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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Permapol P2-937G

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:

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
PPG Industries Australia Pty Ltd (ABN 82 055 500 939)
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, Structural formula, Molecular weight distribution, Spectral data, Purity, Impurities and residual monomers, Additives and adjuvants, Import volume

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)
None

NOTIFICATION IN OTHER COUNTRIES
Environment Canada: NSN14021 (2003)

2. IDENTITY OF CHEMICAL

OTHER NAMES
Permapol P2-937G (L2310)
Mercaptan-terminated polyurethane polymer

MARKETING NAME
Permapol P2-937G

MOLECULAR WEIGHT
M_n > 1000 Da

ANALYTICAL DATA
GPC and IR Spectra provided.

3. COMPOSITION

DEGREE OF PURITY
>95%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

DEGRADATION PRODUCTS
No detailed examination of degradation products has been carried out. Degradation, decomposition or depolymerisation of the notified polymer would only be expected under the following conditions:

In the event of fire, combustion products of pyrolysis (oxygen limited) are likely to include miscellaneous hydrocarbons, water and oxides of carbon, nitrogen and sulphur. Complete combustion will result in water and oxides of carbon and nitrogen and sulphur. As part of the adhesion the polymer will be fully crosslinked and no depolymerisation is expected.
LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

The production and formulation procedures take place in closed systems and stored in sealed vessels, thus, the notified polymer and coatings containing it are rarely exposed to the atmosphere and losses of additives due to volatility are therefore likely to be minimal. The notified polymer is a component of a mixture which will be cured to form a hard film. Losses due to volatility, exudation or leaching are not expected to occur after this time.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa
Clear viscous yellow liquid

No physical-chemical data is available for the notified polymer. The following data has been collected for an analogue polymer, Permapol P2-935 (NICNAS Assessment LTD/1286).

Property	Value	Data Source/Justification
Freezing Point	None recorded. Polymer was a solid at –25°C.	Measured
Pour Point	5.5°C	Measured
Boiling Point	Approximately 240°C with decomposition.	Estimated from observations in the flash point test.
Density	1060.9 kg/m^3 at 20°C	Measured
Vapour Pressure	4 x 10^{-8} kPa at 25°C (maximum)	Measured
Water Solubility	1.33 x 10^{-2} g/L at 20°C	Measured
Hydrolysis as a Function of pH	Found to undergo significant hydrolysis at 50°C in the environmental pH range 4-9.	Estimated
Partition Coefficient (n-octanol/water)	log Pow > 4.44 at 20°C	Estimated
Surface Tension	39.4 mN/m at 18.5°C	Measured
Adsorption/Desorption	Not determined	Based on the high solubility of the polymer in octanol, and surface activity the polymer would be expected to bind to soil.
Dissociation Constant	Not determined	Based on the structure there doesn't appear to be any functional groups that will undergo dissociation.
Particle Size	Not determined	The notified polymer is a liquid at room temperature.
Flash Point	> 240°C at 99.4 kPa	Measured
Flammability	Not determined	Due to the high flash point and high auto ignition temperature the polymer is not expected to be flammable.
Autoignition Temperature	393°C at 99.4 kPa	Measured
Explosive Properties	Not expected to be explosive	Estimated based on chemical structure.

DISCUSSION OF PROPERTIES
For full details of the physical-chemical properties tests 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	1-5	1-5	1-5	1-5	1-5

PORT OF ENTRY
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 200L 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 as a sealant for industrial glazier applications. The sealant products can be used for double glazed glass and can be applied to glass directly, to metal or to nylon corners. It is only used in an industrial environment for glasses for commercial sale. The polymer is used in a range of products at concentrations between 30 and 90%.

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. There are two parts of the sealant product (Part B contains the notified polymer). 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 containing 2-20% of the notified polymer. 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)*
Transport and warehousing personnel	5	-	200
Repackaging and cleaning of equipment	5	8	250
QC testing	1	8	250
Application	500	6	10

Transport and Storage
During transport and storage, workers are unlikely to be exposed to the notified polymer except when the packaging is accidentally breached.

