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

FULL PUBLIC REPORT

Solsperse 19000

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**Director
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FULL PUBLIC REPORT

Solsperse 19000

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Orica Australia Pty Ltd of 1 Nicholson St, Melbourne, Victoria

NOTIFICATION CATEGORY

Limited: Polymer with NAMW ≥ 1000 (greater than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Identity and composition information

Purity

Manufacture/Import Volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for the following physical and chemical properties:

Hydrolysis as a function of pH

Absorption/Desorption

Dissociation Constant

Flammability Limits

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

No

NOTIFICATION IN OTHER COUNTRIES

USA PMN: P-01-184

Japan

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Solsperse 19000

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD Infra Red, ^1H NMR and ^{13}H NMR, and Mass Spectroscopy

Remarks

Spectra obtained were consistent with the expected structure for the notified polymer

TEST FACILITY

Avecia (2000 and 2001)

3. COMPOSITION

DEGRADATION PRODUCTS

The polymer is expected to be stable under normal conditions of use. Under extreme heat conditions e.g. fire, the inks containing the notified polymer will burn emitting noxious fumes containing oxides of carbon, nitrogen and sulphur

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

The polymer is stable under normal conditions of use so this is not expected.

4. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported from the United Kingdom

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>	<10	<30	<30	<30	<30

USE

The notified polymer is a dispersant used up to 2% in solvent based inks applied to paper (newspapers, magazines, catalogues, brochures etc).

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY

Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS

Inks will be manufactured by a variety of companies located throughout Australia.

TRANSPORTATION AND PACKAGING

The notified polymer will be imported in 20kg and 250kg open head steel pails and drums and will be warehoused at Laverton, Victoria, prior to distribution by road or rail to customer sites.

The inks will be stored and transported in polyethylene 20L pails or 200L drums. Transport will be by road or rail.

5.2. Operation Description

Ink manufacture:

The manufacture of the inks will involve two steps. In the first step, pigment, resin, solvent and dispersant (notified polymer) are weighed into a mill and mixed at high speed to produce the ink. The finished product is fed by gravity or pumped from the mill into containers. The closed containers are manually put on pallets and then taken by forklift to the warehouse for storage and distribution.

Ink application:

Inks containing the notified polymer will most likely be used in Publication Gravure and Offset and lithographic printing processes. A typical printing process involves charging the print machine, running the print and distributing the end product. In larger scale operations the inks could be fed to the print machine directly from the bulk containers under some form of controlled pressure. Excess ink is then returned to the same bulk container. Some on-site blending of inks may occur by computer controlled dispensing and metering equipment. The smaller operations may involve hand filling of the print machine reservoir from a small ink container.

Cleaning of the print machine involves removal of excess ink to containers for re-use or recycling, running the paper substrate back and forth and finally wiping with solvent. The solvent wet rags are collected in a metal fire-resistant closed container for disposal.

5.3. Occupational exposure

Number and Category of Workers

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Transport and warehouse workers	1		200
Ink manufacture/milling	40	4	100
Ink manufacture/filling	40	8	100
Ink application/addition to print machine	50	8	300
Ink application/cleaning of equipment	10	8	10

Exposure Details

Transport and distribution:

Transport and warehouse workers will be exposed to the notified polymer only in the event of a spill.

Ink Manufacture:

The notified polymer is a viscous liquid with predicted low vapour pressure and as such dermal contact is expected to be the main route of exposure. Incidental skin contact may occur during weighing and transfer of the dispersant into the high-speed mill, and when filling the ink containers. The notifier's MSDS recommends the use of impervious gloves, coveralls and safety glasses when handling the notified polymer. The milling and filling operations are expected to be conducted under local exhaust ventilation.

Ink application:

The notified polymer is present at a concentration of 1-2% in the formulated ink product and therefore potential exposure to this substance is effectively reduced.

Lithographic inks are more viscous, less mobile and less easily handled. They are more difficult to introduce into the print machine and as such there is greater potential for dermal exposure. Gravure printing uses thin mobile liquid inks. Printing tends to be suited to fast and longer runs with an expected greater potential for producing more ink fly and airborne ink particulates. Gravure printing will be far less common than offset lithographic printing (estimated at a quarter of the number of sites).

Dermal exposure could occur, when opening and handling ink containers, when introducing the ink into the print machine especially in small operations, from intermittent contact with printing rollers and from cleaning operations and contact with contaminated rags. Suitable gloves are expected to be used in all these operations.

