File No: LTD/1349

May 2008

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

# FULL PUBLIC REPORT

## Permapol P2-805

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, Water, Heritage and the Arts.

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

## Permapol P2-805

### 1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
PPG Industries Australia Pty Ltd (ABN 82 055 500 939)
McNaughton Rd
Clayton VIC 3168

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1000 Da.

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, Impurities/ Residual Monomers, Additives/ Adjuvants, Use, Import Volume, Polymer Identity and Composition, Analogue Data (analogue names)

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Vapour Pressure, Water Solubility, Hydrolysis as a Function of pH, Partition Coefficient, Adsorption/ Desorption, Dissociation Constant, Flammability Limits, Autoignition Temperature, Explosive Properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Korea PLC, USA PMN, Japan, China

### 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Permapol P2-805
Polysulfide liquid polymer (name on product MSDS)

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

### 3. COMPOSITION

DEGREE OF PURITY >95 %

### 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Colourless, viscous liquid

| Property | Value | Data Source/Justification |
|---|---|---|
| Glass Transition Temperature | -64.44°C | Measured |
| Pour Point | -26.4°C | Measured |
| Softening Point | -39.4 °C | Measured |
| Density | 1030 kg/m$^3$ at 25°C | Measured |
| Vapour Pressure* | 4 x $10^{-8}$ kPa at 25°C (maximum) | Analogue data |
| Water Solubility* | 1.33 x $10^{-2}$ g/L at 20°C | Analogue data |
| Hydrolysis as a Function of pH* | Found to undergo significant hydrolysis at 50°C in the environmental pH range 4-9. | Analogue data |
| Partition Coefficient | log Pow > 4.44 at 20°C | Analogue data |

| | | |
|---|---|---|
| (n-octanol/water)* | | |
| Adsorption/Desorption | Not determined | Not expected to undergo significant adsorption/desorption based on the high solubility of analogue in octanol (expected to bind to soil). |
| Dissociation Constant | Not determined | Based on the structure there does not appear to be any functional groups that will undergo dissociation. |
| Particle Size | Not determined | Notified polymer is a liquid at room temperature |
| Flash Point | 98.9°C (resin solution) | MSDS |
| Flammability | Not determined | Expected to have high flammability limits based on chemical structure |
| Autoignition Temperature* | 393°C at 99.4 kPa | Analogue data |
| Explosive Properties | Not expected to be explosive | Estimated based on chemical structure |
| Viscosity | 142 Pa.s at 25°C | Measured |
| Acid Number | 0.9970 mg KOH/g | Measured |
| Surface Tension* | 39.4 mN/m at 18.5°C | Analogue data |

*** Data collected for an analogue polymer, Permapol P2-935 (NICNAS Assessment LTD/1286).**

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, please refer to Appendix A.

*Reactivity*

The notified polymer is stable under normal conditions and reactivity to water and air is negligible.

## 5. INTRODUCTION AND USE INFORMATION

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

The notified substance will be imported in a range of sealant products at concentrations between 30 and 90%.

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

| *Year* | *1* | *2* | *3* | *4* | *5* |
|---|---|---|---|---|---|
| *Tonnes* | 1-3 | 1-3 | 1-3 | 1-3 | 1-3 |

PORT OF ENTRY

All major seaports, especially Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS

The sealant products will be imported into Australia by the notifier and distributed to glass manufacturers.

TRANSPORTATION AND PACKAGING

The product containing the notified polymer will be imported into Australia in 200 L sealed drums and transported by road or air to customers. The product will be sold in the original package.

USE

The notified polymer is used in insulating sealant products (30-90% notified polymer) for industrial applications to glass. The notified polymer is only used in industrial environments and used for glass that will only be sold to industries.

OPERATION DESCRIPTION

No manufacture or reformulation of the notified polymer will occur in Australia.

The sealants are applied in an industrial environment to metal, glass or nylon. Prior to application the surface is cleaned. At customer sites, the drum containing Part B is placed under a mixing head and Part A is added. The sealant is then automatically mixed to give a thick adhesive paste. This paste is pumped to a robotic extruder, which applies a thin bead of sealant to the glass under heat. Following application the equipment may be cleaned to remove any excess sealant.

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1 Exposure assessment

#### 6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

| *Category of Worker* | *Number* | *Exposure Duration (hours/day)* | *Exposure Frequency (days/year)* |
|---|---|---|---|
| Storage and transport personnel | 30 | 5 | 150 |
| Manufacturing personnel | 20 | 4 | 200 |
| Quality Assurance personnel | 10 | 3 | 100 |
| Sealant applicators | 50 | 6 | 200 |

EXPOSURE DETAILS
Occupational exposure to the notified polymer during transportation or storage is unlikely, as the notified polymer will be sealed inside drums.

The finished insulating sealant products (containing between 30-90% of the notified polymer) are not reformulated nor repackaged in Australia, therefore worker exposure to the notified polymer may only occur as a result of application processes. Application of the sealant product will only occur in controlled environments at industrial settings.

