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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical in Sanitized® T99-19

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Director
NICNAS

FULL PUBLIC REPORT

Chemical in Sanitized® T99-19

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Clariant (Australia) Pty Ltd (ABN 30 069 435 552)
675-685 Warrigal Rd
Chadstone Vic 3148

Microgenix-Global Australia (ABN 33 004 701 062)
PO Box 5461
Sydney NSW 2001

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 names, Other names, CAS number, Molecular formula, Structural formula, Impurities, Additives/ adjuvants, Molecular weight, Purity, Confidential details of use, Percentage in final product, Spectral data, Identity of manufacturers/ recipients.

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(S)
None.

NOTIFICATION IN OTHER COUNTRIES
None.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Sanitized® T99-19 (Designation for solvent solution containing ~40% notified chemical and notified chemical itself as indicated in test reports).

SPECTRAL DATA

METHOD	Infrared (IR), nuclear magnetic resonance (NMR) and Mass (MS) spectroscopy.
Remarks	Reference spectra were provided.

METHODS OF DETECTION AND DETERMINATION

METHOD	IR, NMR and MS spectroscopy.

3. COMPOSITION

DEGREE OF PURITY
> 75%

IMPURITIES/RESIDUAL MONOMERS
A number of impurities were identified by analytical procedures including residual starting materials and by-products.

ADDITIVES/ADJUVANTS

The imported formulation contains the notified chemical in an organic solvent at ~40%.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical is imported into Australia as a component (~40%) in Sanitized® T99-19.

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

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

USE
The notified chemical will be used to treat air filters for air purification systems and as a textile auxiliary in clothing fabrics.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne and Sydney.

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in sealed 20 L plastic containers and 25 kg jerrycans.

5.2. Operation description

Air filtration

Sanitized T99-19 containing the notified chemical is imported in 20 L plastic containers by ship. The containers are delivered to a third party contractor responsible for preparing the substrate used to manufacture the filters. The notified chemical is stored in a bunded area on site. During application the notified chemical is poured manually to a dye bath. It is added to a solution containing cation-active and non-ionogenic textile chemicals. The concentration of the notified chemical in the bath is < 5% depending on the volume of the filter substrate it is applied to. The solution is stirred and fixation occurs by passing the solution through a pad mangle[1] containing the filter. The notified chemical is chemically bound to filter with a high fixation rate. The substrate is dried and then the filters made to order by cutting and preparing. Once ordered the filters are supplied to air filtration service contractors who maintain the air filtration systems. The filters are changed once yearly and up to 500 filters are expected to be supplied to various customers each year. Following use they are disposed of to landfill.

Alternative processing involves spraying the solution onto the substrate in diluted form although it is not intended to apply the notified chemical in this manner at this time.

Textile processing

Santized® T99-19 containing the notified chemical is imported in 25 kg jerricans by ship to Melbourne. The containers are stored at a Clariant warehouse until an order is placed. The product is delivered to the customer site and is applied to textiles. It is expected that the main application will be to coloured and white socks however it can be applied to all common textile fabrics.

[1] A form of mangle for the impregnation of textiles in open width in which the textile is passed through one or more nips. The textile may be saturated before passing through the nip (the line or area of contact or proximity between two contiguous surfaces that move so as to compress and/or control the velocity of textile material passed between them), or impregnating liquid may be carried as a film on the surface of one of the bowls forming the nip.

The notified chemical is added manually to a dye bath. The addition may be semi-automated using a vacuum pump to transfer the product into the application bath. It is added to a solution containing cation-active and non-ionogenic textile chemicals used in the same bath.

The concentration in the bath is < 5% depending on the volume of substrate it is applied to (from product data sheet). The solution is stirred and fixation occurs by passing the solution through a pad mangle containing the required fabric. The substrate is dried and textile manufacture is completed. The fabric will be sold, as an article, to textile manufacturers for finishing.

Sanitized T99-19 hydrolyses and polymerises rapidly. Therefore, it is impossible to determine its fixation rates (on textile fabrics and microgenix filter substrate), wash- fastness and light fastness.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (hrs/day)*	*Exposure Frequency (days/year)*
Transport (transport personnel are not expected to be exposed to the notified chemical as it is contained within a sealed container).	10	2	100
Application of air filters			
Bath addition	3	5	100
Dipping of filter and drying	4	5	100
Textile processing			
Bath addition	20	5	250
Application and drying of fabric	20	5	250

Exposure Details

Air filtration units

There will be some manual handling of the solution and potential exposure to the dye solution in the bath. Occupational exposure is most likely to occur during transfer of the notified chemical to the bath. The notified chemical is manually poured into the bath, therefore there is the possibility of dermal or ocular exposure as a result of splashes during manual handling. As the notified chemical is corrosive, gloves and eye protection are worn during handling. Inhalation exposure may occur when the solution is applied in an unsealed bath. Exhaust ventilation is present at the site to control inhalation exposure. If spraying were to occur there may be some exposure resulting from the formation of aerosols. Any spraying will occur in a designated spray area with appropriate ventilation to capture volatiles and control exposure.

Textile processing

The exposure scenario and preventative measures are the same as listed above. Due to the automation of the process and the closed containers for dyeing it would be expected that the exposure would be minimal. Workers will have direct contact with the textiles however the notified chemical is chemically bound to the fibre.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured or formulated in Australia, but rather is to be imported in 20 L drums and 25 L jerry cans.