Application
During application the worker may come in contact with the product containing the notified polymer (30-90%) through spills and splatter. This exposure is predominantly dermal however there is a possibility of ocular exposure. The mixing process is automated and the sealant is robotically applied under heat, therefore the level of exposure is expected to be low. The exposure would be minimised by use of appropriate PPE (gloves, coveralls and safety glasses). Inhalation exposure is expected to be minimal as the process is automated and the notified polymer has a high molecular weight and low vapour pressure.

Exposure to the notified polymer is most likely during cleaning of equipment and QC testing. Dermal exposure is expected to be the main route although ocular exposure could occur. The level of exposure would be minimised by use of appropriate PPE.

6.1.2. Public exposure
The notified polymer is not supplied directly to the public. Therefore the public will not be exposed to the notified polymer except in the occurrence of an accidental spill during transportation. The public may come into contact with the notified polymer following application in its final use as glass sealant. However in this form, the notified polymer will be fully cross-linked with the sealant and will not be available for exposure.

6.2. Human health effects assessment

No toxicological investigations are available for the notified polymer. The summarised data in the table below has been collected for an analogue polymer, Permapol P2-935 (NICNAS Assessment LTD/1286). Details of these studies can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	Low toxicity, Oral LD50 >2,000 mg/kg bw
Rat, acute dermal toxicity	Low toxicity, Dermal LD50 > 2,000 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 = 1,000 mg/kg/day
Genotoxicity – bacterial reverse mutation	Non mutagenic
Genotoxicity – in vitro Mammalian Chromosome Aberration Test	Non genotoxic

Toxicokinetics
The analogue polymer is highly lipophilic (log P > 4.44) and may be taken up by micellar solubilisation. However, the analogue polymer has a water solubility of 13.3 mg/L and is expected to have a low to moderate dermal absorption potential. Also, the polymer has a relatively high molecular weight (M_n > 1,000 Da), and therefore the analogue polymer is unlikely to cross biological membranes and dermal uptake is expected to be low. Therefore, it is expected that the notified polymer will be unlikely to cross biological membranes with an expected low dermal uptake.

Acute toxicity
Based on the test data in rats using the analogue polymer, the notified polymer is expected to be of low toxicity via the oral or dermal route.

Irritation and Sensitisation
The analogue polymer is slightly irritating to eyes when tested on rabbits producing hyperaemic to diffuse blood vessels in all test animals 24 hours after instillation. The analogue polymer is slightly irritating to skin when tested on rabbits. Very slight to well-defined erythema was observed in most animals; wherein the skin reactions resolved completely by Day 6. 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. The notified polymer is therefore expected to be slightly irritating to skin and eyes, and a skin sensitiser.

Repeated Dose Toxicity
In a 28-day sub-acute oral toxicity study in rats using the analogue polymer, 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 test substance when administered for 28 consecutive days to the rat. The notified polymer is therefore expected to have a NOEL of 1000 mg/kg/day.

Mutagenicity
The analogue polymer was not mutagenic to *S. typhimurium* and not genotoxic in the *in vitro* mammalian chromosome aberration test. The notified polymer is therefore expected to also be non-mutagenic and non-genotoxic in these tests.

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 expected to be of low acute toxicity via the oral and dermal route. Although it is expected to be slightly irritating to the skin and eyes, the irritancy effects are not serious enough to meet the hazard classification criteria. However, notified polymer is expected to be a skin sensitiser. The risk of skin and eye irritation, and skin sensitisation during transport, storage and application of the notified polymer and articles containing 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.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified substance is not repackaged in Australia.