Sealant mixing
*Description*: Workers are involved in mixing Part A and Part B of the sealant product to produce final mixture for application.
*Exposure*: Dermal and ocular exposure to the notified polymer may occur as a result of drips and splashes.
*Controls*: Workplace training in safe use and handling procedures, use of PPE (eye protection, coveralls, impermeable gloves); exhaust ventilation. There is no manual transfer of the notified polymer as Part A of the sealant product is mechanically mixed with Part B of the sealant product. The finished sealant is mixed in enclosed vessels and applied by machinery that is fully automated. The finished sealant products are likely to have a paste-like consistency thus splashes are less likely to occur.

Quality control testing
*Description*: Small samples of the finished sealant product are extracted from the mixing vessel, via taps, after the finished formulation is fully mixed. These samples are taken by laboratory technicians and analysed.
*Exposure*: Dermal and ocular exposure to the notified polymer may occur as a result of drips and splashes.
*Controls:* Use of eye protection, safety shoes, laboratory coats and impermeable gloves. This quality control process involves less than 10 personnel and only small samples are taken.

Equipment cleaning
*Description*: Workers clean equipment used for mixing the sealant products using solvents. Material is collected and stored on-site in holding tanks prior to disposal by licensed waste contractors.
*Exposure:* Dermal and ocular exposure to the notified polymer may occur as a result of drips and splashes.
*Controls:* Use of PPE, exhaust ventilation, workplace training.

#### 6.1.2. Public exposure
The notified polymer is not supplied directly to the public. The public may come into contact following application in its final use as glass sealant; however, the notified polymer will be fully cross-linked with the sealant and will not be available for exposure.

## 6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer and analogue polymer are summarised in the table below. Details of these studies can be found in Appendix B.

| *Endpoint* | *Result and Assessment Conclusion* |
|---|---|
| Rat, acute oral toxicity | Low toxicity, oral LD50 > 2000 mg/kg bw |
| Rat, acute dermal toxicity* | Low toxicity, dermal LD50 > 2000 mg/kg bw |
| Rabbit, skin irritation* | Slightly irritating |
| Rabbit, eye irritation | Slightly irritating |
| Guinea pig, skin sensitisation – adjuvant test* | Evidence of sensitisation |
| Rat, repeat dose oral toxicity – 28 days* | NOEL = 1000 mg/kg/day |
| Genotoxicity – bacterial reverse mutation * | Non mutagenic |
| Genotoxicity – in vitro Mammalian Chromosome Aberration Test* | Non genotoxic |

***Data originally published in full report of analogue polymer, Permapol P2-935 (LTD/1286)**

Toxicokinetics, metabolism and distribution

Based on the partition coeffcient of the analogue polymer (log P > 4.44), the notified polymer may be lipophilic, which favours absorption across the topmost skin layer (stratum corneum). The analogue also has a water solubility of 13.3 mg/L, which may contribute to low to moderate absorption of the notified polymer through the hydrophilic epidermis layer and potentially penetrate the lower dermal layer that contains blood vessels. However, dermal uptake is likely to be impeded by the high molecular weight of the notified polymer (MW > 5000 Da). The analogue polymer was shown to undergo hydrolysis at pH 4,7 and 9. Therefore, lower molecular weight hydrolysis products may cross biological membranes.

Acute toxicity.

Based on the tests in rats, the notified polymer is expected to be of low toxicity via the oral or dermal route.
A single inhalation toxicity test was also performed on the notified polymer (Products Research & Chemical Corporation, 1976c). This involved placing ten Wistar rats in an inhalation chamber and exposing the animals to aerosols generated by heating a sample of the notified polymer (concentration unknown). The investigators noted that all rats in the control and test groups showed no signs of toxicity and appeared normal fourteen days after exposure.

Irritation and Sensitisation

The notified polymer is slightly irritating to eyes when tested on rabbits, producing non-diffuse redness of the conjunctiva 24 hours after instillation that had resolved by the 48-hour post-exposure observation time.
The notified polymer caused well-defined erythema-eschar formation and slight oedema at the 72-hour observation period in a study on dermal irritancy in rabbits (Products Research & Chemical Corporation, 1976b). However an irritancy rating could not determined based on this study as the investigators made no observations at 48 hours after exposure and also did not comment on the status of the symptoms after 72 hours, hence it was unclear whether the symptoms resolved after this time period. For this reason, a skin irritancy study on the analogue polymer has been used as an alternative. The analogue was found to be slightly irritating to skin when tested on rabbits, causing very slight to well-defined erythema in most animals. All skin reactions resolved completely by Day 6 in all the animals tested. Therefore the notified polymer is expressed as slightly irritating based on the study on dermal irritation of the analogue polymer.

The analogue polymer was shown to be sensitising to skin with positive reactions to the test substance, as supplied and 50% v/v in acetone, in 10/10 animals. Given the structural similarity of the analogue and notified polymers and the potential for lower molecular weight hydrolysis products to be formed, the notified polymer is considered to have skin sensitisation potential.

Repeated Dose Toxicity (sub acute, sub chronic, chronic)

In a 28-day sub-acute oral toxicity study of the analogue polymer in rats, no treatment-related changes were seen in any of the parameters investigated at dosages of 1000, 500 or 150 mg/kg/day. Therefore, a no observed effect level (NOEL) value of 1000 mg/kg/day was derived for the analogue test substance when administered for 28 consecutive days to the rat.

