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

FULL PUBLIC REPORT

Radel® R

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**Director
Chemicals Notification and Assessment**

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FULL PUBLIC REPORT

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Polymers International Australia Pty Ltd (ABN 92 069 883 825)
Unit 2, 58-66 Malcolm Road Braeside VIC 3195.

NOTIFICATION CATEGORY

The notified polymer meets the PLC criteria.

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)

Commercial Evaluation Permit, no. 465 (2 March 2001)

NOTIFICATION IN OTHER COUNTRIES

US EPA (1993)

2. IDENTITY OF CHEMICAL

CHEMICAL NAME

[1,1'-Biphenyl]-4,4'-diol, polymer with 1,1'-sulfonylbis[4-chlorobenzene]

OTHER NAME(S)

Polyphenylsulfone

MARKETING NAME(S)

Radel R-5000, Radel R-5100, Radel R-5100 NT 15.

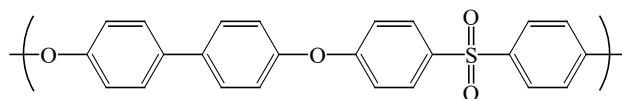
CAS NUMBER

25608-64-4

MOLECULAR FORMULA

$(C_{12}H_{10}O_2.C_{12}H_8Cl_2O_2S)_x$

STRUCTURAL FORMULA



MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn)	21552
Weight Average Molecular Weight (Mw)	55820
Polydispersity Index (Mw/Mn)	2.59
% of Low MW Species < 1000	0.38
% of Low MW Species < 500	0.02

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	Gel Permeation Chromatography (GPC), Fourier Transform Infrared Spectroscopy (FTIR), Size Exclusion Chromatography (SEC), adapted to ASTM D5296-97 Molecular Weight Averages and Molecular Weight Distribution of Polystyrene by High Performance SEC.
Remarks	FTIR Peaks: 3358, 2923, 2852, 1633, 1583, 1483, 1411, 1321, 1294, 1230, 1200, 1164, 1146, 1103, 1073, 1006, 868, 825, 780, 714, 683, 638 cm ⁻¹ . The weight percent of the resins with MW< 1000 and 500 was not measured, but based on a calculation using the SEC software.
TEST FACILITY	Solvay (2000)

3. COMPOSITION

DEGREE OF PURITY

High

HAZARDOUS IMPURITIES

<i>Chemical Name</i>	Thiophene, tetrahydro-, 1,1-dioxide [Sulfolane]
<i>CAS No.</i>	126-33-0 <i>Weight %</i> < 0.15%
<i>Hazardous Properties</i>	At Concentrations equal to or more than 25%: Harmful (Xn): R22 - Harmful if swallowed.

<i>Chemical Name</i>	Benzene, chloro- [Monochlorobenzene]
<i>CAS No.</i>	108-90-7 <i>Weight %</i> < 0.005%
<i>Hazardous Properties</i>	At Concentrations equal to or more than 5%: Harmful (Xn): R20 - Harmful by inhalation.

NON HAZARDOUS IMPURITIES (>1% by weight)

None.

ADDITIVES/ADJUVANTS

None.

POLYMER CONSTITUENTS

<i>Chemical Name</i>	<i>CAS No.</i>	<i>Weight % starting</i>	<i>Weight % residual</i>
[1,1'-Biphenyl]-4,4'-diol, polymer with 1,1'-sulfonylbis[4-chlorobenzene]	25608-64-4	99.85	--
(Monomers: Benzene, 1,1'-sulfonylbis[4-chloro- and [1,1'-Biphenyl]-4,4'-diol)	(80-07-9) (92-88-6)		-- --
Phosphorous trichloride, reaction products with 1,1'-biphenyl and 2,4-bis(1,1-dimethylethyl)phenol [Sandostab P-EPQ]	119345-01-6	0.15	--

RESIDUAL MONOMERS

All residual monomers are expected to be below the relevant cut-offs for classification of the notified polymer as a hazardous substance.

4. INTRODUCTION AND USE INFORMATION

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

Import.

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>	1	5	10	22	45

USE

For use in interior aircraft cabin components, in sterilisable medical devices, in electrical/electronic components, plumbing components, in chemical process components and in automotive applications.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY

Not stated.

IDENTITY OF MANUFACTURER/RECIPIENTS

Polymers International Australia Pty Ltd (Melbourne).

TRANSPORTATION AND PACKAGING

The notified polymer, as pellets, will be shipped in multi-layered 25 kg bags and 500 kg boxes. The liner of these packages comprises kraft paper, polyethylene film and aluminium foil to prevent penetration of moisture into the product.

5.2. Operation Description

The notified polymer will be imported as solid pellets or powder (2.7 mm diameter x 3.0 mm length) ready for moulding and injection into end use products. There will be no reformulation or repackaging of the notified polymer in Australia.

