

File No: PLC/222

April 2002

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

**1,3-Benzenedicarboxylic acid, polymer with hexanedioic acid, 2,2' oxybis[ethanol] and
1,2-propanediol
(PE-218)**

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 Ageing.

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

1,3-Benzenedicarboxylic acid, polymer with hexanedioic acid, 2,2' oxybis[ethanol] and 1,2-propanediol (PE-218)

1. APPLICANT

Henkel Adhesives Australia Pty Ltd of 55 Korong Road West Heidelberg VIC 3081 (ABN 82 001 302 996) has submitted a notification statement in support of their application for an assessment certificate for the synthetic polymer of low concern (PLC), 1,3-Benzenedicarboxylic acid, polymer with hexanedioic acid, 2,2' oxybis[ethanol] and 1,2-propanediol (PE 218). The notifier has not applied for any data to be exempt from publication.

2. IDENTITY OF POLYMER

Chemical name: 1,3-Benzenedicarboxylic acid, polymer with hexanedioic acid, 2,2' oxybis[ethanol] and 1,2-propanediol

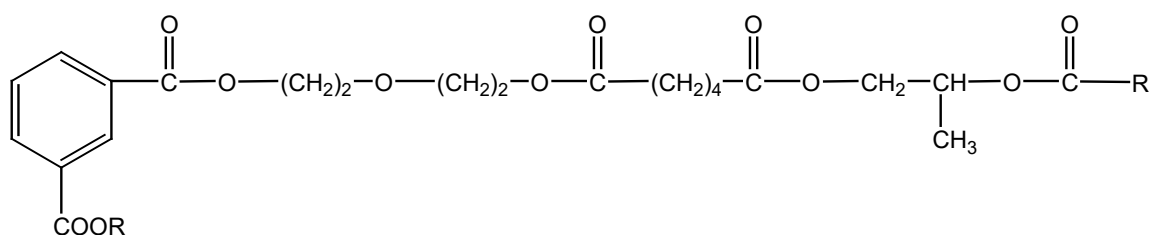
CAS number: 67939-66-6

Other names: Diethylene glycol, adipic acid, propylene glycol, isophthalic acid polymer

Marketing names: PE-218

Molecular formula: $(C_8H_6O_4.C_6H_{10}O_4.C_4H_{10}O_3.C_3H_8O_2)_x$

Structural formula:



Reactive functional groups: none of concern

Molecular weight (MW):

Number-average MW	Weight-average MW	% MW < 1000	% MW < 500	Method
1065	2477	20.6-24.9	8.6-12.6	GPC

Polydispersity: 2.33**Structural identification method:** Infrared spectroscopy**Peaks at** 3512, 2950, 2874, 1734, 1610, 1456, 1418, 1382, 1352, 1288, 1242, 1178, 1134, 1080, 950, 888, 734, 716, 420 cm⁻¹**3. POLYMER COMPOSITION AND PURITY****Polymer constituents**

Constituent	Synonym	CAS no.	% weight	% residual
Hexanedioic acid	Adipic acid	124-04-9	48	nd
1,3-Benzenedicarboxylic acid	Isophthalic acid	121-91-5	4	nd
2,2'-Oxybis[ethanol]	Diethylene glycol	111-46-6	32	0.08
1,2-Propanediol	Propylene glycol	57-55-6	16	0.016

nd – not detectable

Purity (%): >99%**Hazardous impurities (other than residual monomers and reactants):** none**Non-hazardous impurities at 1% by weight or more:** none**Additives/adjuvants:** none**4. PLC JUSTIFICATION**

The notified polymer meets the PLC criteria.

5. PHYSICAL AND CHEMICAL PROPERTIES

Property	Result	Comments
Appearance	Yellowish viscous liquid	
Boiling point	Not determined	
Density	1110 kg/m ³	
Water solubility	Not determined.	The notified polymer is a polyester and is expected to be water insoluble, though the presence of both free OH and CO ₂ H would tend to increase solubility.
Flash Point	>220 °C	
Flammability	Not flammable	
Autoignition temperature	Not determined	The notified polymer is not expected to self-ignite.
Explosive properties	Not determined	The notified polymer is not expected to be explosive under normal conditions of use.
Stability/reactivity	Not determined	The notified polymer is expected to be stable under normal conditions of use.
Hydrolysis as function of pH	Not determined.	The notified polymer contains ester groups, which are amenable to hydrolysis. However, this is not expected under normal environmental temperatures and in the pH range of 4 to 9.
Partition coefficient	Not determined.	The likely hydrophilic nature of the polymer is indicative of partitioning into the organic phase.
Adsorption/desorption	Not determined.	The notified polymer is expected to be immobile in soil due to its low expected water solubility.
Dissociation constant	Not determined.	Not determined. The notified polymer contains acid groups expected to have normal acidity.