Mutagenicity

The analogue polymer was not mutagenic to *S. typhimurium* and not genotoxic in the *in vitro* mammalian chromosome aberration test.

***Classification***
Based on the acceptability of the analogue polymer and its evidence of 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
The notified polymer is of low acute toxicity via the oral and dermal route. Although it is slightly irritating to the skin and eyes, the irritancy effects are not serious enough to meet the hazard classification criteria. However, the notified polymer is expected to be a skin sensitiser. The risk of skin and eye irritation, and skin sensitisation during occupational use of the notified polymer is expected to be acceptable due to the limited exposure, and use of engineering controls and appropriate PPE.

#### 6.3.2. Public health
The risk to public health is considered to be negligible since the product containing the notified polymer is not available to the public. If public exposure were to occur, the risk is also considered negligible as the notified polymer will be cured and contained within the sealant film and not bioavailable.

## 7. ENVIRONMENTAL IMPLICATIONS

### 7.1. Environmental Exposure & Fate Assessment

#### 7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified polymer is not reformulated nor repackaged in Australia, therefore release at site may only occur in the unlikely event of a transport accident where the storage containers have been breached and the contents spilt.

RELEASE OF CHEMICAL FROM USE
During application of the sealant product, minimal release of the notified polymer is expected to occur. It is estimated that less than 1% of the annual introduction volume may be regarded as spilt waste; the sealant product is likely to have a paste like consistency and spills are therefore less likely to occur. Spills would be contained and collected for disposal to landfill.

Residues of the sealant product, containing the notified polymer, which may remain within the import drums, would be disposed to landfill along with the drum. An estimated 1% of the annual introduction volume is likely to remain as residue. Drums may be reconditioned for re-use; in this case the notified polymer will be disposed to landfill as a result of the reconditioning process.

Less than 1% of the annual introduction volume for the notified polymer may be lost to cleaning the industrial equipment. Washings will be collected in on-site holding tanks for removal by licensed waste contractors.

After application and curing, the notified polymer will be immobilised within the film and will not be released to the environment.

RELEASE OF CHEMICAL FROM DISPOSAL
The notified polymer will be disposed to landfill by licensed waste contractors. The notified polymer is likely to be cured prior to disposal.

Glass substrates containing the notified polymer are likely to end up in landfill at the end of their useful life. The notified polymer is expected to degrade by natural processes and due to its chemical properties, the notified polymer should remain immobilised to soil in the surrounding environment.

#### 7.1.2 Environmental fate

The fate of the majority of the notified polymer is the same as the material to which it is applied and will predominantly end up in landfill where it should slowly decompose. In landfill, the notified polymer is expected to be reacted or entrapped within a cured adhesive matrix, and should associate with soil and sediment. Any free notified polymer is expected to degrade in water to form simple organic, sulfur and nitrogen based degradates. Similarly, over time the cured notified polymer is expected to degrade to form simple organic, sulfur and nitrogen compounds. Bioaccumulation is not expected given the high molecular weight and lack of exposure.

### 7.1.3 Predicted Environmental Concentration (PEC)

No significant concentrations of the notified polymer are expected in the aquatic environment based on the limited possibility for release and the low water solubility of the notified polymer. The PEC for the notified polymer has therefore not been calculated.

## 7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the analogue of the notified polymer (Permapol P2-935, LTD/1286) indicate that the notified polymer is expected to be harmful to fish, and moderately toxic to aquatic invertebrates and algae. The ecotoxicological data are summarised in the table below. Details of these studies can be found in Appendix C.

| *Endpoint* | *Result* | *Assessment Conclusion* |
|---|---|---|
| Fish Toxicity | EC50 = 26 mg/L at 96 hours | The analogue polymer is harmful to Rainbow trout. |
| Daphnia Toxicity | EC50 = 9 mg/L at 48 hours | The analogue polymer is toxic to *Daphnia magna*. |
| Algal Toxicity | $E_bC50$ (72 hours) = 7.3 mg/L | The analogue polymer is toxic to algae. |
| Inhibition of Bacterial Respiration | IC50 = > 50 mg/L | A definitive IC50 value couldn't be determined due to its low solubility in water. |

## 7.3. Environmental risk assessment

The notified polymer is not expected to be toxic to the aquatic environment; release to the aquatic environment is not expected at any time during its lifecycle. Therefore, based on the low expected exposure the risk to the aquatic environment from the proposed use is considered acceptable.

# 8. CONCLUSIONS AND REGULATORY OBLIGATIONS

**Hazard classification**

Based on the available data the notified polymer is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. The classification and labelling details are:

- Xi; R43 – May cause sensitisation by skin contact

and

As a comparison only, the classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

| | ***Hazard category*** | ***Hazard statement*** |
|---|---|---|
| Skin Sensitiser | 1 | May cause an allergic skin reaction |
| Environment | Acute 2 and Chronic 2 | Toxic to aquatic life with long lasting effects (based on an acceptable analogue) |

**Human health risk assessment**

Under the conditions of the occupational settings described, the notified polymer not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to public health.

