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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

CYANEX® 923 Extractant

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FULL PUBLIC REPORT

CYANEX® 923 Extractant

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Cytec Australia Holdings Pty Ltd

Suite 1, Level 1 Norwest Quay, 21 Solent Circuit,
Norwest Business Park
Baulkham Hills NSW 2153

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, CAS No., molecular and structural formulae, spectral data, molecular weight, purity, impurities, exact use, import volume.

The above data items are claimed exempt from publication on the basis that their publication would be detrimental to the commercial interests of the applicant.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: dissociation constant, hydrolysis, particle size, adsorption/desorption, bioaccumulation.

Dissociation constant and hydrolysis are irrelevant given the notified chemical's low water solubility; particle size is not applicable for a liquid, adsorption/desorption is not required given the chemical's low environmental release and bioaccumulation is irrelevant given its low water solubility and ready biodegradability.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
The chemical was the subject of a one year CEC permit (No. 247, CEC 262) issued on 10 July 1996. The chemical is also the subject of a 1 year permit submitted prior to the current notification. (CEC 583).

NOTIFICATION IN OTHER COUNTRIES
The chemical chemical has been notified in US, EU, Canada and Korea.

3. COMPOSITION

DEGREE OF PURITY
High

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as a raw material.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-100	10-100	10-100	10-100	10-100

USE
A solvent extraction agent used in metal refining or in acid recovery.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
BHP, Port Kembla.

TRANSPORTATION AND PACKAGING
The notified chemical will be transported in 200 L lined steel drums and/or 1000 L Intermediate Bulk Containers (IBC).

5.2. Operation Description

The notified chemical will be used in a totally enclosed and automated system. The system involves two processes, the extraction and stripping stages, which use the same equipment and solvent.

Extraction

The notified chemical, CYANEX® 923, will be pumped from the 200 L drum to a 100 L stainless steel holding tank (T-3). CYANEX® 923 will be pumped from T-3 into the bottom of a pulsed perforated plate column and contacted counter-currently with 100 L of the electrolyte aqueous solution. CYANEX® 923 selectively extracts the metal ions or acid from the electrolyte solution (continuous phase liquor) as it moves up the column and the loaded solvent/organic liquor from the top of the column is then stored in tank T-4 ready for the stripping stage.

Stripping

The loaded organic liquor from tank T-4 containing CYANEX® 923 complexed with metal or acid will be pumped through the column a second time. This time it will be counter-currently contacted with water which will strip the metal or acid from the CYANEX® 923 and regenerate the solvent. The regenerated CYANEX® 923 will be returned to tank T-3 for reuse.

The spent CYANEX® 923 will be disposed of to a liquid waste facility at the end of its useful life.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and storage	2-4	2-3	10-15
Plant operators	2-4	6-8	30
Laboratory staff	2-4	2-3	30

Exposure Details

Transport and Storage (2-3 hours/day, 10-15 days/year)

The notified chemical will be imported in 200 L drums and/or 1000 L Intermediate Bulk Containers (IBC). The material will be transported from the dockside to the Cytec transport contactor warehouse facility where it will be stored prior to being transported to the customer site. It is anticipated that waterside workers, transport drivers and warehouse workers would only be exposed to the material in

the event of an accident.

Plant Operators (6-8 hours/day, 30 days/year) and Laboratory Staff (2-3 hours/day, 30 days/year)

The notified chemical will be used in a solvent extraction system. The system involves two processes, the extraction and stripping stages, which use the same equipment and solvent. The system is totally closed and automated. The system is designed to minimise exposure of the plant operators and laboratory staff to the solvents, particularly during transfer and cleaning operations. It can be operated by a single person. The holding tanks are sealed. The system is located in a purpose-built, isolated and bunded area which is supplied with local ventilation. Safety glasses and safety clothing must be worn within the work zone. During decanting and cleaning, workers must also wear impervious gloves and respirator if required.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified chemical will be imported for use in a solvent extraction plant.

Release to the environment will occur from:

Residues in empty transport containers (0.5% of import volume): 5 kg/tonne imported
Cleaning of equipment (0.5% of import volume): 5 kg/tonne imported
Final disposal of spent extractant (99% of import volume): 990 kg/tonne imported

Release to sewer from extracted aqueous phase (0.5 ppm of extractant in 100 L water): 50 mg

The extracted aqueous phase will be disposed of to sewer via an on-site treatment plant. The solubility of CYANEX® 923 in water is 0.5 mg/L. Up to approximately 100 L water will be used in the stripping process. Therefore, it is estimated that approximately 50 mg of CYANEX® 923 will be released with the feed and wash water.

Empty containers will be drained and rinsed with solvent. Residues and rinsate will be disposed of to a liquid waste facility. Empty drums will be sent to drum recyclers.

RELEASE OF CHEMICAL FROM USE
Not applicable.

5.5. Disposal

Residues and spent material will be disposed of to a liquid waste treatment facility. Empty drums will be sent to drum recyclers.

5.6. Public Exposure

The notified chemical will be used only for industrial applications and will not be sold to the public. The public may be exposed to the chemical indirectly as a result of accidental spills and from release to the environment.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Colourless to light amber mobile liquid.

Melting Point/Freezing Point
Remarks Test not performed. A value of –5 to 0°C is quoted in internal correspondence.

Boiling Point 71 - 163ºC at 0.027 KPa

METHOD EC Directive 92/69/EEC A.2 Boiling Temperature.
TEST FACILITY Notox, The Netherlands (1986a).

Density 875 kg/m^3 at 22.5ºC

METHOD EC Directive 92/69/EEC A.3 Relative Density.
Remarks Pycnometer method
TEST FACILITY Notox, The Netherlands (1986b).

Vapour Pressure 0.16 kPa at 25ºC.