RELEASE OF CHEMICAL FROM USE

Use in Air filtration

During washing of the bath and application equipment, wash water containing the notified chemical are treated (pH adjustment) before release to sewer (approximately 10%). Other releases will be limited to traces remaining from clean-up of any spills, and from trace residues in empty import containers, approximately 1%. The import containers should be effectively empty after rinsing (i.e. residue of less than 0.1%) and will be disposed of to landfill.

Use in Textile processing

The release during application is the same as noted above. The notifier has indicated that although a technical report is not available use experience shows that the fixation rate is in the order of 98%. There is no release of the notified chemical to the environment during textile use. The notified chemical is chemically bound to the fibre.

5.5. Disposal

Air filtration

There is no release of the notified chemical to the environment during air filtration. In its end use application as a filter, the filter will be disposed of to landfill following use.

Use in Textile processing

It is estimated that up to 10% of the notified chemical will be released during washing or bath renewal, following water treatment, to the sewer. Up to 1% of the notified chemical will be retained as residuals within the import containers and are expected to be disposed of to landfill. In its end use application in socks the notified chemical will be disposed of with the article to landfill.

Notified chemical that is disposed of to landfill, based on the log K_{OC} value, is expected to associate with soil and sediment and degrade relatively quickly via biotic and abiotic means to form various simple carbon, nitrogen and silicon based compounds. Similarly, notified chemical that is released to sewer is expected to associate with soil and sediment, and degrade relatively quickly via biotic and abiotic means to form various simple carbon, nitrogen and silicon based compounds.

5.6. Public exposure

The notified chemical is only used in an industrial environment. Therefore the public will only come in contact with the chemical in the event of a spill or in its end use within the final textile application in sock fabric. The component becomes an integral part of the fabric within socks and is not expected to be released. Additionally there is no release into the environment when used as for air filtration.

6. PHYSICAL AND CHEMICAL PROPERTIES

Physico-chemical property data was provided for the notified chemical (>75% purity) or Sanitized T99-19 (solvent solution containing ~ 40% notified chemical).

Appearance at 20ºC and 101.3 kPa	Clear yellow liquid with an amine odour (Sanitized T99-19) beige solid/ yellowish sticky viscous mass (notified chemical).
Freezing Point	-18 to -26ºC (notified chemical)
METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Visual test conducted with a thermocouple to measure temperature.
TEST FACILITY	RCC (2002a)
Melting Point	The test item (notified chemical) is a liquid at ambient temperature (described as a yellowish sticky viscous mass). It solidifies at < 0°C and liquefies at > 10°C.
METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Measurement was with a Differential Scanning Calorimeter.
TEST FACILITY	Siemens (2006a)
Boiling Point	205.8±2.7°C at 101.3 kPa (notified chemical) 457ºC (calculated using the Meissner's method)

METHOD	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	The boiling point was either measured using scanning calorimetry or calculated using Meissner's method.
TEST FACILITY	RCC (2002b)

Density 961 kg/m^3 at 40°C (could not be calculated at 20°C because of viscosity) (notified chemical)

METHOD	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Measurement was via oscillating densitometer.
TEST FACILITY	RCC (2002c)

Density 1012 kg/m^3 at 20.1°C (Sanitized T99-19)

METHOD	EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Pycnometer method was used.
TEST FACILITY	GAB (2006a)

Vapour Pressure 5.9 x 10^{-7} kPa at 25ºC (notified chemical)

METHOD	Based on procedures outlined in OECD TG 104 Vapour Pressure and EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Calculated using Modified Watson Correlation using the estimated boiling point because the vapour pressure was too low to measure using standard procedures.
TEST FACILITY	RCC (2002d)

Water Solubility Not determined.

Remarks	Solubility could not be determined as the notified chemical adsorbs to the detection equipment. A qualitative test was performed however the notified chemical reacts with water at all pH and temperatures tested and at a concentration of 1g/mL therefore no further information could be obtained Based on the ecotoxicity test in rainbow trout the product containing the notified chemical at 40% in a solvent produces a pale cloudy homogeneous dispersion in water at a concentration of 10 mg/L. However solutions of the notified chemical (>75% purity) were clear and colourless at this concentration
TEST FACILITY	RCC (2002e)

Surface Tension 52.0 mN/m at 20.8ºC (notified chemical)

METHOD	OECD TG 115 Surface Tension of Aqueous Solutions. EC Directive 92/69/EEC A.5 Surface Tension.
Remarks	An aqueous solution was prepared by weighing 0.20831 g of the notified chemical in a 200 mL flask and filling up to the mark with double distilled water, followed by ultra-sonification for 10 minutes. A tensiometer, using the ring method, was employed. The notified chemical was found to be a surface active substance.
TEST FACILITY	RCC (2002f)

Surface Tension 37.5 mN/m at 20.1°C (notified chemical)

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.
Remarks The notified chemical is present at a purity of 80.8% in the solvent. Concentration: 1 g/L. Again, a tensiometer, using the ring method, was employed.

The notified chemical was found to be a surface active substance.
TEST FACILITY GAB (2006a)

Surface Tension 37.9 mN/m at 20°C (Sanitized T99-19)

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.
Remarks Concentration: 1 g/L
TEST FACILITY GAB (2006b)

Hydrolysis as a Function of pH The trimethoxysilane group undergoes hydrolysis to form alcohol groups as shown by the change in colour and form when present in water. A hydrolysis test couldn't be performed as the notified chemical reacts with the solution at all pHs tested

Remarks
TEST FACILITY RCC (2002g)

Partition Coefficient (n-octanol/water) log Pow at 20°C = 2.9

METHOD Calculation method using KOWWIN Ver 1.6 as neither flask shaking or HPLC method were applicable to the notified chemical
Remarks Analytical Method. No analysis of test item samples could be performed due to the physical properties of the test item.

