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July 2013

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

PUBLIC REPORT

Polymer in Disperbyk-112

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 Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

**Director
NICNAS**

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1658	Nuplex Industries (Aust) Pty Ltd Valspar Paint (Australia) Pty Ltd	Polymer in Disperbyk-112	Yes	< 15 tonnes per annum	Dispersant in pigment concentrates for coatings

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available information, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the table below.

<i>Hazard classification</i>	<i>Hazard statement</i>
Eye Damage (Category 1)	H318 – Causes serious eye damage

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):

R38: Irritating to skin

R41: Risk of serious damage to eyes

The environmental hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

<i>Hazard classification</i>	<i>Hazard statement</i>
Acute (Category 1)	H400 - Very toxic to aquatic life
Chronic (Category 1)	H410 - Very toxic to aquatic life with long lasting effects

Human health risk assessment

Under the conditions of the occupational settings described, provided engineering controls are instituted, workers wear adequate PPE (impervious coveralls, gloves and footwear, eye/face protection), and safe work practices are maintained to reduce exposure, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment

On the basis of the PEC/PNEC ratio and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified polymer should be classified as follows:
 - H318 – Causes serious eye damage
- The following should be used for products/mixtures containing the notified polymer:
 - Conc. \geq 3%: H318
 - 1% \geq Conc. < 3%: H319

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified chemical:
 - Automated and enclosed processes for mixing and coating, where possible
 - Use of spray booths during spray application, where possible
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
 - Avoid contact with eyes and skin
 - Have eye wash facilities available during reformulation processes
- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
 - Eye and face protection
 - Impervious coveralls
 - Impervious gloves
 - Impervious footwear
 - Appropriately fitted respiratory protection during spray application

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 Code of Practice for *Spray Painting and Powder Coating* (SWA, 2012) or relevant State or Territory Code of Practice.
- A copy of the (M)SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- The notified chemical should be disposed of to landfill.

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

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

- (1) Under Section 64(1) of the Act; if
 - the polymer has a number-average molecular weight of less than 1000;
 - the notified chemical is proposed to be used in products available to consumers.or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from an additive in industrial coatings, or is likely to change significantly;
 - the amount of polymer being introduced has increased, or is likely to increase, 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 (M)SDS of a product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANTS

Nuplex Industries (Aust) Pty Ltd (ABN: 25 000 045 572)
49-61 Stephen Road
Botany NSW 2019

Valspar Paint (Australia) Pty Ltd (ABN: 40 000 035 914)
Level 4, 2 Burbank Place, Norwest Business Park
Baulkham Hills NSW 2019

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1000$ Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, import volume, and identity of manufacturer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: most physico-chemical properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None.

NOTIFICATION IN OTHER COUNTRIES

Canada
USA (1997)

2. IDENTITY OF CHEMICAL

MARKETING NAME

DISPERBYK-112 (Product containing the notified polymer)

MOLECULAR WEIGHT
> 1,000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Tan-coloured liquid with ester-like odour (Product containing the notified polymer)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	< -18°C	Estimated by the notifier
Boiling Point	146°C*	MSDS of the product
Density	1,020 kg/m ³ at 20°C*	MSDS of the product
Vapour Pressure	< 10 ⁻⁵ kPa at 25°C	Estimated by the notifier
Water Solubility	0.264 g/L at 20°C at pH 7	Measured
Hydrolysis as a Function of pH	Not determined	The notified polymer contains hydrolysable functionality, however, it is not expected to significantly hydrolyse under environmental conditions (pH 4 - 9).
Partition Coefficient (n-octanol/water)	log Pow > 3.3 at 20°C	Calculated based on the reported n-octanol solubility and water solubility of the notified chemical. The notified polymer is surface active, and hence expected to partition to phase boundaries.
Adsorption/Desorption	Not determined	The notified polymer is expected to sorb to soil sediment and sludge based on its surface activity and potential cationicity
Dissociation Constant	pK _{BH} ⁺ = 9.8	Estimated. The notified polymer has a potential to ionise under environmental conditions (pH 4-9, 25 °C)
n-Octanol Solubility	> 582 g/L at 20°C	Measured
Flash Point	47°C (Closed Cup)*	MSDS of the product
Flammability	Flammable (Liquid and Vapour)*	MSDS of the product
Autoignition Temperature	315°C*	MSDS of the product (estimated)
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

* Properties of the product containing the notified polymer that also contains organic solvent

DISCUSSION OF PROPERTIES

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

Reactivity

The notified polymer is expected to be stable under normal conditions of use.

Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified polymer cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals*

(GHS), as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured in Australia. It will be imported as a component of a solution at a concentration of approximately 60%.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	< 15	< 15	< 15	< 15	< 15

PORT OF ENTRY

Sydney

TRANSPORTATION AND PACKAGING

The product containing the notified polymer will be transported by road or railway in sealed metal pails, 25 kg or 200 kg drums. The product containing the notified polymer is classified as Dangerous Goods because of the organic solvent used.

USE

The notified polymer is to be used as a polymeric wetting and dispersing additive for pigment concentrates that will be used in industrial coatings.

OPERATION DESCRIPTION

Storage

The product containing the notified polymer will be stored in pails and drums in a bonded facility. Storage will be in a dry, cool, well-ventilated area away from heat, sources of ignition, explosives, oxidising agents and direct sunlight. Containers will be kept closed when not in use.

Reformulation into pigments

The imported product containing the notified polymer at approximately 60% will be transported to the reformulation sites in sealed metal pails or drums. In the case of drums, the workers will either fit taps to the containers or utilize hand pumps to transfer the product containing the notified polymer. Pails will be handled manually by the workers for transferring the product to pigment concentrates. The pigment concentrates will then be packaged into bags of various sizes and stored in bonded warehouses prior to distribution to coating formulators.

Reformulation into coatings

The formulated pigments containing the notified polymer will be dispensed into the base paints of industrial coatings. The coatings will be mechanically mixed typically on an enclosed gyroscopic mixer or shaker. The process of tinting the coatings with the pigment concentrates will occur either in end-user workshops (such as auto body shops and machinery or equipment manufacturers), or in industrial coatings stores.

End-use

The finished paint products containing < 5% of the notified polymer will be applied by industrial paint operators using brushes (10% of total use), rollers (50% of total use) or spray apparatus (40% of total use).

Spray application will be conducted in spray booths at industrial sites. The finished paint products will not be sold to the public for DIY activities.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport	2 - 3	10 - 15
Reformulation	8	50
Laboratory	1	20
End-use	6	260

EXPOSURE DETAILS

Transport and storage

Transport and storage workers are not expected to be exposed to the notified polymer except in the unlikely event of an accident. In case of accident, the workers may have potential for dermal and ocular exposure to the notified polymer at a concentration approximately 60%. As the product containing the notified polymer is classified as Dangerous Goods due to the organic solvent, the work practices, engineering controls and personal protective equipment (PPE) used for transport and storage workers would reduce their potential exposure.

Reformulation and repackaging

Workers transferring the product containing the notified polymer during reformulation processes may have potential for dermal or ocular exposure to the notified polymer at a concentration of approximately 60%. As the organic solvent used in the product is hazardous, operators would be required to wear PPE including impervious gloves, chemical goggles, impervious coverall clothing and face masks to reduce the potential for exposure. Workers involved in formulating and packaging the pigments or coatings may have potential for dermal and ocular exposure to the notified polymer at various concentrations up to 60%. Inhalation exposure is not expected unless the reformulation processes generate aerosols or mists.

End-use

Spray application

Dermal and ocular exposure to the notified polymer at concentrations < 5% may occur during the spray applications especially when manually adding the coatings to spray guns, spraying the coatings to objects and cleaning the equipment involved in the applications. Inhalation exposure to < 5% notified polymer may occur during spraying application. As the finished coatings contain hazardous solvent, during the spray applications operators would be required to wear appropriate PPE including impervious gloves and coveralls, chemical boots, face shields and respirators to reduce the potential for exposure. Engineering controls in the spray booths would further protect the operators from exposure to the notified polymer.

Brush and roller applications

Dermal and ocular exposure to the notified polymer at concentrations < 5% may occur during brush and roller applications especially when manually decanting the coatings, applying the coatings to objects and cleaning equipment. Workers would be required to wear appropriate PPE including impervious gloves, coveralls, face masks, chemical goggles and, if necessary, respirators to reduce the potential for exposure to other chemicals in the coatings.

Once the coating is dry, it will form an inert film that contains and immobilises the notified polymer and the notified polymer will not be bioavailable for further exposure.

6.1.2. Public Exposure

The public may have potential for dermal contact with surfaces coated with the finished paint containing the notified polymer. However, once the coating is dry, the notified polymer will be contained and immobilised by an inert film and will not be bioavailable for further exposure.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 5,000 mg/kg bw; low toxicity
Rabbit, skin irritation	irritating
Rabbit, eye irritation	severely irritating

Toxicokinetics, metabolism and distribution.

Based on its high molecular weight (> 1000 Da), the potential of the notified polymer to cross the gastrointestinal (GI) tract by passive diffusion, or to be dermally absorbed after exposure is expected to be limited. The notified polymer is expected to be surface active, which may enhance dermal absorption and the absorption of other compounds.

