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

**FULL PUBLIC REPORT**

**Polymer in Pebax 33 series**

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**Director  
NICNAS**

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**FULL PUBLIC REPORT****Polymer in Pebax 33 series****1. APPLICANT AND NOTIFICATION DETAILS**

## APPLICANT(S)

Arkema Pty Ltd (ABN 44 000 330 772)  
Ground Floor, 600 Victoria Street  
RICHMOND VIC 3121

## 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, Use Details, 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

Korea 2005

**2. IDENTITY OF CHEMICAL**

## MARKETING NAME(S)

Polymer in Pebax 33 series (Pebax 3533, 4033, 5533, 6333, 2533, 7033, 7233)

## MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) >10000

% of Low MW Species < 1000 < 5

% of Low MW Species < 500 < 5

## 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

<b>Appearance at 20°C and 101.3 kPa</b>	Colourless, solid pellets
<b>Melting Point/Glass Transition Temp</b>	133 – 172°C
<b>Density</b>	1010 – 1020 kg/m <sup>3</sup> at 20 °C
<b>Water Solubility</b>	0.218% C w/w at 20°C for PEBAX 3533 0.214% C w/w at 20°C for PEBAX 6333  OECD TG 120 – Solution /Extraction Behaviour of Polymers in Water. A sample of ground polymer (10 and 1 g) are mixed with ultrapure water at 20°C and pH of 6.5. The extracts were filtered and then analysed for dissolved organic carbon content.
<b>Dissociation Constant</b>	No acid or base groups are present
<b>Particle Size</b>	Granulometry 5mm (approximately)
<b>Reactivity</b>	Stable under normal environmental conditions
<b>Degradation Products</b>	None under normal conditions of use

The polymer is a polyamide polyether block copolymer and is considered non-biodegradable and stable in water on the basis of its structure. While polyamide bonds hydrolyse, ethers do not. There is a low quantity of water taken into the structure. Relative to nylons of similar MW is 3 to 5 times less water enters the polymer structure. Without water hydrolysis cannot occur and it is not expected in the environmental pH range of 4-9.

#### 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	< 10	< 10	< 10	< 10

##### USE AND MODE OF INTRODUCTION AND DISPOSAL

###### Mode of Introduction

The notified polymer is imported in 25 kg polybags as a 90-100% component in the compounded product, Pebax 33 series of resins, for extrusion applications or manufacture of hot melt glues.

###### Reformulation/manufacture processes

Australian manufacturers will take the imported product and use it directly in extrusion applications or blend it with other materials at high temperature to create adhesives.

###### Use

End use applications are broad and include: sports shoes, ski boots and skis, drive belts, silent running gears, flexible tubing and hot melt glues. The above applications are typically manufactured by extrusion moulding though smaller runs or items may be by injection moulding.

The Pebax resins containing the notified polymer (90 – 100%) are poured from the bags to the holding tank/hopper. In the case of hot melt glue the Pebax resin is mixed within a holding tank with other ingredients. A vacuum hose, gravity feed or screw feed then transports notified polymer to the heating chamber set at 180°C to 270°C depending on the grade. Once molten, the resin is moulded as required into pre-cast moulds by injection moulding or as a continuous piece by extrusion moulding. It is expected that the moulding processes are largely automated. Injection moulded products are then

removed from moulds after cooling. Extrusion moulded products are typically carried along a conveyor, cooled and cut to the desired length. Moulded products are packaged by manual and/or automated means for transportation. The process is expected to be carried out in the presence of local exhaust ventilation. The MSDS recommends the use of eye protection, impervious gloves, apron and respiratory protection where ventilation is not adequate.

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1. Exposure Assessment

#### OCCUPATIONAL EXPOSURE

Dermal and ocular exposure may potentially occur during certain processes involving the notified polymer. However, exposure to significant amounts of the notified polymer is limited because of the largely automated processes, the likely engineering controls present and expected use of personal protective equipment worn by workers.

#### 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 automotive interiors comprised wholly or partly of the notified polymer. Blooming/leeching of the notified polymer from the articles is not expected and hence exposure will be low.

### 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 or analogue chemical.

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
1. Rat, acute oral	LD50 > 4000 mg/kg bw	no	no	Not specifically stated but appears to be in accordance with OECD TG 401
2. Rabbit, skin irritation	non-irritating	no	no	OECD TG 404
3. Rabbit, eye irritation	slightly irritating	no	yes	OECD TG 405
4. Skin sensitisation - adjuvant test	no evidence of sensitisation.	no	no	OECD TG 406 (Buehler and Maximisation tests)
5. Genotoxicity - bacterial reverse mutation	mutagenic/non mutagenic	no	no	Not specifically stated but appears to be in accordance with OECD TG 471
6. Genotoxicity - in vivo micronucleus test	non genotoxic	no	no	Not specifically stated but appears to be in accordance with OECD TG 474

All results were indicative of low hazard.

### 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 minimal exposure to workers and the low intrinsic hazard of the polymer.

#### 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 is of low hazard, and is chemically stable. Therefore, the risk

to public from exposure to the notified polymer is considered to be low.

## **7. ENVIRONMENTAL IMPLICATIONS**

### **7.1. Exposure Assessment**

#### **ENVIRONMENTAL RELEASE**

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

Release to the environment during shipping, transport and warehousing will only occur through accidental spills or leaks of the polybags. Any spilt material will be swept up, washed and dried to be entirely reusable.

The waste polymer from each extrusion and injection moulding is entirely recyclable. Unused material (including offcuts) generally in solid shape form is readily ground and is best recycled at <10% to maintain maximum physical property.

Each time the extruder is cleaned there will be a charge of usually no greater than 2 kg that will be mixed with cleaning resin such as nylon 6 and that can be recycled as letterboxes, garden stakes, oil filter parts, garden furniture and other low value uses in preference to being sent to landfill. Release to the environment from the production process is therefore minimal and would be less than 24 kg per annum.

Less than 0.1% annually (ie <10 kg) will be lost due to residuals in the empty imported bags. The bags will be stockpiled for disposal.

#### **ENVIRONMENTAL FATE**

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

Once incorporated into an article, the notified polymer will be immobilised in the polymer matrix and little release is expected. While many of the applications may be recyclable in the future, it is expected that the diverse uses of Pebax and low volume in any one application will result in most of the resin being land filled at the end of its functional life.

The polymer is expected to be non-biodegradable and stable in water on the basis of its structure. It is likely that in landfill the polymer matrix and the notified polymer would degrade slowly through biotic and abiotic processes into elemental components.

Due to its molecular weight, the notified polymer is not expected to bioaccumulate.

### **7.2. Environmental Hazard Characterisation**

No ecotoxicological data were submitted. Polymers 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. The majority of production waste containing the notified polymer will be reused either back into the process or in other processes.

Direct release to the aquatic environment compartment is not expected.

## **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.

- 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 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 and then placed in a sealable container ready for washing and reuse, if possible, otherwise 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.