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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

**1,4-benzenedicarboxylic acid, -dimethyl ester, polymer with 1,3-propanediol
(SORONA)**

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act* 1989 (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 National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Aged Care.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, National Occupational Health and Safety Commission, Plaza level, Alan Woods Building, 25 Constitution Avenue, Canberra ACT 2600 between 9am to 5pm Monday to Friday.

Copies of this full public report may also be requested, free of charge, by contacting the Administration Coordinator on the fax number below.

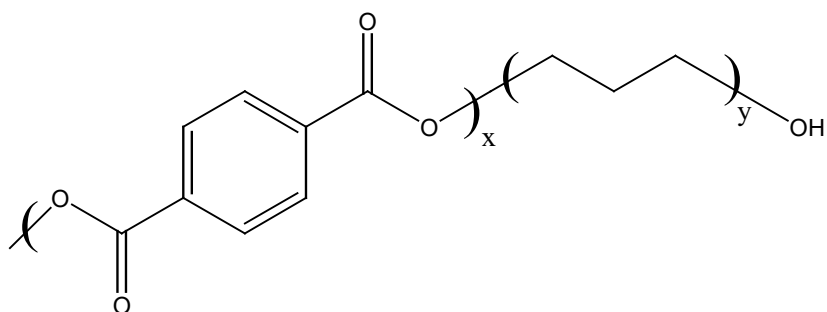
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Reactive functional groups:

The notified polymer contains the low concern hydroxyl and carboxyl groups only.

Molecular weight (MW):

Number-average MW	Weight-average MW	% MW < 1000	% MW < 500	Method
21,500	55,100	0.40	0.17	GPC

Polydispersity: 2.6

Structural identification method: FTIR

Peaks at: 666, 723, 873, 1016, 1 100, 1 244, 1 707, 3 827, 3 927, 3 955 and 3 983 cm⁻¹

3. POLYMER COMPOSITION AND PURITY

Polymer constituents

Constituent	CAS no.	% weight	% residual
1,4 benzenedicarboxylic acid, dimethyl ester	120-61-6	72.0	< 0.04
1,3 propanediol	504-63-2	28.0	< 1

Purity (%): > 94 %

Hazardous impurities (other than residual monomers and reactants): none

Non-hazardous impurities at 1% by weight or more:

Chemical name	CAS no.	% weight
Poly (1,3-propanediol/terephthalic acid)	26590-75-0	< 5

Additives/adjuvants:

Chemical name	CAS no.	% weight
titanium dioxide	26590-75-0	< 5

4. PLC JUSTIFICATION

The notified polymer meets the PLC criteria.

5. PHYSICAL AND CHEMICAL PROPERTIES

Property	Result	Comments
Appearance	Neutral to light yellow, transparent to translucent, pellets of resin	
Melting point	215-230 °C	
Density	1300 -1500 kg/m ³	
Water solubility	Expected to be <1 mg/L	
Particle size	Not applicable	
Flammability	Combustible solid	
Autoignition temperature	Expected to be > 300 °C	
Explosive properties	Not explosive	
Stability/reactivity	Not reactive except in the presence of oxidising agents	Decomposes above 289°C

5.1 Comments on physical and chemical properties

Water solubility was not determined for the notified polymer but solubility test results on similar polyester resins, such as PET used in soft drink bottles, indicate that the water solubility of the notified polymer would be less than 1 mg/L.

The notified polymer contains ester groups, which would not hydrolyse within the environmental range pH of 4-9 due to low water solubility. The polymer also contains terminal hydroxyl and carboxylic acid groups that could be reactive under extreme conditions. It is expected to remain stable under ambient conditions.

6. USE, VOLUME AND FORMULATION

Use:

The notified polymer is used in food contact packaging, fibres and wide range of consumer applications and engineering parts.

It will be imported as Sorona Polyester Resin, a pelletised solid containing > 94% notified polymer. This will be moulded by converters or extruders at temperatures < 289°C to produce the end use products.