**Environmental risk assessment**

The polymer 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 ≥ 1% R43 May cause sensitisation by skin contact

Material Safety Data Sheet

- The following safety phrases should appear on the MSDS and label for the product containing the notified polymer:
  - S24 Avoid contact with skin
  - S36 Wear suitable protective clothing
  - S37 Wear suitable gloves

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - Minimise spills and drips
  - Avoid skin and eye contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Safety glasses with side shields
  - Protective gloves
  - Overalls

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

- As the notified polymer may be a skin sensitiser, employers should determine whether it is necessary to carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of skin sensitisation.

- Sensitised workers should be advised not to further handle the notified polymer.

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

- 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.

Disposal

- The notified chemical should be disposed of by landfill.

Storage

- The following precautions should be taken regarding storage of the notified chemical:

- Store in sealed containers and keep away from direct sunlight.

Emergency procedures

- Spills or accidental release of the notified chemical 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 chemical, 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(2) of the Act; if
- the function or use of the chemical has changed from an ingredient in insulating sealant products for industrial glass application, or is likely to change significantly;
- the amount of chemical being introduced has increased from up to 3 tonnes, 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.

No additional secondary notification conditions are stipulated.

*Material Safety Data Sheet*
The MSDS of the notified chemical and products containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

## APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

**Glass Transition Temperature** -64.44°C

| | |
|---|---|
| Method | Thermal Analysis |
| Remarks | Notified polymer subjected to temperatures ranging from 0°C to –100. |
| Test Facility | Products Research & Chemical Corporation (1988) |

**Pour point** -26.4 °C

| | |
|---|---|
| Method | Thermomechanical Analysis |
| Remarks | No details of the method were provided. |
| Test Facility | Products Research & Chemical Corporation (Year unknown) |

**Softening point** -39.4 °C

| | |
|---|---|
| Method | Thermomechanical Analysis |
| Remarks | No details of the method were provided. |
| Test Facility | Products Research & Chemical Corporation (Year unknown) |

**Density** 1030 kg/$m^3$ at 20°C

| | |
|---|---|
| Method | ASTM E12 |
| Remarks | No details of the method were provided. |
| Test Facility | Products Research & Chemical Corporation (Year unknown) |

**Vapour Pressure*** 4 x $10^{-8}$ kPa at 25°C (maximum)

| | |
|---|---|
| Method | EC Directive 92/69/EEC A.4 Vapour Pressure. |
| Remarks | Determined using the vapour pressure balance method. There were no significant protocol deviations. The method is in accordance with OECD 104 Vapour Pressure. |
| Test Facility | University of Leeds (1994) |

**Water Solubility*** 1.33 x $10^{-2}$ g/L at 20°C

| | |
|---|---|
| Method | OECD TG 105 Water Solubility.<br>EC Directive 92/69/EEC A.6 Water Solubility. |
| Remarks | Flask Method |
| Test Facility | Huntingdon Research Centre Ltd (1994a) |

**Hydrolysis as a Function of pH*** The results indicate that at 25°C, the notified polymer possesses a half-life of 1-365 days at pH 4, 7 and 9.

| | |
|---|---|
| Method | EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH. |
| Remarks | Greater than 68% hydrolysis observed at pH 4, 7 and 9 over 5 days at 50°C. According to the test method, 50% hydrolysis occurring in 24 hour at 50°C is equivalent to a half-life of 1 day at 25°C and 10% hydrolysis occurring in 5 days at 50°C correspond to a half-life of 365 days at 25°C. |
| Test Facility | Huntingdon Research Centre Ltd (1994a) |

**Partition Coefficient (n-octanol/water)*** log Pow > 4.44 at 20°C

| | |
|---|---|
| Method | EC Directive 92/69/EEC A.8 Partition Coefficient. |
| Remarks | Determined as the ratio of the solubilities in water and octanol. Determinations using the shake flask method gave values of log $P_{ow}$ < 2.9 due to surface activity of the test substance. |
| Test Facility | Huntingdon Research Centre Ltd (1994a) |

**Autoignition Temperature*** 393°C

| | |
|---|---|
| Method | EC Directive 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases). |
| Remarks | Due to the high viscosity, the test sample was preheated up to 65°C and then injected into the heated test flask by using a hypodermic syringe. |
| Test Facility | TNO Prins Maurits Laboratory (1994) |

**Viscosity** 142 Pa.s at 25ºC

| | |
|---|---|
| Method | ASTM D1824 |
| Remarks | No details of the method were provided. |
| Test Facility | Products Research & Chemical Corporation (Year unknown) |

**Acid Number** 0.9970 mg KOH/g

| | |
|---|---|
| Method | ASTM D2849 |
| Remarks | No details of the method were provided. |
| Test Facility | Products Research & Chemical Corporation (Year unknown) |

**Surface Tension*** 39.4 mN/m at 18.5°C

| | |
|---|---|
| Method | OECD TG 115 Surface Tension of Aqueous Solutions |
| Remarks | Concentration: 90% saturated aqueous solution. Surface tension was determined using the OECD harmonised ring method. The results indicate that the test substance shows surface activity. |
| Test Facility | Huntingdon Research Centre Ltd (1994a) |

