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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Tolcide PS50A

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

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

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

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Director
NICNAS

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Polymer in Tolcide PS50A

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Rhodia Australia Pty Ltd (ABN 24 050 029 000)
Building 25, Omnico Business Park
270 Ferntree Gully Road
NOTTING HILL, VIC 3168

NOTIFICATION CATEGORY
Limited: Synthetic polymer with NAMW ≥ 1000 (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: Chemical Name, Other Name, CAS Number, Molecular Formula, Structural Formula, Molecular Weight, Spectral Data, Analytical Data, Purity, Polymer Constituents, Hazardous Impurities, Additives, Introduction and Use Information

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Melting Point, Boiling Point, Density, Vapour Pressure

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US EPA 2002, Environment Canada 2002

2. IDENTITY OF CHEMICAL

MARKETING NAMES
Tolcide PS50A (1-5% notified polymer)

MOLECULAR WEIGHT
M_n > 1,000 Da

ANALYTICAL DATA
Reference GPC was provided.

3. COMPOSITION

DEGREE OF PURITY
< 90%

DEGRADATION PRODUCTS
Water treatment products have the potential to biodegrade. Degradation products could include simple aldehydes and acids. When the polymer constituents go on to degrade, products include acetates, sulfonates and malonates. Functional groups in the polymer could lead to non-volatile by-products upon reaction with strong acids or bases. The polymer is thermally stable, however at temperatures above 480°C various decomposition products will be formed including oxides of carbon, sulfur and phosphorus.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
Under normal conditions of use the notified polymer is unlikely to undergo depolymerisation other than by biotic processes. The polymer solution contains small amounts of some reactants, which are volatile and likely to be lost in the aquatic environment.

4. PHYSICAL AND CHEMICAL PROPERTIES

The notified polymer is manufactured in aqueous solution and is never isolated. The values below are therefore either for the polymer solution or are estimated.

APPEARANCE AT 20°C AND 101.3 kPa
The aqueous solution of the product containing the notified polymer is a straw yellow liquid.

Property	Value	Data Source/Justification
Melting Point	90.27°C	Estimated
Boiling Point	480°C	Estimated
Density	1250-1300 kg/m^3 at 20°C	The estimated result is for an aqueous solution which contains < 50% notified polymer.
Vapour Pressure	2.75 x 10^{-12} kPa	Estimated
Water Solubility	> 1000 g/L at 20°C	Estimated
Hydrolysis as a Function of pH	Not determined	The notified polymer does not contain hydrolysable functionality.
Partition Coefficient (n-octanol/water)	log Pow = < -2.58 at 20°C	Estimated
Adsorption/Desorption	log K_{oc} > 7.359	Estimated. In spite of low K_{OW} value and high water solubility, the high molecular weight and negative charges of the notified polymer are expected to cause the polymer to adsorb to soil or sediment.
Dissociation Constant	Not determined	The notified polymer is expected to have several dissociation constants. Based on the potentially anionic functional groups, the pka values are typically expected to be 1.8, 1.89, 4.74 and 4.86. The polymer is therefore expected to be dissociated throughout the environmental pH range (4-9).
Particle Size	Not determined	The notified polymer is never isolated from solution.
Flash Point	Not determined	The notified polymer is never isolated from solution.
Flammability	Not determined	The notified polymer is never isolated from solution.
Autoignition Temperature	Not determined	The notified polymer is never isolated from solution.
Explosive Properties	Not determined	Estimated based on its chemical structure.

DISCUSSION OF PROPERTIES
For full details of tests/calculations of physical and chemical properties, please refer to Appendix A.

Reactivity
The polymer is stable under normal environmental and operating conditions. It will react with strong bases, as is the case for acrylic acid-based polymers.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED POLYMER (100%) OVER NEXT 5 YEARS
The notified polymer will be imported into Australia at a concentration of 1-5% in ready to use products within drums and IBCs.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1-10	1-10	1-10	1-10	1-10

PORTS OF ENTRY
Fremantle, Brisbane, Sydney and Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
The IBC's and drums containing the notified polymer in the water treatment product are supplied to various users, including oilfields offshore of Western Australia, Victoria and South Australia.

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in 200 L drums or IBCs, unloaded from ships, transported by road to warehouses and then distributed to customers. In the case of oilfield use, the product will be transported by road to a dockyard then by ship to offshore oil platforms.

USE
The notified polymer is used in water treatment applications by industry, including offshore oilfields, to aid in the control of biofilms.