The notified polymer will not be manufactured in Australia. It will be imported as pellets mixed with < 5% titanium dioxide pigment in the product, Sorona Polyester Resin into Victoria in 25 kg Kraft paper bags with a sealed polyethylene liner.

Import Volume:

Estimated import volumes for the notified polymer are expected to follow the pattern below:

First year: 50 tonnes
Second year: 200 tonnes
Third year: 300 tonnes
Fourth year: 400 tonnes
Fifth year: 500 tonnes

It is possible the volumes may be up to ten times higher from the third year onwards.

7. OCCUPATIONAL EXPOSURE

Exposure route	Exposure details	Controls indicated by notifier
<i>Transport and storage</i>		
None	exposure is expected only in the event of an accident	None
<i>Article production extrusion and moulding</i>		
Dermal	Workers may be exposed during opening of bags and addition of pellets to hopper of extruder.	Exhaust ventilation, safety glasses, impervious gloves, coveralls and safety boots.

8. PUBLIC EXPOSURE

Public exposure to the notified polymer will occur through the proposed uses in food contact packaging, fibres and a wide range of consumer applications and engineering parts. For the proposed use in food packaging, the possibility of the notified polymer leaching into food would be a potential concern. However, other members of the polyester family that have been used in food packaging are manufactured so that the polymer is sandwiched between impervious layers and is not bioavailable. Since the notifier indicates that the same methods that are currently used by industry to manufacture polyester films, fibres and moulded objects will be used for the notified polymer, the potential exposure of the general public to the notified polymer is likely to be low.

Public exposure to the notified polymer may also occur as the result of a spill during transportation. According to the MSDS for Sorona Polyester Resin, containing 94–100% notified polymer, spills are shovelled into a covered container and disposed in accordance with federal, state and local regulations.

9. ENVIRONMENTAL EXPOSURE

9.1. Release

Up to 0.25% of the notified polymer may be generated from the extrusion process as waste and disposed to landfill. This translates to 1,250 kg/year, assuming the maximum import volume of 500 tonnes/year. However, it is likely that a much greater proportion will ultimately go to landfill as used polymer products, with a much smaller fraction finishing up in the aquatic compartment.

The notified polymer will decompose to form allyl alcohol, acrolein, formaldehyde, ethanol and methanol when held at temperatures in excess of 289°C for extended periods of time. All documented variations of the extrusion process for the notified polymer operate at or below 240°C, so this is not a source of concern.

9.2. Fate

The notified polymer and virtually all commodity plastics are characterised by high molecular weight, insolubility in water, low chemical reactivity, considerable mechanical strength, and resistance to biodegradation, photolysis and hydrolysis. These characteristics are associated with little inherent ecotoxicity hazard (Bartha et al, 1997). Conventional means of waste disposal of plastic products are landfill and incineration. In landfill, the polymer is expected to slowly break down and become part of the soil matrix and not leach from the soil due to its expected low water solubility. Incineration of polymer waste would yield water and oxides of carbon. The polymer is not expected to cross biological membranes, due to its high molecular weight and expected low water solubility, and should not bioaccumulate (Connell, 1990).

Current waste management alternatives designed to reduce the waste going to landfill and for incineration include source reduction through packaging efficiency, waste-to-energy incineration, recycling, and reuse (Bartha et al, 1997). However, it is expected that the establishment of a recycling scheme for the new plastic would take some time.

10. EVALUATION OF HEALTH EFFECTS DATA

No toxicological data were submitted.

11. EVALUATION OF ENVIRONMENTAL EFFECTS DATA

No ecotoxicological data were submitted.

12. ENVIRONMENTAL RISK ASSESSMENT

Release of waste products containing the notified polymer to the aquatic environment is likely in cases of random dumping. The majority of the notified polymer will follow the fate of the products in which it is incorporated and eventually be disposed into landfill. In landfill, the polymer will exist as a stable polyester, is unlikely to be mobile in soil and is expected to very slowly degrade to carbon dioxide through abiotic and biotic processes. The environmental hazard of the notified polymer in landfill is expected to be low.

