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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

PEN Polymer

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

PEN Polymer

1. APPLICANT

Eastman Chemical Limited of Level 8, 15 Talavera Road NORTH RYDE NSW 2113 has submitted a notification statement accompanying their application for assessment of a synthetic polymer of low concern, 2,6-naphthalenedicarboxylic acid, dimethyl ester, polymer with 1,2-ethanediol; hereafter referred to as PEN Polymer. No claims for exempt information were made by the notifier, and the assessment report for PEN Polymer is published here in its entirety.

2. IDENTITY OF THE POLYMER

Chemical Name: 2,6-Naphthalenedicarboxylic acid, dimethyl ester, polymer with 1,2-ethanediol

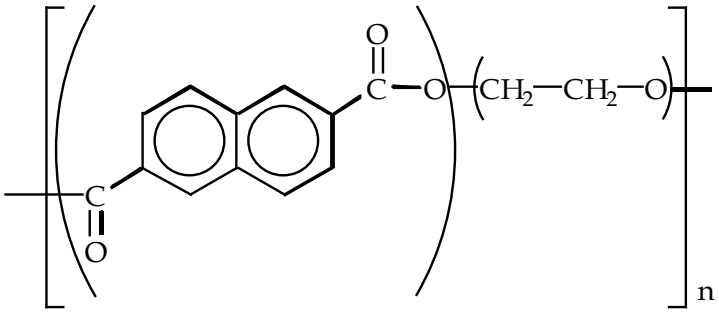
Chemical Abstracts Service (CAS) Registry No.: 25853-85-4

Other Name(s): poly(ethylene naphthalenedicarboxylate)

Trade Name(s): PEN Polymer 18348
Developmental PEN 10533 Polyester

Molecular Formula: $(C_{14}H_{12}O_4 . C_2H_6O_2)_x$

Structural Formula:



Number-Average Molecular Weight: 29 000

Weight-Average Molecular

Weight: 73 400

Maximum Percentage of Low Molecular Weight Species (Polymers and Oligomers)

(Molecular Weight < 1 000): 0.33%
(Molecular Weight < 500): nil

Table 1: Polymer Constituents

Name	*CAS Number*	*% Weight*
2,6-napthalenedicarboxylic acid, dimethyl ester	840-65-3	82
1,2-ethanediol	107-21-1	18

Means of Identification (List of Spectral Data Available): size exclusion chromatography

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: white pellets

Melting Range: 250-290°C

Specific Gravity: 1.3

Water Solubility: insoluble (see comments below)

Particle Size Distribution: particle size is typically > 0.015cm^3

Flammability Limits: not determined

Autoignition Temperature: not determined

Explosive Properties: not determined

Reactivity: can react with strong oxidising agents; hazardous polymerisation will not occur

Comments on Physico-Chemical Properties

The hydrolytic stability of the polymer was examined according to OECD Method 111 (1). The polymer was found to be insoluble in all buffers (pH 4, 7 and 9) and common water miscible organic solvents. The ester linkages of the polymer have the potential to hydrolyse. However, it is anticipated that the insolubility of the polymer will prevent hydrolysis under environmental conditions. The polymer contains no charged groups and will not be cationic or anionic in the typical pH range of use.

The data provided are acceptable for a polymer of low concern.

4. PURITY OF THE CHEMICAL

Table 2: Maximum Weight-Percentage of Residual Monomers

Name	*CAS Number*	*% Weight*
2,6-napthalenedicarboxylic acid, dimethyl ester	840-65-3	< 0.1
1,2-ethanediol	107-21-1	< 0.1

5. USE, VOLUME AND FORMULATION

The notified polymer will not be manufactured in Australia. It will be imported in pellet form for use as a plastic for extruded film and sheet applications and as a moulding plastic for applications such as containers.

Anticipated import volumes are as follows:

Year	*1*	*2*	*3*	*4*	*5*
Import Volume (tonnes)	5	25	45	230	680

6. OCCUPATIONAL EXPOSURE

The notified polymer will be imported into Australia as the pure polymer in 20 or 136 kg fibreboard drums or 545 kg boxes with polyethylene liners. Worker exposure during transport and storage is expected to be negligible.