TEST FACILITY RCC (2002f)

Adsorption/Desorption log K_{oc} >2.9546 (estimated)

METHOD Regression analysis based on octanol/ water partition coefficient of (log Pow=2.9) using a regression equation (Lyman, Reehl, Rosenblatt: Handbook of Chemical Property Estimation Methods, 1990): log K_{OC} = 0.544 . log P_{OW} + 1.377.
TEST FACILITY RCC (2002h)

Dissociation Constant The notified chemical is expected to dissociate to form a salt (containing a quaternary ammonium) and a chloride ion. No measurement has been performed, however it is known that the notified chemical reacts with water but is likely to remain dissociated throughout the environmental pH range.

Particle Size The notified chemical is introduced in solution.

Flash Point 63.7°C at 101.4 kPa (Sanitized T99-19)

METHOD EC Directive 92/69/EEC A.9 Flash Point.
Remarks
TEST FACILITY GAB (2006d)

Flammability Limits The notified chemical is considered to be not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks The notified chemical failed a flammability test for solids. However it melted prior to igniting and this may have affected the final results.
TEST FACILITY GAB (2006e)

Autoignition Temperature 305ºC (Sanitized T99-19)

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
TEST FACILITY Siemens (2006b)

Autoignition Temperature >401ºC (notified chemical)

METHOD 92/69/EEC A.16 Auto-flammability (solids – determination of relative self-ignition temperature)
TEST FACILITY Siemens (2006c)

Thermal Stability Testing The test response shows an endothermic effect in the temperature range of 160-240°C and a small endothermic effect at 270°C. No exothermal effects were observed between 25 and 400°C. (notified chemical)

METHOD OECD TG 113 Screening Test for Thermal Stability and Stability in Air.
TEST FACILITY Siemens (2006d)

Explosive Properties The notified chemical is not expected to be explosive.

Remarks The notified chemical is not expected to be explosive based on structure and is shown to be thermally stable.

Reactivity The test item is not stable in water but forms a hydrolysis product and the main product.

Viscosity 56.2 mPa s at 20ºC (Sanitized T99-19)
25.5 mPa s at 40ºC (Sanitized T99-19)

METHOD OECD TG 114 Viscosity of Liquids.
Remarks The measurement was made with a rotational viscometer.
TEST FACILITY GAB (2006f)

pH 6.91 at 19°C. (Sanitized T99-19)

METHOD CIPAC method MT 75.3
Remarks The notified chemical is present at 38.7% in solvent. This solution is then diluted in water at 1%v/v to determine the pH
TEST FACILITY GAB (2006g)

Persistent foaming 111 mL at 10 s
109 mL at 1 minute
98 mL at 3 minutes
65 mL at 12 minutes
(Sanitized T99-19)

METHOD CIPAC MT 47.2
TEST FACILITY GAB (2006h)

Solubility in organic solvents 1,2 dichloroethane >250g/L at 20°C
methanol >250g/ L at 20°C
acetone 10-14g/L at 20°C
ethyl acrylate <10g/L at 20°C
n-heptane <10g/L at 20°C

p-xylene <10g/L at 20°C
(notified chemical)

METHOD	CIPAC MT 181
Remarks	Increasing amounts of a potential solvent were added to specified amounts of test substance. After shaking in a water bath, dissolution was determined by inspection.
TEST FACILITY	GAB (2006i)

7. TOXICOLOGICAL INVESTIGATIONS

Toxicological data was provided for the notified chemical (>75% purity) or Sanitized T99-19 (solvent solution containing ~ 40% notified chemical).

Endpoint and Result	*Test Substance*	*Assessment Conclusion*
Rat, acute oral LD50 > 2000 mg/kg bw	notified chemical	low toxicity
Rat, acute dermal toxicity	-	not performed as the notified chemical is corrosive
Rabbit, skin irritation	Sanitized T99-19	corrosive
Rabbit, eye irritation	-	not performed as the notified chemical is corrosive
Guinea pig, skin sensitisation – non-adjuvant test.	Sanitized T99-19	Evidence of sensitisation
Rat, repeat dose oral toxicity – 90 days.	notified chemical	NOAEL = 240 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	Sanitized T99-19	non mutagenic
Genotoxicity – in vitro chromosomal aberration test	notified chemical	non genotoxic
Genotoxicity – in vitro mouse lymphoma mutation test	notified chemical	equivocal

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical.
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/HanBrl: WIST (SPF)
Vehicle	PEG 300
Remarks - Method	No deviations from protocol noted.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3/sex	2000	0/6

LD50	> 2000 mg/kg bw
Signs of Toxicity	Slightly ruffled fur was observed in one female 3 and 5 hours after treatment and on the first and second day after treatment. Hunched posture was observed 5 hours after dosing in this same animal.
Effects in Organs	No findings.
Remarks - Results	None.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	RCC (2002i)

7.2. Acute toxicity – dermal

Not performed as the notified chemical is corrosive.

7.3. Acute toxicity – inhalation

Not performed.

7.4. Irritation – skin

TEST SUBSTANCE	Sanitized T99-19
METHOD	ASTM F719-81 1996 guidelines
Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Vehicle	As supplied
Observation Period	48 hours.
Type of Dressing	Occlusive.
Remarks – Method	Area was abraded or non abraded prior to application. Test item was applied for 24 hours.

RESULTS

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

*Calculated on the basis of the scores at 24, 48 for ALL animals on intact skin. Results at 48 hours were unclassified due to the formation of a black scar over the site.

