

File No PLC/678

May 2007

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

FULL PUBLIC REPORT

Lexan XHT8141

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**Lexan XHT8141****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

General Electric Plastics (Australia) Pty Ltd (ABN 92 005 837 454)
175 Hammond Rd
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, Specific Use Details, and Manufacture/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 (2005)

Korea (2005)

Japan (2006)

2. IDENTITY OF CHEMICAL

OTHER NAME(S)

Modified polycarbonate copolymer

MARKETING NAME(S)

Lexan XHT8141 (powder or pellets)

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) >10000

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met (yes/no/not applicable)</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 solid (powder or pellets)
Melting Point/Glass Transition Temp	232-269°C
Density	1229 kg/m ³ at 20°C
Water Solubility	<0.036 mg/L at 20°C at pH 7 <0.031 mg/L at 37°C at pH 2 and 9 OECD TG 120 –shake flask method.
Water stability	The stability of the polymer in water at pHs 1.2, 4.0, 7.0 and 9.0 was determined by gravimetric analysis with FTIR and GPC to determine if there had been any chemical changes. At all pHs there was a minor decrease in weight (at pH 1.2, 0.17% change; pH 4.0, 0.41% change, pH 7.0, 0.52% change and pH 9.0, 1.4% change) but there was no significant chemical changes or degradation.
Particle Size	The powder has a mass median diameter of 107 µm, with: Inhalable fraction (<100 µm): 46% Respirable fraction (<10 µm): 1.5%
Reactivity	Stable under normal environmental conditions
Degradation Products	The notifier has indicated that processing fumes evolved at recommended processing conditions have been found to include trace levels of phenols, alkyl phenols, and diaryl carbonates. Traces of phenylisocyanate, other amide decomposition products and partially oxidised combustion products may also be formed.

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>	50-100	100-200	100-200	100-200	100-200

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The notified polymer is imported as compounded pellets (98-99% notified polymer) or as a powder (99.7% notified polymer) in 25 kg bags or supersacks.

Reformulation/manufacture processes

The notified polymer is not manufactured in Australia.

The compounded pellets will be used directly by plastics manufacturers while the powder will be reformulated with additives and colourants and extruded into pellets before being used in plastics

manufacture.

Reformulation

Plant operators open the bags of notified polymer powder (99.7%) and manually weigh and transfer the powder to a mixer where other additives and colourants are added. The mixer is sealed during mixing and the mixture is discharged via a closed system for transfer to the hopper of the heat-forming equipment, where the mixture is extruded into pellets. Dust extraction is used in the weighing and mixing area.

Plastics Manufacture

Compounded pellets containing the notified polymer (98-99%) are manually transferred from bags into a hopper. The pellets are then injection-moulded (thermo-formed) into shaped parts and cooled on discharge from the forming machine. The thermo-forming process is an automatic process. Plant operators will handle the formed article when transferring it from the forming machine to transport packaging for dispatch.

Use

The notified polymer is used to produce injection-moulded or extruded articles, which may contain up to 100% of the notified polymer.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Transport and Storage

During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached.

Reformulation

Dermal, ocular and inhalation exposure to dust of the notified polymer may occur during reformulation processes, such as opening and closing of bags, weighing, and transferring notified polymer powder. However, exposure to significant amounts of the notified polymer is limited because of engineering controls, such as dust extraction, and the use of personal protective equipment (coveralls, gloves, safety boots, safety goggles and respirators where required) worn by workers. In addition, inhalation exposure will be limited due to the particle size of the imported powder (mean diameter > 100 µm, and < 1.5% of particles in respirable range (< 10 µm)). Exposure to degradation fumes during processing will be limited by the enclosed systems used and the use of exhaust ventilation. Once the notified polymer has been reformulated into pellets the polymer is no longer bioavailable and therefore significant exposure to the notified polymer is not likely during plastics manufacture or handling of finished articles.

End Use

There is potential for extensive contact with articles comprised wholly or partly of the notified polymer during assembly of products using thermo-formed articles. However exposure to the notified polymer itself is expected to be negligible, as at this stage the notified polymer is not considered to be bioavailable.

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 contact with articles comprised wholly or partly of the notified polymer. However at this stage the notified polymer is not expected to be bioavailable. Therefore exposure to the notified polymer itself is expected to be negligible.

6.2. Toxicological Hazard Characterisation

No toxicity data was submitted. The notified polymer meets the PLC criteria and is therefore expected to be of low hazard.

The notified polymer is a water insoluble polymer with a molecular weight greater than 10,000 daltons. However, the US EPA concern regarding lung overloading for this class of polymers (high MW, insoluble) is primarily for polymers with a MW greater than 70,000 daltons (although a data gap for polymers with MW 10,000-70,000 is acknowledged). In addition, the particle size distribution of the powder indicates that the mass median diameter is 107 µm, with only 1.5% of the particles having a diameter less than 10 µm (respirable range). Significant respiration of the polymer powder into the lungs resulting in lung overloading is therefore unlikely.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

Although exposure to the notified polymer could occur during reformulation, the risk to workers is considered to be low due to the intrinsic low hazard of the notified polymer.

The level of atmospheric nuisance dust should be maintained as low as possible. The NOHSC exposure standard for atmospheric dust is 10 mg/m³.

PUBLIC HEALTH

The potential for public exposure to the notified polymer is expected to be negligible. As a result, the notified polymer is unlikely to pose any significant risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

There will be no release in Australia due to manufacture as the notified chemical will not be manufactured here.

Release to the environment during shipping, transport and warehousing will only occur through accidental spills or leaks from damaged transport bags (eg supersacks). Any spilt material will be swept up, and reused, if possible, or disposed of to landfill.

The waste polymer from each extrusion and injection moulding is entirely recyclable. The extruder is cleaned with a charge of general purpose polymer resin. The used cleaning resin can be reused or disposed of to landfill.

Total environmental release from import bag residues and production wastages, is estimated to be 3% (up to 6 tonnes) of the import volume.

ENVIRONMENTAL FATE

The notified polymer is not expected to be released to the aquatic compartment.

Once incorporated into the article, the notified polymer will be immobilised in the polymer matrix and little release is expected. The articles incorporating the notified polymer and any production waste may be recyclable, however, it is expected most will end-up being land filled at the end of the articles service life.

It is likely that in landfill the polymer matrix and the notified polymer would degrade slowly through biotic and abiotic processes. Due to its molecular weight, 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

Release of the notified polymer during importation, transportation and handling would be limited to accidental spills with spilt material being collected and recycled, where possible, or disposed to landfill. The production waste containing the notified polymer will be reused, either back into the process or in other processes, or disposed of to landfill.

Direct release to the aquatic environment compartment is not expected.

The notified polymer is therefore unlikely to pose an unacceptable risk to the environment.

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**

- 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.

- The level of atmospheric nuisance dust should be maintained as low as possible. The NOHSC exposure standard for atmospheric dust is 10 mg/m³.
- 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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, 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 reused or recycled, if possible, but otherwise can be disposed of to landfill or by incineration, if available.

Emergency procedures

- Spills and/or accidental release of the notified polymer should be handled by containment, collection by sweeping (but do not create a powder cloud) and then placed in a sealable container ready for washing and reuse, if possible, other wise disposed of to landfill.

10.1. 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.