NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Supradel

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Director NICNAS

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FULL PUBLIC REPORT

Polymer in Supradel

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Polymers International Australia Pty Ltd (ABN 92 069 883 825)
17-19 Endeavour Way
Braeside VIC 3195

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, Polymer constituents, Use Details, 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 Japan (2005); China (2006); Korea (2006)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Supradel (50 – >99% notified polymer)
EpiSpire (will replace Supradel in early 2007)

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn)

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains a functional group that could be considered to be of high concern. However, the molecular weight of the notified polymer (>10000) is such that this functional group is unlikely to make a significant contribution to the hazard associated with use of the polymer.

>10000

3. PLC CRITERIA JUSTIFICATION

Criterion	Criterion met (yes/no/not applicable)		
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

Melting Point The notified polymer does not melt between 0 -

400 °C.

Density $(1030 \pm 10) \text{ kg/m}^3 \text{ at } 23^{\circ}\text{C}$

Water Solubility <0.5 mg/L at 20°C in water

<0.5 mg/L at 20°C in aqueous buffer pH 1.93 <0.5 mg/L at 20°C in aqueous buffer pH 9.06 <0.5 mg/L at 37°C in aqueous buffer pH 6.99 <0.05 mg/L at 37°C in aqueous buffer pH 2.05 <0.05 mg/L at 37°C in aqueous buffer pH 9.10

(Determined using OECD TG 120)

Off-white/beige pellets or powder.

Dissociation ConstantNot applicable

Particle Size

The substance consisted of particles (no

agglomerates) approximately $50\,-\,1800\mu m$ in

size.

10% < 172.53 μm 50% < 403.53 μm 90% < 718.93 μm

Flammability The notified polymer is not flammable.

The notified polymer does not self-ignite at

temperatures up to 400°C.

<0.025 mg/L at 20°C in cyclohexane (OECD

TG 120)

Reactivity Cross contamination with polyacetyl or

polyoxymethylene resins may result in rapid, possibly violent release of decomposition fumes

at moulding temperatures.

Degradation Products Oxides of carbon, sulfur oxides, hydrocarbons.

5. INTRODUCTION AND USE INFORMATION

Autoignition Temperature

Fat Solubility

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	1	2	3	4	5
Tonnes	<1	1-3	3-10	3-10	3-10

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The notified polymer will be imported into Melbourne and/or Sydney. It will be contained within pellets or powder at concentrations ranging from around 50% to >99%. The mode of distribution within Australia will be by truck. Packaging may include 25 kg paper bags or 1 ton Gaylord boxes.

Reformulation/manufacture processes

There will be no reformulation or repackaging of the notified polymer in Australia. The notified polymer will be imported as solid pellets or powder ready for moulding and injection into end use products.

For the manufacture of injection moulded articles, typically the content of imported sacks is automatically transferred into a hopper equipped with dust extractors. The resin is dried in the hopper and automatically conveyed to the injection machine where it is injected and melted into shapes. The moulded articles are cooled and automatically discharged from the machine. The sheet forming process is likely to be similar, with the notified polymer being melted in an extruder through a die face, producing a sheet of the required size.

The final articles are warehoused and subsequently assembled into finished consumer products.

FULL PUBLIC REPORT 6 December 2006 PLC/661 Page 4 of 7 Rejected parts are collected and sent to grinding machines for re-use.

Use

The notified polymer will be used in the manufacture of injection moulded or sheet formed plastic articles for a variety of industrial and consumer uses. End use applications include electric products, plastic food contact packaging and filtration membranes.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Dermal, ocular and inhalation exposure may potentially occur during certain processes involving the notified polymer, particularly as a result of grinding reject articles for reuse. However, exposure is likely to be limited by the engineering controls and PPE worn by workers and in some instances by the automated processes.

PUBLIC EXPOSURE

The notified polymer will not be sold to the public. There is potential for widespread public exposure to plastic articles containing the notified polymer. However, the notified polymer in plastic articles is not expected to be biologically available as it is of high molecular weight and is bound within a matrix.

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 a toxicological endpoint observed in a genotoxicity test.

Endpoint	Result	Classified?	Effects	Test Guideline
			Observed?	
Genotoxicity - bacterial reverse	non mutagenic	no	no	Similar to OECD TG
mutation (Ames test)				471

The test substance has an identical structure to the notified polymer but has been assigned a different CAS number and its molecular weight appears to be slightly different than that of the notified polymer. The notifier claims that it is identical to the notified polymer, aside from the use of different solvent systems.

The result was 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

Members of the public may make dermal contact with articles containing the notified polymer and will be exposed to goods that have had contact with the notified polymer. However, the risk to public health will not be significant because the notified polymer is of low hazard, and is bound within a matrix. The risk to public health from end use products for therapeutic use is not covered by this report. Such uses are beyond the scope of NICNAS.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

During the manufacture of injection moulded and sheet formed articles, the majority of wastes generated will be collected, reground and reused in the moulding process. Small quantities may be released due to spillage from the hopper or injection machines, and as dust during grinding. The spillage can be cleaned up by mechanical means. Empty import containers containing residual polymer will also be disposed of in a landfill. As the polymer is in solid or powder form it is expected that approximately 0.1% (<5 kg) will remain in import containers. The only manufactured items that are likely to have aquatic exposure during their useful lives are filtration membranes. Losses from abrasion and dissolution of the membranes are expected to be minimal, before replacement of the filtration membrane.

ENVIRONMENTAL FATE

The majority of the notified polymer will be incorporated into moulded and sheet formed articles that will be disposed of in a landfill at the end of their useful lives. The polymer is poorly water soluble and is not expected to be readily biodegradable. The items are therefore likely to eventually undergo in-situ degradation by biotic and abiotic processes to form oxides of carbon and sulphur and water vapour.

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

The notified polymer is unlikely to be hazardous as it has no ionic functionalities, is practically inert, and has a high molecular weight. The notified polymer is unlikely to cross biological membranes due to its high molecular weight. It is also unlikely to be released to the aquatic environment in any significant quantities and has low water solubility. Therefore, the notified polymer is 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 No Significant 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 a 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 disposed of to authorised landfill.

Emergency procedures

• Spills and/or accidental release of the notified polymer should be handled by sweeping up, whilst avoiding creating dust. Do not flush to sewers or waterways. Recover for re-use to the extent practicable and place remainder into suitable containers for disposal.

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.