Remarks – Results	Pale green dermal necrosis noted at intact and abraded skin sites after 1 and 24 hours. Surrounded by well-defined erythema at 24 hours. Dark brown/ black scab precluded observation of the erythema at the 48-hour observation point. The scab was surrounded by a well-defined erythema. Slight oedema was observed in all animals at 1 and 24 hours.
CONCLUSION	The notified chemical is corrosive to skin.
TEST FACILITY	Safepharm (1999a)

7.5. Irritation – eye

Not performed as the notified chemical is corrosive.

7.6. Skin sensitisation

TEST SUBSTANCE	Sanitized T99-19
METHOD	OECD TG 406 Skin Sensitisation - Buehler EC Directive 96/54/EC B.6 Skin Sensitisation – Buehler.
Species/Strain	Guinea pig/Dunkin Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: not applicable topical: 75% (v/v) in 80% aqueous ethanol
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 10
induction phase	Induction Concentration: Intradermal injection: not applicable topical application: as supplied
Signs of Irritation	Moderate dermal irritation (see remarks-results)
CHALLENGE PHASE	
1st challenge	topical application: 75% (v/v) in 80% aqueous ethanol topical application: 50% (v/v) in 80% aqueous ethanol
2nd challenge	topical application: not applicable
Remarks – Method	No deviations from protocol noted.

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	75% (v/v)	6/20	3/20		
	50% (v/v)	0/20	0/20		
Control Group	75% (v/v)	0/10	0/10		
	50% (v/v)	0/10	0/10		

Remarks – Results

Topical induction
Discrete or patchy to moderate erythema and very slight to slight oedema were formed. Crust formation prevented accurate scoring and for 13 test group animals the induction site was changed following application. No reactions were observed in control group.

Topical challenge
Positive skin responses (discrete or patchy erythema) in 6 test animals at 24 hours, which persisted for 48 hours in three animals when applied with 75% (v/v) test substance in 80% ethanol. No reactions observed in control group or at concentrations of 50% (v/v) in 80% ethanol.

Body weight gains were normal.

CONCLUSION There was evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY Safepharm (2000a)

7.7 Repeat dose toxicity

7.7.1 Range Finding Study

TEST SUBSTANCE notified chemical

METHOD Similar to the Main Study (see section 7.7.2)

Species/Strain	SPF bred Wistar rats
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 14 days; Dose regimen: 7 days per week;
Vehicle	PEG 300
Remarks – Method	None.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0
II (low dose)	5/sex	50	0
III (mid dose)	5/sex	200	0
IV (high dose)	5/sex	1000	2

Mortality and Time to Death
Two high dose females were found dead on days 7 and 14.

Clinical Observations
High dose animals showed signs of ruffled fur, emaciation, pale faeces and breathing noises. The incidence and severity of these signs increased with time and indicated systemic toxicity.

Reduced food consumption was observed in high dose animals. Additionally body weights of high dose males were reduced at day 8 and both sexes showed decreased body weights at day 14.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Not tested.

Effects in Organs
Absolute kidney and spleen weights were reduced in high dose males. No similar decrease was observed in females. Heart weights in high dose females were reduced.

Enlargement, liquid contents or gas were noted in the caecum of 3 males and 3 females at 14 days in the high dose group. Enlargement of the caecum with liquid was observed in one mid dose female. Of the two females found dead, one showed liquid stomach contents but no change was observed in the other.

Renal pelvis dilation was noted in one treated male and one untreated male therefore this effect has no toxicological significance.

Remarks – Results
None.

CONCLUSION
Based on the findings of this study, the doses for the 90-day study were determined to be 15 – 240 mg/kg bw/day. Any findings observed in this test were assumed to be cumulative and not reversible.

TEST FACILITY RCC (2002j)

7.7.2 Main Study

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents.
Species/Strain SPF bred Wistar rats
Route of Administration Oral – gavage
Exposure Information Total exposure days: 91/92 days;
Dose regimen: 7 days per week;
Vehicle PEG 300
Remarks – Method Minor deviations from protocol did not affect the validity of the test.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	10/sex	0	0
II (low dose)	10/sex	15	0
III (mid dose)	10/sex	60	0
IV (high dose)	10/sex	240	2

Mortality and Time to Death
One female was dead on day 43 and one male on day 73 likely due to dosing errors of the high dose group.

Clinical Observations
Soft faeces from the first week of treatment until necropsy were seen in control and treated rats and were considered to be due to the vehicle.

Pale faeces were noted in all males at week 11 and continued to the end of the study in mid dose males. Additionally breathing noises were observed in one male in week 3 and dyspnea in one female during week one in mid dose animals.

At the high dose breathing noises were noted in single males during weeks 4, 6 and 7 and in one male continuously from week 7 of treatment. Emaciation was noted in this animal in weeks 10 and 11. This was

considered to be due to a dosing error. Pale faeces were noted in most males and females during week 11 persisting until necropsy.

Reduced hindlimb grip strength was noted in high dose females. The absence of an effect in males suggests it is incidental.

No test related differences in mean locomotor activity were observed. Transient significant reductions were noted during 30-45 min in mid dose males and high dose females. These are considered to be incidental.

A persistent pupillary membrane was noted in one high dose male. This was also observed in two control animals. No other ophthalomoscopic changes were observed.

A transient decrease in mean daily food consumption in high dose animals was noted in both sexes in weeks 7/8 of treatment. Male food consumption continued to be slightly less until week 12/13. This was considered to be due to dosing error in one male and one female. A food spillage caused an increase in food consumption in weeks 4/5 in control females.

