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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in E-4224

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Cytec Australia Holdings Pty Ltd (ABN 45 081 148 629)
Suite 1, 1st Floor, 21 Solent Circuit
Norwest Business Park
Baulkham Hills, NSW 2153.

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:
Chemical name
Other names
CAS number
Molecular formula
Structural formula
Spectral data
Identity and weight % of toxic or hazardous impurities
Non-hazardous impurities
Identity and weight % of additives and adjuvants
Polymer ingredients and weight %
Number average molecular weight
Residual monomers and other reactants
Low molecular weight polymer
Degradation products
Loss of monomers, additives, impurities

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT
None

NOTIFICATION IN OTHER COUNTRIES
USA: TSCA
Canada: CEPA Schedule VI
Korea: NIER, MOL

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
E-4224
CT-648-98
SUPERFLOC C-4224 Flocculant
CYSEP 4224 Processing Aid
SUPERFLOC C-2124 Flocculant

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	The notified polymer may be characterised using infrared and ^{13}C nmr spectroscopy.
Remarks	Reference spectra have been provided.

3. COMPOSITION

DEGREE OF PURITY
Approximately 99 %

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None present at above the relevant cutoffs for classification of the notified polymer as a hazardous substance (NOHSC, 1999b).

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured , reformulated or repackaged in Australia. It will be imported as the product E-4224, containing 10 – 30 % notified polymer in aqueous solution.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The import volume will be in the range of 2 – 11 tonnes per annum during the first five years of importation, averaging around 7 tonnes per annum.

USE
The notified polymer will be used as a flocculant for liquid/solid separation processes in wastewater treatment, including oil refinery wastewater, and also for separation of fermentation broths in biotechnology applications. Approximately 80 % will be used in oil refineries, with the remainder evenly split between the other uses.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Initially United Transport Services warehouse at Arndell Park, NSW; thence to a variety of customer sites.

TRANSPORTATION AND PACKAGING
The notified polymer will be imported by sea by container, initially in 20 L pails, and later in 200 L drums and 1000 L Intermediate Bulk Containers (IBCs). It is likely that different types and sizes of containers will be used for different products as the scale of use is likely to differ. Transport to the warehouse and customer sites will be by road.

5.2. Operation Description

Only end-use applications of the notified polymer will occur in Australia. The procedures used for addition of the flocculant will vary depending on the scale and type of the operation for which the flocculant is used. In smaller scale operations, such as biotechnology applications, addition of the flocculant is likely to be a small, fully manual batch addition. In larger scale operations, such as wastewater treatment, flocculant addition will be via automatic dosing equipment. Addition levels will range between around 0.001 % or less notified polymer in wastewater treatment and of the order of 0.5 to 1 % notified polymer in biotechnology applications. The polymer adsorbs strongly to solids in the mixing tank, which are generally unwanted waste products. The resulting sludge, containing the polymer, is then removed from the system for disposal.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Waterside workers	5 - 10	2 – 3 hr/day	10 – 20 days per year
Transport drivers	5 - 10	2 – 3 hr/day	10 – 20 days per year
Warehouse and storage workers	10 - 20	2 – 3 hr/day	10 – 20 days per year
Plant operators	20 - 60	1 – 8 hr/day	daily

Exposure Details

Waterside, transport and warehouse workers will only handle closed containers of the product containing the notified polymer. No exposure is expected except in the case of an accident involving damage to the packaging.

When the flocculant is added in an automated process, the feed may either be directly from the imported containers (drums or IBCs), or pumped to a large storage tank for the automated dosing system. In both cases, exposure of workers may occur when the imported containers are open for insertion of the pump or metering system and when the pump or metering system is withdrawn from the empty container. This exposure would normally be confined to dermal contact with drips and spills of the product containing 10 – 30 % notified polymer on the surface of the equipment in contact with the flocculant. Accidental ocular contact from splashes may also occur. There may also be dermal exposure during sampling for quality control or during maintenance of the dosing system; contact with the wastewater containing very low levels of notified polymer may also occur.

For a manual process, the required volume of flocculant will be measured from the imported container, eg by dipping or decanting, and added to a vortex in a stirred open tank. Dermal exposure to the product containing 10 – 30 % notified polymer during decanting, and dermal and ocular exposure to splashes on addition to the open tank, may occur.

Eye protection such as splash goggles or face shield is used while handling the notified polymer solution, as the pH of the solution is in the range 3 – 3.5. Skin protection comprises impervious gloves, and apron and coveralls.

5.4. Release

RELEASE OF CHEMICAL AT SITE

No release of the notified polymer is expected during transport and storage except in the event of a transport accident.