At customer sites, polymer pellets will be air conveyed or mechanically dumped into a dryer, where the polymer will be heated to below its melting point and dry air circulated to expel water. The pellets will then be transferred to a feeder hopper of an extruder, where they will be melted prior to injection moulding or extrusion and solidification into sheets.

Dermal exposure to the notified polymer may occur when polymer pellets are transferred between processing equipment and during handling of extruded, solidified material. Inhalation exposure may occur if dust is generated through handling the pelletised polymer.

The notifier states that most of the heating of the polymer is done in closed systems with vents to allow air and water to escape. Local exhaust systems are commonly used to remove airborne contaminants during this process. The notifier also states that significant worker exposure is not expected during cleaning of equipment. If exposure occurs during cleaning and maintenance, it is likely to be to the solidified form of the polymer.

7. PUBLIC EXPOSURE

There is little potential for public exposure to the notified polymer during import, storage, transport or formulation of products containing the polymer.

Small amounts of waste will be generated in the form of residual solid pellets or 'purge polymer' from cleaning of extruders. Disposal of waste copolymer after accidental spillage during transport or from processing operations is expected to be carried out using landfill or incineration in accordance with existing regulations, and this will minimise public exposure.

There may be significant public contact with the notified polymer in the form of plastic extruded film or moulded articles, including containers. However, the substance is a stable, high molecular weight solid polymer and as such it is expected that it would be poorly absorbed across biological membranes into tissues.

8. ENVIRONMENTAL EXPOSURE

. Release

Release to the environment of the notified polymer as a result of production of plastic items is expected to be minimal. The polymer will be fed automatically into extrusion and moulding machinery from a hopper. Scrap will be reground and reused. Contaminated polymer scraps will be deposited into municipal landfills or incinerated. Overall, such waste streams would account for 0.5% of the annual import of the polymer (ie a maximum of 3.4 tonnes of waste polymer may be deposited in landfill at the maximum rate of import).

Used articles containing the polymer will also eventually be deposited in landfills.

. Fate

In the case of accidental spillage, pellets of the polymer are expected to remain where they are deposited. Should a spill occur to water, the pellets should settle onto the bottom sediments, where they could be collected. Due to the negligible solubility of the polymer, leaching from landfill is highly unlikely, and no movement from the landfill site is expected.

Any incineration of the notified polymer will result in the destruction of the polymer and produce oxides of carbon and water.

The majority of the polymer is not expected to be released to the environment until it has been moulded into films, sheeting or containers. Biodegradation is unlikely. Biological membranes are not permeable to polymers of very large molecular size and therefore bioaccumulation of the notified polymer is not expected (2, 3).

The polymer is an analogue of polyethylene terephthalate (PET) and is expected to

replace PET in some applications. As such, it is anticipated that it will become part of the PET waste stream which accounts for approximately 0.6% of the domestic waste stream (4). In 1995, 30% of the PET waste stream was recycled Australia wide (approximately 15 000 tonnes of PET). The figure was higher in Sydney where it reached 53% (4). It is anticipated that the recycling rates of the notified polymer will be similar to that of PET.

9. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided which is acceptable for polymers of low concern according to the Act.

10. ASSESSMENT OF ENVIRONMENTAL HAZARD

Disposal of the notified polymer to landfill is unlikely to present a hazard to the environment as it will be in a pellet form or as finished products. Bioconcentration and leaching are both considered unlikely to occur, due to the high molecular weight of the polymer and its insoluble nature. Biodegradation of the product is also considered unlikely. Incineration of the notified polymer will result in its destruction, producing oxides of carbon and water.

The low environmental exposure of the polymer as a result of the proposed use, together with its expected negligible environmental toxicity, indicate that the overall environmental hazard should be negligible.

11. ASSESSMENT OF OCCUPATIONAL AND PUBLIC HEALTH AND SAFETY EFFECTS

PEN Polymer has been notified as a synthetic polymer of low concern under section 23 for the purposes of section 24A of the Act. The polymer meets the criteria for a synthetic polymer of low concern as specified in regulation 4A of the Act and can be considered of low hazard to human health. No toxicological data were required for notification as a polymer of low concern, however the notifier's Material Safety Data Sheet (MSDS) states that the dermal LD_{50} is greater than 2 000 mg/kg in rats and that a 4-week oral study with the polymer in the same species found no effects at 820 mg/kg/day, which was the highest dose tested. This document also states that the notified polymer is not a skin sensitiser or skin irritant in guinea pigs. The notified polymer caused slight eye irritation in rabbits.