OPERATION DESCRIPTION
The product containing the notified polymer will not be reformulated or repacked in Australia. The product will be stored in the notifier's warehouse and then provided to customers for use in water treatment applications.

The water treatment applications of the product containing the notified polymer involves the following procedures: connection/disconnection of transfer lines to the supply containers of the water treatment product; dosing or pumping of the product utilising an automated closed feed system; automatic and/or manual sampling of the water treated with the product for quality control; testing of pumps and calibration of feeding equipment; and automated treatment of the wastewater prior to seawater discharge.

Prior to discharge to seawater, the water emerging from water handling systems undergoes further treatment. The aqueous phase may be subject to reinjection underground as part of the pressure increase/maintenance process or injected into a disposal well. Also, salespeople will handle the water treatment products containing the notified polymer while demonstrating the applications of the finished products.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Dockside/transport workers	4-8	3-4 hours	10-15 days / year
Plant operators - connection / disconnection of hoses and lines	1000	1 hour	240 days / year
Salespeople	50	0.5 hours	60 days / year
QC Sampler	100	1 hour	100 days / year
QC Chemist	100	1 hour	100 days / year
Testing and calibration of equipment	100	1 hour	100 days / year

EXPOSURE DETAILS
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
Workers are potentially exposed via the dermal route to the notified polymer in spills and drips when connecting and disconnecting hoses. During the manual quality control sampling, dermal exposure may also occur from spills and drips. Dermal exposure is expected to be minimised by the use of appropriate personal protective equipment (PPE) such as coveralls, safety glasses, gloves and safety boots. In the other steps of the water treatment

application procedures, exposure is expected to be negligible since the processes are automated and enclosed.

6.1.2. Public exposure

The product containing the notified polymer will be sold to and used in industry. Direct public exposure is negligible except in the case of an accidental spill.

6.2. Human health effects assessment

The results from toxicological investigations conducted on an aqueous solution of the notified polymer (< 50%) 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 > 2500 mg/kg bw
Rabbit, skin irritation	Non-irritating
Rabbit, eye irritation	Slightly irritating
Guinea pig, skin sensitisation – adjuvant test	No evidence of sensitisation
Genotoxicity – bacterial reverse mutation	Non mutagenic

Toxicokinetics

The notified polymer has M_n > 1,000 Da and there is < 15% low MW (MW < 1,000 Da) species present, < 5% of which are species with MW < 500 Da. Since the water solubility is > 10,000 mg/L and the log P is below zero, the notified polymer may be too hydrophilic to cross the lipid rich environment of the skin. Thus, the notified polymer is unlikely to cross biological membranes and dermal uptake is expected to be low.

Acute toxicity

Based on tests in rats, the notified polymer solution exhibits low toxicity via the oral route.

Irritation and Sensitisation

The notified polymer solution is non-irritating to skin when tested on rabbits. The notified polymer solution is slightly irritating to eyes when tested on rabbits, producing above normal conjunctival redness 24 hours after exposure (1 in 3 animals). The notified polymer solution is not a skin sensitiser under the conditions of the test since there is no evidence of skin sensitisation to guinea pig.

Mutagenicity

The notified polymer solution was not mutagenic to S. typhimurium or E. coli.

Based on the available data the notified polymer is not 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 route, is non-irritating to skin, and is not skin-sensitising. However, it is slightly irritating to the eyes, although the irritancy effects are not serious enough to meet the hazard classification criteria.

The risk of eye irritation during transport, storage and application of the product containing the notified polymer is expected to be acceptable due to the limited exposure, and use of engineering controls and 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 polymer will be imported in water treatment products at a concentration of 1-5%. There will be no reformulation or repackaging in Australia and consequently no environmental release.

RELEASE OF CHEMICAL FROM USE
Oilfield
Small quantities (~1%; up to 100 kg per annum) of residual polymer may be left in the used drums and IBCs. This will be sent to licensed drum recyclers.

The majority (90%; up to 9 tonnes per annum) of the environmental release of the polymer will be into oil reservoirs to pressurize the oilfield, so that oil may be produced at the oilfields production well(s). The polymer component of the biocide formulation is expected to adsorb to rock/silt particles in the oilfield formation and is unlikely to rapidly pass through the formation. It is anticipated that only a small proportion (1%) of the polymer injected into the oilfield at the injection well will be found in water returned to the platform (CHARM 2001).

