File No: LTD/1324

October 2007

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Permapol U-82

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Water Resources.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address: 334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.

Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.

TEL: + 61 2 8577 8800 FAX + 61 2 8577 8888 Website: www.nicnas.gov.au

Director NICNAS

TABLE OF CONTENTS

FULL PUBLIC REPORT	.3
1. APPLICANT AND NOTIFICATION DETAILS	3
2. IDENTITY OF CHEMICAL	3
3. COMPOSITION	3
4. PHYSICAL AND CHEMICAL PROPERTIES	4
5. INTRODUCTION AND USE INFORMATION	5
6. HUMAN HEALTH IMPLICATIONS	5
6.1 Exposure assessment	5
6.1.1 Occupational exposure	5
6.1.2. Public exposure	6
6.2. Human health effects assessment	
6.3. Human health risk characterisation.	
6.3.1. Occupational health and safety	7
6.3.2. Public health	
7. ENVIRONMENTAL IMPLICATIONS	
7.1. Environmental Exposure & Fate Assessment	7
7.1.1 Environmental Exposure	7
7.1.2 Environmental fate	
7.1.3 Predicted Environmental Concentration (PEC)	8
7.2. Environmental effects assessment	8
7.3. Environmental risk assessment.	
8. CONCLUSIONS AND REGULATORY OBLIGATIONS	
Hazard classification	
Human health risk assessment	
Environmental risk assessment	
Recommendations	
Regulatory Obligations	
Bibliography1	1

FULL PUBLIC REPORT

Polymer in Permapol U-82

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

PPG Industries Australia Pty Ltd (ABN: 82 055 500 939)

21-23 Ovata Drive

Tullamarine VIC 3043

NOTIFICATION CATEGORY

Limited: Synthetic polymer with NAMW ≥ 1000 .

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical name; Other names; CAS number; Molecular formula; Structural formula; Molecular weight; Spectral data; Purity; Polymer constituents; Additives/adjuvants; Import volume; Details of use.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Melting point; Boiling point; Vapour pressure; Water solubility; Hydrolysis as a function of pH; Partition coefficient; Absorption/Desorption; Dissociation constant; Flammability limits; Auto-ignition temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Canada (2006)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Permapol U-82 (30-90% notified polymer)

 $(PR-1535,\,PR-1538,\,PR-1547,\,PR-1564,\,PR-1570,\,PR-1574,\,PR-1590,\,PR-1592)\,\,Part\,\,B$

PR-1500 series

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) >1000

REACTIVE FUNCTIONAL GROUPS

Functional Group	Category	Equivalent Weight (FGEW)
Isocyanate	High Concern	904.5

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name

Benzene, 2,4-diisocyanato-1-methyl-

CAS No. 584-84-9 *Weight* % <0.1 (typically)

Hazardous Properties Carcinogen Category 3; R40 Limited evidence of a carcinogenic effect

R26 Very toxic by inhalation

R36/37/38 Irritating to eyes, respiratory system and skin R42/43 May cause sensitisation by inhalation and skin contact

R52-53 Harmful to aquatic organisms. May cause long-term adverse effects in the

aquatic environment.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

Losses from the notified polymer are expected to be minimal prior to its sealant use. Following use of the notified polymer and curing to form a hard film, losses due to volatility, exudation and leaching are not expected to occur.

DEGRADATION PRODUCTS

Degradation, decomposition or depolymerisation of the notified polymer is only expected to occur in the event of a fire or excessive heating. Combustion products are likely to include hydrocarbons, water and oxides of carbon and nitrogen.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Amber liquid