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Static pressure measurements were made with a capacitance manometer. Measurements were done every 45 minutes during a total period of 11 days at a temperature of 25ºC. Because the test chemical has a purity of 94-95% and consists of four compounds, the pressure will not reach a constant value. The composition of the vapour of the test chemical changed with time as a result of the disappearance of the most volatile impurities and/or components. The vapour pressure of the test chemical was derived by extrapolating the curve of the natural logarithm of vapour pressure versus time to measurement 0.

The result indicates that the test material is highly volatile (Mensink *et al*., 1995).
TEST FACILITY Notox, The Netherlands (1986c).

Water Solubility 0.50 ± 0.13 mg/L at 20ºC

METHOD EC Directive 92/69/EEC A.6 Water Solubility.
Remarks In a preliminary test, the solubility of the test chemical was performed by adding 10 mL of water to 118.5 mg of the test chemical and stirring the formulation for two hours. The saturated solution was centrifuged and the supernatant was mixed vigorously with hexane. The hexane fraction of the solution was subject to gas chromatographic analysis for the determination of the concentration of the test chemical at the temperature range of 19.6-21.1ºC. The definitive test using the column elution method was then run.

The result indicates that the test chemical is slightly soluble in water (Mensink *et al*., 1995).
TEST FACILITY Notox, The Netherlands (1986d).

Hydrolysis as a Function of pH

Remarks Test not performed as the notifier indicated that the notified chemical is considered insoluble in water. There are no groups generally considered to be hydrolysable.

Partition Coefficient (n-octanol/water) log Pow at 20ºC = 4.84, 4.67 and 4.37 at a volumetric ratio of octanol/water of 1:6, 1:3 and 2:3, respectively.

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks A stock solution of the test chemical was prepared by dissolving 160.7 mg in 50 mL n-octanol, saturated with water. Three tests were performed at a volumetric ratio of octanol:water =1:3, 2:3 and 1:6. Duplicate samples of each test were used to determine the concentrations of test material in each phase using gas chromatography. The results of the determinations for the three tests show a concentration dependency of the partition coefficient, indicating a deviation from the Nernst Partition law.

The result indicates that the test material is strongly hydrophobic.
TEST FACILITY Notox, The Netherlands (1986e).

Adsorption/Desorption
– screening test

METHOD

Remarks Not determined. Based on the relatively high log Pow and low water solubility, the notified chemical is likely to bind strongly to organic matter in soils and be relatively immobile in soil.

TEST FACILITY

Dissociation Constant Not determined

METHOD OECD TG 112 Dissociation Constants in Water.

Remarks Test not performed as the notified chemical does not contain any functional groups that are expected to dissociate.

TEST FACILITY

Particle Size Not applicable – notified chemical is liquid

Flash Point No flashpoint in the range 25 - 100ºC

METHOD EC Directive 92/69/EEC A.9 Flash Point.

REMARKS A value of 182°C was quoted in internal correspondence.

TEST FACILITY Notox, The Netherlands (1986a).

Flammability Limits Not highly flammable.

METHOD EC Directive 84/449/EEC A.13 Flammability

TEST FACILITY Notox, The Netherlands (1986a).

Autoignition Temperature 276ºC

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).

Remarks Relatively strong generation of gases occurs before the moment of explosion, which indicates decomposition reactions before the explosion.

TEST FACILITY Notox, The Netherlands (1986a).

Explosive Properties Not explosive.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.

Remarks Not sensitive to shock and does not explode under the effect of a flame.

TEST FACILITY Notox, The Netherlands (1986a).

Reactivity

Remarks The notified chemical is thermally stable and is not reactive in contact with air or water from the above tests.

ADDITIONAL TESTS

Fat (or n-octanol) Solubility Miscible in Standard fat HB307 at 37°C

METHOD EC Directive 84/449/EEC A.7

Remarks The fat solubility of the test material was determined by adding different amounts of the test material to standard fat (Natex GmbH, Germany), a synthetic mixture of saturated triglyceride with a fatty acid and triglyceride distribution similar to that of a coconut fat.

The results indicate that the notified chemical is miscible in all proportion with the standard fat at 37°C.

TEST FACILITY Notox, The Netherlands (1986f).

Surface Tension 47.1 mN/m at 19ºC with a 0.50 mg/L aqueous solution.

METHOD EC Directive 92/69/EEC A.5 Surface Tension.

Remarks The determination of the surface tension was performed by means of a Kruss tensiometer type K6 based on the method of ring of Lecomte de Nolly. A saturated aqueous solution of the test material was prepared and a further dilution of the saturated solution were also prepared to determine the surface tension at different concentrations. All solutions were tested at least five times. The measurements were performed at 19ºC and the surface tension of the test substance were determined to be 47.1, 51.3, 52.4, 62.4 and 72.3 mN/m at the respective concentrations of 0.50, 0.38, 0.33 and 0.25 mg/L.

The results indicate that the notified chemical is surface active at the saturated concentration of 0.5 mg/L but becomes non-surface active at the lower concentration of 0.25 mg/L.

TEST FACILITY Notox, The Netherlands (1986g).

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint	*Assessment Conclusion*
Rat, acute oral	LD50 > 5000 mg/kg bw low toxicity
Rat, acute dermal	LD50 > 3000 mg/kg bw low toxicity
Rabbit, skin irritation	Corrosive
Rabbit, eye irritation	Severely irritating
Guinea pig, skin sensitisation - non-adjuvant test.	no evidence of sensitisation.
Rat, dermal repeat dose toxicity - 28 days.	NOAEL for systemic toxicity = 875 mg/kg/d, LOAEL for local effects = 87.5 mg/kg/d
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberrations in human lymphocytes	non genotoxic
Genotoxicity – in vivo mouse bone marrow micronucleus test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE — Notified chemical.

