer should be limited by the expected use of local exhaust ventilation, enclosed processes and personal protective equipment

by workers.

Workers may come into dermal contact with plastic articles manufactured with the notified polymer however, after curing the notified polymer will be incorporated into the polymer matrix and will not be available for exposure.

Although exposure could occur, the notified polymer is not considered to pose an unacceptable risk to the health of workers due to the control measures and the assumed low hazard of the notified polymer.

Public Health Risk Assessment
The notified polymer is intended only for use in industry and as such public exposure to the notified polymer is not expected. The public may come into dermal contact with plastic articles manufactured with the notified polymer, however, in this state the notified polymer will be bound within the polymer matrix and will be unavailable for exposure.

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation
No ecotoxicological data were submitted. Insoluble polymers are not expected to pose a concern to the aquatic environment unless the polymer is in the form of finely divided particles. In these cases toxicity to aquatic organisms occurs only at high concentrations, whereby acute and chronic toxicity values are generally >100 mg/L and > 10 mg/L, respectively. As the notified polymer is water insoluble (≤ 1.5 mg/L) and will only be imported and used in the solid phase, it is therefore not expected to pose a concern to the aquatic environment when used as proposed.

Environmental Risk Assessment
The imported composite containing the notified polymer will undergo thermoplastic extrusion moulding to manufacture parts for automobiles. As the notified polymer is expected to be completely incorporated into the inert polymer matrix of moulded articles, there is expected to be very little release of the notified polymer during the manufacture, use or disposal of the end-use products. Notified polymer residues in empty import containers, accidental spills and wastes generated during the moulding process are expected to be collected and recycled or disposed of to landfill. In landfill, notified polymer contained in waste or articles at the end of their useful life is not expected to be bioavailable, due to its high molecular weight, or mobile, due to its water insolubility. Eventually, the notified polymer is expected to degrade biotically or abiotically to form water and oxides of carbon and nitrogen. The notified polymer is not expected to bioaccumulate due to its high molecular weight and low potential for aquatic exposure based on its reported use pattern.

The notified polymer is not expected to pose an unacceptable risk to the environment based on its low assumed toxicity to aquatic organisms, its low potential to bioaccumulate, the low potential for aquatic exposure and its use as component of a thermoplastic extrusion composite.

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 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 component used in the manufacture of plastic articles, 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 a product containing 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.