File No: LTD/1622

October 2012

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Disperbyk 2091

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:

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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/1622	Nuplex Industries (Aust) Pty Ltd The Valspar (Australia) Corporation Pty Ltd	Polymer in Disperbyk 2091	ND*	< 30 tonnes per annum	Component of industrial coatings and ink

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, 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, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

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.

Hazard classification	*Hazard statement*
Acute Category 3	Harmful to aquatic life

Human health risk assessment
Under the conditions of the occupational settings described, 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

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer in Disperbyk 2091 at the formulation sites and during use of coatings or ink containing the notified polymer in Disperbyk 2091:
  - Avoid contact with skin and eyes

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer in Disperbyk 2091:
  - Coveralls
  - Impermeable gloves

- Safety goggles

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 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.

Environment

- The notified polymer should be prevented from entering drains, sewers and watercourses.

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

- Spills/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 Da;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from being a component of ink or coating for industrial use, or is likely to change significantly;
- the amount of polymer being introduced has increased from 30 tonnes per annum, 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 MSDS of the product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Nuplex Industries (Aust) Pty Ltd (ABN 25 000 045 572)
49-61 Stephen Road, BOTANY, NSW 2019

The Valspar (Australia) Corporation Pty Limited (ABN 40 000 053 914)
Level 4, 2 Burbank Place, BAULKHAM HILLS, NSW 2153

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, polymer constituents, residual monomers/impurities, use details and import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Melting point/Boiling point, Partition Co-efficient, Flammability Limits, Adsorption/Desorption, Dissociation Constant, Explosive Properties, Water Solubility, Oxidising Properties, and Hydrolysis as a function of pH.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (2004) and Canada (2009)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Disperbyk 2091 (product containing the notified polymer)

MOLECULAR WEIGHT
> 1,000 Da

ANALYTICAL DATA
Reference IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 90%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
The notified polymer is stable under normal conditions of use and storage. No loss of monomers or other reactants is expected.

DEGRADATION PRODUCTS
The notified polymer is stable under normal conditions of use and storage. Degradation products on heating are expected to be oxides of carbon, nitrogen and phosphate.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: yellow liquid (product)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	-

Boiling Point	Not determined	Imported in liquid formulation
Density	1075 kg/m^3	Product MSDS
Vapour Pressure	Not determined	Based on the high molecular weight, vapour pressure is expected to be low.
Water Solubility	Not determined	Expected to be dispersible in water based on the presence of hydrophilic functionality and its use in aqueous products.
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionality. However, significant hydrolysis is not expected under environmental conditions (pH 4-9).
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is surface active and will tend to accumulate at the phase interface of octanol and water.
Adsorption/Desorption	Not determined	Expected to partition to surfaces from water in the environment based on its surface activity.
Dissociation Constant	Not determined	The notified polymer is a salt with the potential to dissociate under environmental conditions (pH 4-9).
Particle Size	Not determined	The notified polymer is supplied in liquid formulation.
Flash Point	Not determined	Not isolated from formulation.
Autoignition Temperature	Not determined	Not isolated from formulation.
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative properties

DISCUSSION OF PROPERTIES

Reactivity
The notified polymer is not expected to be reactive under the normal conditions of use and handling.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not 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.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported into Australia at < 50% in a product in sealed steel 25 kg or 200 kg drums for reformulation into paints and inks at < 5%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 30	< 30	< 30	< 30	< 30

PORT OF ENTRY
Melbourne, Sydney, Brisbane, Perth

TRANSPORTATION AND PACKAGING
The notified polymer will be transported by road or rail in sealed 25 kg or 200 kg drums. The paints and inks containing the new polymer will be stored and transported in suitable packages.

USE
Component of industrial coatings and ink at < 5%. The polymer is a wetting and dispersion additive for pigment concentrates.

OPERATION DESCRIPTION
Paint or ink formulation
At the formulation sites, the product containing the notified polymer will be manually weighed or metered directly from the storage drums into the processing vessel. The notified polymer will then be mixed with the other components of the formulated product (pigment, resin, solvent, etc.). The final coating or ink product contains < 5% notified polymer. Samples will be removed at this stage for quality control testing by laboratory technicians. The final product will then be filled into suitable packages.

Paint application
Coatings (< 5% notified polymer) will be applied by spray (90%), brush (5%) or roller (5%) in industrial settings. Prior to application, the paint will be manually stirred and poured into trays or into the spray guns. Spray applications may be performed manually or using an automated system and will be conducted in spray booths at industrial sites.