METHOD
- Species/Strain: Rat/Sprague-Dawley.
- Vehicle: Not stated.
- Remarks – Method: 15-day post administration observation period
  Administration by gavage

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	5000	0

- LD50: > 5000 mg/kg bw
- Signs of Toxicity: Diarrhoea, salivation, decreased activity, wet abdomen area, sore rectal area, abdominal hair loss, nasal discharge, swollen hind legs, sore hind legs.
- Effects in Organs: None.
- Remarks – Results:

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

TEST FACILITY — Food and Drug Research Laboratories, NY, USA (1985a).

7.2. Acute toxicity – dermal

TEST SUBSTANCE — Notified chemical.

METHOD
- Species/Strain: Rabbit/New Zealand White.
- Vehicle: None.
- Type of dressing: Occlusive.
- Remarks – Method:

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality Males*	*Females*	*Combined*
1	5/sex	1000	0	1/5	1/10
2	"	1316	0	1/5	1/10
3	"	1732	0	2/5	2/10
4	"	2280	1/5	1/5	2/10
5	"	3000	0	1/5	1/10

LD50 > 3000 mg/kg bw

Signs of Toxicity - Local: The test site of all animals exhibited moderate erythema and slight oedema.

Signs of Toxicity - Systemic: Anorexia, decreased activity, diarrhea or soft stools, nasal discharge and respiratory irregularity. Other effects seen prior to death were ataxia, cyanosis and hypothermia.

Group mean body weights were lower at day 8; for males at doses of 1000, 1316, 2280 and 3000 mg/kg bw and for females at 1316, 1732, 2280 and 3000 mg/kg bw. The effect was transient and weight gain was noted at termination.

Effects in Organs: Reddening of the lungs in two surviving males at 1000 mg/kg and all animals which died. The lungs of 1 male and 1 female at 3000 mg/kg were described as white and nodular at termination. Eschar formation was noted at all dose levels. Yellow fluid was noted within the thoracic cavity of 1 male and 1 female at 3000 mg/kg.

Remarks – Results

CONCLUSION: The notified chemical is of low toxicity via the dermal route. However, the results indicate that the notified chemical is absorbed through the skin.

TEST FACILITY: Food and Drug Research Laboratories, NY, USA (1986a).

7.3. Acute toxicity – inhalation

Data not provided.

7.4. Irritation – skin

TEST SUBSTANCE: Notified chemical.

METHOD: OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain: Rabbit/New Zealand White

Number of Animals: 6

Vehicle: None.

Observation Period: 76 hours (4 hour treatment plus 72 hours observation).

Type of Dressing: Occlusive.

Remarks – Method

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	4	4	76 hours	4
Oedema	1.3	2	"	2

*Calculated on the basis of the scores at 28, 52, and 76 hours for ALL animals.

Remarks – Results: Moderate to severe eschar in all animals

CONCLUSION The notified chemical is corrosive to skin.

TEST FACILITY Food and Drug Research Laboratories, NY, USA (1986b).

7.5. Irritation – eye

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 6
Observation Period 13 days.
Remarks – Method The eyes were further examined and scored on days 4, 7, 10 and 13.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	1	2	10 days	0
Conjunctiva: chemosis	3.1	4	10 days	0
Conjunctiva:discharge	1	3	4 days	0
Corneal opacity	0	1	1 hour	0
Iridial inflammation	0.05	1	24 hours	0

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

Remarks – Results

CONCLUSION The notified chemical is severely irritating to the eye.

TEST FACILITY Food and Drug Research Laboratories, NY, USA (1985b).

7.6. Skin sensitisation

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 406 Skin Sensitisation – non-adjuvant test (Buehler test).
Species/Strain Guinea pig/Dunkin-Hartley.
PRELIMINARY STUDY Maximum Non-irritating Concentration:
topical: 1%
MAIN STUDY
Number of Animals Test Group: 10 Control Group: 10
induction phase Induction Concentration:
topical application, 1% emulsion
Signs of Irritation No significant skin response.
CHALLENGE PHASE
1st challenge topical application: 1% emulsion
2nd challenge topical application:
Remarks – Method

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	1%	0	0		

Control Group	1%	0	0

Remarks – Results: During induction, 1% of notified chemical produced no significant skin response on any animal. One animal showed slight patchy erythema following the second induction application.

CONCLUSION: There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY: Bushy Run Research Centre (1987).

7.7. 28-day repeat dose dermal toxicity

TEST SUBSTANCE: Notified chemical.

METHOD: OECD TG 410 Repeated Dose Dermal Toxicity: 28-day Study.
Species/Strain: Rat/Fischer 344.
Route of Administration: Dermal – occluded.
Exposure Information: Total exposure days: 28 days;
Dose regimen: 7 days per week;
Duration of exposure dermal): 6 hours/day;
Post-exposure observation period:
Vehicle: None.
Remarks – Method

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0
II (low dose)	5/sex	87.5	0
III (mid dose)	5/sex	288.7	1
IV (high dose)	5/sex	875	0

Mortality and Time to Death

One mid dose male on day 5 unrelated to treatment.

Clinical Observations

The only clinical signs were local irritation. Skin irritation was observed starting on day 2 of dosing for all treated groups. Erythema advanced from mild in the high dose group to moderate by day 13 for all males and 3 of 5 females. Erythema was severe by day 19 for all animals. Erythema extended beyond the dose area for high dose animals. For the low and mid dose animals the erythema tended to remain more localised and the severity increased with time.

Other signs associated with skin irritation in all treatment groups included fissures, erosion, crusting and excoriation. These findings were mostly mild and related to the extensive erythema. Oedema was noted in all animals from the high dose group and one female from the mid dose group.

