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April 2011

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Resene Paint Products

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 Sustainability, Environment, Water, Population and Communities.

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 Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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 Resene Paint Products

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
International Sales & Marketing Pty Ltd (ABN 36 467 259 314)
262 Highett Road
HIGHETT VIC 3190

Resene Paints (Australia) Limited (ABN 65 050 034 529)
64 Link Drive
YATALA QLD 4207

NOTIFICATION CATEGORY
Limited-small volume: Synthetic polymer with Mn <1000 Da (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: CAS number, molecular formula, structural formula, molecular weight, purity, polymer constituents, residual monomers, impurities and 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
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Tego Dispers 651 (containing the notified polymer at up to 35% concentration)
Resene Paint Products (containing the notified polymer at concentrations up to 10%)

MOLECULAR WEIGHT
Mn >500 Da.

ANALYTICAL DATA
A reference HPLC-UV chromatogram was provided.

3. COMPOSITION

DEGREE OF PURITY >90%

ADDITIVES/ADJUVANTS
None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
None expected under normal conditions of use

DEGRADATION PRODUCTS
None expected under normal conditions of use

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Pale orange clear viscous liquid

Property	Value	Data Source/Justification
Melting Point	Reacted and/or decomposed at > 230 °C	Measured
Boiling Point	Reacted and/or decomposed at > 230 °C	Measured
Density	1140 kg/m^3 at 20°C	Measured
Vapour Pressure	<1.2x10^{-3} kPa at 25°C	Measured
Water Solubility	>1000 g/L at 20°C	Calculated
Hydrolysis as a Function of pH	$t_{½}$ > 1 year at 25°C	Measured
Partition Coefficient (n-octanol/water)	At neutral pH, 25°C: log Pow >0.3-1.9 (1.2%) log Pow 1.9-3.0 (1.1%) log Pow 3.0-4.0 (16%) log Pow 4.0-5.1 (9.4%) log Pow 5.1-6.5 (25%) log Pow >6.5 (47%) At pH<3, 25°C: log Pow 5.1-6.5 (14%) log Pow >6.5 (86%)	Measured
Adsorption/Desorption	At neutral pH, 35°C log K_{oc} <1.26 (22%) log K_{oc} 1.26-1.99 (1.7%) log K_{oc} 1.99-5.63 (35%) log K_{oc} >5.63 (41%) At pH<3, 35°C log K_{oc} 1.26-1.99 (1.2%) log K_{oc} 1.99-5.63 (19%) log K_{oc} >5.63 (80%)	Measured
Dissociation Constant	pKa = 1.1 and 6.1	Calculated
Flash Point	172°C (closed cup)	Measured. Notified polymer is a C2 combustible liquid [NOHSC:(1015) 2001]
Flammability	Not predicted to be flammable in contact with water	Estimated
Autoignition Temperature	360°C	Measured
Explosive Properties	Not predicted to be explosive	Calculated
Oxidising Properties	Not predicted to be oxidising	Estimated

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

Reactivity
Stable under normal conditions of use.

Dangerous Goods classification
Based on the submitted physical-chemical data in the above table the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However the data above do not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the polymer.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported as a component of water-based paints at concentrations up to 10%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<0.5	<0.5	<1	<1	<1

PORT OF ENTRY
Brisbane, Melbourne, Sydney.

IDENTITY OF RECIPIENTS
Resene Paints Australia Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be imported as a component of finished paints in 1, 4, 10 and 15 L containers packed in boxes or shipping pallets and transported to a warehouse and then distributed to commercial and retail customers for sale and/or use.

USE
The notified polymer will be used as a component in finished paint products at up to 10% concentration. An estimated 80% of paints containing the notified polymer will be used industrially and the remaining 20% used by Do-It-Yourself (DIY) members of the public. Paints containing the notified polymer will typically be used on substrates such as steel, timber, concrete, etc.