A minor use (10%; up to a tonne per annum) will be for water treatment of extracted waters from the oilfield. The notified polymer in the aqueous phase is separated from produced oil phase and will undergo peroxide treatment prior to discharge. The polymer is water-soluble and is likely to remain in the water at the point of release. This aqueous phase is usually discarded via the overboard line to seawater but may also be re-injected as part of the pressure increase/maintenance process. It is possible to re-inject the seawater into a disposal well, with no environmental release, but this is not a common practice (the notifier indicates currently 20% of wells in Australia) due to the high cost.

Industrial water treatment
Currently the notified polymer will not be used in this manner. However, the future possibility for this use remains. Given that the product is used in open systems there is likely to be some loss from spray and evaporation, however, the main source of release of the polymer to the environment is expected to occur as a result of discharge of water (blowdown) containing the scale inhibitor product from cooling towers during their normal operations. Over 99% of the polymer is likely to enter the environment in this manner. Release is expected to occur on a daily basis. Blowdown water is subject to local Trade Waste agreements. Spent blowdown water is normally released into the sewer under Trade Waste agreements where it undergoes treatment at the local wastewater treatment plant. As such, all of the notified polymer will eventually be released into the sewer either directly, or by way of the end-user's on-site effluent treatment plants.

RELEASE OF CHEMICAL FROM DISPOSAL
IBCs and drums are sent for cleaning and reconditioning by a licensed company. The resultant washings from such companies are typically passed to an on site waste treatment facility and any waste sludge is typically incinerated.

7.1.2 Environmental fate

Two biodegradability studies were presented which indicate that while the notified polymer cannot be classed as ready biodegradable, it is biodegradable in seawater. For the details of the environmental fate studies please refer to Appendix C. The notified polymer can be expected to decompose to produce simple compounds of carbon, water sodium ions, sulphate and phosphate ions which may then react further with calcium to form insoluble calcium phosphates.

7.1.3 Predicted Environmental Concentration (PEC)

Scenario 1.
For use in offshore oil drilling the PEC may be calculated from the concentration of the notified polymer in the overboard line. The product is not continuously dosed, but generally dosed once per week for approximately a 3-hour period. In a worst case scenario (minor use) only the injection into the produced water need be required as only a low percentage of the notified polymer is expected to remain in the recovered injection water. The formulation is added at a dosing rate of up to 1000 ppm in process water, meaning that the concentration in the water will have a maximum concentration of 50 ppm (1000 ppm × 5%). According to the CHARM (2001) model the PEC at a distance up to 500 m from the discharge point is estimated by dividing by 1000. This results in a PEC of 50 µg/L.

The maximum PEC in the benthic environment may be estimated by the amount of notified polymer released from a single production facility during treatment, added to the amount remaining in the benthos once a steady state has

been reached. Currently in Australia there are between 1500 and 2000 operating wells. If a worst-case is assumed where 10% of these wells will use the notified polymer, the maximum consumption at each well, will be 67 kg per annum, which is equivalent to 0.18 kg/day (in reality this is expected to be done in 52 doses of approximately 1.3 kg each week). It is also assumed that the chemical will only be added to the produced water (minor use), with the entire amount being discarded overboard. A steady state will be reached when the equivalent daily disposal rate (k_1; 0.18 kg/day) equals the rate of degradation (k_2) of the chemical in seawater. From the biodegradability data, the slope of the natural log of the amount chemical remaining versus time in days gives a rate constant of -0.0251/day with $t_{1/2}$ of approximately 28 days. The steady state amount is 7.3 kg (0.18 kg/day ÷ 0.0251/day). If a further dosing then occurs a further 0.18 kg will be added to the benthic region with a total of 7.5 kg. If a 500 m radius from the overboard line is considered, consistent with the CHARM model; the aerobic portion of the benthos is considered to be 5 cm deep; and the density is considered as 1.2 g/cm^3 (default value). Then the concentration in the benthic region is 0.16 mg/kg.

Values for the $PEC_{benthic}$ and $PNEC_{benthic}$ have been provided by the notifier based on the CHARM model. However, it is noted that these rely on the modelled Koc and Pow values. It is particularly noted that the PEC value may be calculated using either the Koc or Pow value, with preference given to the Koc value. Given the large difference between the log Koc (> 7.359) and log Pow (< -2.58) values, a reliable $PEC_{benthic}$ cannot be calculated from the estimated Koc and Pow values. The PNEC value likewise requires a Koc value. However, again it is noted that the validity of such a calculation is restricted to relatively non-reactive, non-polar, hydrophobic, organic chemicals and some metals. This does not apply to the notified polymer and therefore, these values are not used by the DEW.