Ink
Ink containing the notified polymer (< 5%) will be applied in industrial settings. Once ready for use, a pipe or hose will be connected to the containers holding ink formulations containing the notified polymer and the ink will be transferred to inkjet printing machines via an automated and enclosed process. The printer will transfer the ink containing the notified polymer onto the printing substrate, which will be dispensed with the ink bound to the surface in a cured, inert matrix. Once the ink has been consumed, the empty ink container will be disconnected from the printer and will be replaced with a new container of ink.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport	2-3	10-15
Coating blending	8	50
Laboratory	1	20
Application	6	260

EXPOSURE DETAILS
Transport and storage workers are not expected to be exposed to the notified polymer except in the unlikely event of an accident.

Paint or ink formulation
Dermal and ocular exposure to the notified polymer may occur when manually weighing, connecting and disconnecting pumps, charging the blending vessels, and taking samples (< 50% notified polymer) from the blending vessel by laboratory technicians. Similar exposure may also occur during routine cleaning and maintenance of equipment, and cleaning up of spills or leaks. Inhalation exposure to vapours and aerosols is not likely during blending due to the low vapour pressure of the notified polymer.

In all cases of where potential exposure may occur, the use of personal protective equipment (PPE) such as coveralls, safety glasses, and gloves used by workers will minimise exposure. Local exhaust ventilation will be employed in areas where weighing and charging of the blending vessels occur, to limit inhalation exposure to the notified polymer.

Paint application
Dermal and ocular exposure to the notified polymer (< 5%) may occur during the manual addition of coating to

spray guns, spray application and when cleaning up equipment. Inhalation exposure is possible during spraying.

Dermal and ocular exposure to the notified polymer (< 5%) may occur during brush and roller application particularly during manual decanting and manual application and when cleaning equipment.

To minimise exposure to the notified polymer the end users will wear eye protection, coveralls, gloves, and, if necessary, an air respirator. Furthermore, all spray applications will be conducted within spray booths at industrial manufacturing facilities to minimise inhalation exposure.

Workers may make dermal contact with the notified polymer once the coating formulation (< 5% notified polymer) is dried. However once dried the coating will form an inert film that will contain and immobilise the notified polymer.

Ink
The printing operators will be involved in the connecting/disconnecting of transfer pipes from the ink containers to the printing equipment. To reduce exposure to inks containing the notified polymer at < 5% and the staining of skin caused by the ink, the printing operators are recommended to wear appropriate personal protective equipment including safety glasses, gloves, coveralls and aprons while performing any printing tasks.

6.1.2. Public Exposure
The notified polymer and products containing the notified polymer will not be available for use by the general public. The public may have dermal exposure to coated or printed surfaces containing the notified polymer; however the notified polymer will be part of an inert matrix and is not expected to be bioavailable.

6.2. Human Health Effects Assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity (concentration not known)

Toxicokinetics, metabolism and distribution
Dermal absorption of the notified polymer is expected to be limited by the high molecular weight (> 1,000 Da). However low molecular weight species may be present.

Acute toxicity
It is not clear from the test report whether the acute oral study, which resulted in a LD50 of > 2000 mg/kg bw in rats, was carried out on the notified polymer at 100% or at a lower concentration. If carried out on the polymer itself, it is indicative of low acute toxicity via the oral route.

No toxicological data was available for other endpoints. The notified polymer contains a functional group of concern for irritation/corrosion, and these effects cannot be ruled out.

Health hazard classification
Based on the limited data available the notified polymer cannot be classified as hazardous according to the Approved Criteria for Classifying Hazardous Substances (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Only limited toxicological data is available on the notified polymer and the notified polymer may cause corrosion/irritation based on structural alerts. The results on the endpoint tested (acute oral toxicity) indicate low hazard for this endpoint; however the concentration tested is not clear. The risk of systemic effects from exposure to the notified polymer is expected to be reduced by its high molecular weight (> 1,000 Da).

Paint/ink formulation

During reformulation workers will handle the notified polymer at < 50%, however exposure is expected to be low, if workplace engineering controls and PPE are used.

Paint application

During application of the coatings, there is potential for inhalation, dermal and ocular exposure to paints containing the notified polymer at concentrations < 5%. Exposure to the notified polymer during end use applications is expected to be low due to the reduced concentration and the use of engineering controls including use of spray booths for spray application and appropriate PPE.

Overall the risk to workers from use in coatings is not considered to be unreasonable.

Ink

Service technicians handling ink products containing the notified polymer (< 5%) may have frequent dermal exposure to the notified polymer, particularly during manual replacement of ink containers, cleaning of ink residues and servicing the printing machine. However, the exposure is expected to be limited by the nature of the printing process and the reduced concentration of the notified polymer within the ink (< 5%). The use of adequate PPE (i.e., impervious gloves) further reduces the risk from exposure. Once the ink is applied to the substrate and dried, the notified polymer would not be bioavailable.