Property	Value	Data Source/Justification
Melting Point	<25°C	Estimated. Notified polymer is a liquid at room
		temperature.
Boiling Point	>150°C at 101.3 kPa	Estimated based on the notifier's experience with
		polymers of similar structure.
Density	1060 kg/m^3	MSDS
Vapour Pressure	Not determined	Vapour pressure is expected to be low, given its high molecular weight.
Water Solubility	Not determined	The notified polymer contains isocyanate groups, which rapidly hydrolyse in water to form amine groups. A suitable analytical method for determining the concentration of the polymer at low levels (1 ppm) is not available. The notifier expects that the solubility of the notified polymer will be in the order of 1-100 mg/L based on structural considerations.
Hydrolysis as a Function of pH	Not determined	The notified polymer contains isocyanate groups, which react spontaneously and violently with water. A suitable analytical method for determining the concentration of the polymer at low levels is not available. The notifier expects that the hydrolysis of the notified polymer will be rapid (within minutes) based on structural considerations.
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is soluble in organic solvents and is expected to have a high n-octanol/water partition coefficient. A test cannot be conducted as it contains isocyanate groups, which react spontaneously and violently with water.
Adsorption/Desorption	Not determined	The notified polymer contains isocyanate groups, which react spontaneously and violently with water. A suitable analytical method for determining the concentration of the polymer at low levels is not available. On release to the environment the notified polymer is expected to react and form a solid material thus it is not expected to be mobile.
Dissociation Constant	Not determined	The notified polymer does not contain any groups likely to dissociate.
Particle Size	Not determined	N/A. The notified polymer is a liquid at room temperature.
Flash Point	204.4°C	MSDS

Flammability	Not determined	The notifier stated that the notified polymer is
		expected to be combustible.
Autoignition Temperature	>204.4°C	Estimated based on the flash point.
Explosive Properties	Not determined	Not expected to be explosive. There are no
-		functional groups present that are known to confer
		explosive properties.

DISCUSSION OF PROPERTIES

Reactivity

Under normal conditions of use, the notified polymer is not expected to be reactive. The notified polymer contains an isocyanate functional group that may undergo reaction with water.

5. INTRODUCTION AND USE INFORMATION

Mode of Introduction of Notified Chemical (100%) Over Next 5 Years

The notified polymer will be imported into Australia in a range of sealant products containing the notified polymer at concentrations of 30-90%.

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

Year	1	2	3	4	5
Tonnes	<5	<5	<5	<5	<5

PORT OF ENTRY: Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS

PPG Industries Australia Pty Ltd

Electrical component manufacturers

TRANSPORTATION AND PACKAGING

The notified polymer will be imported in 1 litre steel round pail tins (two part kits, notified polymer contained in Part B). It will be transported by road to PPG Industries and subsequently to customers by road or air.

Use

The notified polymer is to be used as a sealant for electrical applications.

OPERATION DESCRIPTION

No manufacturing, reformulation or repackaging occurs in Australia.

Part A of the sealant will be manually added into the tin containing Part B of the sealant (30-90% notified polymer). It may be necessary to warm either of the two parts (to temperatures not exceeding 110°C) prior to their addition if they are partially solidified. Following addition of Part A, the mixture (containing the notified polymer at concentrations of 10-50%) will be manually stirred for up to 10 minutes. Quality control testing and equipment cleaning may also occur. The resulting mixture will then be manually applied to the electrical equipment by brush or gauze and air dried to cure into a matrix.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	Number	Exposure Duration	Exposure Frequency
		(hr/day)	(days/year)
Transport and warehousing personnel	5	minimal	200
Application of sealants	500	6	10
Cleaning of equipment	5	8	250
QC testing	1	8	250

Dermal and ocular exposure of workers to the notified polymer (30-90% concentration) may occur during manual addition and mixing; whilst during application of the sealant, QC testing and equipment cleaning operations workers may be exposed to concentrations of 10-50% of the notified polymer. Exposure should be minimised by the use of personal protective equipment during all operations, including gloves, coveralls and safety glasses. In addition, QC operations are expected to be performed in a fume cupboard under mechanical ventilation, and application of the sealants is likely to take place in areas of natural or exhaust ventilation.

Inhalation exposure of workers to the notified polymer may occur during mixing, and if heating of the notified polymer takes place. Such exposure is likely to be minimised by performing heating operations in a fume cupboard under mechanical ventilation and using an air supply respirator during mixing and application.

The notified polymer reacts when Part A and Part B are mixed together, most likely involving reaction of the isocyanate groups. As such, worker exposure to the notified polymer during operations that take place after mixing of the sealant is expected to be low.

Overall, occupational exposure to the notified polymer is expected to be low.