RELEASE OF CHEMICAL FROM USE
During use there will be minimal release of the notified substance. The notified substance is contained within a drum and following mixing is likely to have the consistency of a paste, therefore spills are unlikely to occur. However as a worst case scenario it is assumed that 1% of the notified substance will be released during spills. This will be contained and disposed of by a licensed waste contractor. Approximately 1% may remain in the drum, this will be disposed of to licensed waste contractors. An additional 1% of the notified polymer may be lost during cleaning. This may be released in waterways. However the release will be diffuse throughout Australia and is not likely to impact the environment.

RELEASE OF CHEMICAL FROM DISPOSAL
The notified substance will be disposed of predominantly by licensed waste contractors to landfill. There may be some drum recycling and minimal exposure to the environment that may occur as the result of cleaning of equipment in small applicator areas.

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 hydrolyse in water to form simple organic, sulfur and nitrogen based degradates. Similarly, over time the cured notified polymer is expected degrade to form simple organic, sulfur and nitrogen compounds. Bioaccumulation is not expected given the high molecular weight and lack of aquatic 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 an analogue polymer Permapol P2-935 (NICNAS Assessment 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 analogue polymer is expected to be highly toxic to the aquatic environment. The notified polymer is therefore expected to be also highly toxic to the aquatic environment. However, the appreciable release to the aquatic environment of the notified polymer 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 NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

R43 – May cause sensitisation by skin contact

and

As a comparison only, the classification of 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

Human health risk assessment
Under the conditions of the occupational settings described, the risk to workers is considered to be acceptable.

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 polymer:
  - Concentration ≥ 1% R43 May cause sensitisation by skin contact

- 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 polymer 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 polymer 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 is 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 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 to landfill.

Storage

- The following precautions should be taken regarding storage of the notified polymer:
  - Store in sealed containers

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 polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, 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(2) of the Act; if
  - the function or use of the chemical has changed from sealant for industrial glazier applications, or is likely to change significantly;
  - the amount of chemical being introduced has increased from up to 5 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.

Material Safety Data Sheet
The MSDS of the product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICO-CHEMICAL PROPERTIES

The following physical-chemical property tests were conducted on an analogue polymer, Permapol P2-935 (NICNAS Assessment LTD/1286).

Freezing Point	None Recorded
METHOD	British Standard 4633:1970 (crystallising point)
Remarks	The Dewar flask was filled with a cooling medium (acetone) and solid carbon dioxide was added until a temperature of –35°C was achieved. The test substance was poured into the test jar and the apparatus (glass tubes flanged to the Dewar flask) was assembled. The crystallisation point is taken when the reading is constant for a period of 3 minutes. There was no crystallisation point recorded for the test substance under the conditions of the test, although the test substance was solid at -25°C.
TEST FACILITY	Huntingdon Research Centre Ltd (1994a)
Pour Point	5.5°C
METHOD	ASTM D97 Pour Point
Remarks	A sample tube was filled with the test substance and heated until a temperature of 45°C had been achieved. The tube was then placed in a 24°C cooling bath. When the temperature of the test substance reached 27°C and 9°C, the bath temperatures were consequently reduced to 0°C and –18°C, respectively. Measurements for the pour point were made at 3°C intervals until no flow was observed when the jar was tilted in the horizontal phase (no horizontal movement) for five seconds, and then cooled for a further 3°C.
TEST FACILITY	Huntingdon Research Centre Ltd (1994a)
Density	1060.9 kg/m^3 at 20°C
METHOD	ISO Recommendation R1183
Remarks	The relative density was determined using the pycnometer method. Due to the viscosity of the substance, a wide-necked density bottle was used and the test substance was heated to 50°C until it became a mobile liquid. A calibration factor was used to determine the density of the substance at 20°C.
TEST FACILITY	Huntingdon Research Centre Ltd (1994a)
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. 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.

pH	*T (°C)*	*Half-life (days)*
4	25	1-365
7	25	1-365
9	25	1-365

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)

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)

Flash Point >240ºC at 99.4 kPa

METHOD ASTM D93-80 (Pensky-Martens Closed Cup Method)

Remarks A clean, dry test cup was filled up to the mark with the test substance, which was preheated to 50°C until it was a mobile liquid. The test substance was heated at a rate of 5-6°C/minute from approximately 40°C and the test flame (4mm in diameter) applied with every degree rise in temperature. The results showed a blue halo was observed from 120°C onwards, vapour appeared to burn from 200°C onwards, and at 240°C white grey fumes were being emitted and substance appeared to be boiling. The test substance decomposed to a red brown liquid.