6. USE, VOLUME AND FORMULATION

Use:

The notified polymer is used as a hardener in polyurethane laminating adhesives. It will form part of a two component laminating adhesives for coating flexible packaging for a wide range of consumer products.

Manufacture/Import volume:

The notified polymer will not be manufactured and repackaged in Australia. Approximately 5 tonnes of the polymer will be imported per annum as a component of a number of polyester/polyol hardener formulations at 17% (UR 6084) to 55% (UR 6085) concentration. The notifier indicated that the concentration of the polymer in hardener formulations may vary from 15% to 70% in various products in the future. The adhesive mixture will contain 5 to 16% notified polymer.

Formulation details:

The hardener containing the notified polymer will be transported and stored in 213 and 31 L steel drums at the notifier's site. It will be sent to approximately 5 customer sites for subsequent formulation (polymerisation) into laminating adhesives.

Adhesive formulation will involve automated mixing of the notified polymer and isocyanate-containing polyester/polyether-urethane base components at a ratio of 100:40 (base:hardener) in a closed dosing-unit. When mixed the base and hardener react to form a transparent, age-resistant polyurethane film containing 5-16% notified polymer. The resulting laminate consists of two films that are bonded to each other using the laminating adhesive. The film is heat-transferred onto flexible packaging using rollers on a laminating machine, thereby coating the packaging. The final packaging product containing <0.8% notified polymer is wound onto rolls and stored before being sent to end users to package products.

Cleaning is performed by solubilizing the base components in ethyl acetate and then reacting them with the hardener, forming the cured adhesive that can be disposed of as a standard plastic. The rollers on the laminating machine are also cleaned with rags saturated in ethyl acetate.

7. OCCUPATIONAL EXPOSURE

Exposure route	Exposure details	Controls indicated by notifier
Transport		
<i>Transport and storage (1-2 workers, 0.5 –1 hour/day)</i>		
None anticipated	exposure is expected only in the event of an accident	none

End use

Laminating machine (1-2 workers, 1 hour/day, 270 days/year)

Dermal, ocular and inhalation	Workers may be exposed to drips and spills (containing 15-70% notified polymer) during connecting and disconnecting hoses and manually transferring the notified polymer from the steel drums to the tank of the dosing unit.	Mixing operates automatically as a closed system.
		Laminating machines operates automatically.
		Exhaust ventilation in place.
	Exposure to the adhesive (containing 5-16% notified polymer) is also possible when fitting the unwinding stations and removing laminates from the winding station. Inhalation exposure to vapours containing the notified polymer during lamination.	PPE: overalls (or similar protective apparel) safety glasses and impervious gloves.

Cleaning equipment (1 worker, 10-30 minutes/day, 270 days/year)

dermal	Curing of unused blended adhesive prior to disposal as standard plastic	Exhaust ventilation in place.
	Wiping of adhesive residues from laminating machinery using rags.	PPE: coveralls (or similar protective apparel) impervious gloves and goggles

8. PUBLIC EXPOSURE

The notified polymer is not available for sale to the public and will be used as an ingredient in laminating adhesive products for use in food and other packaging applications. The potential for public exposure to the notified polymer during transport, reformulation or disposal is considered low. Although members of the public will handle packaging and consume food contained in laminated packaging manufactured using the notified polymer, the polymer is unlikely to be bioavailable since it is sandwiched between two impervious layers. Exposure to the public is therefore unlikely.

9. ENVIRONMENTAL EXPOSURE

9.1. Release

No release of the notified polymer is expected during transport or storage to customer sites except in the event of a transport accident.

The notifier anticipates no release of the raw product to the environment during formulation of the lamination adhesive at end user sites. This is because most of the raw ingredients used to formulate adhesives are pumped automatically into a closed dosing unit. A small amount of waste is generated during machine start up and during weekly mix ratio checks. The

notifier anticipates approximately 100 mL of adhesive, containing 5-16% of the notified polymer, is pumped through the machine at start up. A further 50 mL of each component per sample may be pumped through the machine during weekly mix ratio checks. The pumped adhesive is collected in disposable cups or collection trays and disposed of as hard rubbish when the adhesive has cured to inert polyurethane.

A small amount of waste is generated at clean up when the mixed adhesive is removed from the rollers of the laminating machines. The rollers are cleaned, using rags soaked in ethyl acetate, by dissolving the adhesive, and then reacting them with hardener to form cured adhesive. Spills are also cleaned up in the same way. The contaminated rags are collected and disposed of when inert polyurethane forms. The cured adhesive is disposed of as a standard plastic.

The notifier indicates that the amount of container residue will vary with the drum size and thoroughness of emptying, and that it is possible to completely remove the adhesives from their containers. The 213 L drums contain polyethylene liners, which can be removed from the drums when empty. Following emptying of the smaller containers, they are exposed to atmospheric moisture, or to a small amount of water, to insure reaction to inert material, which can be easily removed and disposed of.