RELEASE OF CHEMICAL FROM USE

No release is anticipated during use of the notified polymer as a flocculant in biotechnology applications. In these applications, the flocculant is typically used in pre-treatment processes in which flocculation is followed by centrifuging and filtering. These procedures are expected to remove all of the solids, including the notified polymer, from the liquids. The desired end product will usually be contained in the aqueous supernatant liquid. Clearance of the supernatant of unwanted contaminants, which include the notified polymer, is proven using analytical techniques. The unwanted solid material is expected to end up in landfill.

Some release of the polymer into the aquatic environment is possible during oil refining and wastewater treatment application. For example, in water treatment applications at oil refineries, the flocculant is added at the end of the primary treatment stage and prior to secondary treatment. During secondary treatment, the solids containing the notified polymer are settled out, while the effluent goes through to tertiary treatment. Similar procedures are expected to occur in other wastewater treatment applications. The notifier claims that field trials indicate less that 0.002 % of the polymer will remain in the liquid following flocculation. As such, the notifier conservatively estimates 1 % of the flocculant could be released in the effluent while the remaining 99 % will be retained in the solid flocculated wastes.

Assuming a maximum annual import volume of 50 tonnes of imported product, and a 99 % removal by binding, up to 10890 kg/year will be released to landfill for all sites including residues in containers; and 110 kg/year will be released into the sewer or waterways for all sites.

5.5. Disposal

The waste sludge, containing the notified polymer, is expected to be disposed in landfill.

5.6. Public exposure

It is expected that during transport, storage and use, exposure of the general public will be minimal, except in the event of an accidental spill of aqueous preparations containing the notified polymer. Care should be taken as these will render surfaces very slippery. Spills should be contained and absorbed with inert material and placed into appropriate labelled containers. Water and absorbent material should be added to the spill until the "slipperiness" is removed. Waste should be recycled if possible, or disposed of by thermal treatment or incineration in accordance with local, state, and federal regulations.

As a component in flocculant products for industrial use, the notified polymer will not be sold to the public. Once used the notified polymer will be contained in flocculated solid matter and disposed to landfill. Consequently, public exposure to the notified polymer is unlikely.

6. PHYSICAL AND CHEMICAL PROPERTIES

No test reports for physical and chemical properties were provided. A number of the quoted values are for the imported product, E-4224, which is a 10 – 30 % aqueous solution of notified polymer.

Appearance at 20ºC and 101.3 kPa White, grainy solid; imported as a slightly off-white dispersion with a polyamine odour.

Boiling Point 100ºC at 101.3 kPa

Remarks Result for product E-4224.

Density Approximately 1100 kg/m^3

Remarks Result for product E-4224.

Vapour Pressure 2.4 kPa at 20ºC

Remarks Result for product E-4224. The notified polymer is not expected to be volatile due to its high molecular weight and ionic nature.

Water Solubility 69.6 to 79.5 % w/w at 20°C

METHOD EC Directive 92/69/EEC A.6 Water Solubility (Flask Method).

Remarks The marketed products are solutions of 10 – 30 % notified polymer in water. A water solubility test was performed by placing various amounts of test material in double-distilled water, and shaking the test vessels at 30°C for 72 hours. The material was then allowed to stand for 24 hours before estimating solubility visually. The water solubility range could not be narrowed down further due to the gelatinous nature of the test material in water. At high concentrations the test material absorbed the double-distilled water to form a very viscous immobile gel.

TEST FACILITY SafePharm Laboratories Ltd (2002).

Hydrolysis as a Function of pH Not determined

Remarks Side chains may be hydrolysed under extreme pH conditions.

Partition Coefficient (n-octanol/water) Not determined

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient (Shake Flask Method).

Remarks Analytical Method: Gel permeation chromatography

Following a preliminary test, a definitive test was performed with 2 replicates of three test ratios each of water:octanol. Test mixtures were shaken by inversion for 5 minutes. After separation, aliquots of both phases were removed for analysis. The results indicate the test substance will have a poor affinity for lipids.

TEST FACILITY SafePharm Laboratories Ltd (2002).

Adsorption/Desorption Not determined

Remarks The notified polymer is expected to bind strongly to negatively charged soil particles and organic matter. Polycationic polymers, designed for use as flocculants, bind with dissolved organic carbon in the water column and eventually settle out and accumulate in sediments (Nabholz *et al* 1993).
The notifier, as a conservative estimate, anticipates 99 % of the notified polymer will be removed as solid waste, citing field trials showing clearance of polymer in liquid to < 20 ppm (< 0.002 %). The notifier provided raw data from field trials which showed settling rates, but no data on the final concentrations of the polymer remaining in the supernatant.