Any inhalation exposure will be mainly the result of mist generation in high speed printing processes. The inks involved are all solvent based and therefore a minimum of 5 air changes per hour is advised. It is expected that there will be local or extract ventilation in all the printing sites.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Ink Manufacture

Potential spills during manufacture of inks will be contained through bunding. Less than 600 kg of the notified polymer will be released due to minor spills (less than 150 kg) and solvent cleaning of manufacturing equipment (less than 450 kg). This amount is expected to be either recycled in manufacturing or incinerated by licensed waste disposal contractors. The residual polymer left in drums is estimated to be less than 600 kg, which will be incinerated during drum recycling.

RELEASE OF CHEMICAL FROM USE

Good work practices are expected to minimise spillage during the printing process but solvent waste containing the notified polymer will be generated in cleaning ink application equipment (including the

solvent wet rags used to clean equipment). Less than 600 kg of the notified polymer will be collected by licensed waste disposal contractors for incineration.

The majority of the notified polymer will be bound to printed paper, which will be disposed of to landfill, recycled or incinerated. If recycled, all of the developer containing the notified polymer will be removed from the paper/pulp during the deinking stage of the recycling process and will remain in the aquatic phase or end up in the resultant sludge, which will be disposed of to landfill. Up to 900 kg residual polymer will be left in ink containers, which may be incinerated during container recycling. Smaller containers however, are more likely to be sent to landfill.

5.5. Disposal

Most of the waste polymer resulting from the ink manufacture and printing processes including the import drum residues is expected to be disposed of by incineration. Residual polymer left in ink containers may be landfilled. Ink residues in drums should not be disposed of to landfill if the ink is in liquid state. Solvent containing ink wastes are generally recycled or re-blended, distilled to recover the solvents or used as a fuel and incinerated.

The majority of the imported notified polymer will be bound to printed paper, which will be disposed of to landfill, recycled or incinerated.

5.6. Public exposure

Members of the public may be exposed to the notified polymer through handling of printed paper. However, the majority of the notified polymer is bound to the pigment, which in turn is encapsulated in the ink varnish. Once printed onto paper the notified polymer is bound and unavailable for release.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Brown Viscous Liquid
Melting Point/Freezing Point	-5°C
Remarks	From manufacturer's MSDS
Boiling Point	Approx 200°C at 101.3 kPa
Remarks	From manufacturer's MSDS
Density	0.956 kg/m ³
Remarks	From manufacturer's MSDS
Vapour Pressure	2.95 x 10 ⁻¹⁴ KPa at 25°C (Estimated theoretically).
Remarks	The vapour pressure estimate (noted to be fairly approximate) has been derived using MMP software and based on Lyman <i>et al</i> (1982). This very low estimate of vapour pressure is consistent with the high boiling point.
Water Solubility	3.4 x 10 ⁻³ g/L at 23°C ± 1°C
METHOD	Turbidimetric Method
REMARKS	The water solubility was determined by monitoring the decrease in turbidity with decreasing concentration. A concentrated suspension of the test substance was prepared in duplicate by dissolving approximately 0.002 g in 1 mL tetrahydrofuran and diluting to 100 mL with distilled water. Successive dilutions of the suspension were made with distilled water and the turbidity of each dilution measured using a turbidimeter.
	The test substance is slightly soluble (Mensink et al. 1995).

TEST FACILITY Avecia (2000)

Hydrolysis as a Function of pH Not determined.

Remarks Due to its very low water solubility, the notified polymer is unlikely to hydrolyse in the environmental pH range of 4 to 9 despite the presence of potentially hydrolysable groups.

Partition Coefficient (n-octanol/water) $\log P_{ow} > 4$ (estimated).

REMARKS The $\log P_{ow}$ could not be measured directly by the shake flask method due to the difficulty in distinguishing the water-octanol interface indicating that the test substance had precipitated out of solution. It was estimated using the water and n-octanol solubilities determined as summarised above and below. A nominal value of 10% w/w (100,000 mg/L) solubility in n-octanol was used for this purpose.

TEST FACILITY The high $\log P_{ow}$ is consistent with the poor water solubility indicating a high affinity for the organic phase and component of soils and sediments.
Avecia (2000)

Adsorption/Desorption Not determined.

Remarks The very low water solubility, the high solubility in n-octanol and the high $\log P_{ow}$ indicate that the notified polymer can become associated with soils and sediments and be immobile in soil. This will be strengthened by the cationic nature of the polymer.

Dissociation Constant Not determined.