The occupational risk posed to transport and storage workers is negligible, given the expected negligible exposure to the notified chemical under normal circumstances, and the anticipated low health hazard.

The occupational health risk to workers involved in the melting and extruding of the notified polymer is low. Dermal contact is expected to be the main form of exposure, although some inhalation of polymer dust may occur. It should be noted that the potential for the formation of explosive dust-air mixtures exists, and airborne dust

levels should be kept to a minimum when handling the polymer in pellet form (see MSDS). Melting and extrusion of the notified polymer is expected to take place in closed systems, which will limit contact with the polymer in molten form, and local exhaust ventilation will be employed.

There is negligible potential for public exposure to the polymer arising from importation, storage, transportation and melt extrusion or injection moulding, Similarly, the potential for public exposure to the chemical during transport and disposal of process waste and clean-up waste after a spill is very minor. This is minimised by the recommended practices during storage, transportation and waste disposal.

While there may be significant public contact with the notified polymer in the form of plastic film and plastic articles such as containers, there seems no likely route of exposure and absorption. However, it appears likely that some of the film or articles may be used for food contact application, and there is evidence that some residues could be removed from the polymer by exposure to foods. In studies of residues extracted from the polymer by various food-simulating solvents, the residues extracted comprised low molecular weight oligomers and a mixture of PEN oligomers, depending on the polarity of the solvent. The molecular weights of these oligomers were in the range of 299 to 580; levels of the residues were in the range of 2 to 77 parts per billion on an 'in-food' basis. Data from these tests suggests that these residues may be the products of hydrolysis. The toxicity and absorption of these residues across biological membrane is not known, but given that the levels of these oligomers likely to migrate are very low, the hazard appears to be very low. The notified polymer appears to be of low toxicity, and there is likely to be very low absorption across biological membranes into tissues because of its high molecular weight.

The notifier states that articles made from PEN Polymer will be very similar to those made from PET, and that the notified polymer has been approved by the US FDA for 'certain food contact applications'.

Based on the above information, it is unlikely that the notified polymer will pose a significant hazard to public health when used in the proposed manner.

12. RECOMMENDATIONS

To minimise occupational exposure to PEN Polymer the following guidelines and precautions should be observed:

- It is good work practice to wear industrial clothing which conforms to the specifications detailed in Australian Standard (AS) 2919 (5) and occupational footwear which conforms to Australian and New Zealand Standard (AS/NZS) 2210 (6) to minimise exposure when handling any industrial chemical;

- Spillage of the notified polymer should be avoided, spillages should be cleaned up promptly and put into containers for disposal;

- Good personal hygiene should be practised to minimise the potential for ingestion;

- A copy of the MSDS should be easily accessible to employees.

It appears likely that some of the film or articles containing the notified polymer could be used for food contact applications. If this is the case, the notifier may need to contact the individual Australian State jurisdictions, as State food laws require that manufacturers ensure that materials used in food packaging are fit for that purpose.

13. MATERIAL SAFETY DATA SHEET

The MSDS for the notified polymer was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (7).

This MSDS was provided by the notifier as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the notifier.

14. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act secondary notification of PEN Polymer shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

15. REFERENCES

1. Organisation for Economic Co-operation and Development 1995-1996, *OECD Guidelines for the Testing of Chemicals on CD-Rom*, OECD, Paris.

2. Gobas, F.A.P.C., Opperhuizen, A. & Hutzinger, O. 1986, 'Bioconcentration of hydrophobic chemicals in fish: relationship with membrane permeation', *Environmental Toxicology and Chemistry*, vol. 5, pp. 637-646.

3. Anliker, R., Moser, P. & Poppinger, D. 1988, 'Bioaccumulation of dyestuffs and organic pigments in fish. Relationships to hydrophobicity and steric factors', *Chemosphere*, vol. 17, no. 8, pp. 1631-1644.

4. Planet Ark 1997, *The Planet Ark Recycling Report*, http://www.planet.ark.com.au/recycle/index.htm.

5. Standards Australia 1987, *Australian Standard 2919-1987, Industrial Clothing*, Standards Association of Australia, Sydney.

6. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear*, Standards

Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

7. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]*, Australian Government Publishing Service, Canberra.