Dissociation Constant Not determined

Remarks The notified polymer does not contain any acidic or basic functional groups. Full dissociation of the ionic groups is expected in aqueous solution.

Particle Size Not determined

Remarks The notified polymer is never isolated from aqueous solution.

Flash Point > 100ºC

Remarks Pensky-Martens closed cup.

Flammability Limits Not flammable

Autoignition Temperature Will not self-ignite

Explosive Properties Not explosive

Reactivity

Remarks The notified polymer is expected to be stable under normal environmental conditions.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity
Rat, acute dermal 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 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Sprague-Dawley CD (Crl:CD(SD)IGS BR)
Vehicle	Distilled water, dose volume 40 mL/kg bw
Remarks - Method	The notified polymer was administered in two doses of 20 mL/kg bw, at a 1 hour interval

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3 per sex	2000	0/6

LD50	> 2000 mg/kg bw
Signs of Toxicity	All animals showed hunched posture which cleared by 3 days after dosing. Piloerection and/or diarrhoea were observed in five animals on the day of dosing.
Effects in Organs	No gross abnormalities were seen at necropsy.
Remarks - Results	All animals gained weight through the study.

CONCLUSION The notified polymer is of low toxicity via the oral route.

TEST FACILITY SafePharm Laboratories Ltd (1999a)

7.2. Acute toxicity - dermal

TEST SUBSTANCE Notified polymer.

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.

Species/Strain	Rat/Sprague-Dawley CD (Crl:CD(SD)IGS BR)
Vehicle	Distilled water
Type of dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	2000	0/10

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	No erythema or oedema was observed.
Signs of Toxicity - Systemic	No clinical signs of systemic toxicity were observed.
Effects in Organs	No gross abnormalities were seen at necropsy.
Remarks - Results	All animals gained weight through the study.

CONCLUSION The notified polymer is of low toxicity via the dermal route.

TEST FACILITY SafePharm Laboratories Ltd (1999b)

7.3. 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	Moistened with distilled water
Observation Period	3 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0.33	0	0.33	1	24 hr	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: Slight erythema was seen at 1 hour and 24 hours in two animals, clearing by 48 hours.

CONCLUSION: The notified polymer is slightly irritating to skin.

TEST FACILITY: SafePharm Laboratories Ltd (1999c)

7.4. 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: 7 days
Remarks - Method: An observation was made at 7 days to determine the reversibility of the observed irritation.

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	1.7	1.7	2.0	2	72 hours	0
Conjunctiva: chemosis	1.0	1.7	2.0	2	72 hours	0
Conjunctiva: discharge	1.3	1.7	2.0	3	72 hours	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results: All animals showed severe conjunctival irritation at 1 hour after dosing; the irritation persisted beyond 72 hours, with scores of 2 for redness, chemosis and discharge at 72 hours in one animal. All signs of conjunctival irritation cleared by day 7. No evidence of corneal or iris irritation was observed.

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

TEST FACILITY: SafePharm Laboratories Ltd (1999d)

7.5. Genotoxicity - bacteria

TEST SUBSTANCE: Notified polymer.

METHOD: OECD TG 471 Bacterial Reverse Mutation Test.

	EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2 uvrA
Metabolic Activation System	10 % rat liver S9 fraction from animals pretreated with phenobarbitone and β-naphthoflavone
Concentration Range in Main Test	a) With metabolic activation: 50 - 5000 µg/plate. b) Without metabolic activation: 50 - 5000 µg/plate.
Vehicle	Polyethylene glycol (PEG 400)
Remarks - Method	Two independent experiments were performed in triplicate.

RESULTS

Remarks - Results	No signs of cytotoxicity were observed at any concentration. Precipitation was observed at and above 1500 µg/plate in all tests. No increases in the number of revertant colonies were seen in either test, either in the presence or absence of metabolic activation. Appropriate positive controls were used and in all cases produced large increases in the number of revertant colonies, confirming the sensitivity of the test system.

CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	SafePharm Laboratories Ltd (1999e)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	E-4224 (15 – 22 % notified polymer in water)

METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Inoculum	Effluent from a sewage treatment plant
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Concentration of dissolved oxygen
Remarks - Method	A total of 5 vessels were prepared for the test. These were as follows: (1) the mineral medium, containing only mineral medium solution, (2) the inoculum blank, containing only the microbial inoculum, (3) the procedural control, containing 1 and 2, and sodium benzoate, (4) the test suspension, containing inoculum and a nominal concentration of 7.73 mg/L of test substance, and (5) the toxicity control, containing inoculum, the test substance and sodium benzoate. At intervals of 0, 7, 10, 14, 21, and 28 days, a portion of the test solution was syphoned off for measurement of the dissolved oxygen concentration. Samples were also analysed for the nitrite and nitrate concentration.

