

File No PLC/719

September 2007

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

FULL PUBLIC REPORT

Polymer in Extem XH and 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**

TABLE OF CONTENTS

FULL PUBLIC REPORT	3
1. APPLICANT AND NOTIFICATION DETAILS	3
2. IDENTITY OF CHEMICAL	3
3. PLC CRITERIA JUSTIFICATION	3
4. PHYSICAL AND CHEMICAL PROPERTIES	4
5. INTRODUCTION AND USE INFORMATION	4
6. HUMAN HEALTH IMPLICATIONS	4
6.1. Exposure Assessment	4
6.2. Toxicological Hazard Characterisation	5
6.3. Human Health Risk Assessment	5
7. ENVIRONMENTAL IMPLICATIONS	5
7.1. Exposure Assessment	5
7.2. Environmental Hazard Characterisation	6
7.3. Environmental Risk Assessment	6
8. CONCLUSIONS	6
8.1. Level of Concern for Occupational Health and Safety	6
8.2. Level of Concern for Public Health	6
8.3. Level of Concern for the Environment	6
9. RECOMMENDATIONS	6
10.1. Regulatory Obligations	6

FULL PUBLIC REPORT**Polymer in Extem XH and 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 (2005), Canada (2006)

2. IDENTITY OF CHEMICAL

OTHER NAME(S)

Polyetherimide polymer

MARKETING NAME(S)

Extem XH, Extem UH

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn)	>10000 Da
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% of Low MW Species < 1000 Da	< 1%
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% of Low MW Species < 500 Da	< 1%
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POLYMER CONSTITUENTS

The notified polymer contains only low concern functional groups.

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	Light brown pellets
Glass Transition Temp	Approximately 267°C
Density	1330 kg/m ³ at 20°C
Water Solubility	3.65×10 ⁻³ g/L at 25°C during hydrolysis testing, which is consistent with the polymer structure.
Dissociation Constant	No acidic or basic groups are present.
Particle Size	Pellets are nominally 2.5 mm long and 2.5 mm in diameter.
Reactivity	Stable under normal environmental conditions.
Degradation Products	No degradation is expected under normal conditions of use. The notified polymer was stable at pH 1.2, 4, 7 & 9 at 40°C for 14 days (1 day only at pH 1.2).

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>	1-50	1-50	1-50	1-50	1-50

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The notified polymer will not be manufactured in Australia. It will be imported as solid pellets (1-100%) in 680 kg bulk sacks. Blends with other commercially available polymers and fillers may also potentially be imported in the future.

Reformulation/manufacture processes

The notified polymer will be imported as a solid pellet, which will be used in thermal injection moulding operations. 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 requiring high temperature properties.

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, film, automotive parts, electrical parts and cookware.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Dermal and ocular exposure may potentially occur during certain processes involving the notified polymer, such as when opening the bulk sacks and transferring into the feed hopper. However, exposure to significant amounts of the notified polymer is limited because of use of automated processes, the engineering controls and expected appropriate personal protective equipment worn by workers. Inhalation exposure is limited as the pellet size is greater than the inhalation range. However the pellets may break into small particulates. Workers will need to wear dust mask if dust is generated.

PUBLIC EXPOSURE

The notified polymer will not be sold to the public except in the form of finished articles. There is potential for small amount of public exposure to articles such as reflectors, circuit boards and cookware comprised wholly or partly of the notified polymer. However, the notified polymer is unavailable for exposure.

6.2. Toxicological Hazard Characterisation

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 (summarised below) or on an analogous polymer described in the MSDS and summary provided by the notifier.

However the polymer is of high molecular weight (>10,000Da). 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.

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
Rat, acute oral toxicity	LD ₅₀ >2000 mg/kg bw	no	no	OECD TG 425
Mutagenicity, bacterial reverse mutation test	non-mutagenic	no	no	OECD TG 471

All results were indicative of low hazard.

Bacterial reverse mutation study:

In the preliminary toxicity assay, some precipitate was observed at 100 µg per plate but in the absence of toxicity. In the mutagenicity assay, some precipitate was observed beginning at 150 or 500 µg per plate, but in the absence of toxicity.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

The risk to workers presented by the notified polymer is expected to be low, based on the minimal exposure to workers and the low intrinsic hazard of the polymer. High molecular weight polymers used in respirable size range (<10 µm) are of concern because of the risk of lung overloading. However the notified polymer is imported in pellet form and is not expected to cause concern via inhalation. Dust may be generated from pellets during handling by physical means and workers will need to wear a dust mask. 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 imported pellets containing the notified polymer will not be available to the public. Members of the public may make dermal contact with articles containing the notified polymer where the notified polymer is unavailable for exposure. Therefore the risk to public health will be negligible.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

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

The notified polymer disposed of 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**

The risk to occupational health and safety is considered to be low under the conditions of the occupational settings described. Workers should avoid inhalation of the dust generated by handling the pellets. Handling of the pellets should be under Local Exhaust Ventilation.

8.2. Level of Concern for Public Health

There is negligible risk 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. RECOMMENDATIONS**CONTROL MEASURES****Occupational Health and Safety**

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer in pellet form if dust is generated:
 - Use Local Exhaust Ventilation when handling the notified polymer in pellet form
 - Wear a dust mask

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.

10.1. 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.
 - the notified polymer is introduced in a particulate form (particulates within the inhalable/respirable range), such as powder.
- or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from the production of high temperature service materials, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 50 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.