Remarks The notified polymer is not expected to dissociate due to its poor solubility in water. There are also no groups, which could potentially dissociate.

Particle Size

Remarks Not applicable as notified polymer is a liquid.

Flash Point $205 \pm 10^{\circ}\text{C}$

METHOD Setaflash Tester, ASTM D3828-87
TEST FACILITY Syngenta (2001)

Flash Point $>95^{\circ}\text{C}$

METHOD TAG closed cup to Japanese Industrial Standard JIS K 2265 'Testing Methods for Flash Point of Crude Oil and Petroleum Products'
TEST FACILITY Syngenta (2001)

Flash Point 218°C

METHOD Cleveland open cup to Japanese Industrial Standard JIS K 2265 'Testing Methods for Flash Point of Crude Oil and Petroleum Products'
TEST FACILITY Syngenta (2001)

Autoignition Temperature $395\text{-}400 \pm 5^{\circ}\text{C}$

METHOD To Standard IEC 79-4: "Electrical Apparatus for Explosive Atmospheres, Part 4, Methods of Test for Ignition Temperature".
TEST FACILITY Syngenta (2001)

Explosive Properties

Remarks Not available for polymer but it is expected to be stable under normal use conditions

Reactivity

Remarks

The polymer is stable but like other organic compounds should be segregated from reactive materials such as oxidising agents.

ADDITIONAL TESTS

n-Octanol Solubility

Miscible in all proportions at 25°C ± 1°C

METHOD	Visual Method
REMARKS	The test substance was mixed in varying proportions with n-octanol, stirred for 15 to 20 minutes and checked for any undissolved material.
TEST FACILITY	Avecia (2000)

Stability Testing

METHOD	OECD TG 113 Screening Test for Thermal Stability and Stability in Air.
Remarks	Accelerated Storage test conducted (CIPAC). No significant degradation occurred
TEST FACILITY	Avecia (2000)

7. TOXICOLOGICAL INVESTIGATIONS

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Rat, acute oral	LD50 >2000 mg/kg bw low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Genotoxicity - bacterial reverse mutation	non mutagenic

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 96/54/EEC B.1 tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Sprague-Dawley Crl:CD (SD) IGS BR
Vehicle	Distilled Water
Remarks - Method	

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	3/females	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity	No signs of toxicity were noted during the study
Effects in Organs	No abnormalities detected
Remarks - Results	

CONCLUSION	The notified chemical is of low toxicity via the oral route.
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TEST FACILITY	SafePharm Laboratories (2000a)
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7.2. Irritation – skin

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	

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	2	3			
Erythema/Eschar	0	0.33	0	1	24	0
Oedema	0		0	0	0	0

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

Remarks - Results Very slight erythema was seen at one treated skin site at the 24 hour observation but was not seen at the 48 hour observation. Treated skin sites of all animals appeared normal at the 72-hour observation

CONCLUSION The notified chemical is slightly irritating to skin.

TEST FACILITY SafePharm Laboratories (2000b)

7.3. Irritation - eye

TEST SUBSTANCE Notified polymer

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Observation Period 72 hours
Remarks - Method

RESULTS

Lesion	Mean Score* Animal No.			Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period
	1	2	3			
Conjunctiva: redness	0.66	0.33	0.33	2	48hr	0
Conjunctiva: chemosis	0	0	0	1	1	0
Conjunctiva: discharge	0	0.33	0	2	24hr	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	0	0	0

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

Remarks - Results Individual reactions included moderate conjunctival irritation. Treated eyes appeared normal 48 – 72 hours after treatment.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY SafePharm (2000c)

7.4. Genotoxicity - bacteria

TEST SUBSTANCE Notified polymer

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 92/69/EEC B.14 Mutagenicity – Reverse Mutation Test using Bacteria. Pre incubation procedure
Species/Strain *S. typhimurium*:
TA1535, TA1537, TA98, TA100, TA102.
E. coli: WP2 uvrA⁻.
Metabolic Activation System Phenobarbitone/β-naphthoflavone induced rat liver S9 fraction
Concentration Range in Main Test a) TA100 with and without metabolic activation: 5-1500 µg/plate.
b) TA98, TA1535, TA1537 without metabolic activation only: 5-1500 µg/plate.
c) TA102, WP2uvrA⁻ with and without metabolic activation: 15-5000 µg/plate
d) TA98, TA1535, TA1537 with metabolic activation only: 15-5000 µg/plate
Vehicle DMSO
Remarks - Method Two independent experiments using pre-incubation test, with and without

metabolic activation were conducted in triplicate. Experiment 1 (Test 1) was used as a range-finding study for the main study (Test 2)