OPERATION DESCRIPTION
Paint products containing the notified polymer (up to 10%) may be mixed with other components prior to application by professional tradesmen or DIY users. Alternatively, they may be applied without prior mixing with other components. Some spray painting may be conducted using spray booths.

In domestic settings, professional painters and DIY enthusiasts will apply the paints containing the notified polymer to a variety of surfaces such as internal walls. This will involve opening of containers, stirring the paint, perhaps mixing with other components, and applying the paint using roller or brush.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

EXPOSURE DETAILS
Professional painters working in industrial settings may come into contact with the notified polymer (≤10%) through inhalation (during spray application), dermal and ocular routes. The use of a respirator and/or local exhaust ventilation would minimise inhalation exposure. Dermal and ocular exposure would be reduced by the use of personal protective equipment (PPE) such as gloves, coveralls, safety glasses.

When used in domestic settings by professional painters, dermal and ocular exposure to the notified polymer (≤10%) may occur and workers are expected to use PPE, such as overalls to minimise such exposure.

After application and once dried, the notified polymer will be trapped in an inert polymer matrix and will not be bioavailable.

6.1.2. Public exposure
Paints containing the notified polymer will be available for the public to purchase for DIY application by roller or brush. DIY users will be exposed to the notified polymer at concentrations up to 10% in such paints, mainly via dermal and ocular routes. These users are expected to use little or no personal protective equipment in order to minimise such exposure.

Members of the public may come into contact with articles that have been coated with the paints containing the notified polymer. However, once the paints are dried, the notified polymer will be trapped in an inert polymer matrix and will not be bioavailable.

6.2. Human health effects assessment

No toxicological data on the notified polymer were submitted. Given the notified polymer is expected to be ionised and has a molecular weight >500 Da., passage across biological membranes is expected to be limited.

A product containing the notified polymer at ≤35% is reported in a MSDS provided by the notifier to be of low acute oral toxicity (LD50 > 2000 mg/kg bw) and non-irritating to the skin and eyes in studies conducted according to OECD test guidelines.

The notified polymer does not contain any functional groups with alerts for irritation or sensitisation (US EPA, (2010), Barratt et al., (1994)).

Health hazard classification
In the absence of toxicological data, the notified polymer cannot be classified according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Inhalation is expected to be the main route of exposure during manual spray application of paints containing the notified polymer (≤10%). Dermal and ocular exposure is also anticipated during application. After application and once dried, the notified polymer will be trapped in an inert polymer matrix and will not be bioavailable.

Considering the relatively low concentration (≤10%) of the notified polymer in paints, the risk to workers during handling and application of paints containing the notified polymer is not expected to be unacceptable with the appropriate use of PPE.

6.3.2. Public health
Dermal exposure to paints containing the notified polymer (≤10%) is expected during manual application by brush or roller. After application and once dried, the notified polymer will be trapped in an inert polymer matrix and will not be bioavailable.

Considering the infrequent use of smaller quantities by DIY users, the the relatively low concentration (≤10%) of the notified polymer in paints, and anticipated low systemic absorption from dermal exposure the risk to the public is not expected to be unacceptable during brush or roller application.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE
There is no expected release of the notified polymer to the environment from manufacturing or reformulation processes as it will be imported as a packaged, formulated paint.

RELEASE OF CHEMICAL FROM USE
The formulated paint containing the notified polymer will be used by professionals (80%) with the remainder being used by do-it-yourself (DIY) practitioners (20%). The coatings will be applied to various substrates including metal, timber and concrete, typically by spray, roller and brush. Residual paint containing the notified polymer may be released to the environment from disposal of excess paint or from cleaning of equipment. Residue from professional spray painting applications results in losses of up to 30% overspray which is expected to be captured and disposed of to landfill. Professional painters are expected to brush out excess paint onto newspaper or rags etc before rinsing brushes and rollers and capturing the rinse in a container. The waste paint in the container is expected to be allowed to cure before disposal as solid waste (2%). The excess paint in containers is expected to be stored for later use or disposed of to landfill.