***Tests conducted on an analogue polymer, Permapol P2-935 (NICNAS Assessment LTD/1286).***

# APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

## B.1. Acute toxicity – oral

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer (Permapol P2-805) |
| METHOD | Acute Oral Toxicity – Determination of LD50 (based on Turner, 1965) |
| Species/Strain | Rat/Wistar |
| Vehicle | Test substance administered as supplied (colourless viscous liquid) |
| Remarks - Method | Five rats were fed the test substance by intubation at two dosage levels and were then allowed to eat rat pellets and water ad libitum. Rats were observed for fourteen days and final body weights were recorded. |

RESULTS

| *Group* | *Number of Animals* | *Dose mg/kg bw* | *Mortality* |
|---|---|---|---|
| 1 | 5 | 16000 | 0 |
| 2 | 5 | 8000 | 0 |

| | |
|---|---|
| LD50 | > 2000 mg/kg bw |
| Signs of Toxicity | Clinical observations not performed. |
| Effects in Organs | Necropsy not performed. |
| Remarks - Results | All five rats dosed at 16000 mg/kg bw and one rat dosed at 8000 mg/kg bw showed weight loss. |
| CONCLUSION | The notified chemical is of low toxicity via the oral route. |
| TEST FACILITY | Products Research & Chemical Corporation (1976a) |

## B.2. Acute toxicity – dermal

| | |
|---|---|
| TEST SUBSTANCE | Analogue polymer (Permapol P2-935) |
| METHOD | EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal). |
| Species/Strain | Rat/Sprague-Dawley |
| Vehicle | Test substance administered as supplied (clear viscous yellow liquid) |
| Type of dressing | Semi-occlusive. |
| Remarks - Method | There were no significant deviations from the protocol |

RESULTS

| *Dose mg/kg bw* | *Number and Sex of Animals* | *Mortality* |
|---|---|---|
| 2000 | 5 males | 0 |
| 2000 | 5 females | 0 |

| | |
|---|---|
| LD50 | >2000 mg/kg bw |
| Signs of Toxicity - Local | No irritation or other dermal changes at site of application |
| Signs of Toxicity - Systemic | None |
| Effects in Organs | None |
| Remarks - Results | Slightly low bodyweight gains were recorded for all female animals on Day 8; and in one male animal and one female animal on Day 15. All the other animals achieved the anticipated weight gains by Day 15. |
| CONCLUSION | The notified chemical is of low toxicity via the dermal route. |

TEST FACILITY Huntingdon Research Centre Ltd (1994b)

**B.3. Irritation – skin**

TEST SUBSTANCE Analogue polymer (Permapol P2-935)

METHOD EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation)
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 3 (2 males, 1 female)
- Vehicle: Test substance administered as supplied (clear viscous yellow liquid)
- Observation Period: 6 days
- Type of Dressing: Semi-occlusive
- Remarks - Method: There were no significant deviations from the protocol.

RESULTS

| *Lesion* | *Mean Score* Animal No.* | | | *Maximum Value* | *Maximum Duration of Any Effect* | *Maximum Value at End of Observation Period* |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | | | |
| *Erythema/Eschar* | 1 | 1.3 | 2 | 2 | < 6 days | 0 |
| *Oedema* | 0.67 | 1 | 1 | 1 | < 6 days | 0 |

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results: No skin reactions were observed 30 minutes after removal of the dressing. Very slight oedema was seen in all animals at the 24, 48 and 72-hour observations, subsiding to no oedema in two animals on Day 5 and one animal on Day 6. Very slight to well-defined erythema was noted in two animals from the 24-hour observation and persisted to Day 4. Well-defined erythema was observed in one animal from the 24-hour observation subsiding to very slight erythema at Day 5. Oedema and erythema resolved completely by Day 6. There were no signs of toxicity in any rabbit during the observation period.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY Huntingdon Research Centre Ltd (1994c)

**B.4. Irritation – eye**

TEST SUBSTANCE Notified polymer (Permapol P2-805)

METHOD Acute Eye Irritation Testing (Interagency Regulatory Liaison Group, 1981a)
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 6
- Observation Period: 72 hours
- Remarks - Method: Results were determined using the Draize scoring method

RESULTS

| *Lesion* | *Mean Score** | *Maximum Value* | *Maximum Duration of Any Effect* | *Maximum Value at End of Observation Period* |
|---|---|---|---|---|
| *Conjunctiva: redness* | 0.44 | 2 | 48 | 0 |
| *Conjunctiva: chemosis* | 0 | 0 | 0 | 0 |
| *Conjunctiva: discharge* | 0 | 0 | 0 | 0 |
| *Corneal opacity* | 0 | 0 | 0 | 0 |
| *Iridial inflammation* | 0 | 0 | 0 | 0 |

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks - Results: At the 24-hour reading, four animals exhibited conjunctivae redness. No other ocular reactions were observed during the 72-hour evaluation period.

CONCLUSION: The notified chemical is slightly irritating to the eye.

