

File No PLC/726

September 2007

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

FULL PUBLIC REPORT

ULTEM XH6050

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. Toxicological Hazard Characterisation	4
6.2. Human Health Exposure and Risk Assessment	5
7. ENVIRONMENTAL IMPLICATIONS	5
7.1. Exposure Assessment	5
7.2. Environmental Hazard Characterisation	5
7.3. Environmental Risk Assessment	5
8. MATERIAL SAFETY DATA SHEET	6
8.1. Material Safety Data Sheet	6
9. CONCLUSIONS AND REGULATORY OBLIGATIONS	6
Level of Concern for Occupational Health and Safety	6
Level of Concern for Public Health	6
Level of Concern for the Environment	6
Recommendations	6
Regulatory Obligations	7
9. BIBLIOGRAPHY	7

FULL PUBLIC REPORT**ULTEM XH6050****1. APPLICANT AND NOTIFICATION DETAILS****APPLICANT(S)**

General Electric Plastics (Australia) 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, CAS Number, Molecular Formula, Structural Formula, Molecular Weight, Number Average Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Maximum Introduction Volume, Specific Use Details, Manufacture/Import Volume, Notification in Other Countries

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

The notified polymer has been notified in other countries.

2. IDENTITY OF CHEMICAL**MARKETING NAME(S)**

ULTEM XH6050, ULTEM EXUM0104-1000, ULTEM EXUM0025

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

<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 brownish transparent pellets
Melting Point/Glass Transition Temp	247°C
Density	1322.1 kg/m ³ at 25°C
Water Solubility	<100 mg/L at 40°C A specific amount of the test substance was weighed and purified water was added to obtain the test solution. The test solution was equilibrated at 25°C after stirring for 24 hours in a 40°C water bath. The results were determined through gravimetric and TOC analysis and showed that the test substance is hardly soluble in water.
Dissociation Constant	No dissociable groups present.
Particle Size	The notified polymer is in the form of granules in the range of 3-5mm, with average length of 3.5mm and diameter of 2.1mm.
Reactivity	The notified polymer is stable under normal environmental conditions. Testing at pH 1.2, 4, 7 and 9 at 40°C for 14 days (24 hours at pH 1.2) showed no degradation.
Degradation Products	None under normal conditions of use.

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>	10-100	10-100	10-100	10-100	10-100

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction and Operation description

The notified polymer will be imported as light brownish transparent pellets either in bags or in tote bags/boxes. The pellets will be imported by sea and transported by road from the Port of Melbourne to the General Electrics site at Dandenong in Victoria where it will undergo injection moulding.

Reformulation/manufacture process

The pellets will be weighed and mixed with other materials in a sealed mixer. Dust extractors are used in the weighing and mixing area. The mixture is discharged via a closed system before mechanically transferring to a hopper that feeds the thermal injection moulding equipment. The notified polymer will be thermo-formed into shaped articles and cooled after discharge from the moulding machine. This process is fully automated. The moulded articles will be sold to manufacturers that would then use the articles as components of other finished products.

Use

The notified polymer will be injection-moulded and extruded into industrial articles requiring high temperature properties like reflectors, circuit boards and electrical connectors. The notified polymer will be encapsulated within an inert matrix at 50-99% of the finished product.

6. HUMAN HEALTH IMPLICATIONS

6.1. Toxicological Hazard Characterisation

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

6.2. Human Health Exposure and Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

During transport and storage, dermal and ocular exposure to the notified polymer may occur in the event of accidental breaching of the sealed containers containing the bags. Workers involved in the injection moulding process 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 because of the engineering controls in place and personal protective equipment worn by workers. Once the notified polymer has been injection-moulded into shaped articles, it is fixed into the polymer matrix and is therefore no longer bioavailable. Exposure to the polymer in the finished plastic articles is therefore negligible.

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

The notified polymer will not be sold directly to the public. The public will be potentially exposed to the notified polymer within manufactured plastic articles. However, in this state, the notified polymer will be bound within an inert matrix and unavailable to cause any risk to public health. Therefore, the introduction of the notified polymer is unlikely to present any risk to public health for the notified uses.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

Manufacture of the notified polymer will not lead to any exposure of the Australian environment, as it will occur overseas. The notified polymer will be imported into Australia in granular form.

Release of the notified polymer during formulation into articles may come in the form of container residues, accidental spillages, production waste, and from the disposal of finished articles. Most of the waste generated from this release will be recycled, however, may also be disposed to landfill as normal industrial waste through a licensed waste collector. The fate of the notified polymer will be that of the finished product i.e. landfill. Estimated environmental release of the notified polymer is summarised in the following table:

Source of release	% Volume	Released to
Residual notified polymer within import containers	~1%	Recycling or landfill
Accidental spills	~1%	Recycling or landfill
Production waste	~1%	Recycling or landfill
End-of-useful-life disposal of finished articles	~97%	Recycling or 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. MATERIAL SAFETY DATA SHEET

8.1. 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.

9. CONCLUSIONS AND REGULATORY OBLIGATIONS

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.

Level of Concern for Public Health

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

Level of Concern for the Environment

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

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.

Storage

- The following precautions should be taken by workers regarding storage of the notified polymer:
 - Keep packaging tightly closed in a cool and dry place.
 - Keep pellets away from heat and sources of ignition.

Emergency procedures

- Spills and/or accidental release of the notified polymer should be collected by sweeping and shovelling into suitable containers for disposal. Do not create a powder cloud by using a brush or compressed air.

Regulatory Obligations

Secondary Notification

The Director of Chemicals Notification and Assessment 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.

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.

9. BIBLIOGRAPHY

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.