RESULTS

CT-648-98		*Sodium benzoate*	
Day	*% degradation*	*Day*	*% degradation*
14	0	14	83.2
28	0	28	89.2

Remarks - Results	The overall mean oxygen depletion for the test suspension after 28 days was < 0.0 mg O_2/mg test substance indicating 0 % degradation. This

compared to 89 % of the reference substance degraded after 28 days. The toxicity control did not inhibit degradation, since 35 % degradation of the reference material occurred within 14 days.

CONCLUSION The notified polymer is not readily biodegradable.

TEST FACILITY Toxikon Corporation (1999a).

8.1.2. Bioaccumulation

No test data for bioaccumulation were provided by the notifier. However, high molecular weight and low affinity for lipids of the notified polymer would preclude it moving across biological membranes, and hence the polymer should not bioacccumulate.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

Test 1

TEST SUBSTANCE Notified polymer (84 % purity)

METHOD OECD TG 203 Fish, Acute Toxicity Test–semi-static conditions.

Species	Rainbow Trout (*Oncorhynchus mykiss*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	Test concentrations by spectrophotometry
Remarks – Method	Following a preliminary range-finding study, fish were exposed, in groups of 10, to an aqueous solution of the test material containing nominal concentrations of 0.10, 0.18, 0.32, 0.56 and 1.0 mg/L. The number of mortalities and sub-lethal effects were determined 3 and 6 hours after the start of the test and then daily until the end of the test period. The measured test concentrations at 0 and 24 hours in the stock solution were near nominal, whereas measured concentrations at 48 and 73 hours were 21% and 196% of nominal. The variability was considered to be possibly due to the non-specific method of analysis.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*6h*	*24h*	*48h*	*72h*	*96h*
Control		10	0	0	0	0	0
0.10		10	0	0	0	0	0
0.18		10	0	0	0	0	0
0.32		10	0	0	0	0	0
0.56		10	0	0	0	4	6
1.0		10	0	0	9	10	10

LC50	0.53 mg/L at 96 hours (CI = 0.45-0.63 mg/L)
NOEC (or LOEC)	0.32 mg/L at 96 hours.
Remarks – Results	The highest test concentration resulting in 0% mortality was 0.32 mg/L, and the lowest test concentration resulting in 100% mortality was 1.0 mg/L. Sublethal effects of exposure to the notified polymer were observed at test concentrations of 0.56 mg/L and above. These included swimming at the surface, swimming at the bottom of the test vessel and loss of equilibrium.

CONCLUSION The notified polymer is highly toxic to rainbow trout (Mensink *et al*. 1995).

TEST FACILITY SafePharm Laboratories Ltd (1999f).

Test 2

TEST SUBSTANCE	Notified polymer (84 % purity)
METHOD	Acute Toxicity Test Mitigated by Humic Acid. US EPA Draft Ecological Effects Test Guideline OPPTS 850.1085
Species	Rainbow Trout (*Oncorhynchus mykiss*)
Exposure Period	96 hour
Auxiliary Solvent	None
Water Hardness	121 mg $CaCO_3$/L
Analytical Monitoring	Dissolved organic carbon for the concentration of humic acid.
Remarks – Method	Following a preliminary range-finding test, fish were exposed, in two groups of 10, to aqueous solutions containing nominal concentrations of 3.2, 5.6, 10, 18 and 32 mg/L of the test substance, and using dilution water with humic acid at a concentration of 10 mg/L. A further test was performed using nominal concentrations of 10, 18, 32, 56 and 100 mg/L and dilution water containing 20 mg/L of humic acid. Test solutions containing humic acid were observed to form brown solutions/dispersions upon preparation at 0 hours. After 24 hours, the dilution water containing 10 mg/L humic acid, and 0 (control), 10, 18 and 32 mg/L of test substance, remained brown solutions/dispersions. At concentrations of 3.2 and 5.6 mg/L a heavy brown precipitate was observed at the bottom of the test vessel. In the test solutions containing 20 mg/L of humic acid, a brown precipitate formed in vessels with concentrations of 10 and 18 mg/L of the test material.

