

File No PLC/806

January 2009

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

FULL PUBLIC REPORT

Ultem EXUM0196

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, Water, Heritage and the Arts.

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

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

SABIC Innovative 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 and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities and Import Volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

NOTIFICATION IN OTHER COUNTRIES

Canada, Japan, Korea.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Ultem EXUM0196

OTHER NAME(S)

PCP endcapped U2 polymer

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) > 10,000 Da

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

Criterion

Molecular Weight Requirements
Functional Group Equivalent Weight (FGEW) Requirements
Low Charge Density
Approved Elements Only
Stable Under Normal Conditions of Use
Not Water Absorbing
Not a Hazard Substance or Dangerous Good

Criterion met

Yes
Yes
Yes
Yes
Yes
Yes
Yes

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Off-white/yellow pellets
Glass Transition Temp	218°C
Density	1,270 kg/m ³
Water Solubility	< 5 mg/L at 20°C An upper limit for the water solubility was determined by a gravimetric method. This involved shaking an aqueous suspension of the notified polymer at 40°C for 24 hours, followed by filtration. Water solubility was determined from the weight of recovered test material, and confirmed by TOC analysis of the filtrates
Particle Size	
Reactivity	Stable under normal environmental conditions
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>
Tonnes	1-2	1-2	1-2	1-2	1-2

Use

The notified polymer will be used as a synthetic thermoplastic polymer for use in automotive, electronics and film products.

Mode of Introduction and Disposal

The notified polymer will not be manufactured in Australia. It will be imported in products or by itself at concentrations up to 100% in the form of small off-white/yellow pellets or powder to Melbourne by sea in 25, 100 or 1000 kg containers. The notified polymer will be distributed to customers where it will be reformulated in some cases prior to end use in plastic extruders to form plastic articles.

6. HUMAN HEALTH IMPLICATIONS

Hazard Characterisation

The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. This is supported by the following toxicological testing conducted on the notified polymer.

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
Genotoxicity - bacterial reverse mutation	non mutagenic	no	OECD TG 471

The notified polymer was negative in a bacterial reverse mutation assay (Ames test) at concentrations up to 5000 µg/plate, conducted both with and without metabolic activation using a method equivalent to OECD TG 471.

Occupational Health and Safety Risk Assessment

The notified polymer meets the PLC criteria. Thus, it is expected to be generally a low health hazard to workers, following oral, dermal or ocular exposure. However, as the notified polymer may contain a small fraction of particulates in the respirable range (<10 µm), there is a potential health risk to workers when handling the notified polymer in powder form.

The health effects of inhalation exposure to the notified polymer are unknown. The notified polymer is unlikely to be absorbed from the lung due to its low water solubility and high molecular weight, so deposition in the deep lung is probable, combined with an inability of the lungs to dislodge the particles. Inhaled particulates are known to interfere with cell function in the airways, causing inflammatory-like reactions*. Therefore, bronchial or pulmonary irritation is possible following inhalation exposure to particles containing the notified polymer,

* R.C. Rylander (1997) Organic dusts. In: Roth RA, ed. *Comprehensive Toxicology, Volume 8: Toxicology of the Respiratory System*. Elsevier Science Ltd., pp. 415-424.

arising from deposition of water-insoluble particles in the lung. The US EPA have similarly expressed concern regarding high molecular weight (70,000 Da or greater) insoluble polymer particles of respirable size, as they can potentially result in irreversible lung damage. However, there is a data gap for polymers with MW between 10,000 and 70,000 Da. The notified polymer falls within this range. The Australian recommended exposure standard for 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)”.

Appropriate control measures (e.g. local exhaust ventilation, dust masks) to mitigate inhalation exposure to respirable particles of the notified polymer should be implemented when the level of atmospheric dust is above the ACGIH exposure standard of 3 mg/m³.

Handling of the notified polymer in powder (and to a lesser extent pellet) form may generate airborne dusts and grinding, sanding or sawing may produce a dust explosion hazard. The MSDS provided by the notifier states that dust accumulation should be avoided by bonding, grounding and venting. The notifier states that the level of inhalation exposure to atmospheric dust is expected to be reduced by the use of exhaust ventilation. The use of particulate respirators would also help minimise dust levels.

The notifier states that fumes generated during the extrusion process may present a hazard. However, the notifier states that engineering controls such as exhaust ventilation will be implemented to remove fumes. The notifier also states that toxic and flammable fume condensates may accumulate in exhaust equipment and recommends their removal periodically to minimise the potential for fire and toxicity.

Overall, the OHS risk presented by the notified polymer is not expected to be unacceptable, based on the engineering controls and the assumed low hazard of the polymer.

Public Health Risk Assessment

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 finished plastic articles comprised wholly or partly of the notified polymer. However, the risk to public health will be negligible because the notified polymer is bound within a matrix and is not bioavailable.

7. ENVIRONMENTAL IMPLICATIONS

Environmental Risk Assessment

Environmental exposure to the notified polymer is expected to be restricted to spills, which can be readily contained and collected for safe disposal as the polymer is a solid. The notified polymer has very low water solubility and is not expected to be bioavailable, whether as raw material or after incorporation into plastic articles. Therefore, the notified polymer is not expected to pose a risk to the environment when it is used as proposed in thermoplastics.

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 considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following precautionary measures during handling of the notified polymer in powdered form and during use of the extrusion equipment to minimise inhalation exposure of workers:
 - Avoid the formation of airborne dusts
 - Local exhaust ventilation should be used
 - Respiratory protection should be available to workers.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during the application where dust may be generated:
 - Use of a dust mask (adequate for respirable particle sizes) as needed.
- 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 dust should be maintained as low as possible. The ACGIH exposure standard for atmospheric dust is 3 mg/m³.

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 by landfill.

Emergency procedures

- Spills and/or accidental release of the notified polymer should be handled by collection, containment 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 synthetic thermoplastic polymer or is likely to change significantly;
 - the amount of notified polymer being introduced has increased, or is likely to increase significantly;
 - if 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 secondary notification is required.

Material Safety Data Sheet

The MSDS of 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.