The high molecular weight and expected low water solubility should prevent polymer bioaccumulation.

Given the above considerations, the overall environmental hazard is expected to be low.

13. HEALTH AND SAFETY RISK ASSESSMENT

13.1. Hazard assessment

Toxicology data on the notified polymer is summarised in the MSDS for Sorona Polyester Resin, which contains 94–100% notified polymer, 0–5% titanium dioxide and 0–1% of the isomer impurity of the notified polymer. The MSDS indicates that the notified polymer has an oral LD₅₀ of >5000 mg/kg body weight in rats. Given the high molecular weight, very little of the polymer is expected to penetrate biological membranes and as residual monomers are at low levels, the notified polymer is unlikely to present a toxicological hazard.

13.2. Occupational health and safety

There is little potential for significant occupational exposure to the notified polymer in the transport and storage of the polymer solution other than in the event of an accidental spill.

During the extrusion and moulding processes, the main exposure route for the notified polymer will be dermal. However, the polymer is imported as pellets and exposure is expected to be low. Once the pellets are extruded, the polymer will be molten, then harden and not become bioavailable. The high molecular weight of the polymer will preclude absorption through the skin. Given the low hazard of the polymer and the protective measures including local exhaust ventilation, coveralls, protective eyewear and impervious gloves used during extrusion and moulding, the health and safety risk to workers is very low.

13.3. Public health

The notified polymer will be manufactured as a film to replace polyesters and polymers used in food contact packaging, fibres and a wide range of consumer applications and engineering parts. The potential exposure of the general public to the notified polymer is likely to be low for the proposed uses.

14. MSDS AND LABEL ASSESSMENT

14.1. MSDS

The MSDS of the notified polymer solution provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as part of the assessment report. The accuracy of the information on the MSDS remains the responsibility of the applicant.

14.2. Label

The label for the notified polymer solution provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC,

1994b). The accuracy of the information on the label remains the responsibility of the applicant.

15. RECOMMENDATIONS

Control measures (for extruder/ moulder)

OHS

No special precautions are required for the notified polymer; however, in the interests of good occupational health and safety local exhaust ventilation during the polyester sheet extrusion process is required.

Personal protective equipment used to minimise occupational exposure to the notified polymer should conform to Australia- New Zealand or other internationally acceptable standards.

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

16. REQUIREMENTS FOR SECONDARY NOTIFICATION

Secondary notification may be required if:

- (i) any of the circumstances stipulated under subsection 64(2) of the Act arise; or
- (ii) the notified polymer is introduced in a chemical form that does not meet the PLC criteria;

If any importer or manufacturer of the notified polymer becomes aware of any of these circumstances, they must notify the Director in writing within 28 days.

17. REFERENCES

Bartha R. et al (1997). *Plastics*. In: Ecological Assessment of Polymers, pp 167-184. Van Nostrand Reinhold, New York, USA

Connell D. W. (1990) General characteristics of organic compounds which exhibit bioaccumulation. In Connell D. W., (Ed) Bioaccumulation of Xenobiotic Compounds. CRC Press, Boca Raton, USA.

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National Occupational Health and Safety Commission (1994b) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]. Australian Government Publishing Service, Canberra.

Standards Australia (1990) Australian Standard 3765.2-1990, Clothing for Protection against Hazardous Chemicals Part 2 Limited protection against specific chemicals. Standards Association of Australia.

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Standards Australia/Standards New Zealand (1994a) Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear. Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1994b) Australian/New Zealand Standard 1715-1994, Use and Maintenance of Respiratory Protective Devices. Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1994c) Australian/New Zealand Standard 1716-1994, Respiratory Protective Devices. Standards Association of Australia/Standards Association of New Zealand.

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