RESULTS

Test Substance Concentration mg/L		*Number of Fish*	*Mortality in dilution water containing 10 mg/L of humic acid*					
Nominal	*Replicate*		*3h*	*6h*	*24h*	*48h*	*72h*	*96h*
Control	R1	10	0	0	0	0	0	0
	R2	10	0	0	0	0	0	0
3.2	R1	10	0	0	0	0	0	0
	R2	10	0	0	0	0	0	0
5.6	R1	10	0	0	0	0	0	0
	R2	10	0	0	0	0	0	0
10	R1	10	0	1	10	10	10	10
	R2	10	0	1	10	10	10	10
18	R!	10	2	10	10	10	10	10
	R2	10	2	10	10	10	10	10
32	R1	10	10	10	10	10	10	10
	R2	10	10	10	10	10	10	10

Test Substance Concentration mg/L		*Number of Fish*	*Mortality in dilution water containing 20 mg/L of humic acid*					
Nominal	*Replicate*		*3h*	*6h*	*24h*	*48h*	*72h*	*96h*
Control	R1	10	0	0	0	0	0	0
	R2	10	0	0	0	0	0	0
10	R1	10	0	0	0	0	0	0
	R2	10	0	0	0	0	0	0
18	R1	10	1	10	10	10	10	10
	R2	10	3	10	10	10	10	10
32	R1	10	2	10	10	10	10	10
	R2	10	2	10	10	10	10	10

56	R1	10	10	10	10	10	10	10
	R2	10	10	10	10	10	10	10
100	R1	10	10	10	10	10	10	10
	R2	10	10	10	10	10	10	10

LC50 7.5 mg/L at 96 hours in dilution water containing 10 mg/L humic acid.
13 mg/L at 96 hours in dilution water containing 20 mg/L humic acid.

NOEC (or LOEC) 5.6 mg/L at 96 hours in dilution water containing 10 mg/L humic acid.
10 mg/L at 96 hours in dilution water containing 20 mg/L humic acid.

Remarks – Results In the dilution water containing 10 mg/L humic acid, sub-lethal effects of exposure to the test material were observed at concentrations of 10 and 18 mg/L. In the dilution water containing 20 mg/L humic acid, sub-lethal effects of exposure to the test material were observed at concentrations of 18 and 32 mg/L. The sub-lethal responses were swimming at the surface and at the bottom of the test vessels.

CONCLUSION The presence of humic acid in the dilution water was observed to mitigate the toxicity of the test material to rainbow trout. The higher the concentrations of humic acid the greater the reduction in toxicity. The mitigating effects are thought to be due to the test material binding to the humic acid in the dilution water and thereby reducing bioavailability of the substance.

TEST FACILITY SafePharm Laboratories Ltd (1999g).

Test 3

TEST SUBSTANCE Notified polymer (84 % purity)

METHOD OECD TG 203 Fish, Acute Toxicity Test–semi-static conditions.
Species Bluegill Sunfish (*Lepomis macrochirus*)
Exposure Period 96 hours
Auxiliary Solvent None
Water Hardness 100 mg $CaCO_3$/L
Analytical Monitoring Stock solution concentrations.
Remarks – Method Following a preliminary range-finding study, fish were exposed, in groups of 10, to an aqueous solution of the test material containing nominal concentrations of 0.56, 1.0, 1.8, 3.2 and 5.6 mg/L of test substance. The test concentrations in the test vessels were below the limit of quantification of the analytical method employed, while the measured stock solution concentrations of 100 mg/L were shown to be near nominal.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*					
Nominal	*Actual*		*3h*	*6h*	*24h*	*48h*	*72h*	*96h*
Control		10	0	0	0	0	0	0
0.56		10	0	0	0	0	0	0
1.0		10	0	0	0	0	0	0
1.8		10	0	0	0	3	4	7
3.2		10	0	0	8	10	10	10
5.6		10	0	0	10	10	10	10

LC50 1.6 mg/L at 96 hours (CI = 1.3-1.9).

NOEC (or LOEC)	1.0 mg/L at 96 hours.
Remarks – Results	The highest test concentration resulting in 0 % mortality was 1.0 mg/L, while the lowest test concentration resulting in 100 % mortality was 3.2 mg/L. Sub-lethal effects of exposure to the notified substance were observed at concentrations of 1.8 mg/L and above. These effects were swimming at the surface and at the bottom of the test vessels.
CONCLUSION	The notified polymer is moderately toxic to bluegill sunfish (Mensink *et al*. 1995).
TEST FACILITY	SafePharm Laboratories Ltd (1999h).