TEST FACILITY: Products Research & Chemical Corporation (1976d)

### B.5. Skin sensitisation

TEST SUBSTANCE: Analogue polymer (Permapol P2-935)

METHOD: EC Directive 96/54/EC B.6 Skin Sensitisation - Magnusson and Kligman

Species/Strain: Guinea pig/ Dunkin/Hartley

PRELIMINARY STUDY: Maximum Non-irritating Concentration:
intradermal: 1% v/v in 5% acetone
topical: as supplied and 50% v/v in acetone

MAIN STUDY

Number of Animals: Test Group: 10 Control Group: 5

INDUCTION PHASE: Induction Concentration:
Intradermal: 1% v/v in a 50:50 mixture of Freund's complete adjuvant and 5% acetone in Alembicol D.
Topical: as supplied (without pre-treatment and pre-treated with 10% w/w sodium lauryl sulphate in petrolatum)

Signs of Irritation: Intradermal: Necrosis was recorded at sites receiving Freund's complete adjuvant in both the test and control animals. Slight irritation was observed in test animals receiving 1% v/v in 5% acetone with very slight irritation in controls.
Topical: Slight erythema was observed in test and control animals following topical application as supplied.

CHALLENGE PHASE

1st challenge: Topical: as supplied and 50% v/v in acetone

Remarks - Method: There were no significant protocol deviations, in reference to test procedures, from the test which is similar to OECD 406. However, the grading scale for the evaluation of challenge patch test reactions used in this test is as follows: 0 – No erythema/oedema; 1 – Slight erythema/oedema; 2 – Well-defined erythema/oedema; 3 – Moderate erythema/oedema; 4 – Severe erythema/oedema.

RESULTS

| *Animal* | *Challenge Concentration* | *Number of Animals Showing Skin Reactions after:* | | | |
|---|---|---|---|---|---|
| | | *1st challenge* | | *2nd challenge* | |
| | | *24 h* | *48 h* | *24 h* | *48 h* |
| *Test Group* | As supplied | 10/10 | 10/10 | - | - |
| | 50% v/v in acetone | 10/10 | 10/10 | - | - |
| *Control Group* | As supplied | 0/10 | 0/10 | - | - |
| | 50% v/v in acetone | 0/10 | 0/10 | - | - |

Remarks - Results: No signs of ill health or toxicity were recorded and bodyweight increases were observed in all of the animals.

Challenge phase, test substance as supplied
No (0/5) control animals showed skin reactions to the test substance, as supplied, 24 and 48 hours after the test.

All (10/10) test animals showed skin reactions to the test substance, as supplied. At the 24-hour observation of the test animals, the following results were obtained: Moderate erythema in 1/10, Well-defined erythema

in 8/10, Necrosis in 1/10; and Well-defined oedema in 8/10, Slight oedema in 2/10. Dryness and sloughing of the epidermis was also observed in 2/10 animals, as well as necrotic patch (1/10) and necrotic edge (1/10). At the 48-hour observation of the test animals, the following results were obtained: Well-defined erythema in 6/10, Necrosis in 4/10; and Moderate oedema in 1/10, Well-defined oedema in 7/10, Slight oedema in 2/10. Thickening, dryness and sloughing of the epidermis was also observed in 7/10 animals, as well as necrotic patch (2/10) and necrotic edge (2/10).

Challenge phase, test substance in 50% v/v in acetone
No (0/5) control animals showed skin reactions to the test substance, 50% v/v in acetone, 24 and 48 hours after the test.

All (10/10) test animals showed skin reactions to the test substance, 50% v/v in acetone. At the 24-hour observation of the test animals, the following results were obtained: Well-defined erythema in 9/10, Slight erythema in 1/10; and Well-defined oedema in 2/10, Slight oedema in 4/10, No oedema in 4/10. Dryness and sloughing of the epidermis was also observed in 3/10 animals. At the 48-hour observation of the test animals, the following results were obtained: Well-defined erythema in 5/10, Slight erythema in 5/10; and Well-defined oedema in 1/10, Slight oedema in 7/10, No oedema in 2/10. Necrotic patch (1/10) and necrotic edge (2/10) were also observed.

These observations were clearly test-substance related since the results at the 72-hour observation, for both test substance as supplied and 50% v/v in acetone, were the same as in the 48-hour observation.

The dermal reactions seen in all of the test animals were more marked than in the controls.

CONCLUSION — There was evidence of skin sensitisation to the notified polymer under the conditions of the test.

TEST FACILITY — Huntingdon Research Centre Ltd (1994d)

### B.6. Repeat dose toxicity

TEST SUBSTANCE — Analogue polymer (Permapol P2-935)

METHOD — EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
EC Directive 92/69/EEC Part B, Method B.7 Sub-Acute Toxicity (Oral)

| | |
|---|---|
| Species/Strain | Rats / Sprague-Dawley |
| Route of Administration | Oral – gavage |
| Exposure Information | Total exposure days: 28 days<br>Dose regimen: 7 days per week<br>Post-exposure observation period: |
| Vehicle | Test substance administered as supplied |
| Remarks - Method | There were no significant deviations from the protocol. Due to the viscosity of the test substance, the doses were warmed to 40°C before being administered. |

The only organs examined for microscopic pathology were the adrenals, heart, kidneys, liver, spleen, testes and any gross lesions.