Absolute body weights were reduced slightly (5.8%) in male rats treated with 875 mg/kg/day.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Haematology
Elevated leucocyte counts were statistically higher in high dose males. Other changes were

minimal and were not attributed to treatment.

Effects in Organs and histopathlogy

Ratios of organ weights tended to be elevated due to low body weights although the body weight reductions did not achieve statistical significance. A dose related increase in relative kidney weight was observed but was not correlated with histopathological findings.

Treatment related gross pathology and histopathological findings were limited to the area of treatment. Lesions observed in all groups included hyperkeratosis, acanthosis and spongiosis of the epidermis with inflammation ranging from suppurative to ulcerative epidermal damage. In addition, oedema, haemorrhage and dermal fibrosis were present in some animals. The severity of acanthosis and ulcerative epidermitis were less severe in the mid and low dose groups. Examination of the sciatic nerve in animals from the high dose group indicated no abnormal histologic findings.

Minimal foci or multifocal hepaptitis was diagnosed in 3 treated rats in the high dose group

Remarks – The principal effects observed in the study were due to the corrosive nature of the test substance.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) for systemic toxicity was established as 1 mL/kg bw/day (875 mg/kg/day) in this study. However, no NOAEL was established for local effects. The LOAEL for local effects was 87.5 mg/kg/day.

TEST FACILITY Bushy Run Research Centre (1986).

7.8a. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Plate incorporation procedure
Species/Strain *S. typhimurium*:
TA1538, TA1535, TA1537, TA98, TA100.
Metabolic Activation System Aroclor 1254-induced rat liver S9 fraction.
Concentration Range in Main Test a) With metabolic activation: 0 - 3000 µg/plate.
b) Without metabolic activation: 0 - 3000 µg/plate.
Vehicle DMSO

RESULTS

Metabolic Activation	*Test Chemical Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1		None	None	None
Test 2				
Absent				
Test 1	3333	None	None	None
Test 2				

Remarks – Results

CONCLUSION The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Pharmakon Research International (1985).

7.8b. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Plate incorporation procedure
Species/Strain *S. typhimurium*:
TA1538, TA1535, TA1537, TA98, TA100.
Metabolic Activation System Aroclor 1254-induced rat liver S9 fraction.
Concentration Range in Main Test a) With metabolic activation: 0 - 10000 µg/plate.
b) Without metabolic activation: 0 - 10000 µg/plate.
Vehicle DMSO

RESULTS

Metabolic Activation	*Test chemical concentration (µg/plate) resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1	None	None	667 (slight)	None
Test 2				
Absent				
Test 1	None	None	667 (slight)	None
Test 2				

Remarks – Results

CONCLUSION The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Microbiological Associates (1987).

7.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
EC Directive 92/69/EEC B.10 Other effects – Mutagenicity: *In vitro* Mammalian Cytogenetic Test.
Cell Type/Cell Line Human lymphocytes.
Metabolic Activation System Aroclor 1254-induced rat liver S9 fraction.
Vehicle Ethanol.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Present			
Test 1	7.8, 15.6 and 31.3	3 hours	21 hours
Test 2	30, 60 and 120	3 hours	21 hours
	90	3 hours	45 hours
Absent			
Test 1	3.9, 7.8 and 15.6	21 hours	21 hours
Test 2	12.5, 20 and 30	21 hours	21 hours
	30	45 hours	45 hours

*The above cultures were selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1		62.5	250	None
Test 2				
- 21 hour harvest		120 (reduced mitotic index)		None
- 45 hour harvest		120 (reduced mitotic index)		None
Absent				
Test 1		31.3	125	None
Test 2				
- 21 hour harvest		60		None
- 45 hour harvest		30 (reduced mitotic index)		None

Remarks – Results: It is stated that +S9 cultures were treated for 3 hours, centrifuged, and the cell pellet resuspended in fresh medium. It is assumed that the fresh medium does not contain the test substance.

CONCLUSION: The notified chemical was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY: Huntingdon Life Sciences (1996).

7.10. Genotoxicity – in vivo

TEST SUBSTANCE: Notified chemical.

METHOD: OECD TG 475 Mammalian Bone Marrow Chromosomal Aberration Test.
Species/Strain: Mouse/CD-1.
Route of Administration: Intraperitoneal – 2 injections separated by 24 hours.
Vehicle: Corn oil.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time Hours*
1	5/sex	48	6 hours after second injection
2	5/sex	159	"
3	5/sex	476	"
TEM	5/sex	0.15	"

TEM = triethylenemelamine (positive control).

RESULTS
Doses Producing Toxicity: Doses $\geq$ 425 mg/kg.
Genotoxic Effects: None.
Remarks – Results

CONCLUSION: The notified chemical was not clastogenic in this in vivo mouse bone marrow micronucleus study under the conditions of the test.

TEST FACILITY: Microbiological associates (1986).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Inoculum	Activated sludge bacteria.
Exposure Period	28 days.
Auxiliary Solvent	Evaporative solvent.
Analytical Monitoring	Dissolved oxygen analyser.
Remarks – Method	Test substance was dissolved in evaporative solvent and cast on glass fibre filters. Test concentrations of 1 mg/L, 2 mg/L and 5 mg/L were used. The inoculum consisted of an activated sludge bacteria from Bergen County, New Jersey. The reference substance was aniline. The test media included (a) non-inoculated dilution water (b) inoculated diluted water (c) 1, 2 and 5 mg/L notified chemical and (d) 2 mg/L aniline as reference substance. The tests were performed in sealed bottles at 20°C.