Mean body weight in males was marginally lower for high dose males from week 7 to week 11 (probably due to the dosing error). No other body weight differences were observed.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Haematology: Increased hematocrit and red blood cell count were noted in treated males which were due to low control values (compared to historical data) and are considered unrelated to the treatment.

All other differences (reduced red cell distribution width in males, reduced haemoglobin distribution width in males, increased haemoglobin distribution width in females and reduced absolute reticulocyte count in males) remained within the 95% tolerance limits of historical controls and are considered incidental. The increase in relative reticulocyte count in lose dose males was reduced, whilst this exceeded the historical control data no dose response relationship was observed so the effect was considered to be incidental.

Clinical chemistry: Aspartate aminotransferase was significantly higher in high dose males and alanine aminotransferase activity was increased in high dose animals compared to controls. This was likely to be a test item-related change.

Sodium levels were significantly increased in mid dose animals and high dose males. Potassium levels were significantly increased in high dose males. Significant increases in chloride values were noted in mid and high dose females. These indicate the kidney is part of the metabolic pathway.

A dose related decrease in glucose levels was noted in treated animals.

Absolute and relative alpha-1 globulins were significantly lower in females and absolute and relative beta globulins were significantly increased in females at all dose levels. A dose related increase in absolute and relative gamma globulin was noted in treated males. The differences in the electrophoretic functions were not considered to be changes of toxicological relevance.

A decrease in absolute and relative alpha-2 globulins in low dose females was considered to be due to the high control values compared to historical data.

Urinalysis: High dose female rats produced significantly less urine than control rats after 13 weeks. Relative density and osmolality of the urine from high dose animals was significantly increased compared to controls.

Effects in Organs

Increases in absolute kidney weight and kidney to body weights were observed in high dose males and considered to be due to the test substance.

Absolute brain weight, liver to body weight ratio and reduced thymus-to-brain weight ratios observed in high dose males were considered to be incidental to the test item. No other changes were observed.

The two animals found dead during testing showed distension of the gastrointestinal system with gas, red focus on the thymus and the female had red discolouration of the lung and mediastinal lymph nodes.

There were considered to be no treatment related microscopic findings.

Remarks – Results	Increased liver enzyme activity in high dose animals was considered to be an adaptive change. Kidney effects considered to be representative of a compensatory metabolic response induced by the test substance were the changes in plasma electrolytes in mid and high dose animals, together with reduced urine volume in high dose females, increased relative density and osmolality in high dose animals slightly increased kidney weights. The kidney and liver effects were not considered to be adverse.

CONCLUSION
The No Observed Effect Level (NOEL) was established as 15 mg/kg bw/day in this study, based on pale faeces, electrolyte and kidney weight and urine changes in rats exposed for 90 days to higher doses of the test substance. A No Observed Adverse Effect level (NOAEL) was established at 240 mg/kg bw/day as all changes were perceived to be minor.

TEST FACILITY RCC (2002k)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Sanitized T99-19

METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2 *uvr*A Plate incorporation method.
Metabolic Activation System	Rat liver S9 fraction plus phenobarbitone / β-naphthoflavone.
Concentration Range in Main Test	a) With metabolic activation: 15 – 5000 µg/plate. b) Without metabolic activation: 5 – 1500 µg/plate.
Vehicle	Distilled water
Remarks – Method	No deviation from protocol noted.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1	1500	≥1500	>5000	Negative
Test 2		1500	>5000	Negative
Absent				
Test 1	500	500	>5000	Negative
Test 2		500	>5000	Negative

Remarks – Results	Toxicity was observed at 500 µg/L without S9 activation and at 1500 µg/L with activation. Negative controls were within historical limits (although not within the range considered normal by the test laboratory) and positive controls demonstrated the sensitivity of the test.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Safepharm (2000b)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
Cell Type/Cell Line V79 Cell line (Chinese hamster)
Metabolic Activation System Phenobarbital/β-naphthoflavone-induced rat liver S9 fraction.
Vehicle DMSO
Remarks – Method Pretest – cytotoxicity (indicated by reduced cell number) was observed at concentrations greater than 28 µg/mL.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period (hrs)*	*Harvest Time (hrs)*
Present			
Test 1	0.3, 0.6, 1.3, 2.5, 5.0*, 10.0*, 15.0*, 25.0	4	18
Test 2	5.0*, 10.0*, 15.0*, 25.0*, 37.5, 50.0	4	28
Absent			
Test 1	0.3, 0.6, 1.3, 2.5, 5.0*, 10.0*, 15.0*, 25.0	4	18
Test 2	1.3*, 2.5*, 5.0*, 10.0, 15.0, 25.0	18	-
Test 3	2.5, 5.0, 10.0*, 15.0	28	-

*Cultures 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	24	>25	>25	>25
Test 2		>25	15	>25
Absent				
Test 1	24	>25	15	>25
Test 2		>25	>25	>25
Test 3		>25	>25	>25

Remarks – Results Statistically significant increases in aberrations were observed in the absence of S9 mix after 18 hours with 1.3 µg/mL and at 28 hours with 10 µg/mL and in the presence of S9 mix after 28 hours with 10 µg/mL. However the percentage of aberrations were in the historical control range, there was a lack of dose response and there was no significant increase in exchange-type aberrations. Therefore they are not considered to be representative of clastogenic potential.

CONCLUSION The notified chemical was not clastogenic to Chinese hamster V79 cells treated in vitro under the conditions of the test.