RESULTS

| *Dose mg/kg bw/day* | *Number and Sex of Animals* | *Mortality* |
|---|---|---|
| 0 | 5 males, 5 females | 0 |
| 150 | 5 males, 5 females | 0 |
| 500 | 5 males, 5 females | 0 |
| 1000 | 5 males, 5 females | 0 |

*Mortality and Time to Death*
There were no mortalities observed for any animal throughout the treatment period.

*Clinical Observations*
There were no clinical findings observed for any animal throughout the treatment period. There were no differences in bodyweight gain or food consumption values.

*Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis*
The packed cell volume (PCV) and haemoglobin values for treated groups of males were statistically higher than in controls but still within the expected range of the particular age and strain of the rats used. Since there was no dosage relationship established, the differences in controls are considered to be attributable to chance.

From the biochemistry results, there were no differences from control that were considered to be related to treatment. Although the glutamic-pyruvic transaminase (GPT) and the glutamic-oxaloacetic transaminase (GOT) levels were statistically higher than controls for male rats receiving 1000 mg/kg/day, in the absence of any histopathological change the differences were considered to be unrelated to the treatment. Chloride ion levels were statistically higher for males treated at 1000 mg/kg/day and higher than control bilirubin for all treated female groups. Individual values were within the expected range for rats and minor differences were not related to treatment.

*Effects in Organs*
There were no differences from control that were considered to be related to treatment. Females in the highest dose group had significantly higher spleen weights. Wide variation within groups was observed with values generally within the expected range for the age and strain of the animal. Microscopic changes were observed in some organs, however it was unrelated to the test substance and considered incidental.

Remarks – Results
The NOEL was determined to be 1000 mg/kg bw/day based on the absence of any treatment related effects. Although small statistically significant differences were observed between some treated animals and the control animals. These changes were not considered to be related to treatment with the test substance.

CONCLUSION
The No Observed Effect Level (NOEL) was established as 1000 mg/kg bw/day in this study.

TEST FACILITY Huntingdon Research Centre Ltd (1994e)

## B.7. Genotoxicity – bacteria

TEST SUBSTANCE Analogue polymer (Permapol P2-935)

METHOD OECD TG 471 Bacterial Reverse Mutation Test
Plate incorporation procedure
EC Directive 92/69/EC B. 14 Other Effects – Mutagenicity: *Salmonella typhimurium* – Reverse Mutation Assay

| | |
|---|---|
| Species/Strain | *S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100 |
| Metabolic Activation System | Aroclor 1254 induced rat liver S9-mix |
| Concentration Range in Main Test | a) With metabolic activation: 50-5000 µg/plate<br>b) Without metabolic activation: 50-5000 µg/plate |
| Vehicle | Dimethyl sulfoxide (DMSO) |
| Remarks - Method | There were no significant deviations from the protocol. |

RESULTS

| *Metabolic Activation* | *Test Substance Concentration (µg/plate) Resulting in:* | | | |
|---|---|---|---|---|
| | *Cytotoxicity in Preliminary Test* | *Cytotoxicity in Main Test* | *Precipitation* | *Genotoxic Effect* |
| *Absent* | | | | |
| Test 1 | >5000 | >5000 | >5000 | Negative |
| Test 2 | | >5000 | >5000 | Negative |
| *Present* | | | | |
| Test 1 | >5000 | >5000 | >5000 | Negative |
| Test 2 | | >5000 | >5000 | Negative |

Remarks - Results: There were no substantial increases observed in revertant colony numbers of any of the tester strains following treatment with the test substance at any dose level, and in the presence or absence of S-9 mix in either mutation test. The positive controls confirmed the sensitivity of the test system.

CONCLUSION: The notified polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY: Huntingdon Research Centre Ltd (1993a)

**B.8. Genotoxicity – in vitro**

TEST SUBSTANCE: Analogue polymer (Permapol P2-935)

METHOD: OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test
EC Directive 92/69/EEC B.10 Other Effects – Mutagenicity: *In vitro* Mammalian Cytogenetic Test

Species/Strain: Human
Cell Type/Cell Line: Lymphocytes
Metabolic Activation System: Aroclor 1254 induced rat liver S9-mix
Vehicle: DMSO
Remarks - Method: There were no significant protocol deviations.

| *Metabolic Activation* | *Test Substance Concentration (µg/mL)* | *Exposure Period* | *Harvest Time* |
|---|---|---|---|
| *Absent* | | | |
| Test 1 | 0.4, 0.8, 1.6, 3.1, 6.25, 25*, 50, 100*, 200* | 18 hours | 18 hours |
| Test 2a | 25*, 100*, 50, 200* | 18 hours | 18 hours |
| Test 2b | 200*, 100*, 50, 25*, 12.5, 6.25 | 18 hours | 32 hours |
| *Present* | | | |
| Test 1 | 0.4, 0.8, 1.6, 3.1, 6.25, 25*, 50, 100*, 200* | 3 hours | 18 hours |
| Test 2a | 25*, 100*, 50, 200* | 3 hours | 18 hours |
| Test 2b | 25*, 100*, 50, 200* | 3 hours | 32 hours |

*Cultures selected for metaphase analysis.