DIY painters may follow the same practice as professional painters with rollers and brushes, however, it has

been estimated that between 10 and 15% of paint remains unused by householders at the end of a job. Much of this may be used for subsequent jobs but it is estimated that residue in used paint containers will account for approximately 5% of the paint containing the notified polymer which is expected to be disposed of to landfill. Incorrectly disposed paints (containing the notified polymer) from waste and washing of equipment may be released to sewer, drains or ground.

Residual product in end-use containers is expected to be thermally decomposed during metal drum recycling or disposed of to landfill with the used containers.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer is expected to share the fate of the substrate to which it has been applied. Notified polymer in coatings applied to metal articles will be either thermally decomposed during metal recycling at the end of the substrate's useful life, or disposed of to landfill. Cured coating removed by physical means (e.g. sandpaper/scraping) and non-metal articles at the end of their useful life are expected to be disposed of to landfill.

7.1.2 Environmental fate

The majority of the notified polymer will be contained within a dry cured film of the coatings and is not expected to be readily bioavailable. However, a proportion of the imported quantity of notified polymer may enter the sewer system as a result of washing of application equipment and improper disposal. The notified polymer is not readily biodegradable but, based on the range of soil adsorption coefficients under environmental conditions and the potential for surface activity, some partitioning to sludge is expected. Notified polymer remaining in the water phase may be released from sewage treatment plants to receiving waters, where it will disperse and eventually degrade. Bioaccumulation of the notified polymer in organisms is not expected due to its high water solubility. A small proportion of the notified polymer may be applied to land when effluent is used for irrigation, and residues in empty containers are expected to be disposed of to landfill. Due to the solubility of the notified polymer in water, residues in landfill, soil and sludge are likely to be mobile, and there is a potential of leaching in landfill. However, most of the notified polymer is expected to be disposed of to landfill after being dried or cured into solids and trapped in the paint matrix, in which case leaching is unlikely to occur. The notified polymer is expected to undergo biotic or abiotic degradation in landfill, or thermal decomposition during metal reclamation, to form water and oxides of carbon and phosphorus.

For the details of the environmental fate studies, refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

Under the worst case scenario, it is assumed that 5% of the annual import volume is released to sewer, from the washing of application equipment, and that there is no removal of the notified polymer in the sewage treatment plant (STP). The resultant Predicted Environmental Concentration (PEC) in sewage effluent on a nation wide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	5%	
Annual quantity of chemical released to sewer	50	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	0.14	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.03	µg/L
PEC - Ocean:	0.003	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is

assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.032 µg/L may potentially result in a soil concentration of approximately 0.216 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 1.079 µg/kg and 2.158 µg/kg, respectively.

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	96 h LC50 = 14 mg/L	Harmful to fish
Daphnia Toxicity	48 h EC50 = 40 mg/L	Harmful to aquatic invertebrates
Algal Toxicity	72 h E_rC50 = 142 mg/L	Not harmful to algae

Under the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified polymer is considered to be harmful to fish and daphnia, but not harmful to algae. Based on its acute toxicity to aquatic biota, the notified polymer is formally classified under the GHS as 'Acute Category 3; Harmful to aquatic life'. On the basis of its acute toxicity to aquatic biota, and its lack of rapid degradability, the notified polymer is formally classified as 'Chronic Category 3; Harmful to aquatic life with long lasting effects'.

7.2.1 Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the endpoint for the most sensitive species (fish) and an assessment factor of 100, as acute endpoints from three trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish)	14	mg/L
Assessment Factor	100	
PNEC:	140	µg/L

7.3. Environmental risk assessment

Based on the above PEC and PNEC values, the following Risk Quotient (Q) has been calculated:

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	0.03	140	2.0×10^{-4}
Q - Ocean:	0.003	140	2.0×10^{-5}

The risk quotient (Q = PEC/PNEC) for aquatic exposure is calculated to be << 1 based on the above calculated worst case PEC and PNEC. The Q value of < 1 indicates the notified polymer is not expected to pose an unacceptable risk to the aquatic environment from its proposed use pattern at the proposed maximum import volume.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