Scenario 2.
Although not currently used in water treatment for industrial applications a worst case PEC may be estimated assuming that all of the polymer discarded to sewer is in accordance with trade waste agreements. If it is assumed that 99% goes to sewage treatment plants (STP) located throughout Australia on a daily basis with no removal on-site or in STPs, then the PEC may be calculated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	99%	
Annual quantity of chemical released to sewer	9,900	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	27.12	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.496	million
Removal within STP	0%	
Daily effluent production:	4,099	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	6.62	µg/L
PEC - Ocean:	0.66	µg/L

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	EC50 > 1490 mg/L	Not Harmful
Daphnia Toxicity	EC50 17 mg/L	Harmful
Americamysis bahia Toxicity	EC50 257 mg/L	Not Harmful
Acartia tonsa Toxicity	EC50 2467 mg/L	Not Harmful
Algal Toxicity	EC50 2775 mg/L	Not Harmful
Inhibition of Bacterial Respiration	EC50 1030 mg/L	Not Harmful

7.2.1 Predicted No-Effect Concentration

The PNEC was calculated from the lowest EC50 (daphnia) and dividing by a safety factor of 100 as three trophic levels were provided.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Daphnia)	17	mg/L
Assessment Factor	100	
Mitigation Factor	1.00	
PNEC:	170	µg/L

7.3. Environmental risk assessment

Scenario 1
The maximum PEC at the overboard line is 50 mg/L. This shows a potential risk to aquatic organism. However, rapid dilution of a factor of 1000 within 500 m of the discharge point will see the PEC fall to 50 µg/L. The RQ for the vicinity within 500 m of the discharge point is 0.29 (50 µg/L ÷ 170 µg/L). As described above this is based on the maximum PEC and a more realistic PEC will be lower. Further degradation of the polymer is not taken into account, either by peroxide treatment prior to discharge or biodegradation post discharge. Although there may be some effects near the discharge point, the effects may be considered localised and the risk to aquatic species based on the RQ is considered acceptable.

No data have been provided for benthic dwelling organisms and an RQ cannot be calculated. It is, however, noted that the notified polymer is not harmful to aquatic species other than daphnia. The worst case concentration of 0.16 mg/kg sediment will mean that with a conservative safety factor of 1000, the LC50 of the chemical to a sediment dwelling organism will need to be less than 160 mg/kg sediment to demonstrate a potential risk. Given that all other species (other than daphnia), showed lower toxicity than this, it is unlikely that the release of the chemical in this scenario will present an unacceptable risk to the benthic environment. Further, most of the chemical (90%) is likely to be used in water injection, meaning that the concentration in the benthos is likely to be even lower.

Scenario 2
The risk to aquatic organisms from the release of the notified polymer as detailed in scenario 2 is presented below.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	6.62	170	**0.04**
Q - Ocean:	0.66	170	**< 0.01**

On the basis of the above worst case scenarios, the risk to the aquatic environment is expected to be acceptable.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

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*
Environment	Acute Category 2 and Chronic Category 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
On the basis of the PEC/PNEC ratio:

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

Recommendations

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 in the product Tolcide PS50A:
  - Avoid eye contact.
  - Do not mix with incompatible materials: strong bases, strong reducing agents, strong acids, and strong oxidising agents.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced in the product Tolcide PS50A:
  - Safety glasses with side shields or full-face shield as appropriate.

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

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

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of by licensed waste disposal.

Storage

- The following precautions should be taken by workers regarding storage of the notified polymer:
  - Store in an area that is cool, dry and well ventilated.
  - Store away from strong bases, strong reducing agents, strong acids and strong oxidising agents.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment (diking, etc.), recovery and reuse to the extent practicable. Unrecoverable amounts should be adsorbed with diatomaceous earth, sand or inert absorbent and transferred to suitable containers for disposal. Wash residue with large amounts of water. Do not flush to drains or waterways. Collect wash water for 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 water treatment applications by industry including offshore oilfields to aid in the control of biofilms, or is likely to change significantly;
- the amount of chemical being introduced has increased from 10 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 products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICO-CHEMICAL PROPERTIES

Melting Point 90.27°C

METHOD	The above value is an estimate using MPBPWIN v 1.41 of EPIWIN version 3.12 programme developed by the Syracuse Research Corporation, USA.
Remarks	Results were based on an estimation and extrapolation of the melting point using a polymer with M_n > 1,000 Da and containing specified numbers and type of the polymer's monomers.
TEST FACILITY	Not applicable. Refer to Rhodia UK Limited (2006).