RESULTS

| *Metabolic Activation* | *Test Substance Concentration (µg/mL) Resulting in:* | | | |
|---|---|---|---|---|
| | *Cytotoxicity in Preliminary Test* | *Cytotoxicity in Main Test* | *Precipitation* | *Genotoxic Effect* |
| *Absent* | | | | |
| Test 1 | > 200 | > 200 | 100 | Negative |
| Test 2a | | > 200 | 100 | Negative |
| Test 2b | | > 200 | 100 | Negative |
| *Present* | | | | |
| Test 1 | > 200 | > 200 | 100 | Negative |
| Test 2a | | > 200 | 100 | Negative |

| | | | |
|---|---|---|---|
| Test 2b | > 200 | 100 | Negative |

| | |
|---|---|
| Remarks - Results | There were small but statistically significant increases in the number of aberrant cells for the first test in the presence of S9-mix, and for the second test in the absence of S9-mix (32 hour harvest). Both of these values were found to be within the range of the historical controls. There were no further increases in aberrant cells observed. The positive controls confirmed the sensitivity of the test system. |
| CONCLUSION | The notified polymer was not clastogenic to human lymphocytes treated in vitro under the conditions of the test. |
| TEST FACILITY | Huntingdon Research Centre Ltd (1993b) |

## BIBLIOGRAPHY


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

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 (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.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

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.

Huntingdon Research Centre Ltd (1993a) Bacterial Mutation Assay (CLD 78/931177, 16 November 1993). Huntingdon Research Centre Ltd, Cambridgeshire, England (unpublished report provided by the notifier).

Huntingdon Research Centre Ltd (1993b) Metaphase Chromosome Analysis of Human Lymphocytes Cultured *In Vitro* (CLD 79/931236, 22 December 1993). Huntingdon Research Centre Ltd, Cambridgeshire, England (unpublished report provided by the notifier).

Huntingdon Research Centre Ltd (1994a) Physico-Chemical Properties (CLD 86/942161, 17 June 1994). Huntingdon Research Centre Ltd, Cambridgeshire, England (unpublished report provided by the notifier).

Huntingdon Research Centre Ltd (1994b) Acute Dermal Toxicity to the Rat (CLD 81/931699/AC, 10 January 1994). Huntingdon Research Centre Ltd, Cambridgeshire, England (unpublished report provided by the notifier in full public report of Permapol P2-935).

Huntingdon Research Centre Ltd (1994c) Skin Irritation to the Rabbit (CLD 82/932053/SE, 11 January 1994). Huntingdon Research Centre Ltd, Cambridgeshire, England (unpublished report provided by the notifier).

Huntingdon Research Centre Ltd (1994d) Skin Sensitisation in the Guinea Pig (CLD 84/932022/SS, 10 January 1994). Huntingdon Research Centre Ltd, Cambridgeshire, England (unpublished report provided by the notifier).

Huntingdon Research Centre Ltd (1994e) Twenty-Eight Day Oral Toxicity Study in Rats (CLD 90/942753, 15 November 1994). Huntingdon Research Centre Ltd, Cambridgeshire, England (unpublished report provided by the notifier).

Interagency Regulatory Liaison Group, Testing Standards and Guidelines Work Group (1981a) Recommended Guideline for Acute Eye Irritation Testing. Washing, D.C. pp 12.

Products Research & Chemical Corporation (1976a) Acute Oral Toxicity – Determination of $LD_{50}$ (Test report no. 1-2-7726-4, 27th August 1976). Products Research & Chemical Corporation, California, USA (unpublished report on Permapol P2-805 provided by the notifier).

Products Research & Chemical Corporation (1976b) Primary Dermal Irritant (Test report no. 1-2-7726-1, 8th September 1976). Products Research & Chemical Corporation, California, USA (unpublished report on Permapol P2-805 provided by the notifier).

Products Research & Chemical Corporation (1976c) Inhalation Toxicity by Heating (Test report no. 1-2-7726-3, 8th September 1976). Products Research & Chemical Corporation, California, USA (unpublished report on Permapol P2-805 provided by the notifier).

Products Research & Chemical Corporation (1976d) Eye Irritation Test (Draize) (Test report no. 1-2-43088, 8th April 1982). Products Research & Chemical Corporation, California, USA (unpublished report on Permapol P2-805 provided by the notifier).

Products Research & Chemical Corporation (1988a) Thermal Analysis Report. (Test run date 2nd July 1988). Products Research & Chemical Corporation, California, USA (unpublished report on Permapol P2-805 provided by the notifier).

Products Research & Chemical Corporation (Year unknown). Test Report on Permapol P2-805. Products Research & Chemical Corporation, California, USA (unpublished report provided by the notifier).

TNO Prins Maurits Laboratory (1994) Auto-Ignition Temperature of Huntingdon Reference No. K93/3757 (Report No. PML 1993-C171, 3 January 1994). TNO Prins Maurits Laboratory, Rijswijk, The Netherlands (unpublished report provided by the notifier).

Turner, R.A. (1965) Screening Methods in Pharmacology. Academic Press, New York and London, pp. 302-304 and 60-62.

University of Leeds (1994) Determination of Vapour Pressure by Balance Method (Sponsor's Project No. CLD 86, 17 October 1994). School of Chemistry, University of Leeds, Leeds, England (unpublished report provided by the notifier).