TEST FACILITY RCC (2002l)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 476 In vitro Mammalian Cell Gene Mutation Test.
Cell Type/Cell Line Mouse lymphoma/L5178Y
Metabolic Activation System Phenobarbital/β-naphthoflavone-induced rat liver S9 fraction.
Vehicle DMSO

Remarks – Method Pretest - exposed for 4 & 24 hours without activation and 4 hours with activation.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period (hrs)*	*Expression Time (hrs)*
Present			
Test 1	0.8, 1.6, 3.1, 6.3, 13, 25, 50	4	72
Test 2			
Absent			
Test 1	0.8, 1.6, 3.1, 6.3, 13, 25, 50	4	72
Test 2	0.3, 0.6, 1.3, 2.5, 5.0, 10.0, 20.0	24	48

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect**
Present				
Test 1		13.0	25	25
Test 2		5.0	>20	>20
Absent				
Test 1		6.3	25	25
Test 2				

* An apparent genotoxic effect was observed but see the discussion below

Remarks – Results

Two cultures were used in each of the tests.

For Test 1 in the absence of S9 an increase in mutation frequency was apparent in both cultures at 13 µg/mL. However, in culture II the relative cloning efficiency was 9.5% which is just below the level of 10% where the result could be rejected on the basis of high toxicity artefacts and in culture I the increase was less than 2-fold (although close to 2-fold) and there was low relative suspension growth and relative total growth. Applying the Global Evaluation Factor (GEF) described by Moore et al., 2006, of 126 for the microwell method suggests that culture I is negative. However, there appears to be a trend which was not tested statistically and could indicate a positive response taken together with the results of culture II as the toxicity was borderline for rejection of the positive response.

In the presence of S9 an increase in mutation frequency was apparent in both cultures at 25 µg/mL. In one of these the threshold of twice the solvent control frequency was well exceeded. However, the relative total growth of 6.3% suggested the result could be due to high toxicity artefacts. Again no trend analysis was performed although, by inspection the trends appear weak. In culture II the increase in mutant colonies was less than two-fold and the GEF was under 126.

In Test I using the criteria of Moore et al. (2006) the positive control should show an induced mutation frequency of 300 x 10^{-6} to be accepted. This is not the case for this experiment. Therefore, on this basis the positive controls would be rejected. This suggests it is difficult to demonstrate genotoxicity in this system under the conditions used in Test I.

In Test II with a treatment time of 24 hours, the positive controls were acceptable and no increase in the mutation frequency was observed with the test article at the top dose of 5 µg/mL which was toxic but the relative cloning efficiency and relative total growth were both > 10%. At 10 µg/mL the cultures could not be continued because of toxicity.

CONCLUSION	The genotoxicity of the notified chemical to the mouse lymphoma cell line treated in vitro under the conditions of the test was equivocal.
TEST FACILITY	RCC (2002m)

8. ENVIRONMENT

8.1. Environmental fate

Environmental fate data was provided for the notified chemical (>75% purity) or Sanitized T99-19 (solvent solution containing ~ 40% notified chemical).

8.1.1 Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 A Ready Biodegradability: DOC Die-Away Test. EC Directive 92/69/EEC C.4-A Biodegradation: Determination of the " Ready" Biodegradability: Dissolved Organic Carbon (DOC) Die-Away Test
Inoculum	Aerobic activated sludge from wastewater treatment plant
Exposure Period	28 days
Auxiliary Solvent	Nil
Analytical Monitoring	Not determined as the notified chemical binds to the equipment and quantitative determination cannot be obtained.
Remarks – Method	The test item was melted in a water bath at 40°C for 10 minutes and homogenized before use. At sampling, deposits on the test vessels were scraped off and resuspended in the test vessels.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% degradation*	*Day*	*% degradation*
3	7	3	91
6	70	6	100
10	84		
14	76		
21	79		
28	75		

Remarks – Results	The test item was readily biodegradable since the pass level for ready biodegradability (70% removal of DOC in a 10-day window within a 28-day period) was reached. In the abiotic control, the test item and poisoned mineral medium, no significant degradation was recorded within the exposure period of 28 days, based on DOC measurements. The reference item sodium benzoate was completely biodegraded within 6 days of exposure confirming the suitability of the activated sludge. In the toxicity control containing the test item, the reference item sodium benzoate, and activated sludge, the DOC content decreased by 82% within 14 days of exposure. Thus, the test item can be assumed to be not inhibitory to activated sludge.
CONCLUSION	The notified chemical can be classed as ready biodegradable.
TEST FACILITY	RCC (2002n)

8.1.2 Inherent biodegradability

TEST SUBSTANCE	Sanitized T99-19
METHOD	OECD TG 302B Inherent biodegradability; Modified Zahn-Wellens/ EMPA test EEC Commission Directive 87/302/EEC, US EPA Fate, Transport, and Transformation Test Guidelines OPPTS 835.3200.
Inoculum	Activated sewage sludge micro organisms
Exposure Period	28 days
Auxiliary Solvent	Nil
Analytical Monitoring	DOC
Remarks – Method	The test material at a concentration of approximately 50 mg C/L was exposed to activated sewage sludge micro-organisms with culture medium in the dark at 24 ± 1°C for 28 days. The degradation of the test material was assessed by the determination of dissolved organic carbon removal. Control cultures with inoculum and the standard material, diethylene glycol (Digol), together with an abiotic test vessel, an abiotic control vessel and a toxicity control vessel were used for validation purposes.

RESULTS

Test substance		*Digol*	
Day	*% degradation*	*Day*	*% degradation*
1	15	1	2
2	20	2	5
3	40	3	16
6	88	6	57
8	91	8	99
10	93	10	9
14	93	14	98
16	91	16	98
21	96	21	99
28	101	28	103

Remarks – Results

Degradation values in excess of 100% are considered to be due to sampling error.