RESULTS

Test substance		*Aniline*	
Day	*% degradation*	*Day*	*% degradation*
5	18.0	5	100
15	78.2	15	100
28	96.2	28	100

Remarks – Results	The reference substance has reached 100% degradation by 5 days, thus satisfying the requirement that the reference substance had to attain >60% degradation, confirming the validity of the study. The notified substance has attained 60% degradation within 10 days of reaching 10%, thus satisfying the requirement as ready biodegradable.
CONCLUSION	The notified chemical can be classed as ready biodegradable.
TEST FACILITY	United States Testing Company (1989a).

8.1.2. Bioaccumulation

No bioaccumulation study was conducted. The ready biodegradability of the test substance should preclude bioconcentration when exposed to aquatic organisms.

8.2. Ecotoxicological investigations

8.2.1a. Acute toxicity to fish – Rainbow Trout

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 203 Fish, Acute Toxicity Test - static.
Species	*Salmo gairdneri*
Exposure Period	96 hours.
Auxiliary Solvent	DMF.
Water Hardness	40 - 45 mg $CaCO_3$/L
Analytical Monitoring	None.
Remarks – Method	The rainbow trout used in the test had a mean weight of 0.77 g and mean standard length of 38 mm. All fish were held in culture tanks on a 16 h daylight photoperiod and observed for at least 14 days prior to testing. The trout were not fed during the tests. All test organisms were observed once every 24 h for mortality and sub-lethal effects. Water quality

parameters of temperature, dissolved oxygen and pH were measured throughout the test and were within acceptable limits.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality (%)*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0		10		0	0		0
0.018		10		0	0		0
0.032		10		0	0		0
0.056		10		0	0		0
0.10		10		0	0		20
0.18		10		30	60		70
0.32		10		90	100		100

LC50	0.21 mg/L at 24 hours 0.14 mg/L at 96 hours (CI 0.11-0.18)
NOEC (or LOEC)	0.056 mg/L at 96 hours
Remarks – Results	All results were based on the nominal concentrations. The 96 h no-observed effect concentration was estimated to be 0.056 mg/L based on the lack of mortality and observed sub-lethal effects. The abnormal effects of mortality, loss of equilibrium, fish on the bottom of test chamber and/or quiescence were observed in the 0.10, 0.18, and 0.32 mg/L test concentration during the 96-h exposure period. An examination of the fish culture and acclimation records for this test indicated that the fish were in good condition for testing.

CONCLUSION The notified chemical is highly toxic to *Salmo gairdneri*.

TEST FACILITY ABC Laboratories (1987a).

8.2.1b. Acute toxicity to fish – Bluegill Sunfish

TEST SUBSTANCE Notified chemical.

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

Species	*Lepomis macrochirus*
Exposure Period	96 hours.
Auxiliary Solvent	DMF.
Water Hardness	40 - 45 mg $CaCO_3$/L
Analytical Monitoring	None.
Remarks – Method	The bluegill sunfish used in the test had a mean weight of 0.51g and mean standard length of 27 mm. All fish were held in culture tanks on a 16 h daylight photoperiod and observed for at least 14 days prior to testing. The fish were not fed during the tests. All test organisms were observed once every 24 h for mortality and sub-lethal effects. Water quality parameters of temperature, dissolved oxygen and pH were measured throughout the test and were within acceptable limits.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality (%)*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0		10		0	0		0
0.10		10		0	0		0
0.18		10		0	0		0
0.32		10		0	0		0
0.56		10		30	100		100
1.0		10		100	100		100

LC50	0.64 mg/L at 24 hours 0.42 mg/L at 96 hours (CI 0.32-0.56)
NOEC (or LOEC)	0.32 mg/L at 96 hours
Remarks – Results	All results were based on the nominal concentrations. The 96 h no-observed effect concentration was estimated to be 0.32 mg/L based on the lack of mortality observed sub-lethal effects. The abnormal effects of mortality, loss of equilibrium, fish on the bottom of test chamber and/or quiescence were observed in the 0.56 and 1.0 mg/L test concentrations during the 96-h exposure period. An examination of the fish culture and acclimation records for this test indicated that the fish were in good condition for testing.

CONCLUSION The notified chemical is highly toxic to *Lepomis macrochirus*.

TEST FACILITY ABC Laboratories (1987b).

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical.

METHOD Standard Methods for the Examination of Water and Wastewater. American Public Health Association, 1980.
Methods of Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians. Committee on Methods for Toxicity Tests with Aquatic Organisms, 1975.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Acetone.
Water Hardness	225–275 ppm $CaCO_3$
Analytical Monitoring	None.
Remarks – Method	The static Daphnia bioassay was conducted in a 250-mL glass beaker. These vessels were kept at 20ºC in a temperature controlled area. The lighting was maintained on a 16-h daylight photoperiod, with 30 minute simulated dawn and dusk periods. All test organisms were observed once every 24 h for mortality and abnormal effects such as surfacing, clumping of the daphnia together and daphnids lying on the bottom of the test chambers. Water quality parameters of temperature, dissolved oxygen and pH were measured at test termination and were within acceptable limits.

RESULTS

Concentration mg/L		*Number of D. magna*	*Percent Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0		10 in duplicate	0	0
0.056		"	0	0
0.10		"	0	0
0.18		"	0	0
0.32		"	5	25
0.56		"	5	100
1.0		"	40	100

LC50	1.3 mg/L at 24 hours 0.37 mg/L at 48 hours (CI 0.32-0.56)
NOEC (or LOEC)	0.18 mg/L at 48 hours
Remarks – Results	All results were based on the nominal concentrations. The no-observed effect concentrations based on the lack of mortality and abnormal effects was 0.18 mg/L after 48 h. The abnormal effects of mortality, quiescence, surfacing, clumping and/or daphnids lying on the bottom of the test

vessels were observed at concentrations of 0.32, 0.56 and 1.0 mg/L.

CONCLUSION The notified chemical is highly toxic to *Daphnia magna*.