In the absence of toxicological data, the notified polymer cannot be classified according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

The classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2009) 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***

Aquatic Environment	Acute Category 3	Harmful to aquatic life
	Chronic Category 3	Harmful to aquatic life with long lasting effects

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

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

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

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 at ≤10% in Resene Paint Products
  - Avoid contact with skin and eyes
  - Do not inhale vapours/mists

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer at ≤10% in Resene Paint Products during roller and brush application:
  - Overalls
  - Gloves
  - Respiratory protection if used in non-ventilated areas

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

- Spray applications should be carried out in accordance with the Safe Work Australia *National Guidance Material for Spray Painting* [NOHSC (1999)] or relevant State and Territory Codes of Practice.

- 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 *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Public Health

- The following measures should be taken to minimise public exposure to the notified polymer at ≤10% in Resene Paint Products:
  - Application by brush or roller only
  - Avoid contact with skin and eyes
  - Use respiratory protection if used in non-ventilated areas

Disposal

- The notified polymer should be disposed of to landfill.

Storage

- The following precautions should be taken by International Sales & Marketing Pty Ltd and Resene Paints (Australia) Limited regarding storage of the notified polymer:
  - Store in accordance with the National Standard for the Storage and Handling of Workplace Dangerous Goods [NOHSC:1015(2001)] when stored and handled with fire risk dangerous goods.

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 chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
  - the importation volume exceeds one tonne per annum notified polymer;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from a component of paints at ≤10%, or is likely to change significantly;
  - the polymer has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the polymer 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 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: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point Reacted and/or decomposed at >230ºC

Method OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Differential scanning calorimetry
The notified polymer decomposed before melting
Test Facility NOTOX B.V. (2010)

Boiling Point Reacted and/or decomposed at >230ºC

Method OECD TG 103 Boiling Point.
EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Differential scanning calorimetry
The notified polymer decomposed before boiling
Test Facility NOTOX B.V. (2010)

Density 1140 kg/m^3 at 20ºC

Method OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks Determined by pycnometer
Test Facility NOTOX B.V. (2010)

Vapour Pressure <1.2x10^{-3} kPa at 25ºC

Method OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Determined by Modified Watson Correlation method using boiling point of >230ºC
Test Facility NOTOX B.V. (2010)

Water Solubility >1000 g/L at 20ºC

Method OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Flask method. Visual inspection of the test substance at a nominal concentration of 1003 mg/g found the test sample was clear with no undissolved test substance present. The pH was not determined since a gel was formed.
Test Facility NOTOX B.V. (2010)

Hydrolysis as a Function of pH $t_{½}$ > 1 year at 25°C

Method OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$ <hours or days>*
4	25	> 1 year
7	25	> 1 year
9	25	> 1 year

Remarks At pH 4, pH 7, and pH 9 a degree of hydrolysis of <10% was observed after days. Therefore, the half-life of the test substance at 25°C is > 1 year.
Test Facility NOTOX B.V. (2010)

Partition Coefficient (n-octanol/water)

At neutral pH, 25ºC:
log Pow 0.3-1.9 (1.2%)
log Pow 1.9-3.0 (1.1%)
log Pow 3.0-4.0 (16%)
log Pow 4.0-5.1 (9.4%)
log Pow 5.1-6.5 (25%)
log Pow >6.5 (47%)

At pH<3, 25ºC:
log Pow 5.1-6.5 (14%)
log Pow >6.5 (86%)

Method: OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks: HPLC method. A C4 column and acetonitrile/water solvent gradient was required to elute from the column all compounds of the test substance. The method was conducted at pH<3 and neutral pH, to determine the partition coefficient for the test substance in its non-ionised form and also under environmentally relevant conditions, respectively.

The guidelines indicate this method is not applicable to surface active agents and, as the chemical structure of the notified polymer indicates it may have surface active properties, these results should be treated with caution.