Overall the risk to workers from use in printing is not considered to be unreasonable.

6.3.2. Public Health

Paint

Paint products containing the notified polymer will not be sold to the public. The public may experience dermal exposure to surfaces to which paint containing the notified polymer has been applied. However, exposure is not expected as the notified polymer (< 5%) will be bound within the paint film. Therefore the risk to the public from the notified polymer is not considered to be unreasonable.

Ink

The inks containing the notified polymer at < 5% will not be sold to the public. The public may have contact with the dried printed materials, however the notified polymer will be bound in the print matrix and will not be bioavailable. Therefore, exposure of the public to the notified polymer is not expected, and the risk is not considered 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 manufactured in Australia and no release from this activity is expected. Environmental release may occur during importation, storage, transport and distribution due to accidental spills. In the event of a spill, the notified polymer is expected to be contained and collected with an inert material and be safely disposed of in accordance with local regulations.

Imported products containing the notified polymer will be reformulated into ink or paint products in Australia. During reformulation, up to 1% of the total annual import volume of the notified polymer (300 kg) is estimated to be released to sewers due to reformulation equipment washing. Accidental spills (1%) and residues in import drums (1%) will be collected by licensed waste contractors and are expected to be disposed of to landfill. During the recycling of empty drums, small amount of notified polymer from residues (1%) may be released to onsite sewage treatment where it will be treated, removed and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

Paint formulations containing the notified polymer are likely to be applied by spray techniques to a variety of substrates by industrial or commercial users. It is estimated that approximately 20-30% of the notified polymer will be lost from overspray when applied to articles. The overspray will be captured by engineering controls such as spray booths or on kraft paper or newspaper. Captured overspray is expected to be disposed of to landfill. It is estimated that 1% of notified polymer may be released to sewers from paint and printing application equipment washings following its use. During industrial use, it is estimated that less than 1% of the notified polymer may be spilt. Any wastes from spills are expected to be contained, collected and disposed to landfill. Residues remaining in end-use product containers (less than 1% of the total imported volume) are expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Notified polymer used in paints is expected to share the fate of the substrate to which it has been applied and is predominantly expected to be disposed of to landfill. Notified polymer in paints applied to metal articles may be thermally decomposed during metal reclamation processes at the end of the articles useful life. Notified polymer used in inks is expected to be disposed of to landfill along with the printed articles or be recycled when used on paper.

7.1.2. Environmental Fate

No environmental fate data were submitted. The majority of the notified polymer is expected to be disposed of to landfill along with the coated/printed articles or may be recycled when used on paper. In landfill, the notified polymer forms an inert polymeric matrix. In this form, it is not expected to be mobile or bioavailable, and therefore not expected to bioaccumulate. During paper recycling processes, the notified polymer may partition to the supernatant water based on its expected water solubility and is expected to be released to sewers. Some of the notified polymer is expected to be removed during the sewage treatment plant (STP) processes due to its high molecular weight. Based on the proportion of low molecular weight species below 1000 Da, 50% of the notified polymer is estimated to partition to sludge during STP processes. Sludge containing the notified polymer is expected to be disposed of to landfill or applied to soil for remediation of agricultural land. Notified polymer released to surface waters is expected to disperse and degrade. In water, landfill and soil, the notified polymer is expected to eventually degrade to form water and oxides of carbon, nitrogen and inorganic salts.

7.1.3. Predicted Environmental Concentration (PEC)

The notified polymer may be released to sewers through the disposal of wastewater generated during its reformulation, use and disposal.

The predicted environmental concentration (PEC) due to releases from reformulation is calculated assuming point-source release from site(s) of reformulation ($PEC_{point\text{-}source}$). It is also assumed that the reformulation happens 50 days per year with release into one STP that services 10% of the Australia population in one geographic location (452 ML/day). Based on the proportion of low molecular weight species below 1000 Da, it is assumed that 50% of the notified polymer is removed by adsorption to sludge during STP processes. A predicted $PEC_{point\text{-}source}$ are 6.64µg/L and 0.66 µg/L for river and ocean water, respectively, if the daily chemical release (300 kg/50 days × 50% removal = 3 kg/day) is diluted by the daily effluent production (452 ML).