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer (84 % purity)
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – static test conditions.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	Test concentrations by spectrophotometric analysis.
Remarks - Method	Following a preliminary range-finding test, 2 replicates of 10 animals each were exposed to nominal concentrations of 0.32, 0.56, 1.0, 1.8, 3.2, 5.6, 10, 18 and 32 mg/L of the test substance. Analyses of the concentration of test material was carried out on 5.6, 10, 18, 32 mg/L the test concentrations at 0 and 48 hours, and 100 mg/L stock solution at 0 hours. Concentrations below 5.6 mg/L were below the detection limit. Measured test concentrations were in excess of 80 % of nominal, except for a marked decline (55 and 39 % of nominal) in concentrations of 18 and 32 mg/L at 48 hours. The decline was thought to be due to the physical instability of the test material at these concentrations.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Replicate*		*24 h*	*48 h*
Control	R1	10	0	0
	R2	10	0	0
0.32	R1	10	0	0
	R2	10	0	0
0.56	R1	10	0	0
	R2	10	0	0
1.0	R1	10	0	0
	R2	10	0	0

1.8	R1	10	0	2
	R2	10	0	3
3.2	R1	10	0	7
	R2	10	0	6
5.6	R1	10	0	9
	R2	10	0	10
10	R1	10	6	10
	R2	10	3	10
18	R1	10	9	10
	R2	10	9	10
32	R1	10	10	10
	R2	10	10	10

LC50	11 mg/L at 24 hours 2.6 mg/L at 48 hours (CI = 2.2-3.1).
NOEC (or LOEC)	6.3 mg/L at 24 hours
Remarks - Results	The EC_{50} values are based on the time-weighted mean measured test concentrations given the decline in the measured concentrations over the 48 hour exposure period.
CONCLUSION	The test substance is moderately toxic to *Daphnia magna* (Mensink *et al*. 1995).
TEST FACILITY	SafePharm Laboratories Ltd (1999i).

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	E-4224 (15 – 22 % notified polymer in water)
METHOD	In house test protocol, following OECD GLP and Guidelines.
Species	*Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Range Nominal	0.0625, 0.125, 0.25, 0.5, and 1 mg whole material (wm)/L
Concentration Range Actual	Not measured
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Determination of the stability, purity, and characterization of the test substance was not performed.
Remarks - Method	Following a range-finding test, a definitive test was performed against algal cells using 3 replicates of each test concentration and 6 for the controls. All test solutions were prepared by mixing the required amount of test substance with the algal medium. Algal counts were conducted at 24, 48 and 72 hours after the start of the test. The pH of the test medium varied between 7.0 and 7.8 over the test period. The EC_{50} was determined using probit analysis.
RESULTS	After 72 hours of exposure, the percentage inhibition of cell growth compared to the control ranged from 3.24 % at nominal concentrations of 0.065 mg wm/L to 99.9 % at 1.0 mg wm/L. Observation of cell morphology detected no changes in cells exposed to the test material compared to the control.
EC50	E_bC_{50} = 0.16 mg wm/L (C.I. = 0.14-0.19 mg wm/L) E_rC_{50} could not be calculated
NOEC (or LOEC)	0.0625 mg wm/L
Remarks - Results	The test was performed using the end product (E-4224), which is contained in a solution of water and other ingredients. As such, the

	toxicity to algae may not be attributable to the notified polymer, but to one or a combination of the ingredients in the product, one of which is another cationic polymer at similar levels. The toxicity could be underestimated by up to a factor of 5 based on the concentration of the test material in the final product.
CONCLUSION	The test substance is very highly toxic to algae (Mensink *et al*. 1995).
TEST FACILITY	Toxikon Corporation (1999b).

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified polymer is a high molecular weight cationic polyelectrolyte intended for use as a flocculant in a number of industrial applications including biotechnology, oil refining and wastewater treatment applications. The polymer is able to flocculate suspended solids by scavenging negatively charged clays and humic substances, thereby forming larger flocs which are removed from the liquid phase by sedimentation or filtration.

The notifier, as a conservative estimate, anticipates 99 % of the notified polymer will be removed as solid waste, while the remaining 1 % of unconsumed flocculant could be discharged from each user site into the municipal sewer with the effluent water. It is expected that the 1 % of polymer released into the sewer from WWTP at user sites would continue to be adsorbed onto negatively charged colloidal material, and also eventually partition into sludge and sediments. Thus assuming a maximum annual import volume of 50 tonnes of end use product, being used evenly among 9 user sites over a 365 days period, we calculated the daily predicted environmental concentration (PEC) for the aquatic environment as follows:

A: Import volume of notified polymer (year 5)	11000 kg
B: Daily release per site (9 user sites)	3.35 kg
C: Loss by adsorption during use per site (99%)	3.31 kg
D: Release into company effluent (1%)	0.04 kg
E: Capacity of WWTP	2 ML
G: Concentration in company effluent	0.02 mg/L
H: Dilution factor in city sewer (1:125)	1.6×10^{-4} mg/L
I: Dilution factor in rural sewer (1:5)	4×10^{-3} mg/L
J: Loss by adsorption in city sewer (99%)	1.6×10^{-6} mg/L
K: Loss by adsorption in rural sewer (99%)	4×10^{-5} mg/L

These calculations assume all of the imported volume of polymer is used in oil refinery or wastewater treatment applications with on-site sewers. The values indicate that most of the polymer (up to 10890 kg) will be adsorbed and partition into solid phases in the on-site wastewater treatment facilities, where it will most likely be disposed to landfill with dewatered sludge.