The results of the abiotic test vessel showed 24% loss of DOC occurred over the study period. Correction of the DOC degradation rate of the test material for abiotic loss showed that the test material achieved 77% biodegradation after 28 days. Given that even after correction for abiotic loss of test material, the degradation rate was in excess of 70% the test material can be considered to be ultimately biodegradable.

The standard material, Digol, attained 103% degradation after 28 days, thereby confirming the suitability of the inoculum and culture conditions. The toxicity control (Digol and the test material) attained 96% degradation after 28 days therefore confirming that the test material was not toxic to the sewage treatment micro-organisms used in the study.

CONCLUSION The notified chemical can be classed as ultimately biodegradable.

TEST FACILITY Safepharm (2000c)

8.1.2. Bioaccumulation

The notified chemical is ready biodegradable, undergoes rapid hydrolysis in water and has a log Pow = 2.9. Based on these properties of the substance, it is not expected to bioaccumulate.

8.2. Ecotoxicological investigations

Ecotoxicological data was provided for the notified chemical (>75% purity) or Sanitized T99-19 (solvent solution containing ~ 40% notified chemical).

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – zebra fish, 96 h static test EC Directive 92/69/EEC C.1 Acute Toxicity for Fish- zebra fish, 96 h static test
Species	Zebra fish (*Brachydanio rerio*)
Exposure Period	96 h
Auxiliary Solvent	Nil
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	Not determined as the test substance binds to the HPLC equipment, therefore a quantitative assessment is not possible.
Remarks – Method	A static test without test medium renewal was performed to assess the acute toxicity of the test item and its degradation products. The test item was melted in a water bath at about 40°C for about 10 minutes and homogenized prior to dissolving 100 mg in 1000 mL test water by intense stirring for 15 minutes at room temperature. Dead fish were removed at least once daily and discarded. The LC50 and the 95% confidence interval at the observation dates were calculated by Moving Average Interpolation on the basis of nominal test item concentrations. All test results are based on nominal concentrations.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
0		7	0	0	0	0	0
0.46		7	0	0	0	0	0
1.0		7	0	0	0	0	0
2.2		7	0	5	5	6	6
4.6		7	2	7	7	7	7
10		7	7	7	7	7	7

LC50	1.6 mg/L at 96 hours. (95% CI: 1.2-2.2 mg/L)
NOEC	1.0 mg/L at 96 hours.
Remarks – Results	At 2.2 mg/L and 4.6 mg/L apathy, mucus secretion and tumbling during swimming were observed in live fish. No remarkable observations were made concerning the appearance of the test media. All test media were clear solutions throughout the entire test duration.
CONCLUSION	The notified chemical is toxic to zebra fish.
TEST FACILITY	RCC (2002o)

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Sanitized ® T99-19
METHOD	OECD TG 203 Fish, Acute Toxicity Test – rainbow trout, 96 h semi-static test EC Directive 92/69/EEC C.1 Acute Toxicity for Fish- rainbow trout, 96 h semi-static test
Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	96 h
Auxiliary Solvent	Nil
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	pH, temperature, dissolved oxygen.
Remarks – Method	For the purpose of the definitive study, the test material was dissolved directly in dechlorinated tap water with the aid of ultrasonification for approximately 20 minutes. The concentration, homogeneity and stability of the test material in the test solutions were not determined at the request of the Sponsor. The LC50 values and associated confidence limits at 24 hours using the ToxCalc computer software package were calculated by the trimmed Spearman-Karber method of Hamilton *et al* (1997) and at 48, 72, and 96 hours using the geometric mean method.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
0		10	0	0	0	0	0
1.0		10	0	0	0	0	0
1.8		10	0	0	10	10	10
3.2		10	0	1	10	10	10
5.6		10	0	10	10	10	10
10		10	0	10	10	10	10

LC50	1.3 mg/L at 96 hours.
NOEC	1.0 mg/L at 96 hours.
Remarks – Results	Sublethal effects included swimming at the surface, loss of equilibrium and the presence of moribund fish. These were observed at 3.2 and 10 mg/L. As the test media of the 10 mg/L test concentration was observed to be a very pale cloudy homogenous dispersion, and the test material may have formed micro-dispersions, not detected by visual inspection, at the remaining test concentrations, microscopic examination was performed on the gill filaments of all the dead fish. The gill filaments were observed to be free of test material indicating a toxic response as opposed to a physical effect of the test material.
CONCLUSION	The notified chemical is toxic to zebra fish.
TEST FACILITY	Safepharm (2000d)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Daphnia Magna, 48 hour immobilization static test EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - Daphnia Magna, 48 hour immobilization static test
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Nil
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	Not determined as the test substance binds to the HPLC equipment, therefore a quantitative assessment is not possible.
Remarks – Method	A static test without test medium renewal was performed to assess the acute toxicity of the test item and its degradation products. The test item was melted in a water bath at about 40°C for about 10 minutes and homogenized prior to use. The EC50 and the 95% confidence interval at the observation dates were calculated by Moving Average Interpolation on the basis of nominal test item concentrations.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0		20	0	0
0.046		20	0	0
0.10		20	0	0
0.22		20	0	2
0.46		20	10	20
1.0		20	20	20

LC50	0.29 mg/L at 48 hours (95% CI: 0.25-0.34 mg/L)
NOEC	0.1 mg/L at 48 hours
Remarks – Results	All biological results are related to the nominal test item concentrations. No remarkable observations were made concerning the appearance of the test media. All test media were clear solutions throughout the entire test duration.
CONCLUSION	The notified chemical is very toxic to *Daphnia magna*.
TEST FACILITY	RCC (2002p)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	Freshwater green algae (*Scenedesmus subspicatus*)
Exposure Period	72 hours
Concentration Range Nominal	0, 0.011, 0.034, 0.11, 0.34, 1.1, and 3.4 mg/L
Concentration Range Actual	Not determined as the test substance binds to the HPLC equipment, therefore a quantitative assessment is not possible.
Auxiliary Solvent	Nil
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	Not determined as the test substance binds to the HPLC equipment, therefore a quantitative assessment is not possible.
Remarks – Method	All test results are based on the nominal concentrations of the test item.