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>	500 (TA100), 1500 (WP2uvrA ⁻)			
Test 1		500 (TA100), 500(TA1535), 500 (TA1537) 1500 (WP2uvrA ⁻) 1500 (TA102) 1500 (TA98)	500	None
Test 2		500 (TA100), 500(TA1535), 500 (TA1537) 1500 (WP2uvrA ⁻) 1500 (TA102) 1500 (TA98)	500	None
<i>Present</i>	1500 (TA100), 5000 (WP2uvrA ⁻)			
Test 1		1500 (TA100) 1500 (TA1537) 5000 (TA1535) 5000 (TA102) 5000 (TA98)	500	None
Test 2		1500 (TA100) 1500 (TA1537) 5000 (TA1535) 5000 (TA102) 5000 (TA98)	500	None
Remarks - Results	No significant increase in the frequency of revertant colonies was recorded for any bacterial strain used with any dose of the test material in two separate experiments either with or without metabolic activation.			
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.			
TEST FACILITY	SafePharm Laboratories (2002)			

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301C Ready Biodegradability: Modified MITI Test (I)
Inoculum	Activated sludge from 10 locations in Japan including return sludge from sewage plants and surface water and surface soil (in contact with the atmosphere) associated with rivers, lakes and sea.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Dissolved Organic Carbon (DOC) and HPLC analysis
Remarks - Method	In addition to the test substance (100 mg/L), blank samples and samples containing a reference substance (aniline) were measured.

RESULTS

Remarks - Results	Detailed data on the biodegradation of the test substance or the reference substance over time were not included in the report. After 28 days, the biodegradation of the test substance was 81% and 94% based on the DOC levels and the HPLC analysis, respectively. The reference substance degraded up to 78% after 14 days thus validating the study.
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CONCLUSION	The test substance is readily biodegradable.
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TEST FACILITY	Kurume Laboratory (2001)
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8.1.2. Bioaccumulation

No bioaccumulation data were provided. The very low water solubility, the high n-octanol solubility and the high estimated log P_{ow} may indicate a potential for bioaccumulation. However, the high molecular weight will limit bioaccumulation.

8.2. Ecotoxicological investigations

8.2.1. Algal growth inhibition

TEST SUBSTANCE	Notified polymer
METHOD	Brixham Environmental Laboratory Standard Operating Procedure BA217, version 05
Species	<i>Selenastrum capricornutum</i>
Exposure Period	72 hours
Concentration Range	
Nominal	0, 0.10, 1.0, 10 and 100 mg/L
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Not reported
Remarks - Method	The 100 mg/L test solution was prepared by dispersing 0.10 mg of the test substance in 1000 mL of culture medium. No details on the pH, lighting and temperature were included in the summary test report provided.

RESULTS

E _r C ₅₀	In the range of 0.1-1.0 mg/L
Remarks - Results	The 100 mg/L test solution was observed to be a milky opaque suspension. No information was provided on cell damage or measured test concentrations.
CONCLUSION	The test substance is very toxic to algae.
TEST FACILITY	Brixham Environmental Laboratory (2000)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The total import volume of the notified polymer will ultimately be disposed of to landfill, incinerated or recycled with paper. The main environmental exposure, however, will result from printed-paper, which may be disposed of to landfill, incinerated or recycled. During the paper recycling process, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. Trade sources estimate the washing process will recover 30-60% of the total amount of ink and therefore, at least 30% of the notified polymer in the recycled paper will be disposed of with sludge in landfill. Any of the notified polymer partitioned to the supernatant water will be released to sewer.

The high log P_{ow} and n-octanol solubility and the poor water solubility of the notified polymer indicate a high affinity for the organic phase and component of soils and sediments. In landfill, the notified polymer bound to the printed-paper or sludge is not expected to be released easily. Due to its cationic charges, the notified polymer is expected to interact strongly with negatively charged colloidal material in soils with a high content of carboxylic acid residues. Therefore, if released in landfill it can be expected to be adsorbed to soil and not further transported in the soil environment. Further, due to its ready biodegradability, it is anticipated that the notified polymer bound to printed-paper and to sludge would eventually degrade due to biotic and abiotic processes.

Cationic polymers with a number average molecular weight greater than 1,000 are assumed to partition mainly to the solids phase and to be 90% removed relative to the total influent concentration. The remainder of 10% is assumed to be discharged in the form of polymer sorbed to sludge solids (Boethling and Nabholz 1997). Therefore, the majority of the notified polymer entering sewage systems is expected to be adsorbed to sludge at treatment facilities.