TEST FACILITY ABC Laboratories (1987c).

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species	*Selenastrum capricornutum*
Exposure Period	96 hours
Concentration Range Nominal	0–0.32 ppm
Concentration Range Actual	Not measured
Auxiliary Solvent	Ethanol.
Water Hardness	Not stated.
Analytical Monitoring	Not stated.
Remarks – Method	No reported deviation from the approved method. Initial cell count was 1 × 10^4 cells/mL. The test medium was a sterile OECD Algal Medium in a 125 mL glass capped flask. It was incubated with light cycle of 16 h and 8 h dark at 20ºC. Three replicates per concentration were used for nominal concentrations of 0.32, 0.10, 0.056, 0.032, 0.018 and 0.01 mg/L.

RESULTS

Biomass		*Growth*	
E_bC_{50} mg/L at 96 h	*NOEC mg/L*	*ErC50 mg/L*	*NOEC mg/L*
0.11	Not calculable	Not calculable	Not calculable

Remarks – Results It appears the cell growth was insufficient at 24 and 48 hours to establish concentration–effect relationships for all concentrations and for the blank control. The median effects could not, therefore, be calculated for these time periods. The E_bC_{50} at 72 hours was 0.06 ppm. However, because of the assay's failure to measure or reveal the diminishing effect at the low concentration, the information obtained from the test data are limited to the E_bC_{50} values. When the data were statistically plotted for dose-response linearity, the correlation coefficients of 0.57 and 0.58 for 72 and 96 hours, respectively, indicated a less than linear response. The fit of a theoretical response curve does not permit the estimation of the no effect concentration.

CONCLUSION The notified chemical was highly toxic to algae under the conditions of the test.

TEST FACILITY United States Testing Company (1989b).

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE Notified chemical.

METHOD Test Methods: BIO-D MIC 286-7 (MIC), BIO-D AEROB/TOX 352-7 (Aerobic Biotoxicity) and BIO-D ANAEROB/TOX 352-7 (Anaerobic Biotoxicity).

A number of tests were conducted: minimum inhibitory concentration (MIC), biotoxicity to sewage, aerobic biotoxicity and anaerobic biotoxicity.

Minimum Inhibitory Concentration (MIC)
The test was conducted using the test method BIO-D MIC 286-7. The sample was tested at serial dilution from 50,000 ppm down to 0 ppm. Each concentration was inoculated with either activated sludge or digester sludge. Aerobic sewage was a suspension from a trickling filter system and anaerobic sewage from a mixed anaerobic digestor. Because of the low solubility of the test substance, it was cast on fiber glass discs and added to the test vessel incubated at temperature of 20 (aerobic) and 35ºC (anaerobic) for 48-72 hours. The growth media are Standard Methods Broth (aerobic) and Fluid Thioglycollate Medium (Anaerobic). The results are recorded on the basis of medium growth.

The aerobic MIC and anerobic MIC for the test substance was found to be 5000 and ≥50,000 ppm, respectively.

Aerobic biotoxicity

The test was conducted using the test method BIO-D AEROB/TOX 352-7. This test measures the inhibitory or toxic effect of a test substance on aerobic sewage metabolism. It is a respirometric assay which measures the oxygen consumption of sewage when combined with the test substance and nutrients. The sample was tested at concentrations of 5,000, 1,000, 500, 100, 50, and 10 ppm. The test vessels were incubated at ambient temperature of 30ºC for up to 5 days. The respiratory metabolism was recorded daily using the manometer. Tests were run continuously but not monitored on weekends. All concentrations were tested in duplicate with repeat test in triplicate.

The sample did not demonstrate inhibitory properties to aerobic sewage metabolism at 5,000 ppm, in contrast to the aerobic MIC. Although a slightly less aerobic metabolism was observed at 50 ppm, it was considered not to be indicative of biotoxicity.

Anaerobic biotoxicity
The test was conducted using the test method PRO/BIO-D ANAEROB/TOX 352-7. This test measures the inhibitory or toxic effect of a test substance in anerobic sewage. It is based on a method following the metabolism of organic substance into methane and carbon dioxide. The test vials were incubated at 35-37ºC and gases produced were measured using monameter on a daily basis for up to 28 days. All test concentrations were performed in duplicate.

The test substance did not demonstrate inhibitory properties to anaerobic sewage organisms at 50,000 and 10,000 ppm. Although lower concentrations may have resulted in less anaerobic metabolic activity, the results were considered not indicative of biotoxicity. The data are clearly non-linear in concentration-effect relationship and may be attributed to lack of sewage homogeneity and intra-test variability in measurement.

TEST FACILITY United States Testing Company (1989c).

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical is highly volatile (160 Pa at 25°C) and loss to the atmosphere is a potential removal process from the sewers and aquatic environments. It is classified as readily biodegradable where it has attained 96% degradation after 28 days exposure with activated sludge inoculum in the closed bottle test. It is slightly soluble in water (0.5 mg/L at 25°C) and has a high log K_{ow} of 4.84 and 4.37 (20°C) at a volumetric ratio of octanol/water of 1:6 and 2:3, respectively. Although it has a low water solubility and is miscible in fat, its ready biodegradability would be unlikely to result in bioaccumulation in exposed aquatic organisms.

The notified chemical will be imported for use as an extractant in a solvent extraction process for the extraction of minerals, organic acids and phenols. No release of the notified chemical is

expected during transportation, except in the event of an accidental spill. The MSDS contains suitable procedures for containing spills. The notified chemical will be used in a totally enclosed and automated system involves two processes, extraction and stripping, using the same equipment and solvent.