The log Pow for the notified polymer was calculated by the Rekker calculation method to be 8.25.

Test Facility: NOTOX B.V. (2010)

Adsorption/Desorption – screening test

At neutral pH, 35°C
log K_{oc} <1.26 (22%)
log K_{oc} 1.26-1.99 (1.7%)
log K_{oc} 1.99-5.63 (35%)
log K_{oc} >5.63 (41%)

At pH<3, 35°C
log K_{oc} 1.26-1.99 (1.2%)
log K_{oc} 1.99-5.63 (19%)
log K_{oc} >5.63 (80%)

Method: OECD TG 121 Estimation of Adsorption Coefficient (K_{oc}) on Soil and on Sewage Sludge using HPLC
EC Directive 440/2008 C.19 Estimation of Adsorption Coefficient (K_{oc}) on Soil and on Sewage Sludge using HPLC

Remarks: The method was conducted at pH<3 and neutral pH, to determine the partition coefficient for the test substance in both its non-ionised and ionised form, respectively.

Test Facility: NOTOX B.V. (2010)

Dissociation Constant

pKa = 1.1 and 6.1

Method: Perrin Calculation Method (pKalc 5.0, module in Pallas 3.0, CompuDrug International San Francisco, CA USA)

Remarks: The study author reported it was not possible to determine the pKa by titration due to the presence of an impurity in the test substance.

Test Facility: NOTOX B.V. (2010)

Flash Point

172ºC

Method: EC Directive 92/69/EEC A.9 Flash Point.

Remarks: Determined using the Pensky-Martens closed cup method

Test Facility: NOTOX B.V. (2010)

Flammability Not predicted to be highly flammable in contact with water

Method	EC Directive 92/69/EEC A.12 Flammability (Contact with Water).
Remarks	Predicted based on structure
Test Facility	NOTOX B.V. (2010)

Autoignition Temperature 360ºC

Method	EC Directive 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Test Facility	NOTOX B.V. (2010)

Explosive Properties Not predicted to be explosive

Method	EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks	Calculated based on oxygen balance
Test Facility	NOTOX B.V. (2010)

Oxidizing Properties Not predicted to be oxidizing

Method	EC Directive 440/2008 A.21. Oxidizing Properties (Liquids).
Remarks	Predicted based on structure
Test Facility	NOTOX B.V. (2010)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer (35% aqueous solution)
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Inoculum	Activated sludge from a predominantly domestic sewage treatment plant
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Biological oxygen demand (BOD)
Remarks - Method	In accordance with the guidelines above, the dissolved oxygen uptake of inoculated medium containing the test substance (5.25 mg active ingredient/L) in completely full closed bottles stored in the dark was measured over 28 days. A reference control (sodium acetate, 2 mg/L) and a toxicity control (sodium acetate and test substance) were run in parallel. Biodegradation was determined by measuring the oxygen depletion in the medium, corrected for the blank, and expressed as a percentage of the chemical oxygen demand (COD: 0.52 mg test substance/L). Test conditions were: 19 to 20°C, pH 6.95 to 7.30.

RESULTS

Test substance		*Sodium acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	0	7	76
14	0	14	76
21	7	21	78
28	5	28	79

Remarks - Results	All acceptability criteria were fulfilled, therefore the test is considered valid. The toxicity control achieved 34% biodegradation after 14 days and, as this is above the guideline limits of 25% degradation, the test substance is not considered inhibitory to microbe respiration. The test substance achieved ≤7% biodegradation over the course of the study and, therefore, under the conditions of the test, the test substance is not considered to be readily biodegradable.
CONCLUSION	The notified polymer is not readily biodegradable
TEST FACILITY	Dr. U. Noack-Laboratorium (2001a)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer (35% aqueous solution)
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static
Species	*Brachydanio rerio* (Zebra Fish)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	67 mg $CaCO_3$/L
Analytical Monitoring	Dissolved organic carbon analysis (DOC)

Remarks – Method The test was conducted in accordance with the guidelines above, following the principles of good laboratory practice (GLP).