Acute toxicity.

The notified polymer was of low acute oral toxicity in rats.

Irritation and sensitisation.

The notified polymer was irritating to the skin and severely irritating to the eyes of rabbits.

Health hazard classification

Based on the available information, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	Hazard statement
Eye Damage (Category 1)	H318 – Causes serious eye damage

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):

R38: Irritating to skin*

R41: Risk of serious damage to eyes

* Due to differences between the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia and the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), the polymer was classified as a skin irritant under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) only.

6.3. Human Health Risk Characterisation**6.3.1. Occupational Health and Safety**

The notified polymer causes serious eye damage and is a skin irritant and therefore adverse effects may occur unless controls have been put in place to limit worker exposure.

Dermal, ocular and possibly inhalation exposure of workers to the notified polymer at concentrations of up to approximately 60% may occur during reformulation processes. Exposure will be minimised by the use of semi-automated processes and PPE (industrial protective clothing, solvent resistant gloves, goggles and face mask).

Dermal, ocular and inhalation exposure to the notified polymer at concentrations < 5% may occur during application of coatings by brush roller and spray. During spray application, the risk related to the irritant nature of the notified polymer would be limited by the use of sufficient engineering controls, such as spray booths. In addition, workers are expected to wear PPE, which will include respirators during spray operations, and skin and eye protection during all application processes.

Overall, provided engineering controls are instituted, workers wear the PPE described above, and safe work practices are maintained to reduce exposure, the risk to workers is not considered to be unreasonable.

6.3.2. Public Health

The products containing the notified polymer will not be available to the public. The public may come into contact with surfaces of cured and dried products containing the notified polymer. The notified polymer will be incorporated into the matrix of the paint and will not be bioavailable. Therefore the risk to the public from the use of the notified polymer is not expected to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will not be manufactured in Australia; therefore, there will be no release from this activity. Environmental release during importation, transport and distribution may occur as a result of accidental spills. In the event of a spill, the notified polymer is expected to be contained and collected with an inert absorbent material and disposed of in accordance with local regulations.

During reformulation activities, wastewater from equipment washing containing residues of the notified polymer is expected to be disposed of via accredited waste disposal contractors. Wastes and spills (3% of the annual import volume) during reformulation activities will be contained on-site and disposed of in accordance with local regulations. Residues in import containers are expected to be disposed of to landfill; however, the residues were expected to be cured prior to disposal to landfill.

RELEASE OF CHEMICAL FROM USE

The main release of the notified polymer from end-use is expected as a result from overspray, spills, and leaks, from cleaning of equipment and from residues in empty containers. Spills and overspray are expected to be collected with absorbent material and/or engineering controls. The collected wastes and empty containers are expected to be disposed of to landfill. Up to 1% of import volume is expected to release to sewer during end-use due to equipment rinsing.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer in coatings is expected to share the fate of metal and wood substrates to which it has been applied. The notified polymer is likely to be either thermally decomposed during metal reclamation processes or disposed of to landfill at the end of the useful life of the article to which it has been applied.

7.1.2. Environmental Fate

The notified polymer is not readily biodegradable based on the environmental fate study provided. For the details of the environmental fate study please refer to Appendix C. The notified polymer has a tendency to sorb to surface boundaries based on its surface activity and potential cationicity, and it is likely to partition to suspended solids and sediments in receiving waters. Hence, it is not anticipated to be significantly bioavailable to aquatic organisms. Given that the notified polymer has a high molecular weight, it is not expected to bioaccumulate as it is too large to cross the biological membranes. The notified polymer that may be released to sewers is expected to mainly partition to sludge, and be disposed of to landfill. The majority of the notified polymer is expected to be cured within an inert polymer matrix adhering to articles following its use in coating applications. Notified polymer that is disposed of to landfill is expected to remain associated with the substrate to which it has been applied. In its cured form it is not expected to be mobile, bioavailable or biodegradable. Ultimately, the notified polymer is expected to eventually degrade via biotic and abiotic processes in landfill, or by thermal decomposition during metal reclamation processes, to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The Predicted Environmental Concentration (PEC) was calculated assuming that 2% of the total import volume of polymer would be released to sewer annually due to washing of reformulation and application equipment. It was assumed that 90% of the notified polymer partitions to sludge in STPs as it is a polymer with potential cationicity (Boethling and Nabholz, 1997) and the release of the notified polymer will occur over 260 days per annum into the total Australian effluent volume. This corresponds to release only on working days, based on a 5 day work week. The results of the calculation are shown in the table below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment

