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

FULL PUBLIC REPORT

Elastollan 1085 A53

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**Director
Chemicals Notification and Assessment**

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FULL PUBLIC REPORT**Elastollan 1085 A53****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

PD Plastics (Aust) Pty Ltd (ABN: 42 091 476 505)
762 Arthurs Seat Road
ARTHURS SEAT VIC 3836

NOTIFICATION CATEGORY

Synthetic Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

No details are claimed exempt from publication.

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, Korea, USA

2. IDENTITY OF CHEMICAL

CHEMICAL NAME

1,4-Butanediol, polymer with 1,1'-methylenebis[4-isocyanatobenzene], methyloxirane and oxirane

OTHER NAME(S)

Thermoplastic polyurethane
1,4-butanediol, polymer with MDI and polyethylene-polypropylene glycol

MARKETING NAME(S)

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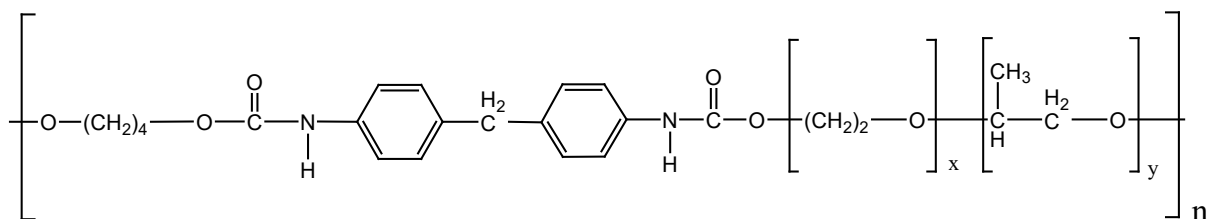
CAS NUMBER

34407-15-3

MOLECULAR FORMULA

$(C_{15}H_{10}N_2O_2.C_4H_{10}O_2.C_3H_6O.C_2H_4O)_x$

STRUCTURAL FORMULA



MOLECULAR WEIGHT

Number Average Molecular Weight (Mn)	53000
Weight Average Molecular Weight (Mw)	229000
Polydispersity Index (Mw/Mn)	4.32
% of Low MW Species < 1000	0.7
% of Low MW Species < 500	0.15

3. COMPOSITION

POLYMER CONSTITUENTS

<i>Chemical Name</i>	<i>CAS No.</i>	<i>Weight % starting</i>	<i>Weight % residual</i>
Oxirane, methyl-	75-56-9	40.79	<0.001
Oxirane	75-21-8	13.6	<0.001
Benzene, 1,1'-methylenebis[4-isocyanato-	101-68-8	33.7	<0.001
1,4-Butanediol	110-63-4	10.6	<0.001
Water	7732-18-5	0.01	0
Benzenepropanoic acid, 3,5-bis(1,1-dimethylethyl)-4-hydroxy-, 2,2-bis[[3-[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]-1-oxopropoxy]methyl]-1,3-propanediyl ester	6683-19-8	0.5	0
Benzenepropanamide, N,N'-1,6-hexanediylbis[3,5-bis(1,1-dimethylethyl)-4-hydroxy-	23128-74-7	0.5	0
Octadecanamide, N,N'-1,2-ethanediylbis-	110-30-5	0.3	0

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
No Substantial Degradability	Yes
Not Water Absorbing	Yes
Low Concentrations of Residual Monomers	Yes
Not a Hazardous Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. 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>	36	36	36	36	36

USE

The notified chemical will be used in the manufacture of injection moulded articles and masterbatch.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

The notified polymer will be imported as pellets of 4 mm x 3 mm in 25 kg sealed bags. No repackaging of the notified polymer will occur in Australia. The notified polymer will be transported by road from the wharf directly to the end users.

The notified polymer will be used either as a base pellet in masterbatch production or directly into injection moulded components.

During the masterbatch process, the base pellets may be compounded with other raw materials to form coloured plastic pellets known as masterbatch. The plant operator manually weighs out the base pellets and transfers the requisite amount into plastic bags. The base pellets and other ingredients including a concentrated dye are transferred into a mixer. The mixer is sealed during mixing. After mixing, the extruder operator releases the mixture from the sealed dispenser into the extruder, or the mixer may open directly into the extruder below through a sealed tube. In the extruder, the mixture is melted and extruded through die holes in long spaghetti-like strings, passes through a cooling water bath into a pelletiser and classifier, which cuts the strings into pellets, which are graded and conveyed to a hopper for storage. A quality control technician scoops a portion of the masterbatch into a sample container for testing. The quality of the pellets is tested against a battery of quality control tests using standard laboratory procedures. Following quality control testing, a packaging operator will bag the masterbatch into a 25 kg capacity drum, ready for distribution to customers.

In an injection process, the base pellets and masterbatch are either vacuum transferred or manually tipped into the feeding hopper on the injection-moulding machine. The mixed pellets are then fed into the barrel of the machine by gravity. Once heated, the melted pellets are moulded to form the shape of the plastic article, then cooled within the closed mould, prior to ejection into a suitable receptacle. Extruded or injection-moulded plastic articles will contain less than 1% notified polymer.