Although the notifier did not indicate how the used solvent is disposed of after the stripping process, it is likely that it would be incinerated. The regenerated notified chemical will be returned to the holding tank for reuse. The spent notified chemical will be disposed of to a liquid waste facility at the end of its useful life. The spent extractant will be disposed of by a licensed waste contractor such as Cleanaway. There it will be destroyed by incineration. Empty drums will be sent to drum recyclers.

The notifier indicates that releases to the environment will occur as a result of (i) the rinsing of the remaining residues in 200 L import drums (0.5% of the import volume), (ii) cleaning of the equipments (0.5 % of the import volume) and (iii) disposal of the spent extractant (99% of the import volume). It is expected that residues and rinsates will be disposed of to a liquid waste facility and be incinerated.

The extracted aqueous phase will be disposed of to sewer via an on-site treatment plant. The solubility of the notified chemical in water is 0.5 mg/L. In 100 L water used in the extraction and stripping process, it is estimated that approximately 50 mg of the notified chemical will be released with the feed and the wash water. The notifier has indicated that the number of batches of 100 L water containing 50 mg of extractant released to sewer will be 30. Thus, 1500 mg will be released to sewer per year.

Following its use in Australia, virtually all of the notified chemical will be disposed of to a liquid waste facility and incinerated. The incinerated product will mainly be composed of phosphorus residues which are unlikely to pose an environmental hazard. Using a worst case scenario, 1,500 mg of the notified chemical per year from the extraction process will be discharged to sewer and none is attenuated within these systems. Australia has a population of ~19.5 million people, and an average value for water consumption of 200 L/person/day has been adopted for this national-level assessment (3900 ML/day for total population). Therefore, the concentration of notified chemical in the Australian sewerage network may approximate 1×10^{-3} ng/L (ie. 1.5×10^{3} mg ÷ 365 days/year ÷ 3900×10^{6} L = 0.001 ng/L). Based on dilution factors of 0 and 10 for inland and ocean discharges of STP-treated effluents, outfalls, predicted environmental concentrations (PECs) of the notified chemical in freshwater and marine surface waters may approximate 1×10^{-9} mg/L and 1×10^{-10} mg/L, respectively.

Using the SIMPLETREAT model for modelling partitioning and losses in sewage treatment plants (STPs; European Commission, 1996), the percent removal from solution by STPs may potentially approximate 87% by biodegradation and ~7% (eg. 20 kg) released to air through volatilisation. Approximately 6% (eg. 580 kg) of the inflow concentration of the notified chemical may potentially remain in solution, passing through the STP. Thus, the PEC concentrations in treated effluents and irrigation re-use waters may actually be 6% of that estimated with allowance for potential STP removal, i.e. estimated average effluent concentration of 6×10^{-11} and 6×10^{-12} mg/L for freshwater and marine waters, respectively.

It is apparent that partitioning to biosolids in STPs Australia-wide would result in very low concentration of the notified chemical in biosolids assuming that 1,500 mg of the notified chemical would be discharged to sewer per year. Based on the assumption that 0.1 tonnes of biosolids is generated for each ML of STP effluent, this may result in an average biosolid concentration of 1×10^{-5} mg/kg assuming 100% attenuation in sludge during the STP process. Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1000 kg/m^3 and a soil mixing zone of 0.1 m, the concentration of the notified chemical may approximate 1×10^{-6} mg/kg in the applied soil, assuming accumulation of the notified chemical in soil for 10 years under repeated biosolids application. Thus an estimated worst case PEC for the notified chemical in soils following application of biosolids would be 1×10^{-6} mg/kg.

The effluent re-use (eg. irrigation purposes) concentration of the notified chemical may

potentially approximate 1×10^{-9} mg/L, assuming no attenuation during the STP process. STP effluent re-use for irrigation in Australia 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 0.1 m of soil (density 1000 kg/m^3). Using these assumptions, irrigation with a concentration of 1×10^{-9} mg/L may potentially result in a soil concentration of approximately 1×10^{-7} mg/kg assuming accumulation of the notified chemical in soil for 10 years under repeated irrigation. Thus, 1×10^{-7} mg/kg is an estimated worst case PEC for the notified chemical in soils following effluent irrigation.

9.1.2. Environment – effects assessment

In summary, the aquatic toxicity data indicate:

Rainbow trout: 96 h LC50	0.14 mg/L
Bluegill sunfish: 96 h LC50	0.42 mg/L
Daphnia magna: 48 h LC50	0.37 mg/L
Selenastrum capricornutum: 96 h E_bC_{50}	0.11 mg/L

Using the lowest LC50 datum of 0.11 mg/l for *Selenastrum capricornutum*, a predicted no effect concentration (PNEC) of 1.1×10^{-3} mg/L has been derived by dividing the LC50 value by a safety factor of 100 since four test results are available. Note, however, that the algal test result is unreliable though very close to that for rainbow trout.

Based on the available data the notified chemical should be classified and labelled as follows under the OECD (2002) Globally Harmonised System for the Classification and Labelling of Chemicals: *Acute Hazard Category 1*. The toxicity Classification is based on acute toxicity to fish, invertebrates and algae at ≤ 1 mg/L.

9.1.3. Environment – risk characterisation

Location	PEC (mg/L) or mg/kg	PNEC (mg/L)	Risk Quotient (RQ)[a]	
Australia wide STPs				
Ocean outfall	1×10^{-10} mg/L (6.0×10^{-11}) [b]	1.1×10^{-3} mg/L	~1×10^{-7}	(6×10^{-8}) [b]
Inland River	1×10^{-9} mg/L (6.0×10^{-12}) [b]	1.1×10^{-3} mg/L	~1×10^{-6}	(6×10^{-7}) [b]

a. RQ = PEC ÷ PNEC. b. RQ values calculated assuming 87% attenuation of notified chemical by biodegradation, 7% loss through volatilisation during STP process based on SIMPLETREAT model (European Commission, 1996).