RESULTS

Concentration mg active ingredient/L		*Number of Fish*	*Cumulative mortality (%)*			
Nominal	*DOC*		*24 h*	*48 h*	*72 h*	*96 h*
0	1	7	0	0	0	0
6.25	-	7	0	0	14	14
12.5	-	7	0	0	14	29
25	15	7	14	100	100	100
50	32	7	100	100	100	100
100	56	7	100	100	100	100

LC50 14 mg /L at 96 hours (95% CI: 12-15 mg/L)
NOEC 6.25 mg/L at 96 hours.
Remarks – Results The test item showed concentration related foam formation at test initiation and turbidity throughout the test.

There was no mortality in the control and constant conditions were maintained throughout the test. Therefore the test is considered valid.

The mortality of 1 fish (14%) in the concentration level of 6.25 mg/L was reported as not significant and, as this test concentration caused no other effects, the NOEC was therefore determined to be 6.25 mg/L.

Sublethal effects observed in test concentrations ≥12.5 mg/L include lethargy, slow escape reflex, no escape reflex, and fish on their side.

CONCLUSION The notified polymer is harmful to fish

TEST FACILITY Dr U Noack-Laboratorium (2000)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified polymer (35% aqueous solution)

METHOD OECD TG 202 *Daphnia* sp. Acute Immobilisation Test - Static
EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - Static
Species *Daphnia magna* STRUAS
Exposure Period 48 hours
Auxiliary Solvent None
Water Hardness 264 mg $CaCO_3$/L
Analytical Monitoring Dissolved organic carbon analysis (DOC)
Remarks - Method The test was conducted in accordance with the guidelines above, following the principles of good laboratory practice (GLP). Statistical values were determined by probit analysis.

RESULTS

Concentration mg active ingredient/L		*Number of D. magna*	*Number Immobilised (%)*	
Nominal	*DOC*		*24 h*	*48 h*
0	2.38	4 × 5	0	0
10	-	4 × 5	0	5
18	-	4 × 5	5	25
32	16.64	4 × 5	15	25
58	27.85	4 × 5	75	85
100	47.73	4 × 5	90	100

LC50	40.0 mg/L at 48 hours (95% CI: 36.5-43.9 mg/L)
LOEC	10 mg/L at 48 hours
Remarks - Results	The test item of 100 mg/L was a turbid suspension. All other concentrations were clearly dissolved throughout exposure. All validity criteria of the guideline were fulfilled.
CONCLUSION	The notified polymer is harmful to aquatic invertebrates
TEST FACILITY	Dr. U. Noack-Laboratorium (2001b)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer (35% aqueous solution)
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Desmodesmus subspicatus* (formerly known as *Scenedesmus subspicatus*)
Exposure Period	72 hours
Concentration Range	Nominal: 1.56, 3.13, 6.25, 12.5, 25, 50, 100 and 200 mg active ingredient/L
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Dissolved organic carbon analysis (DOC)
Remarks - Method	The test was conducted in accordance with the guidelines above, following the principles of good laboratory practice (GLP). Statistical values were determined by probit analysis, one way analysis of variance (ANOVA) and Dunnett's test.

RESULTS

Biomass		*Growth*	
E_bC50 *mg/L at 72 h*	*NOEC* *mg/L*	*E_rC50* *mg/L at 72 h*	*NOEC* *mg/L*
38 (95% CI: 32-46)	6.25	142 (95% CI: 105-194)	6.25

Remarks - Results	The test item was dissolved by visual examination in all test replicates throughout the test period. The effects of the test substance are based on the nominal concentrations of the active ingredient. All validity criteria were met and constant conditions were maintained throughout the test. Inhibition effects were found to be reversible.
CONCLUSION	The notified polymer is not harmful to algae
TEST FACILITY	Dr. U. Noack-Laboratorium (2001c)

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