6. EXPOSURE INFORMATION

6.1. Summary of Environmental Exposure

Since the notified polymer will not be manufactured locally, there will be no environmental exposure associated with this process in Australia.

It is estimated that the loss of the notified polymer as residue in empty import pellet containers to be up to 0.1% and due to spills during production to be up to 0.1% (up to a total of 72 kg per annum). Spilled material, being solid and in pellet form, will typically be collected with a broom and bagged, and may be melted and reprocessed or disposed of to landfill as normal industrial waste via a waste contractor. The import bags containing the residues may be recycled.

Some scrap plastic will be reprocessed and reused in commercial applications. The notifier estimated that less than 1% of the plastic waste from commercial processing would be released to the environment after recycling, therefore, up to 150 kg per year may be disposed of to landfill as scrap plastic. The majority of the notified polymer will be incorporated into moulded or extruded plastic articles, which will be eventually disposed of to landfill at the end of their useful lives.

6.2. Summary of Occupational Exposure

Dermal and ocular exposure can occur during certain formulation processes. However, exposure to significant amounts of the notified polymer is limited because of the engineering controls and personal protective equipment worn by workers.

Workers may be exposed to dust particles generated from the compounding of the resin. Dermal exposure to the pellets may also occur. However, exposure to significant amounts of the notified polymer is limited because of the engineering controls and personal protective equipment worn by workers.

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

6.3. Summary of 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 comprised partly of the notified polymer.

7. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa
Melting Point/Glass Transition Temp
Density
Water Solubility

Odourless, transparent to opaque granules
170°C
1150 kg/m³ (temperature not given)
Not soluble.

Reactivity

The notifier indicates that thermoplastic polyurethanes are generally regarded as insoluble in water though the presence of polyoxyethylene glycol may confer some greater solubility. Expected to have low reactivity under normal conditions.

Degradation Products

Carbon monoxide, carbon dioxide, hydrogen cyanide, isocyanates, nitrogen oxides, are possible thermal degradation products.

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

No toxicology data were submitted. However, the MSDS for the notified polymer gives an oral LD50 for rats of greater than 2000, which indicates low acute oral toxicity.

8.2. Human Health Hazard Assessment

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by acute toxicity study reported in the MSDS for the notified polymer.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

No toxicological data were submitted. The MSDS indicated that the notified polymer is poorly biodegradable.

9.2. Environmental Hazard Assessment

Nonionic polymers that have molecular weights greater than 1000 are generally of low concern (Nabholz *et al.* 1993).

10. RISK ASSESSMENT

10.1. Environment

Almost all of the notified polymer will be used to manufacture various injection-moulded articles. Once incorporated in moulded articles, the notified polymer is expected to be inert and is unlikely to pose a risk to the environment. It is anticipated that the majority of wastes generated during the manufacture of articles will be collected and reused.

Almost all of the notified polymer imported (up to 36 tonnes per annum including from spills, container residues, waste from manufacture of articles and processing of plastic scrap and the plastic articles at the end of their useful lives) will eventually be disposed of to landfill as inert solid waste. In landfill, the polymer contained in waste or the articles is expected to be immobile due to its inert state and its poor water solubility. Although not expected to be readily biodegradable, it is anticipated that prolonged residence in an active landfill environment would eventually degrade the notified polymer due to abiotic or slow biotic processes to give water vapour and oxides of carbon and nitrogen.

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 will result in limited if any exposure to the aquatic environment. While no ecotoxicity data are available, due to the limited release to water it is unlikely that the polymer would exist at levels which could pose a threat to aquatic organisms. The high molecular weight indicates a low potential for bioaccumulation.

Based on its 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.

10.2. Occupational Health and Safety

The OHS risk presented by the notified polymer is expected to be low. The notified polymer may be present in formulations containing hazardous ingredients. If these formulations 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.

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

10.3. 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 bound within a matrix and unlikely to be bioavailable.

11. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

11.1. Environmental Risk Assessment

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

11.2. Human Health Risk Assessment

11.2.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

11.2.2. Public health

There is Low Concern to public health when used as described in the notification.

12. MATERIAL SAFETY DATA SHEET

12.1. 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.

13. 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.

Environment

Disposal

- The notified polymer can be used without reconditioning or may be disposed of with domestic refuse according to local regulations.
- Contaminated packaging can be recycled once completely emptied.

Emergency procedures

- Spills/release of the notified polymer should be handled by sweeping or shovelling up.

13.1. 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.

No additional secondary notification conditions are stipulated.

14. BIBLIOGRAPHY

Nabholz JV, Miller P & Zeeman M (1993) Environmental Risk Assessment of New Chemicals Under the Toxic Substances Control Act (TSCA) Section Five. In: Landis WG, Hughes JS & Lewis MA ed Environmental Toxicology and Risk Assessment, ASTM STP 1179, American Society for Testing and Materials, Philadelphia, PA.