TEST FACILITY Huntingdon Research Centre Ltd (1994a)

Autoignition Temperature 393°C

METHOD 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)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

The following toxicological investigations were conducted on an analogue polymer, Permapol P2-935 (NICNAS Assessment LTD/1286).

B.1. Acute toxicity – oral

TEST SUBSTANCE	Permapol P2-935
METHOD	EC Directive 92/69/EEC B.1 bis Acute Toxicity (Oral) – Fixed Dose Method
Species/Strain	Rat / Sprague-Dawley
Vehicle	Test substance administered as supplied.
Remarks – Method	There were no significant deviations from the protocol. The method is in accordance with OECD 401 Acute Oral Toxicity.

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	Piloerection was observed in all rats for 24 hours. There were no other clinical signs observed and recovery was complete after 24 hours.
Effects in Organs	None
Remarks – Results	All rats achieved the anticipated bodyweight gain.
CONCLUSION	The test substance is of low toxicity via the oral route.
TEST FACILITY	Huntingdon Research Centre Ltd (1994b)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	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.
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 test substance is of low toxicity via the dermal route.
TEST FACILITY	Huntingdon Research Centre Ltd (1994c)

B.3. Irritation – skin

TEST SUBSTANCE 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.
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 test substance is slightly irritating to the skin.

TEST FACILITY Huntingdon Research Centre Ltd (1994d)

B.4. Irritation – eye

TEST SUBSTANCE Permapol P2-935

METHOD EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain Rabbit / New Zealand White
Number of Animals 3 (2 males, 1 female)
Observation Period 7 days
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			
Conjunctiva: redness	0.3	0.3	0.3	1	< 48 hours	0
Conjunctiva: chemosis	0	0	0	0	< 24 hours	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	0	0	0

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

Remarks - Results Above normal conjunctival chemosis was evident one hour after dosing in all animals, normalising at one day after instillation. A diffuse crimson colouration of the conjunctivae was noted one hour after dosing in all the animals, with the level of response decreasing over the following days before

resolving in all instances between one and two days after instillation. No corneal damage or iridial inflammation was observed and there were no signs of toxicity in any rabbit during the observation period.

CONCLUSION — The test substance is slightly irritating to the eye.

TEST FACILITY — Huntingdon Research Centre Ltd (1994e)

B.5. Skin sensitisation

TEST SUBSTANCE — 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 test substance under the conditions of the test.

TEST FACILITY — Huntingdon Research Centre Ltd (1994f)

B.6. Repeat dose toxicity

TEST SUBSTANCE — 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 Dose regimen: 7 days per week Post-exposure observation period: 0 days
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 related 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 (1994g)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE 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 b) Without metabolic activation: 50-5000 µg/plate
Vehicle	Dimethyl sulfoxide (DMSO)
Remarks - Method	There were no significant deviations from the protocol.

RESULTS

Metabolic	*Test Substance Concentration (µg/plate) Resulting in:*

Activation	*Cytotoxicity in Preliminary Test*	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>5000	>5000	>5000	Negative
Test 2	>5000	>5000	>5000	Negative
Present				
Test 1	>5000	>5000	>5000	Negative
Test 2	>5000	>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 test substance 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: 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	> 200	100	Negative
Test 2b	> 200	> 200	100	Negative
Present				
Test 1	> 200	> 200	100	Negative
Test 2a	> 200	> 200	100	Negative
Test 2b	> 200	> 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 test substance was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY

Huntingdon Research Centre Ltd (1993b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

The following ecotoxicological tests were conducted on an analogue polymer, Permapol P2-935 (NICNAS Assessment LTD/1286).