The notified polymer is not expected to readily degrade either through biotic or abiotic mechanisms in the environment. No biodegradation of the end product containing the polymer occurred during the 28-day Ready Biodegradability test. However, the polymer contains groups on the side-chain which could undergo hydrolysis under extreme temperature and pH conditions leaving the polymer backbone intact.

9.1.2. Environment – effects assessment

The notifier provided test reports for two species of fish, and for daphnia and freshwater algae. The results of these tests indicate the notified polymer is moderately toxic to bluegill sunfish and daphnia, and is highly toxic to rainbow trout and freshwater algae. The most sensitive species is algae with an LC_{50} of 0.16 mg/L. The LC_{50} for algae could be as low as 0.03 mg/L given the test was conducted using nominal concentrations of the end product, which contained the notified polymer in a solution. The results of the Acute Toxicity Test Mitigated by Humic Acid indicate that the toxicity of the notified polymer is significantly reduced in the

presence of humic acid.

A predicted no effects concentration (PNEC) can be determined when at least one acute LC_{50} for each of the three trophic levels is available (ie. fish, daphnia, algae). The PNEC is calculated by taking the LC_{50} value of the most sensitive species, and dividing this value by an assessment safety factor. The most sensitive species was freshwater algae with a 96 hour LC_{50} of 0.16 mg/L (0.03 mg/L of notified polymer). Using a worst-case scenario safety factor of 100 (OECD), the $PNEC_{aquatic}$ is 3×10^{-4} mg/L.

No information was provided on the toxicity of the substance to soil or sediment dwelling organisms. Polycationic polymers designed for use as flocculants bind with dissolved organic carbon in the water column and eventually settle out and accumulate in sediments (Nabholz *et al* 1993). As such these substance are a potential hazard to benthic organisms. However, sediment toxicity testing with species which ingest sediment has shown that polycationic polymers with charge densities > 3.0 cations/1000 MWn, (or with more than 4.2 % amine nitrogen) as is the case here, are not bioavailable to cause any toxicity and are thus of low concern (Nabholz *et al* 1993).

9.1.3. Environment – risk characterisation

The notifier has indicated that at least 99 % of the polymer will partition into solid phases during application with the possibility of the remaining 1 % being released into the aquatic environment via industrial wastewater treatment facilities. Consequently, the daily PEC of the notified polymer discharged from each on-site treatment facility and into the domestic sewer of metropolitan and rural areas are in the order of 1.6×10^{-4} mg/L and 4×10^{-3} mg/L, respectively.

The polycationic nature of the notified polymer indicates that it will continue to bind strongly to organic and clay colloids in the sewer. Hence the polymer is expected to be largely eliminated either by settling in clarification tanks or by adsorption onto organic biomass in the sewer. The daily PEC in the sewer, assuming a continued 99 % binding rate, is in the order of 1.6×10^{-6} and 4×10^{-5} mg/L (for metropolitan and rural areas, respectively). These values would be further reduced once the polymer is released into the natural receiving waters.

The ecotoxicity data indicate the notified polymer is moderately toxic to bluegill sunfish and daphnia, and is highly toxic to rainbow trout and algae. The PEC/PNEC ratios calculated using the worst case algal toxicity are 0.05 for a metropolitan area, and 0.13 for a rural area, indicating no immediate concern for either metropolitan or rural areas.

The presence of humic acid in the dilution water was observed to mitigate the toxicity of the test material to rainbow trout. The higher the concentrations of humic acid in the test water the greater the reduction in toxicity. It is thought that this occurred because the test material bound to the humic acid in the dilution water, thereby reducing its bioavailability. Consequently, in natural waters where dissolved organic material and humic acids are typically present (Bolto, 1994), it is expected that the toxicity of the notified polymer to aquatic organisms would be further reduced by its adsorption onto suspended colloids (Nabholz *et al* 1993).

The environmental exposure and overall environmental hazard from the use of the notified polymer in waste-water treatment and oil refinery applications is acceptable, provided that the notified polymer is used in the correct dose commensurate with the quantity of organic compounds and suspended solids in the treatment facilities, which would allow the predicted 99 % removal. However, given the substance is not readily biodegradable and is toxic to aquatic organisms, it is recommended that the following statements be included in the MSDS: "Toxic to aquatic organisms." "Avoid overdosing treatment water." "Contain all spills. Do not allow it to enter waterways."