6.1.2. Public exposure

The product containing the notified polymer will not be sold to the general public, and will only be used for industrial purposes. The public may come into contact with the notified polymer only after it has been applied to electrical components. However, in this form, the notified polymer is not expected to be available for exposure as it will be fully cross-linked within the sealant. Therefore, exposure of the public to the notified polymer is negligible.

6.2. Human health effects assessment

No toxicity data were submitted.

The notified polymer contains isocyanate functional groups that are of concern for irritation/corrosion (USEPA 2002), dermal and respiratory sensitisation (Barratt 1994, USEPA 2002), severe respiratory irritation (Health Canada 2006), pulmonary toxicity and potentially cancer (USEPA 2002).

The USEPA specifies that structures with isocyanate equivalent weights of >5,000 are presumed not to pose a hazard under any conditions. In addition, concerns are generally confined to species with molecular weights <1,000. The isocyanate functional group equivalent weight of the notified polymer is 905 (ie <5,000), however, its high molecular weight (>1,000) may mitigate the health concerns of the notified polymer associated with this functional group. It should be noted that the proportion of low molecular weight species (15 - 20% <1000, 2 - 5% <500) might be a cause for concern. Hence, adverse health effects cannot be ruled out on the basis of molecular weight considerations.

The notified polymer is classified as a hazardous substance in accordance with the *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004). According to the Approved Criteria, isocyanate substances are to be classified if there is no evidence to indicate that the substance does not cause respiratory hypersensitivity. Thus, the following risk phrase is to be applied to the notified polymer: R42 May cause sensitisation by inhalation.

The notified polymer contains an impurity, Benzene, 2,4-diisocyanato-1-methyl- (ie. Toluene-2,4-diisocyanate) (CAS number 584-84-9), that is classified as hazardous, with the following risk phrases:

Carcinogen Category 3; R40 Limited evidence of a carcinogenic effect R26 Very toxic by inhalation R36/37/38 Irritating to eyes, respiratory system and skin R42/43 May cause sensitisation by inhalation and skin contact

The notifier has stated that impurity levels are closely monitored and that Toluene-2,4-diisocyanate will typically be present at concentrations <0.1%, which is below the concentration cut off for hazard classification of the mixture. However, it is possible that this impurity may occasionally be present at concentrations above the cut off level in the products, and thus care should be taken when handling the products containing the notified

polymer.

Based on the potential for respiratory sensitisation, the notified polymer is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Dermal and ocular exposure are the main routes of worker exposure to the notified polymer (10-90% concentration) during manual handling of the sealant product containing the notified polymer. Inhalation exposure may also occur, however, the expected low vapour pressure limits this route of exposure.

Acute systemic effects from exposure to the notified polymer cannot be ruled out, due to the lack of available toxicological data. However, if dermal exposure occurs, absorption through the skin is not expected to be significant, based upon a study that found that polymeric isocyanates remain on the skin as unreacted species for many hours (Bello 2006).

Skin and eye irritation/corrosion as well as respiratory irritation during use of the notified polymer cannot be completely ruled out. However, such effects are likely to be caused only by the low molecular weight species (<1,000), which make up a small, though significant, proportion of the notified polymer.

Adverse effects resulting from repeated exposure to the notified polymer may potentially occur, including dermal and respiratory sensitisation, pulmonary toxicity and perhaps cancer. Again, such effects are only likely to result from the low molecular weight species.

Given the potential for adverse health effects resulting from handling of products containing the notified polymer, engineering controls as well as skin, eye and respiratory protection are recommended to reduce such risk.

6.3.2. Public health

The exposure of the public to the notified polymer is expected to be negligible; therefore the risk to public health is negligible.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer is manufactured and packaged into end-use containers overseas.

RELEASE OF CHEMICAL FROM USE

During use there will be minimal release of the notified polymer. The notified polymer is contained within a single-use container and is expected to have the consistency of a paste and therefore, spills are unlikely to occur, and would be readily contained. Approximately 1% of the total annual import volume of notified polymer may remain as residue within containers, which will be disposed of to licensed waste contractors. A further 4% of notified polymer may be lost during cleaning of reusable application equipment and from the disposal of single-use brushes and gauze material, which are expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer will be disposed of predominantly by licensed waste contractors to landfill. The notified polymer that has been applied to substrate will share the fate of the substrate, which is expected to be to sent to landfill. In landfill, the notified polymer is expected to remain entrapped within the stable cured matrix and be environmentally inert. Overtime the notified polymer may eventually degrade via biotic and abiotic pathways to form simple carbon and nitrogen based compounds.