Boiling Point 480°C

METHOD	The above value is an estimate using MPBPWIN v 1.41 of EPIWIN version 3.12 programme developed by the Syracuse Research Corporation, USA.
Remarks	Results were based on an estimation and extrapolation of the boiling point using a polymer with M_n > 1,000 Da and containing specified numbers and type of the polymer's monomers.
TEST FACILITY	Not applicable. Refer to Rhodia UK Limited (2006).

Density 1250-1300 kg/m^3 at 20°C

METHOD	Estimation
Remarks	The result is for the aqueous notified polymer (< 50%) as manufactured. No test report is available.
TEST FACILITY	Non-GLP in-house result for < 50% aqueous solution of the notified polymer.

Vapour Pressure 2.75 x 10^{-12} kPa

METHOD	The above value is an estimate using MPBPWIN v 1.41 of EPIWIN version 3.12 programme developed by the Syracuse Research Corporation, USA.
Remarks	Results were based on an estimation and extrapolation of the vapour pressure using a polymer with M_n > 1,000 Da and containing specified numbers and type of the polymer's monomers.
TEST FACILITY	Not applicable. Refer to Rhodia UK Limited (2006).

Water Solubility > 1000 g/L at 20°C

METHOD	The above value is an estimate using Wat Sol (v1.01 est) of EPIWIN version 3.12 programme developed by the Syracuse Research Corporation, USA.
Remarks	The notifier indicates that in practice, the polymer is designed to be infinitely soluble. If the polymer is added to water as described in OECD Method 105, it will first dissolve and form a true solution. As more of the polymer is added, the solution will begin to thicken and then first form a colloidal solution and then a gel. Finally, as available water becomes limiting, a moist mass of polymer will form. This phenomenon is claimed to have been documented in the literature.
TEST FACILITY	Not applicable. Refer to Rhodia UK Limited (2006).

Partition Coefficient (n-octanol/water) log P_{OW} at 20°C = < -2.58

METHOD	The above value is an estimate using KOWWIN v 1.67 of EPIWIN version 3.12 programme developed by the Syracuse Research Corporation, USA.
Remarks	In practice, given that the polymer is of such high water solubility, the degree of partitioning to octanol will be low and hence log P_{OW} will be low as predicted.
TEST FACILITY	Not applicable. Refer to Rhodia UK Limited (2006).

Adsorption/Desorption – screening test

$\log K_{OC} > 7.359$

METHOD	The above value is an estimate using PCKOCWIN v 1.66 of EPIWIN version 3.12 programme developed by the Syracuse Research Corporation, USA.
Remarks	The result suggests that the polymer will adsorb to soil. In spite of low Kow value and high water solubility, the high molecular weight and negative charges of the notified polymer is expected to cause the polymer to adsorb to soil.
TEST FACILITY	Not applicable. Refer to Rhodia UK Limited (2006).

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified Polymer (< 50% aqueous solution)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat / Sprague-Dawley
Vehicle	Test substance administered as supplied.
Remarks - Method	There were no deviations from the protocol.

RESULTS

Dose mg/kg bw	*Number and Sex of Animals*	*Mortality*
2000	3 males	0
2000	3 females	0

LD50	> 2500 mg/kg bw
Signs of Toxicity	There were no clinical signs of systemic toxicity.
Effects in Organs	There were no abnormalities noted at necropsy.
Remarks - Results	All animals showed an expected gain in bodyweight during the study.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	Safepharm Laboratories Limited (2000a)

B.2. Irritation – skin

TEST SUBSTANCE	Notified Polymer (< 50% aqueous solution)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit / New Zealand White
Number of Animals	3 males
Vehicle	Test substance administered as supplied.
Observation Period	3 days
Type of Dressing	Semi-occlusive.
Remarks - Method	There were no deviations from the protocol.

