

File No PLC/718

25 October 2007

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

FULL PUBLIC REPORT

Polymer B in Extem UH

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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FULL PUBLIC REPORT**Polymer B in Extem UH****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

General Electric Plastics (Aust) Pty Ltd (ABN 92 005 837 454)
175 Hammond Road DANDENONG VIC 3175

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, 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 (2006), EU (2006), Canada (2006), Japan (2006)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Ultem, Ultem XHT03, EXUM 0142, Extem UH

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) > 10000 Da

% of Low MW Species < 1000 Da < 1%

% of Low MW Species < 500 Da < 1%

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains high concern functional groups, but since the Mn is > 10000 Da there is no restriction on FGEW therefore the notified polymer meets the PLC criteria.

3. PLC CRITERIA JUSTIFICATION

<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 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 to brown pellet or solid plastic powder with slight odour
Melting Point	> 400°C
Glass Transition Temp	Approximately 341°C
Density	1415 kg/m ³ at 19.5°C
Water Solubility	Approximately 1 × 10 ⁻³ g/L at 40°C
Dissociation Constant	The notified polymer does not contain any acidic or basic groups.
Particle Size	Mass median diameter < 29.1 µm % respirable (< 10 µm) = 6.48% % inhalable (< 100 µm) = 92.95%
Reactivity	Stable under normal environmental conditions
Degradation Products	No degradation is expected under normal conditions of use. There is a hydrolysable functionality, but this shouldn't occur at ambient environmental conditions at the pH 4-9 range.

5. INTRODUCTION AND USE INFORMATION

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>	1-2	1-2	1-2	1-2	1-2

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The notified polymer will not be manufactured in Australia. It will be imported as powder or solid pellets (containing 1-100% notified polymer) in bulk containers.

Reformulation/manufacture processes

The notified polymer will be imported as powder or solid pellets, which will be used in thermal injection moulding operations. The powder will be reformulated into a pellet form in Australia. In most cases, the material will be transferred from the shipping or other bulk container into the feed hopper of the injection moulding process. The pellets containing the notified polymer will be heated until molten, and additives may be added before extrusion. After extrusion, the polymer may be stored in hoppers or directly reheated and injection-moulded to form articles.

Use

The notified polymer will be used in the production of high service temperature engineering materials, which will be moulded or extruded into articles or components such as reflectors, circuit boards, connectors, stock shapes, films or other compounded products. Finished articles will contain the notified polymer at 5-100%.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Dermal and ocular exposure with pellets/powder containing the notified polymer (up to 100%) may potentially occur during certain processes involving the notified polymer, such as injection moulding. However, such exposure will be limited because of the largely automated processes, and the engineering controls and personal protective equipment worn by workers (gloves and safety goggles).

Inhalation exposure may occur where the notified polymer is imported in powder form and blended with other materials prior to injection moulding. A proportion (approximately 7%) of the polymer used for injection moulding is potentially respirable (mean particle size < 10 µm). The most likely exposure scenarios involve the transfer of powders to hoppers and the cleaning up powder residues with an industrial vacuum cleaner and its emptying and cleaning. Inhalation exposure to powder/dust is expected to be controlled by Local Exhaust Ventilation (LEV) and/or a respirator (where exposure to powder cannot be controlled by engineering control). Dust generation requiring the use of a respirator to control inhalation exposure may occur while cleaning.

PUBLIC EXPOSURE

The notified polymer will not be sold to the public except in the form of finished articles. There is potential for extensive public exposure to articles such as electronic items comprised wholly or partly of the notified polymer.

Members of the public may make dermal contact with articles containing the notified polymer. However, the risk to public health will be negligible because the notified polymer is resistant to degradation and unlikely to be bioavailable.

6.2. Toxicological Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of no significant health impact. This is supported by toxicological endpoints observed in testing conducted on an analogous polymer (summary provided). However one form of the polymer (the powder form) contains approximately 7% respirable particle and is of high molecular weight (> 10000 Da). Water insoluble high molecular weight polymers used in respirable size range (< 10 µm) have the potential to cause lung overloading. There is no information on the inhalation toxicity of the polymer.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

The OHS risk presented by the notified polymer is expected to be low, based on the expected minimal exposure to workers.

Water insoluble high molecular weight polymers (> 10000 Da) used in respirable size range (< 10 µm) have the potential to cause lung overloading. Workers will need to have adequate respiratory protection against inhalation of the polymer. Automated processes and/or respirators are required when handling the powder.

The Australian recommended exposure standard for nuisance dust is 10 mg/m³ [NOHSC 3008:(1995)], but a recommended exposure limit of 3 mg/m³ has been suggested by the American Conference of Governmental Industrial Hygienists (ACGIH) for “respirable (insoluble) particulates (not otherwise regulated)”.

PUBLIC HEALTH

The notified polymer will not be available to the public. Members of the public may make dermal contact with products containing the notified polymer. However, the risk to public health will be negligible because the notified polymer would not be bioavailable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

The estimated environmental release from accidental spillage and residue remaining in empty boxes/bags is less than 1% of the 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 completely incorporated into an article so there is no release from an article or end use disposal of the article.

Estimated environmental release of the notified polymer (range 1-100% in products) is summarised in the following table.

Source of release	% Volume	Released to
Residual notified polymer within import containers	< 0.5%	Landfill
Accidental spills and equipment cleaning	< 1.0%	Landfill
End-of-useful-life disposal of finished articles	> 98.5%	Landfill

ENVIRONMENTAL FATE

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. Due to the large molecular weight and low water solubility, the notified polymer is not expected to bioaccumulate.

7.2. Environmental Hazard Characterisation

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

7.3. Environmental Risk Assessment

Based on the proposed use pattern, the release of the notified polymer to the environment is expected to be very low. The use pattern of the notified polymer in injection moulded parts will result in limited if any exposure to the aquatic environment. While no ecotoxicity data are available, due to limited release to water it is unlikely that the polymer would exist at levels which could pose a risk to aquatic organisms. The high molecular weight indicates a low potential for bioaccumulation.

Based on the reported exposure levels and use pattern, the polymer is not considered to pose a risk to the environment when it is stored, transported and used in the proposed manner.

8. CONCLUSIONS

8.1. Level of Concern for Occupational Health and Safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

8.2. Level of Concern for Public Health

There is Negligible Concern to public health when used in the proposed manner.

8.3. Level of Concern for the Environment

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

9. MATERIAL SAFETY DATA SHEET

9.1. 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.

10. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer in powder form:
 - Use of Local Exhaust Ventilation when handling the notified polymer in powder form
 - Avoid the formation of airborne dusts
 - Where engineering controls are not adequate, use polymer pellets instead of powder
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during certain processes where dust may be generated:
 - Use of respirator when handling notified polymer in powder form and during cleanup operations
 - Use of gloves, safety goggles and overalls
- 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 nuisance dust should be maintained as low as possible. The ASCC exposure standard for atmospheric dust is 10 mg/m³ but a recommended exposure limit of 3 mg/m³ has been suggested by the American Conference of Governmental Industrial Hygienists (ACGIH) for “respirable (insoluble) particulates (not otherwise regulated)”.

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.

Environment

Disposal

- The notified polymer should be disposed of to landfill.

Storage

- Store in a cool dry place. Avoid excessive heat and ignition sources.

Emergency procedures

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

10.1. Secondary Notification

The Director of NICNAS 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.

- changes in the operations such as significant exposure to the polymer power is expected

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.