The PEC due to releases from use and disposal is calculated assuming diffuse release Australia-wide ($PEC_{Australia\text{-}wide}$). The worst case scenario for $PEC_{Australia\text{-}wide}$ is where all imported notified polymer is used in printing ink on paper substrate. Based on typical recycling rate of paper products in Australia, it is estimated that 50% of the notified polymer will be released to sewer from paper recycling processes. It is assumed that 50% of the notified polymer will be removed by adsorption to sludge during STP processes and that release occurs on 260 days per year. The calculated result is summarised in the table below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	30,000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	15,000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	57.69	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	50%	Mitigation
Daily effluent production:	4,523	ML
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River:	6.38	µg/L
PEC - Ocean:	0.64	µg/L

Based on the above calculations, the maximum PEC for combined release from point-source and Australia-wide releases of the notified polymer is 13.02 µg/L (= 6.64 + 6.38) for river water and 1.30 µg/L (= 0.66 + 0.64) for ocean water, respectively.

The PEC for soils is calculated for the application of effluent and biosolids based on the above worst case scenario for diffuse release Australia-wide.

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 63.783 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/m^3 and a soil-mixing zone of 10 cm, the concentration of the notified polymer may approximate 425 µg/kg in applied soil. This assumes that degradation of the notified polymer occurs in the soil within 1 year from application. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated biosolids application, the concentration of notified polymer in the applied soil in 5 and 10 years may approximate 2125 µg/kg and 4250 µg/kg, respectively.

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 chemical 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 6.378 µg/L may potentially result in a soil concentration of approximately 42.52 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 212.6 µg/kg and 425.2 µg /kg, respectively.

7.2. **Environmental Effects Assessment**

Ecotoxicological investigations were conducted on the notified polymer for fish and the results are summarised in the table below. Details of the study can be found in Appendix B.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 (96 h) = 17.7 mg/L NOEC (96 h) = 12.5 mg/L	Harmful to fish

Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) the notified polymer is considered to be acutely harmful to fish. Therefore, based on the acute toxicity to fish, the notified polymer is formally classified as harmful to aquatic life under the GHS. On the basis of the available data, the notified polymer is not classified for long-term hazard under the GHS.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) was calculated using the acute ecotoxicological endpoint for fish (LC50 (96 h)) and an assessment factor of 1000, as only one trophic level endpoint is available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Fish (LC50 (96 h))	17.70	mg/L
Assessment Factor	1,000	
PNEC:	17.70	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	13.06	17.7	0.735
Q - Ocean:	1.30	17.7	0.073

The risk quotient (Q = PEC/PNEC) for aquatic exposure is calculated to be < 1 based on the above calculated PEC and PNEC values. The calculated risk quotient indicates a relatively narrow safety margin as a result of the toxicity of the notified polymer. However, the worst case scenario for aquatic exposure assumes 100% of the imported notified polymer is used in printing of paper substrate which is unlikely based on reported use in both paint and ink products. As the risk quotient is < 1, the notified polymer is therefore not expected to pose an unreasonable risk to the aquatic environment based on its assessed use pattern.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer (concentration unknown)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/SPF-Wistar
Vehicle	None
Remarks - Method	No protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 per sex	2,000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity	The test substance did not cause any toxic symptoms.
Effects in Organs	No clear pathologic findings occurred in the final autopsy in any of big body cavities and no pathological changes could be macroscopically observed which were due to the test procedure or the test substance.
Remarks - Results	There was no test dependent deviation on the development in weight gains after 14 days observation when comparing with controls.

CONCLUSION	The test substance is of low toxicity via the oral route.
TEST FACILITY	Pharmatox (2003)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Ecotoxicological Investigations

B.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test (1992)-Static.
Species	Golden orfe (*Leuciscus idus* L.)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	200 mg $CaCO_3$/L
Analytical Monitoring	Oxygen and pH meter
Remarks – Method	Conducted according to the guidelines above with no significant deviations from the protocol. No measured concentration of the test substance throughout the rest.

RESULTS

Concentration (mg/L)		*Number of Fish*	*Mortality (%)*				
Nominal	*Actual*		*6 h*	*24 h*	*48 h*	*72 h*	*96 h*
3.1		10	0	0	0	0	0
6.3		10	0	0	0	0	0
12.5		10	0	0	0	0	0
25.0		10	0	100	100	100	100
50.0		10	0	100	100	100	100

LC50	17.7 mg/L at 96 hours (95% confidence limit)
NOEC	12.5 mg/L at 96 hours
Remarks – Results	All validity criteria for the test were satisfied. Ten dead fish were observed in the test concentrations of 25 mg/L or higher after 24 hours exposure.
CONCLUSION	The notified polymer is harmful to fish
TEST FACILITY	BioChem agrar (2003)

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