RESULTS

Remarks - Results	There were no skin reactions observed at any of the observation points. The test material produced a primary irritation index of 0.0.
CONCLUSION	The notified polymer is non-irritating to the skin.
TEST FACILITY	Safepharm Laboratories Limited (2000b)

B.3. Irritation – eye

TEST SUBSTANCE	Notified Polymer (< 50% aqueous solution)
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit / New Zealand White
Number of Animals	3 males
Observation Period	3 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	0	0.33	1	< 48 hours	0
Conjunctiva: chemosis	0	0	0	0	0	0
Conjunctiva: discharge	0	0	0	2	< 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: There were no corneal or iridial effects noted during the study. Minimal to moderate conjunctival irritation was noted in all treated eyes at the 1-hour observation and in one animal at the 24-hour observation. All treated eyes appeared normal at the 48-hour observation.

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

TEST FACILITY: Safepharm Laboratories Limited (2000c)

B.4. Skin sensitisation

TEST SUBSTANCE: Notified Polymer (< 50% aqueous solution)

METHOD: OECD TG 406 Skin Sensitisation – Magnusson & Kligman Maximisation Test.

Species/Strain: Guinea pig / albino Dunkin Hartley

PRELIMINARY STUDY: Maximum Non-irritating Concentration:
intradermal: 1% v/v in distilled water
topical: 50% v/v in distilled water

MAIN STUDY

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

INDUCTION PHASE: Induction Concentration:
intradermal: 1% v/v in distilled water
topical: Undiluted as supplied

Signs of Irritation: Discrete or patchy to moderate and confluent erythema was noted at the intradermal induction sites of all test group animals at the 24-hour observation with discrete or patchy erythema at the 48-hour observation. Discrete or patchy erythema was noted at the intradermal induction sites of all control group animals at the 24-hour and 48-hour observations.

Moderate and confluent erythema and very slight to slight oedema were noted at the topical induction sites of all test group animals at the 1-hour observation with moderate and confluent erythema and incidents of very slight oedema at the 24-hour observation. Bleeding from the intradermal induction sites was noted in three test group animals at the 1-hour observation. Discrete or patchy erythema noted at the treatment sites of two control group animals at the 1-hour observation. Bleeding from the intradermal induction sites was noted in one control group animal at the 1-hour observation. No skin reactions were noted at the treatment sites of control group animals at the 24-hour observation.

CHALLENGE PHASE

1st challenge: topical: 50% v/v in distilled water
topical: 25% v/v in distilled water

Remarks - Method: There were no significant deviations from the protocol.

Remarks - Results: The test substance produced a 0% (0/10) sensitisation rate. There were no skin

reactions noted at the challenge sites of the test and control group animals at the 24-hour or 48-hour observations.

CONCLUSION — There was no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.

TEST FACILITY — Safepharm Laboratories Limited (2000d)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE — Notified Polymer (< 50% aqueous solution)

METHOD — OECD TG 471 Bacterial Reverse Mutation Test.
Plate incorporation procedure.

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9 fraction from Phenobarbitone/β-naphthoflavone-induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 50-5000 µg/plate b) Without metabolic activation: 50-5000 µg/plate
Vehicle	Sterile distilled water
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 µg/plate	> 5000 µg/plate	> 5000 µg/plate	Negative
Test 2		> 5000 µg/plate	> 5000 µg/plate	Negative
Present				
Test 1	> 5000 µg/plate	> 5000 µg/plate	> 5000 µg/plate	Negative
Test 2		> 5000 µg/plate	> 5000 µg/plate	Negative

Remarks - Results — The test substance did not cause a marked increase in the number of revertant colonies in any of the tester strains either in the presence or absence of metabolic activation. The positive controls validated the sensitivity of the test system.

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

TEST FACILITY — Safepharm Laboratories Limited (2000e)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified Polymer (< 50% aqueous solution)
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test
Inoculum	Activated sewage sludge micro-organisms
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Dissolved oxygen measured by oxygen meter and BOD probe
Remarks – Method	No significant protocol deviations

RESULTS

Test substance		*Sodium benzoate*	
Day	*% degradation*	*Day*	*% degradation*
3	10	3	47
9	7	9	69
15	8	15	81
21	10	21	80
28	11	28	80

Remarks – Results	All relevant OECD criteria were met. The toxicity control attained 28% degradation after 28 days thereby confirming that the test material was not toxic to the sewage treatment microorganisms used in the study. Sodium benzoate attained 80% degradation after 28 days thereby confirming the suitability of the inoculum and test conditions.
CONCLUSION	The notified polymer cannot be classed as ready biodegradable.
TEST FACILITY	Safepharm Laboratories Limited (2000f)