7.1.2 Environmental fate

No environmental fate data were submitted. The notified polymer is expected to be stable once reacted, based on its structure and use pattern.

7.1.3 Predicted Environmental Concentration (PEC)

As release to the aquatic environment is not expected at any time during the life-cycle of the notified polymer within Australia, it is not possible to calculate a PEC.

7.2. Environmental effects assessment

No ecotoxicity data were submitted. Non-ionic polymers of NAMW >1000 are generally of low concern to the aquatic environment.

7.3. Environmental risk assessment

While ecotoxicity data for the notified polymer was not provided, based on the high NAMW and structure, the notified polymer is not expected to pose undue hazard to the aquatic environment. Approximately 2% of the polymer is expected to become waste during application and cleaning. This quantity is collected and disposed of by licensed waste contractors, therefore there is no release to sewerage or to the subsequent aquatic environment. Based on the low toxicity and low exposure the notified polymer is not expected to pose a risk to the environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Given that no toxicological data were provided for the notified polymer the substance cannot be classified in accordance with the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Human health risk assessment

The risk to workers is considered to be acceptable, provided that the recommended control measures are implemented.

When used in the proposed manner the risk to the public is considered to be acceptable.

Environmental risk assessment

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

Recommendations

REGULATORY CONTROLS Hazard Classification and Labelling

- Use the following risk phrases for products/mixtures containing the notified chemical:
 - Concentration $\geq 1\%$: R42 May cause sensitisation by inhalation.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer:
 - Handle in well-ventilated areas.
 - Perform heating operations in a fume cupboard.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - Avoid contact with eyes and skin.
 - Avoid inhalation exposure.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:

- Gloves, coveralls and safety glasses.
- Air supply respirators where inhalation is possible.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- Employers should ensure that all workplaces comply with the exposure standards for isocyanates in accordance with *Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment* [NOHSC: 1003(1995)].
- A copy of the MSDS should be easily accessible to employees.
- The notified polymer should be handled in accordance with provisions of State and Territory legislation regarding the Handling of Combustible and Flammable Liquids.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

Disposal

• The notified polymer should be disposed of to landfill.

Storage

• The notified polymer should be stored in accordance with provisions of State and Territory legislation regarding the Storage of Combustible and Flammable Liquids.

Emergency procedures

• Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified polymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS 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 polymer has a number-average molecular weight of less than 1000;
 - the polymer has a higher percentage of low molecular weight species, ie. >20% with MW <1000, and >5% with MW <500;
 - additional toxicological data on the polymer becomes available.

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from sealants for electrical applications, or is likely to change significantly;

- the amount of chemical being introduced has increased from 5 tonnes per annum, or is likely to increase, significantly;
- if the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet

The MSDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the notifier.

BIBLIOGRAPHY

- Barratt MD, Basketter DA, Chamberlain M, Admans GD and Langowski JJ (1994), An Expert System Rulebase for Identifying Contact Allergens. *Toxicology In Vitro* 8(5), 1053-1060
- Bello D, Smith T J, Woskie S R, Streicher R P, Boeniger M F, Redlich C A, Liu Y (2006). An FTIR investigation of isocyanate skin absorption using *in vitro* guinea pig skin. *J Environ. Monit.*, 8: 523-529.
- FORS (Federal Office of Road Safety) (1998) Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 6th Edition, Canberra, Australian Government Publishing Service
- Health Canada (2006) NSN Health Assessment Summary. (unpublished NSN document provided by Health Canada).
- NOHSC (1994) 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) Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment [NOHSC: 1003(1995)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.
- NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
- NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edition [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.
- United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.
- US EPA (2002) US Environmental Protection Agency TSCA New Chemicals Program (NCP) Chemical Categories, 1200 Pennsylvania Avenue, N.W, Washington, D.C. 20460