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Permapol P2-935
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test. EC Directive 92/69/EEC C.4-E Biodegradation: Determination of the "Ready" Biodegradability: Closed Bottle Test
Inoculum	Activated sewage sludge bacteria
Exposure Period	28 d
Remarks - Method	The test substance was dissolved in diethyl ether to give a stock solution of 560 mg/10 mL. 10µL aliquots of stock solution were placed on individual pieces of Whatman GFA glass filter paper and the solvent allowed to evaporate to dryness. One piece of paper was placed in each test bottle prior to filling with inoculated medium.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
4	5	4	69
7	0	7	77
11	-	11	81
14	12	14	79
18	11	18	78
21	3	21	83
25	7	25	83
28	8	28	74

Remarks - Results	Cultures containing both test substance and standard substances combined showed an oxygen depletion value 17% higher than that anticipated on the basis of results from separate cultures. Consequently, the test substance is not considered to have an inhibitory effect on sewage bacteria under the condition of this test.
CONCLUSION	The test substance cannot be classed as ready biodegradable.
TEST FACILITY	Huntingdon Research Centre Ltd (1994h)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Permapol P2-935
METHOD	OECD TG 203 Fish, Acute Toxicity Test Static EC Directive 92/69/EEC C.1 Acute Toxicity for Fish Static
Species	Zebra fish
Exposure Period	96 h
Water Hardness	170.2 mg $CaCO_3$/L
Remarks – Method	The test solution was prepared by mixing the test substance with water, stirring by a magnetic stirrer for 24 hours. This was followed by

ultrasonicating for 20 minutes. The resulting solution was cloudy and it was used as it is.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
100	69.28	10	0	0	0	0	0
20	-	10	0	0	0	0	0

LC50 > 100 mg/L at 96 hours.
NOEC (or LOEC) > 100 mg/L at 96 hours.

CONCLUSION The test substance is not harmful to zebra fish.

TEST FACILITY Supervision and Test Center for Pesticide Safety Evaluation and Quality Control (2006)

C.2.2. Acute toxicity to fish

TEST SUBSTANCE Permapol P2-935

METHOD OECD TG 203 Fish, Acute Toxicity Test Static
EC Directive 92/69/EEC C.1 Acute Toxicity for Fish Static

Species Rainbow trout
Exposure Period 96 h
Water Hardness 169 ± 15 mg $CaCO_3$/L
Remarks - Method 92, 200, 440, 920 and 2000 mg of the test substance was stirred with the aid of a powerhead pump in 20 L of softened, dechlorinated tap water for approximately 24 hours to produce 4.6, 10, 22, 46 and 100 mg/L as Water Accommodated Fractions (WAF) respectively.

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality*				
Nominal[a]		*3h*	*24h*	*48h*	*72h*	*96h*
0	7	0	0	0	0	0
4.6	7	0	0	0	0	0
10	7	0	0	0	0	0
22	7	0	0	0	0	1
46	7	0	0	7	7	7
100	7	0	7	7	7	7

[a] As a water accommodated fraction.

LC50 26 mg/L at 96 h. (22-36, 95% confidence limit)
NOEC (or LOEC) 10 mg/L at 96 h.
Remarks - Results Loss of equilibrium observed in 1 fish at 4.6 mg/L at 96 hours, no other abnormalities observed at less than 10 mg/L. At 22 and 46 mg/L a loss of pigmentation was observed. LC50 calculated using logistic model with 15% confidence limits estimated by the likelihood ratio method (Williams 1986).

CONCLUSION The test substance is harmful to rainbow trout.