No release of the notified polymer will occur at end use because it will be incorporated into the film covering the packaging products and will be inert.

9.2. Fate

The majority of the notified polymer will polymerise to form a very high molecular weight and stable polymer, which will be incorporated in the film covering the packaging products. Therefore the fate of the polymer will follow that of the packaging products with which it is associated. It is expected that most of these packages will be disposed of through domestic garbage and will eventually find their way into landfill. However, some may be incinerated and some may be suitable for recycling. A small amount of waste polymer may be generated during formulation of the laminating adhesives, as a result of incidental spills, or container residues. This material will harden when cured, and is expected to be disposed of as a standard plastic in landfill.

In landfill, the cured adhesives and packaging products containing the polymer, will be immobile, and are expected to be degraded slowly by microbial and abiotic processes. Incineration will destroy the polymer producing water vapour and oxides of carbon.

Under normal usage, the notified polymer will not enter the aquatic environment or pose a threat to aquatic organisms. Should the polymer enter the aquatic environment, it is expected to harden. In any case, the high molecular weight would prevent movement across biological membranes. As such, the notified polymer is not expected to bioaccumulate.

10. EVALUATION OF HEALTH EFFECTS DATA

No toxicological data were submitted.

The notified polymer is not classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999). It contains low level of residual monomers. No hazardous impurities, additives and adjuvants are present at above the cut-offs for classification of the notified polymer as a hazardous substance.

11. EVALUATION OF ENVIRONMENTAL EFFECTS DATA

No ecotoxicological data were provided.

12. ENVIRONMENTAL RISK ASSESSMENT

The majority of the notified polymer will polymerise to form a very high molecular weight and stable polymer, which will be incorporated into the packaging products. Most of these packages will be landfilled or incinerated at the end of their useful life. A small amount of waste polymer may be generated during formulation or in container residues. This material will harden when cured, and will also be disposed of in landfill. In landfill, the polymer is expected to be immobile and to slowly degrade. Incineration will destroy the polymer producing water vapour and oxides of carbon.

Under normal usage, the notified polymer will not enter the aquatic environment or pose a threat to aquatic organisms. Should the polymer enter the aquatic environment, its high molecular weight would prevent movement across biological membranes. As such, the notified polymer is not expected to bioaccumulate.

The low environmental exposure of the notified polymer as a result of the proposed use indicates the overall environmental hazard should be low.

13. HEALTH AND SAFETY RISK ASSESSMENT

13.1. Hazard assessment

No toxicological information has been provided for the notified polymer. The notified polymer contains low concentrations of residual monomers. Since the notified polymer has high molecular weight, it is not expected to be absorbed across the skin or other biological membranes, and resultant systemic toxicity would be limited. The polymer meets the PLC criteria and is unlikely to be a hazardous substance according the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

13.2. Occupational health and safety

There is little potential for 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 adhesive formulation (manual transfer in the absence of mechanical delivery system, blending and connecting/disconnecting hoses during automated delivery), end use, and cleaning of equipment, the main exposure route for the notified polymer will be dermal. The high molecular weight of the polymer will preclude its absorption through the skin. Standard protective measures including local exhaust ventilation, coveralls (or similar protective apparel), protective eyewear and impervious gloves used during these activities should provide sufficient protection against the notified polymer.

The final adhesive mix, containing the notified polymer, could contain a wide variety of additional ingredients, which may cause adverse health effects. Exhaust ventilation, personal protective equipment, such as safety glasses, impervious gloves and coveralls (or similar protective apparel) should provide adequate protection to workers handling the adhesive mix.

Inhalation exposure to vapour is not expected to be significant due to the low volatility of the notified polymer.

The notified polymer becomes unavailable for absorption once it is incorporated in the laminated material. Given the engineering controls and supplementary personal protective clothing, the health risk for workers during formulation and end-use is expected to be low.

Conclusion

The notified polymer per se presents a low hazard to human health. The control measures in place during adhesive formulation and end-use will ensure sufficient protection against the notified polymer. No specific risk reduction measures are necessary.

13.3. Public health

The notified polymer is not available for sale to the public. Although members of the public may handle packaging and consume food from laminated packages manufactured using the notified polymer, the risk to public health from the notified polymer is likely to be low because the notified polymer is sandwiched between two impermeable layers and is unlikely to be bioavailable.

14. MSDS AND LABEL ASSESSMENT

14.1. MSDS

The MSDS of the notified polymer 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 provided by the notifier for the hardener containing the notified polymer 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

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer:
 - Exhaust ventilation during adhesive formulation and end use
 - Enclosed and automated mixing
 - Automated laminating processes
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - Avoid spills and splashes during manual transfer of the polymer into the dosing unit and cleaning operations,
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
 - overalls (or similar protective apparel)
 - safety glasses
 - impervious gloves

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.

15.1 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 Section 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 Section 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.

16. REFERENCES

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

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.