For manufacturing 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 melted and injected into shaping moulds. The moulded articles are cooled and automatically discharged from the machine. They are then warehoused and subsequently assembled into finished consumer products. Rejected parts including sprues and runners are collected and sent to grinding machines for re-use.

5.3. Occupational exposure

Number and Category of Workers

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Hopper loader for dryer	1	a couple of hours	once a month
Injection machine operator	1	>0.5 day	180 days/year
Grinder operator	1	a couple of hours	once a fortnight

Exposure Details

The potential route of worker exposure to the notified polymer will be skin contact and inhalation. Spillages and dust generation at hopper, dryer, injection and grinding machines may also potentially cause mechanical irritation of the eyes, skin, nose, throat and mucous membranes. In addition, high dust concentrations within the manufacturing plant have a potential for combustion or explosion.

The notifier indicates that adequate ventilation will be in place to prevent workers from breathing dust and particulates. The machines will be fitted with local exhaust ventilation to also prevent overheating of the workplace. At the injection machine where the resin is heated at temperatures above 300°C for an extended period, some degradation of the resin and/or cross-contamination with polyacetal and polyoxymethylene resins may occur. This may give rise to fumes containing oxides of carbon and nitrogen, aldehydes, acrylonitriles, ammonia and various organic vapours. It is expected that these fumes will be captured and scrubbed. Use of an appropriate respirator, dust goggles and eye protection is required. Protective clothing and gloves will be worn if prolonged or repeated exposure is anticipated. Cross contamination can be avoided by thorough cleaning of moulding and other processing equipment with purging compound prior to product changeover. Any incidents of accidental spillages will be contained and removed by mechanical means such as vacuuming or sweeping. It is intended that dust formation will be avoided and the release will be kept out of water supplies and sewers. Copies of the MSDS will be readily accessible in all work areas.

5.4. Release

RELEASE OF CHEMICAL AT SITE

During the manufacture of injection moulded articles, the majority of wastes generated will be collected, reground and reused in the moulding process. Small quantities of the notified polymer will be released due to spillage at the hopper and injection machines and as dust generated during grinding. The spillage will be cleaned up by vacuuming and the dust contained by dust extractors at hopper and dryer. On occasions the injection machine will be purged and the scrap material either reclaimed or disposed of to landfill. It is expected up to 250 kg per annum of the notified polymer will be disposed of to landfill. Empty import containers containing residual polymer will also be disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The majority of the notified polymer will be incorporated into moulded and extruded articles that will, at the end of their useful lives, be disposed of to landfill.

5.5. Disposal

Spills/release of the notified polymer will be contained and removed through mechanical means as described in the MSDS (ie. vacuuming and sweeping up) and will not be allowed to enter waterways and sewage system. The waste resulting from manufacture of moulded articles and spills should be disposed of to landfill.

5.6. Public exposure

The public is unlikely to be exposed to the notified polymer during transport, storage and manufacture of moulded articles, except in the event of an accidental spill. Containment of spills will be in accord with the MSDS and government regulations. Dust generation will also be avoided.

There may be a high level of public exposure through dermal contact with plastic articles made from the notified polymer. However, in this form the polymer is not bioavailable.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Odourless, opaque or coloured pellets or powder.
Melting Point	Not determined.
Remarks	Softening point was determined to be 220 °C.
Density	1290 kg/m ³
Remarks	Test report not provided.
Water Solubility	<1 g/L
Remarks	The notified polymer (10 g of pellets) was added to deionised water (15 mL) and shaken for 24 h at room temperature (20°C). The aqueous solution was decanted, the recovered volume determined and then concentrated to 2 mL by gentle heating at 50°C. The concentrated solution was analysed by GC for extractable chemicals prior to being evaporated to dryness and the weight of the residue determined.
Hydrolysis as function of pH	Not determined.
Remarks	The notified polymer contains chemical linkages that could be expected to undergo hydrolysis under extreme pH conditions. However, in the environmental pH range of 4 to 9, significant hydrolysis is unlikely to occur.
Partition coefficient	Not determined.
Remarks	The hydrophobic nature of the notified polymer is indicative of partitioning into

the organic phase.

Adsorption/desorption	Not determined.
Remarks	The notified polymer is expected to be immobile in soil due to its low water solubility.
Dissociation constant	Not determined.
Remarks	The notified polymer does not contain any groups that can dissociate.
Particle Size	diameter: 2.7 mm \pm 0.5 mm length: 3.0 mm \pm 0.5 mm
Remarks	Test report not provided.
Flammability Limits	Not flammable.
Remarks	Test report not provided.
Autoignition Temperature	502°C
Remarks	Test report not provided.
Explosive Properties	Not determined.
Remarks	High dust concentrations have a potential for combustion or explosion.
Reactivity	Stable to 426°C
Remarks	Prolonged exposure to temperatures in the 398°C-426°C range can result in severe degradation. Cross contamination with polyacetal or polyoxymethylene resins may result in the rapid, possibly violent, release of decomposition fumes at moulding temperatures.