No data on bioaccumulation was included in the notification, but the high log P_{ow} and n-octanol solubility and the low water solubility indicate a potential for bioaccumulation. However, the ready biodegradability and the high molecular weight of the polymer will reduce this potential.

9.1.2. Environment – effects assessment

The results of one toxicity test were provided.

<i>Organism</i>	<i>Duration</i>	<i>End Point</i>	<i>mg/L</i>
Algae	72-h	E _r C50	0.1 – 1.0

A predicted no effect concentration (PNEC - aquatic ecosystems) of $> 0.1 \mu\text{g/L}$ ($> 1.0 \times 10^{-4} \text{ mg/L}$) has been derived by dividing the minimum end point value of $> 0.1 \text{ mg/L}$ by a worst-case scenario uncertainty (safety) factor of 1000 (as toxicity data are available only for one trophic level).

9.1.3. Environment – risk characterisation

The notified polymer will enter the environmental compartments via disposal of waste printed-paper (to landfill, recycling or incineration) and waste material or sludge containing the polymer to landfill sites. When incinerated the notified polymer will be destroyed generating water vapour and oxides of carbon, nitrogen and sulphur. In landfill, the polymer can be expected to become immobile and eventually degrade.

Recycling may take place in a number of centres throughout Australia. A predicted environmental concentration (PEC) in the aquatic environment is estimated below using a worst-case scenario where a maximum of 27,300 kg (30,000 kg minus the losses during ink manufacture and printing of up to 2700 kg) is released to sewers nationwide due to paper recycling (Environment Australia 2003).

However, considering the extent of paper recycling, recovery of ink containing the polymer during paper recycling and the removal in sewage treatment, the following assumptions are used to estimate the PEC:

- only 50% of the printed-paper containing the notified polymer will be recycled;
- approximately 50% of the polymer in the recycled paper will be recovered in the aqueous phase with the ink removed during recycling; and
- 90% of the polymer entering the sewage treatment is adsorbed on to the sludge.

Assuming a national population of 20 million and that each person contributes an average 200 L/day to overall sewage flows, the daily release on a nationwide basis to receiving waters is estimated to be 18.7 kg/day. The predicted concentration in sewage effluent on a nationwide basis is estimated to be 0.4675 µg/L. Based on dilution factors of 1 and 10 for inland and ocean discharges of STP-treated effluents, the PECs of the notified polymer in fresh and marine water are 0.4675 µg/L and 0.0467 µg/L, respectively.

Based on the above PEC values, the risk quotients (PEC/PNEC ratios) for the aquatic environment are <4.7 and <0.5 for freshwater and marine water, respectively. The value for freshwater is slightly above 1, indicating a potential concern to the aquatic compartment. However, the calculations are based on the maximum tonnage and a limit value for the PNEC. If a PNEC of 0.5 µg/L is assumed, the freshwater quotient is <1.

Further, most natural waters contain colloidal humic material, which is negatively charged as a consequence of its high content of carboxylate groups. The notified polymer released to the water compartment would become associated with colloidal material and eventually assimilated into bottom sediments and would be unlikely to be re-mobilised. Therefore, when the sewer water is discharged into aquatic environment, the resulting risk quotients can be expected to be reduced below 1. Based on the above risk assessment, the ink manufacture of the notified polymer is unlikely to pose an unacceptable risk to the aquatic life.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Workers involved in manufacturing of ink are assessed as having a greater risk of exposure than workers handling the finished ink (containing 1-2% notified polymer) during printing processes, as these workers will handle concentrated amounts of the notified polymer. Due to the physical nature of the notified polymer (viscous liquid, low vapour pressure) dermal contact is expected to be the main route of exposure. Engineering controls and the use of PPE should reduce exposure to the notified polymer.

Dermal and inhalation exposure are the most likely routes workers during printing. Dermal exposure is most likely with the use of lithographic inks and/or in smaller operations where print machines are hand filled. Inhalation exposure is most likely in gravure printing where there is a greater potential for producing more ink fly and airborne ink particulates.

The US EPA generic scenario for manufacturing and printing of ink quotes dermal exposure of 1800 mg/day, assuming incidental contact with hands when transferring ink to printers, connecting transfer lines etc. With a 1% concentration and 70kg operative this leads to a potential dermal exposure to the notified chemical of 0.26 mg/kg/day.