Total Annual Import/Manufactured Volume	15,000	kg/year
Proportion expected to be released to sewer	2%	
Annual quantity of chemical released to sewer	300	kg/year

Days per year where release occurs	260	days/year
Daily chemical release:	1.15	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	90%	Mitigation
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.03	µg/L
PEC - Ocean:	0.003	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 2.3 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1500 kg/m³ and a soil-mixing zone of 10 cm, the concentration of the notified chemical may approximate 0.02 mg/kg in applied soil. This assumes that degradation of the notified chemical occurs in the soil within 1 year from application. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated biosolids application, the concentration of notified chemical in the applied soil in 5 and 10 years may approximate 0.1 mg/kg and 0.2 mg/kg, respectively.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m³). Using these assumptions, irrigation with a concentration of 0.03 µg/L may potentially result in a soil concentration of approximately 0.2 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 0.9 µg/kg and 1.7 µg/kg, respectively.

7.2. Environmental Effects Assessment

An environmental effect endpoint for the notified polymer is presented in the table below. Details of the study can be found in Appendix C.

Endpoint	Result	Assessment Conclusion
Fish Toxicity (96 h)	LC50 = 0.89 mg/L	Very toxic to fish

Based on the endpoint for the notified polymer, it is expected to be very toxic to fish. Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009), the notified polymer is formally classified as Acute Category 1; Very Toxic to aquatic life. Based on the acute toxicity of the notified polymer and lack of ready biodegradability, it has been formally classified under GHS as Chronic Category 1; Very toxic to aquatic life with long lasting effects.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) was calculated using the available endpoint and an assessment factor of 1000. The most conservative assessment factor of 1000 was used since only one measured ecotoxicological data of the notified polymer for fish was reported.

<i>Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment</i>		
LC50 (Fish).	0.89	mg/L
Assessment Factor	1,000	
PNEC:	0.89	µg/L

7.3. Environmental Risk Assessment

<i>Risk Assessment</i>	<i>PEC µg/L</i>	<i>PNEC µg/L</i>	<i>Q</i>
Q - River:	0.03	0.89	0.029
Q - Ocean:	0.003	0.89	0.003

The Risk Quotients ($Q = PEC/PNEC$) for a conservative discharge scenario have been calculated to be < 1 for the river and ocean compartments. The notified polymer is not rapidly biodegradable in the environment however it is not likely to significantly bioavailable as it is expected to be removed from the water column due to its strong potential to adsorb on suspended solids and sediments in water. It is not expected to bioaccumulate based on its high molecular weight. Although the notified polymer is very toxic to aquatic species, it is unlikely to result in ecotoxicologically significant concentrations in aquatic environment for the assessed use pattern. Therefore, there is no unreasonable risk to the aquatic environment from the assessed use scenario.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Water Solubility** 0.264 g/L at 20°C at pH 7

Method OECD TG 105 Water Solubility.
Remarks Flask Method.
The mean water solubility of the test substance at pH 1, pH 7 and pH 10 was determined to be 0.208, 0.264 and 0.235 g/L, respectively, at approximately 20°C.
Test Facility Springborn Smithers (2005a)

Fat (or n-octanol) Solubility > 582 g/L (n-Octanol) at 20°C

Method Determining the n-Octanol Solubility of a Substance. Springborn Smithers laboratories Protocol No.: 032304/OECD/CEPA/n-Octanol Solubility.
Remarks Shake-flask Method.
The test substance was highly soluble in n-octanol at a 1:1 ratio. The mean n-octanol solubility of the test substance at 20 °C was determined to be > 582 g/L.
Test Facility Springborn Smithers (2005b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 401 Acute Oral Toxicity
Species/Strain	Rat/SPF-Wistar (Winkelmann, Paderborn)
Vehicle	Test substance administered as supplied
Remarks - Method	The compound was heated to 60 °C to reduce the viscosity prior to it being administered by gavage. No significant protocol deviations.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
I	5 per sex	2,000	0/10
II	5 per sex	5,000	0/10

LD50	> 5,000 mg/kg bw
Signs of Toxicity	There were no deaths or test substance-related clinical signs or remarkable body weight changes during the study period.
Effects in Organs	There were no remarkable necropsy findings.
Remarks - Results	There was no significant differences in bodyweight gain over the 14 day observation period.