TEST FACILITY Huntingdon Research Centre Ltd (1994i)

C.2.3. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Permapol P2-935

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static
EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - Static

Species *Daphnia magna*
Exposure Period 48 h
Water Hardness Not given
Remarks - Method 200, 92, 44, 20, 9.2, 4.4 and 2.0 mg of the test substance was each dispersed in 2 litres of Elendt M7 media and stirred with the aid of a magnetic stirrer overnight to produce a series of water accommodated fractions (WAF) equivalent to 100, 46, 22, 10, 4.6, 2.2 and 1.0 mg/L.

RESULTS

Concentration mg/L Nominal	*Number of D. magna*	*Number Immobilised*	
		24 h [acute]	*48 h [acute]*
1	20	0	0
2.2	20	0	0
4.6	20	1	1
10	20	1	4
22	20	6	11
46	20	14	20
100	20	16	20

EC_{50} 9 mg/L at 48 h (7-11 95% confidence limit)
NOEC (or LOEC) 1.0 mg/L at 48 h
Remarks - Results Measured concentrations at 0 hours indicate quantity of the test substance actually present. At 48 hours, however, all test concentrations decreased, the lowest four falling below the limit of detection. Therefore, it is not possible to use mean measured concentrations for the calculations of the results.

CONCLUSION The test substance is toxic to *Daphnia magna*.

TEST FACILITY Huntingdon Research Centre Ltd (1994j)

C.2.4. Algal growth inhibition test

TEST SUBSTANCE Permapol P2-935

METHOD OECD TG 201 Alga, Growth Inhibition Test.
EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species Unicellular green alga *Selenastrum capricornutum*
Exposure Period 72 h
Concentration Range Nominal: 2-90 mg/L
Actual: 0.06-69 mg/L
Water Hardness Not given
Remarks - Method 200, 92, 44, 20, 9.2, 4.4 and 2.0 mg of the test substance was each dispersed in 2 litres of sterile nutrient medium with the aid of a magnetic stirrer overnight to produce a series of water accommodated fractions (WAF) equivalent to 100, 46, 22, 10, 4.6,and 2.2 mg/L. 100 mL of algal pre-culture was mixed with 900 mL of each of these solutions to give the final test series of 90, 41, 20, 9, 4.1 and 2 mg/ L (as WAF).

RESULTS

Biomass	*Growth*

E_bC50 mg/L at 72 h	NOEL mg/L	E_rC50 mg/L at 0-72 h	NOEL mg/L
7.3	< 0.06	11.6	< 0.06

Remarks - Results: Measured concentrations at 0 hours indicate the quantity of the test substance actually present. At 72 h, however, all test concentrations decreased, the lowest three falling below the limit of detection. Therefore, it is not possible to use mean measured concentrations for the calculations of the results. However, based upon the initial measured concentrations an estimate of the results can be made.

CONCLUSION: The test substance is toxic to alga.

TEST FACILITY: Huntingdon Research Centre Ltd (1994k)

C.2.5. Inhibition of microbial activity

TEST SUBSTANCE: Permapol P2-935

METHOD: OECD TG 209 Activated Sludge, Respiration Inhibition Test.
EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test

Inoculum: Mixed population of activated sewage sludge micro-organisms
Exposure Period: 3 h
Concentration Range: Nominal: 50 mg/L
Remarks – Method: 100 mg of the test substance was dissolved directly in a 1000 mL of test water with the aid of ultrasonic disruption to produce a stock solution of 0.1 mg/mL. 250 mL of this solution, when diluted to 500 mL with culture medium, synthetic sewage and activated sludge gave a final test concentration of 50 mg/L. This was the highest test concentration that could be prepared due to low solubility of the test substance.

RESULTS
IC50: > 50 mg/L
NOEC: 50 mg/L
Remarks – Results: A definitive IC50 value couldn't be determined due to its low solubility in water.

CONCLUSION: The EC50 value for the test substance has been determined as > 50 mg/L for 3 hour contact time. A definitive EC50 value cannot be determined for the test substance due to its low solubility in water.

TEST FACILITY: Huntingdon Research Centre Ltd (1994l)

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