C.1.2. Ready biodegradability in seawater

TEST SUBSTANCE	Notified Polymer (< 30% aqueous solution)
METHOD	OECD 306: Biodegradability in seawater
Inoculum	None
Exposure Period	60 days
Auxiliary Solvent	None
Analytical Monitoring	Dissolved oxygen measured by Polarographic electrode
Remarks – Method	No significant protocol deviations.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% degradation*	*Day*	*% degradation*
7	15.3	7	73.0
13	22.5	13	77.8
22	24.7	22	72.5
28	32.7	28	86.0
60	78.5		

Remarks – Results	Test validity criteria with respect to reference material biodegradation and oxygen consumption in blank flasks were both met. Biodegradation is expressed as a percentage of ThoD or COD.
CONCLUSION	The notified polymer can be classed as biodegradable in seawater.
TEST FACILITY	ILAB (2002)

C.1.3. Bioaccumulation

The compound is water soluble, has a low Kow and is biodegradable and is therefore unlikely to bioaccumulate.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified Polymer (< 50% aqueous solution)
METHOD	OSPARCOM (1995) (amended March 2005) protocol for fish acute toxicity
Species	*Scophthalmus maximus*
Exposure Period	96 hours
Analytical Monitoring	None
Remarks – Method	The method used was that required by OSPARCOM for assessment of marine toxicity for offshore chemicals. A limit test was conducted as no effects were seen in the range finding tests that were undertaken. As the test substance was characterised as being soluble, it was added to the test system directly via seawater.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	-	7		0	0	0	0
3200	-	7		0	0	0	0

LC50	> 3200 mg/L at 96 hours; > 1484 mg/L corrected for concentration of test substance.
NOEC	3200 mg/L at 96 hours; 1484 mg/L corrected for concentration of test substance.
Remarks – Results	The results are based on nominal test concentrations only. There were no significant deviations to the protocol other than the salinity which was 1‰ above the criterion.
CONCLUSION	The notified polymer is not harmful to *Scophthalmus maximus*.
TEST FACILITY	Opus Plus Limited (2005a)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified Polymer (< 50% aqueous solution)
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test and Reproduction Test – Static Test. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – Static Test
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	~ 250 mg $CaCO_3$/L
Analytical Monitoring	GPC
Remarks – Method	The test was carried out using test concentrations that were corrected for active ingredient content. Therefore results are quoted in terms of active ingredient. The EC50 was calculated by the maximum likelihood probit method using Toxcalc software.

RESULTS

Concentration mg ai/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual**		*24 h*	*48 h*
0	LOQ	20	0	0
1.8	LOQ	20	0	0
3.2	LOQ	20	0	0
5.6	5.04	20	0	0
10	10.5	20	0	0
18	17.3	20	0	15
32	28.4	20	0	18
56	57.9	20	0	20
100	88.3	20	0	20

LOQ = Limit of Quantification. * Average of values taken at 0 and 48 hours.

LC50	17 mg/L at 48 hours (95% CI: 14-20 mg/L)
NOEC	10 mg/L at 48 hours.
Remarks – Results	Analysis of the test media at 0 and 48 hours showed measured test concentrations ranging from 80 to 108% for the 5.6, 10, 18, 32, 56 and 100 mg/L test concentrations at 0 and 48 hours. Analysis of the 1.0, 1.8 and 3.2 mg/L test concentrations showed measured test concentrations to be less than the limit of quantification which was assessed down to 5.0 mg/L. Therefore, the results are based on the nominal test concentrations only. Observations made on the test material preparations at 0, 24 and 48 hours showed all the test concentrations to be clear, colourless solutions.
CONCLUSION	The notified polymer is harmful to *Daphnia magna*.
TEST FACILITY	Safepharm Laboratories Limited (2001)

C.2.3. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified Polymer (< 30% aqueous solution)
METHOD	US EPA 1985. Hazard Evaluation Procedure EPA-540/9-85-010. Acute Toxicity Test for Estuarine and Marine Organisms (Shrimp 96-Hour Acute toxicity test - Static).
Species	*Americamysis bahia*
Exposure Period	96 hours

Water Hardness	Not stated
Analytical Monitoring	None
Remarks – Method	The culture and dilution water was a 70:30 mix of full seawater and dechlorinated tap water, equivalent to a salinity of 25±1‰. The LC50 was calculated by moving average angle method.