7. TOXICOLOGICAL INVESTIGATIONS

No toxicological data were submitted.

8. ENVIRONMENT

No ecotoxicological data were submitted.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Wastes from manufacture of moulded and extruded articles, plus any residual polymer remaining in empty import containers will be disposed of to landfill. The moulded articles at the end of their useful lives will also be disposed of to landfill.

In landfill, the polymer will become associated with the soil matrix and not leach into the aquatic compartment due to its low water solubility. Although not expected to be readily biodegradable, the polymer will eventually degrade through biotic and abiotic processes to give water vapour and oxides of carbon and nitrogen. Overall, under normal usage there will be no release to the aquatic environment.

9.1.2. Environment – effects assessment

No ecotoxicological data were submitted for the notified polymer. Due to its high molecular weight, the polymer is not expected to cross biological membranes, and therefore is not expected to bioaccumulate.

9.1.3. Environment – risk characterisation

The majority of the notified polymer will be used to manufacture various injection moulded articles. Once moulded, the notified polymer is expected to be inert and is unlikely to pose a risk to the environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Inhalation, dermal and ocular exposure can occur during certain manufacturing processes. However, exposure to significant amounts of the notified polymer is limited because of the engineering controls and personal protective equipment worn by workers. Employers are responsible for maintaining the level of atmospheric nuisance dust below the NOHSC exposure standard of 10 mg/m³ TWA (NOHSC, 1995). Personal protective equipment (impervious gloves, eye protection and protective clothing) is also required for protection of workers against hot processes.

During transport and storage, workers are unlikely to be exposed to the notified polymer. In the event of an accident, spills will be removed according to the MSDS and government regulations.

9.2.2. Public health – exposure assessment

The notified polymer is intended only for use in the plastic manufacturing industry. It will not be sold to the public except in the form of finished moulded articles. There is potential for extensive public exposure to articles comprised wholly or partly of the notified polymer. However, in this form the polymer becomes inert and is not expected to cross biological membranes. The public exposure is therefore determined to be low.

9.2.3. Human health - effects assessment

The notified polymer meets the PLC criteria and therefore low hazard is expected due to the lack of reactive functional groups and the inability of the polymer to penetrate biological membranes.

The MSDS indicates that dusts generated from the notified polymer may cause mechanical irritation to the eyes, and to the respiratory tract if inhaled. Repeated or prolonged skin contact with dusts may result in mild irritation.

9.2.4. Occupational health and safety – risk characterisation

The OHS risk presented by the notified polymer is expected to be low, given the low hazard of the polymer, the automated process and engineering controls, and safety measures including use of appropriate personal protective equipment by workers.

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* (NOHSC, 1999), workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

9.2.5. Public health – risk characterisation

The notified polymer will not be available to the public in raw forms. Members of the public may make dermal contact with products containing the notified polymer. However, the domestic use of these products is mostly in “hidden” applications, such as the internal workings of computers and automobiles, in electrical appliances, battery operated tools and electric powered hand tools. As a result, the risk to public health will be negligible. Furthermore, in the form of plastic articles, the polymer is bound within a matrix, is chemically stable and unlikely to be bioavailable.

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

10.1. Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10.2. Environmental risk assessment

On the basis of the information available, the polymer is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is Negligible Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

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 a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified polymer 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.

12. 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.
- Hopper, dryer, injection and grinding machine operators should wear suitable industrial clothing, safety glasses, dust goggles and protective gloves. Particulate respirators should be used as required, to minimise exposure to dust.
- Engineering controls such as ventilation, process automation and use of enclosed moulded injection systems should be implemented to reduce worker exposure to dust.
- Occupational exposure to nuisance/respirable dust or decomposition products during extruding articles made from the notified polymer should be maintained below the relevant NOHSC Exposure 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 in landfill.

Emergency procedures

- Spills/release of the notified polymer should be handled as outlined in the MSDS.

12.1. 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.

13. BIBLIOGRAPHY

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

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

NOHSC (1995) Exposure Standards for Atmospheric Contaminants in the Occupational Environment [NOHSC:3008(1995)] & [NOHSC:1003(1995)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

Solvay (2000) Molecular weight data for Radel R5000/R5100 NT by Size Exclusion Chromatography (SEC). Alpharetta, GA, Solvay Advanced Polymers, LLC (unpublished report submitted by the notifier).