On the basis of the ready biodegradability of the notified chemical, and the low amount of notified chemical discharged to sewer, there is unlikely to be an environmental hazard in the aquatic system. The very low RQ value further indicates the low likelihood of an environmental hazard to the aquatic life based on its reported use and estimated disposal patterns.

Based on low exposure potential, reuse of biosolids and effluent for agricultural purposes is unlikely to pose an unacceptable risk to the health of soil organisms.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Workers likely to be exposed to the notified chemical are those involved in transport and storage, extraction and stripping operation, disposal and maintenance.

Plant operators will have limited exposure as the processes of extraction and stripping are

totally closed and automated.

Dermal, inhalation and ocular exposure to the notified chemical may occur when workers connect the 200 L drum to the holding tank for pumping. Worker exposure is not expected during extraction and stripping processes. The notified chemical is fully contained and will automatically extract the metal ions or acid from the electrolyte solution and become stored in a tank (T4) for the stripping stage. From T4 it will be automatically pumped through a column and then the regenerated chemical is returned to Tank T-3 for re-use.

Exposure may occur when workers empty the tanks and during clean up operations. It is not clear how workers drain the tanks and dispose of the notified chemical. However, it is expected that the solution will be pumped into a drum for disposal.

9.2.2. Public health – exposure assessment

Public exposure is not expected as the notified chemical will only be used in industrial situations.

9.2.3. Human health - effects assessment

The notified chemical is of low acute oral and dermal toxicity. However, with mortality at all doses, the dermal study demonstrated that the chemical could be absorbed through the skin. Inhalation toxicity was not provided; but given the low vapour pressure, inhalation toxicity is not likely to be high.

Animal studies indicated that the notified chemical is corrosive to skin and eyes, but is not a skin sensitiser. In the dermal repeat dose toxicity test in rats, skin irritation was seen in all treated animals. Histopathological lesions included hyperkeratosis, acanthosis and spongiosis of the epidermis with inflammation ranging from suppurative to ulcerative epidermal damage. The NOAEL for systemic effects was 875 mg/kg bw/day. However, no NOAEL was established for local effects; the LOAEL was 87.5 mg/kg bw/day. The notified chemical was not genotoxic or mutagenic in any of the tests submitted.

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The appropriate risk phrase is:

R34 Causes burns

9.2.4. Occupational health and safety – risk characterisation

Acute risk

The main acute hazards of the notified chemical are skin and eye irritation, due to the corrosive nature of the chemical.

Exposure assessment showed that plant operators are expected to have limited contact with the notified chemical. Dermal exposure to small amounts may only occur in stages where workers are connecting or disconnecting pipes from drums and tanks. These workers will need to have skin and eye protection such as protective clothing, impermeable gloves and goggles/face shield.

During extraction and stripping, the risk of exposure to the notified chemical to workers will be low, as the processes are totally contained and automated.

Repeated dose risk

The notified chemical was severely irritating to skin following repeat dose dermal dose studies. However, based on systemic effects, the NOAEL was 1 mL/kg bw/day (875 mg/kg/day). For a 70 kg bw worker and dermal absorption factor of 100%, the equivalent amount of notified chemical is 70 mL. This calculation does not take into account safety factors. It is unlikely for workers to be exposed to such repeated amounts of notified chemical.

Therefore, the risk to workers is low provided that the notified chemical is totally contained during use and automatic processes are in place.

9.2.5. Public health – risk characterisation

Public health risk is assessed as low since exposure to the notified chemical is not expected unless there is an accidental spill.

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

10.1. Hazard classification

Human health

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

R34 Causes burns.

Environment

Based on the available data the notified chemical should be classified and labelled as follows under the OECD (2002) Globally Harmonised System for the Classification and Labelling of Chemicals: *Acute Hazard Category 1*. The toxicity classification is based on acute toxicity to fish, invertebrates and algae at ≤1 mg/L.

The classification according to the current EC criteria is:
R50 Very toxic to aquatic organisms.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio:

The chemical is not considered to pose a risk to the 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.

10.3.2. Public health

There is Negligible Concern to public health when used according to instructions.

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

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  R34 Causes burns
  R50 *Very toxic to aquatic organisms*
  S24/25 Avoid contact with skin and eyes
  S36 wear suitable protective clothing
  S37 wear suitable gloves

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥ 10%: R34 (Causes burns)
  - 5% ≤ conc < 10% R36/38 (Irritating to eyes and skin)

- The notified chemical should be classified as follows under the ADG Code:
  - *Class 8; packaging group II*

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - *Enclosed and automated processes*

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - Avoid spills

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - *Protective clothing, impermeable gloves and goggles/face shield.*

  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 chemical 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 following concentration limits should be implemented for release of the notified chemical to the environment:
  - *0.0011 mg/L (based on PNEC calculations)*

Disposal

- The notified polymer should be disposed of to landfill in accordance with the methods described in the Material Safety Data Sheet, including by licensed waste contractor and

in accordance with local jurisdiction waste management guidance.

Emergency procedures

- Spills/release of the notified polymer should be handled by trained personnel in accordance with the material safety data sheet provided by the manufacturer.
- Spills/release of the notified chemical should be contained using sand or inert powder and earth. Collect and seal in properly labelled drums for disposal to landfill in accordance with relevant Government regulations.
- Avoid disposing to natural waterways or stormwater.

Transport and Packaging

– *Australian Code for the Transport of Dangerous Goods by Road and Rail* (DOTARS, 1996).
International Maritime Dangerous Goods Code (IMO, 2000).

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 subsection 64(1) of the Act; if:
A new algal test is required if use changes in such a way that release to the aquatic environment is significantly increased. The hazard calculations under the new use pattern would also need to be revised or

(2) Under subsection 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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