A median value concentration of ink of 0.45 mg/m³ has been reported from a monitoring study at a newspaper plant in San Francisco. For an 8 hour day, 1.3m³/h inhalation rate, 70 kg operative and 1% concentration, the daily exposure assuming 100% uptake from the lungs is 0.0006 mg/kg/day.

Engineering controls and the use of PPE should reduce exposure to the notified polymer. Controls which adequately cover exposure to organic solvent vapours to below the advised

occupational exposure standards should also control inhalation exposure to the notified polymer to a level of no concern.

Exposure during transport and warehousing is only likely in the case of accidental spills.

9.2.2. Public health – exposure assessment

Public exposure to the notified polymer is expected to be negligible, as the notified polymer is bound to the paper and is not biologically available

9.2.3. Human health - effects assessment

The notified polymer has low acute oral toxicity in rat. It is a slight skin and eye irritant in rabbits and is non- mutagenic in a bacterial reverse mutation assay. The high molecular weight of the notified polymer indicates that it will not be readily absorbed.

The notifier's MSDS indicates that mists or aerosols may be irritating to the respiratory system.

Based on the limited information available, the notified polymer is not determined to be a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

9.2.4. Occupational health and safety – risk characterisation

Workers involved in manufacturing will handle concentrated amounts of notified polymer when weighing, transferring and mixing. Dermal and inhalation exposure are the most likely routes. The notified polymer is described as a slight eye and skin irritant; therefore, workers will require skin (gloves and overalls) and eye protection (goggles). Mists and aerosols of the notified polymer may be irritating to the respiratory system. Since the vapour pressure of the notified polymer is low, the inhalation risk to workers is likely to be low. In addition, the use of adequate ventilation, including local exhaust ventilation will provide respiratory protection.

During printing processes, dermal and inhalation exposure to 1-2% notified polymer may occur. At these concentrations the ink may exhibit eye and skin irritation. Therefore, workers will need to use personal protective equipment (gloves, overalls and goggles) to protect them against dermal, and accidental ocular exposure. Mist generation may occur during high speed printing processes. As mists and aerosols of the notified polymer may be irritating to the respiratory system, workers should have adequate ventilation or use respirators.

Exposure to printing workers was estimated to be 0.26mg/kg bw/day. This estimate is low, so in view of high molecular weight and poor absorption, the risk of systemic effects is very low.

9.2.5. Public health – risk characterisation

Public exposure to the notified polymer is expected to be negligible and therefore, the risk to public health from exposure to the notified polymer is considered low

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

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

As a comparison only, the classification of notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

According to the criteria of the GHS (United Nations, 2003), the notified polymer is classified as Acute I (very toxic to aquatic life).

10.2. Environmental risk assessment

On the basis of the mitigated PEC/PNEC ratio, the notified polymer is not considered to pose a risk to the aquatic environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described (engineering controls and personal protective equipment).

10.3.2. Public health

There is Negligible Concern to public health when used as specified in the notification.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS

Hazard Classification and Labelling

- Use the following safety phrases for the notified polymer (as introduced and in inks)

S24/S25	Avoid contact with skin and eyes
S36/37/39	Wear suitable protective clothing, gloves and eye/face protection
S38	In case of insufficient ventilation, wear suitable respirator

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical [as introduced and in the ink]:
 - Exhaust ventilation during weighing, milling, filling manufacture operations and charging and running of the print machine.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical [as introduced and in the ink]:
 - NOHSC exposure standards for all of the components of the final ink formulation should not be exceeded in the workplace
 - Prevent splashes and spills
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical [as introduced and

in the ink]:

- Chemical resistant gloves, protective clothing which protects the body, arms and legs and goggles or safety glasses.

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

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

Disposal

- The notified polymer should be disposed of through a licensed waste contractor. Normally suitable for incineration by an approved agent.

Emergency procedures

- Clean up any spills immediately. Contain and prevent runoff into drains and waterways.
- Use absorbent material (soil, sand or any other inert material), collect and seal in properly labelled containers or drums for disposal.
- Advise local emergency services, if sewers or waterways have been contaminated.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the method of use changes in such a way as to further increase the environmental exposure of the notified substance particularly to natural waters, or
 - additional information becomes available on adverse environmental effects of the notified substance, or
 - the import quantity is to be increased greater than 30 tonnesor
- (2) Under Section 64(2) of the Act:
 - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

Any secondary notification should include full results and reports for fish, daphnia and algae studies as well as more specific information on the likely adsorption to sludge etc..

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