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

When the flocculant is added in an automated process, exposure of workers may occur when the imported containers are open for insertion of the pump or metering system and when the pump or metering system is withdrawn from the empty container, and during sampling for scientific testing, and maintenance. For a manual process, the required volume of flocculant will be measured from the imported container, eg by dipping or decanting, and added to a vortex in a stirred open tank. This is expected to lead to a higher risk of exposure than automated addition due to the greater handling time and increased splash risk.

Exposure would normally be confined to dermal contact with drips and spills of the product containing 10 – 30 % notified polymer on the surface of the equipment in contact with the

flocculant. Accidental ocular contact from splashes may also occur.

Eye protection such as splash goggles or face shield is used while handling the notified polymer solution, as the pH of the solution is in the range 3 – 3.5. Skin protection comprises impervious gloves, and apron and coveralls.

9.2.2. Public health – exposure assessment

The notified polymer will not be sold to the public. Use as a flocculant for liquid/solid separation processes in industries such as oil refining, biotechnology (eg. fermentation processes) and wastewater treatment will result in disposal of flocculated solid matter containing the notified polymer to landfill.

9.2.3. Human health - effects assessment

The notified polymer was of low acute oral toxicity (LD50 > 2000 mg/kg bw) and low dermal toxicity (LD50 > 2000 mg/kg bw) in rats. it was a very slight skin irritant in rabbits, with maximum Draize scores of 1, and irritation persisting less than 48 hours. It was irritating to rabbit eyes, with conjunctival effects persisting beyond 3 days, although all effects cleared by 7 days. The effects were below the thresholds for classification of the notified polymer as an eye irritant. The notified polymer was not mutagenic in bacteria.
Based on the submitted data, the notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b).

9.2.4. Occupational health and safety – risk characterisation

The notified polymer is not classified as a hazardous substance, however instillation of the notified polymer in rabbit eyes led to significant conjunctival irritation which persisted beyond three days. While the effects were below the threshold for classification, they represent a hazard which should be protected against. In addition the solutions are acidic, with a pH in the range 3 – 3.5. For these reasons, the safety phrases S25: Avoid contact with eyes and S39: Wear eye/face protection should be applied to the products containing the notified polymer. The notifier indicated that splash goggles or a face shield are worn while workers are handling the products.
It is not expected that dermal contact with the products will result in significant occupational risk, based on the low hazard associated with skin contact. Occupational risk will be confined (apart from in the case of accidents) to workers handling the imported products during dosing, sampling and maintenance, particularly in the case of manual addition where the risk of splashing is expected to be greatest. At any time these products are handled, eye protection should be worn; gloves and industrial clothing should also be used. After water treatment and flocculation of the solids, very little risk from the notified polymer is expected because of the tight binding of the polymer in the floc, and the low concentration of polymer remaining in the treated water.

9.2.5. Public health – risk characterisation

With public exposure to the notified polymer being unlikely, except in the event of an accidental spill, the hazard from public exposure to the notified polymer throughout all phases of its life-cycle is considered to be negligible.

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* (NOHSC, 1999b).

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio: The polymer is not considered to pose a risk to the environment based on its reported use pattern, provided that the substance is used in the correct doses which are commensurate with the quantity of organic compounds and suspended solids and the facilities contain on-site treatment plants.

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.

10.3.2. Public health

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

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the products containing the notified polymer provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). They are 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 the products containing the notified polymer provided by the notifier were 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

- Use the following warning statements and safety phrases for the imported products containing the notified polymer:
  - Toxic to aquatic organisms;
  - Avoid overdosing treatment water.
  - Contain all spills. Do not allow it to enter waterways;
  - S25: Avoid contact with eyes;
  - S39: Wear eye/face protection.

CONTROL MEASURES

Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
  - Safety goggles or face shield
  - Industrial clothing, impervious gloves.

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

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

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

State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of by thermal treatment or incineration at approved facilities.

Emergency procedures

- Spills/release of the notified polymer should be absorbed onto an inert material and contained in sealed containers for disposal. Spills should not be allowed to enter waterways.

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
- If use will result in significant release from industrial effluent plants in rural areas without on-site treatment, it is recommended that a secondary notification should be made providing details of the plants effluent releases including sewerage capacity and flows to enable a more accurate assessment of hazard. In addition, full scientific test reports should be provided that prove the binding capabilities of the notified polymer and clarify the concentrations that will remain in the supernatant.

or

(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.

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