RESULTS

Concentration mg/L		*Number of A. bahia*	*Number Immobilised*			
Nominal	*Actual*		*24h*	*48h*	*72 h*	*96 h*
0	-	10	0	0	0	0
180	-	10	0	0	0	0
320	-	10	0	0	0	0
560	-	10	0	0	0	0
1000	-	10	0	4	5	5
1800	-	10	3	10	10	10

LC50	1000 mg/L at 96 hours (95% CI: 840-1200 mg/L); 257 mg/L corrected for concentration.
NOEC	560 mg/L at 96 hours; 144 mg/L corrected for concentration.
Remarks – Results	The results are based on nominal test concentrations only.

CONCLUSION The notified polymer is not harmful to *Americamysis bahia*

TEST FACILITY Brixham (2003)

C.2.4. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified Polymer (< 30% aqueous solution)

METHOD ISO 14669 (1999) Water Quality – Determination of acute lethal toxicity to marine copepods (Copepoda; Crustacea)

Species	*Acartia tonsa*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Not stated
Analytical Monitoring	None
Remarks – Method	The test substance was characterised as soluble and therefore was prepared as a dilution series. The calculations were calculated using appropriate (not specified) statistical methods from Toxcalc (V.5).

RESULTS

Concentration mg/L		*Number of A. tonsa*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	-	40	-	1
1000	-	20	0	1
1800	-	20	0	1
3200	-	20	0	0
5600	-	20	0	2
10000	-	20	2	11

LC50	9633.33 mg/L at 48 hours; 2476 mg/L corrected for concentration.
NOEC	5600 mg/L at 48 hours; 1439 mg/L corrected for concentration.

Remarks – Results	The results are based on nominal test concentrations only. The result is from repeat testing due to 12.5% control mortality in the first test. An informal reference toxicant [3,5 dichlorophenol (DCP)] gave a 48 hour LC50 of 0.83 mg/L which is within the guideline criteria. All test validity criteria were satisfied.
CONCLUSION	The notified polymer is not harmful to *Acartia tonsa*.
TEST FACILITY	ERT (2003)

C.2.5. Algal growth inhibition test

TEST SUBSTANCE	Notified Polymer (< 50% aqueous solution)
METHOD	ISO 10253 1998 Water quality – marine algal growth inhibition test
Species	*Skeletonema costatum*
Exposure Period	72 hours
Concentration Range Nominal	100, 320, 1000, 3200 and 10000 mg/L
Concentration Range Actual	Not measured analytically
Auxiliary Solvent	None
Water Hardness	Not applicable
Analytical Monitoring	None
Remarks – Method	The method used was that required by OSPARCOM for assessment of marine toxicity for offshore chemicals. There were no significant deviations to the protocol. The controls were prepared as 4 replicates and the test concentrations as 2 replicates. The calculations were calculated using appropriate (not specified) statistical methods from Toxcalc (V.5).

RESULTS

Growth	
E_rC50 *mg/L at 72 h*	*NOE_rC* *mg/L*
5982 (95% CI: 5630 – 6280)	3200

Remarks – Results	The results are based on nominal concentrations of the formulated product. The value corrected for concentration is 2775 mg/L. An informal reference toxicant (3,5 DCP) gave a 72 hour EC50 of 3.46 mg/L which is within the guideline criteria.
CONCLUSION	The notified polymer is not harmful to *Skeletonema costatum*.
TEST FACILITY	Opus Plus Limited (2005b)

C.2.6. Inhibition of microbial activity

TEST SUBSTANCE	Notified Polymer (< 50% aqueous solution)
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sewage sludge micro-organisms
Exposure Period	3 hours
Concentration Range Nominal	32, 100, 320, 1000 and 3200 mg/L

Remarks – Method	Oxygen consumption rates and percentage inhibition values for the control, test and reference materials were measured after 30 minutes and 3 hours. The reference substance 3,5-DCP was included.

RESULTS

IC50	2200 mg/L; 1027 mg/L corrected for concentration.
NOEC	100 mg/L; 46.7 mg/L corrected for concentration.
Remarks – Results	Observations made on the test preparations throughout the study period showed that at all test concentrations no undissolved test material was visible. The pH measurements performed on the test preparations at the end of the exposure period showed a significantly lower pH value at test concentrations of 1000 and 2000 mg/L compared to the other test vessels which may have contributed to the increased toxicity observed at these test concentrations. The reference substance had an EC50 of 10 mg/L and is within the acceptable range.

CONCLUSION	The notified polymer may be considered at worst to be harmful to activated sewage sludge microorganisms.
TEST FACILITY	Safepharm Laboratories Limited (2000g)

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