CONCLUSION	The notified polymer is of low toxicity via the oral route.
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TEST FACILITY	Pharmatox (1997a)
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B.2. Irritation – skin

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Test substance administered as supplied
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations

RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	2	2	2.3	4	> 14 days	1
<i>Oedema</i>	1	1	0.7	1	< 7 days	0

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

Remarks - Results	There were no deaths or test substance-related clinical signs or remarkable body weight changes during the study period.
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There were no signs of erythema or oedema present at the 1 hour observation. At the 24 hour observation all animals had slight erythema which increased over time peaking at the 72 hour observation before subsiding by the 7 day observation with no sign of erythema in 2 animals at the 14 day observation with only slight erythema present in the remaining

animal. Slight oedema was present in 2 animals at the 24 hour observation and all animals at the 48 and 72 hour animals but had cleared by the 7 day observation.

CONCLUSION The notified polymer is irritating to the skin.

TEST FACILITY Pharmatox (1997b)

B.3. Irritation – eye

TEST SUBSTANCE Notified polymer

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain Rabbit/New Zealand White

Number of Animals 1

Observation Period 7 days

Remarks - Method The test substance was administered to just 1 animal in the first instance and due to the severe effects seen no further animals were utilised.

The test was stopped at day 7 due to the severity of the effects seen and no further animals were tested.

No significant protocol deviations

RESULTS

<i>Lesion</i>	<i>Mean Score* Animal No.</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1			
<i>Conjunctiva: redness</i>	1.7	2	> 7 days	2
<i>Conjunctiva: chemosis</i>	2.3	3	> 7 days	3
<i>Conjunctiva: discharge</i>	2	2	> 7 days	2
<i>Corneal opacity</i>	0	4	> 7 days	4
<i>Iridial inflammation</i>	0	0	0	0

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

Remarks - Results

A single application of the test material to the non-irrigated eye of one rabbit produced moderate conjunctival irritation and severe corneal opacity. Conjunctival irritation was present from the first observation at 1 hour til the end of the study at 7 days. Corneal opacity was first observed at the day 4 observation and increased in severity until the end of the test.

The test animal lost approximately 20% of its bodyweight during the test period.

CONCLUSION The notified polymer is severely irritating to the eye.

TEST FACILITY Pharmatox (1997c)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 B Ready Biodegradability: CO ₂ Evolution Test.
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	Nil
Analytical Monitoring	CO ₂ Evolution
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported.

RESULTS

<i>Test substance</i>		<i>Sodium benzoate</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
0	0	1	0
4	3.5	3	53.3
7	3.0	7	66.1
10	3.4	10	69.4
14	4.2	14	73.3
28	1.6	28	86.3

Remarks - Results All validity criteria for the test were satisfied. The toxicity control exceeded 25% biodegradation (required by guideline) showing that toxicity was not a factor affecting the low biodegradability of the test substance. The mean cumulative net CO₂ evolved (percent biodegradation) from the aqueous medium fortified with test substance at 10 mg C/L was 1.6% on day 28. It did not pass the criterion for ready biodegradability of > 60% degradation (CO₂) reached within the 10 day window. Therefore, the test substance cannot be classified as readily biodegradable according to the OECD 301 B (1992) guideline

CONCLUSION The notified polymer is not readily biodegradable

TEST FACILITY Springborn Smithers (2005c)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static
Species	Rainbow trout (<i>Oncorhynchus mykiss</i>)
Exposure Period	96 hours
Auxiliary Solvent	Acetone (0.01)
Water Hardness	42 - 46 mg CaCO ₃ /L
Analytical Monitoring	At 0 and 96 hours
Remarks – Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported.

RESULTS

<i>Concentration (mg/L)</i>		<i>Number of Fish</i>	<i>Cumulative Mortality (%) (96 hour)</i>
<i>Nominal</i>	<i>Measured</i>		
Control	Control	10	0
Solvent Control	Solvent Control	10	0
0.63	0.3	10	0
1.3	0.47	10	0
2.5	12	10	80
5.0	2.5	10	100
10	3.2	10	100

LC50

0.89 (0.47-2.5) mg/L at 96 hours. at 48 hours.

NOEC

0.47 mg/L at 96 hours

Remarks – Results

All validity criteria for the test were satisfied. All the test solutions were clear and colorless with no visible undissolved test substance. However, the treatment solution of the highest nominal concentration, 10 mg/L, was observed to be slightly cloudy with an oily film and small amount of undissolved test substance at the surface of the solution. The second highest nominal test concentration of 5.0 mg/L was observed to be clear and colorless with a small amount of oily film on the surface. Analytical measurements were performed to quantify the actual exposure concentrations of the test substance. Hence, the toxicity values were calculated based on the mean measured concentration of the initial and final measured concentrations.

CONCLUSION

The notified polymer is very toxic to fish

TEST FACILITY

Springborn Smithers (2005d)

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