RESULTS

Biomass		*Growth*	
E_bC_{50}	*NOEC*	*E_rC_{50}*	*NOEC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
0.14	0.034	0.39	0.034
(0.09-0.22)		(0.25-0.67)	

Remarks – Results: The test item had a statistically significant inhibitory effect on the growth (biomass and growth rate) of *Scenedesmus subspicatus* after the exposures period of 72 hours at concentrations of 0.11 mg/L and above.

CONCLUSION: The notified chemical is very toxic to algae.

TEST FACILITY: RCC (2002r)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE: Sanitized T99-19

METHOD: OECD TG 209 Activated Sludge, Respiration Inhibition Test.
EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test.

Inoculum: Synthetic sewage
Exposure Period: 3 hours
Concentration Range Nominal: 10, 32, 100, 320 and 1000 mg/L
Remarks – Method: The rate of respiration was determined after 30 minutes and 3 hours contact time and compared to data for the control and a reference material, 3,5-dichlorophenol.

RESULTS

IC50: 140 mg/L
NOEC: 32 mg/L
Remarks – Results: Concentrations of 320 and 1000mg/L the test material was observed to cause foaming. The validation criteria for the control respiration rates and reference material EC_{50} values have been satisfied.

CONCLUSION: The notified chemical is not harmful to sewage microbes.

TEST FACILITY: Safepharm (2000e)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The majority of imported notified chemical is expected to be disposed of to landfill, predominantly associated with the end-use items to which it is affixed. In landfill, the notified chemical is expected to degrade by biotic and abiotic means to form simple carbon, nitrogen and silicon based compounds.

It is anticipated that up to 3% may be released to sewer from spent dye-bath during use. In order to provide a conservative estimate, a fixation rate of 90% is assumed thus for the purposes of the following calculation 10% of the notified chemical is assumed to be released to the sewer during cleaning. The notifier has provided the following calculations.

Process or dilution factor	City textile processing	Country textile processing
Typical notified chemical use per day (assumes 90% processed in the city and 10% processed in the country over 250 days with 5 tonne imported annually)	18 kg	2 kg
Quantity in wash water (at a fixation rate of 90%)	1.8 kg	0.2 kg
STP daily volume	100 ML[a]	4 ML
Concentration in effluent at STP	18 µg/L	50 µg/L
Concentration remaining after degradation at STP (assumes 75% degradation after 28 days[b])	4.5 µg/L	12.5 µg/L
Concentration remaining after partitioning to sludge (assuming 80% is partitioned to sludge)	0.9 µg/L	2.5 µg/L
Final concentration in effluent	0.9 µg/L	2.5 µg/L
Freshwater PEC (Dilution factor 1:1)	0.9 µg/L	2.5 µg/L
Ocean PEC (Dilution factor 1:10)	0.09 µg/L	0.25 µg/L

[a.] The STP daily volume of the two main STPs in metropolitan Melbourne are 485 ML and 370 ML of water per day (Melbourne Water 2005 "Essential Facts – The Sewerage System" http://www.melbournewater.com.au/content/library/publications/fact_sheets/sewerage/the_sewerage_system.pdf#search=%22western%20trunk%20sewer%20daily%20volume%22

[b] Based on the results of the ready biodegradability test.

Given the majority of the notified chemical will be processed in Melbourne the estimates above are considered by the notifier to be conservative by between a factor of 3 and 5 times.

The basis for the 75% degradation and 80% partition to sludge are tenuous as the former is based on a 28 day ready biodegradability test (compared with the likely <24 h retention time within an STP) and the latter presumably from the K_{OC} (which is an estimate of an estimate). Therefore, DTEWR has used SimpleTreat to determine mitigation, which shows 88% removal through this process. The following PECs have been derived by DTEWR, assuming 100% release in either a city or a country area of the proposed 5 tonne per year annual volume:

	City	Country	
Total Annual Import/Manufactured Volume	5,000	5,000	kg/year
Proportion expected to be released to sewer	10%	10%	
Annual quantity of chemical released to sewer	500	500	kg/year
Days per year where release occurs	250	250	days/year
Daily chemical release:	2.000	2.000	kg/day
Individual Sewage Treatment Plant Average Daily Flow:	300	4	ML/day
Removal within STP	88%	88%	
Dilution Factor – River	1.0	1.0	
Dilution Factor – Ocean	10.0	10.0	

PEC - River:	0.80	60.00	µg/L
PEC - Ocean:	0.08	6.00	µg/L

9.1.2. Environment – effects assessment

Aquatic ecotoxicity testing found the notified chemical to be toxic to very toxic to aquatic organisms, with the most sensitive being Daphnia. The following PNEC has been calculated as follows:

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Invertebrates).	0.29	mg/L
Assessment Factor	100	
PNEC:	2.90	µg/L

9.1.3. Environment – risk characterisation

Based on the above exposure scenarios and effects assessment, the following risk quotient (Q) has been calculated:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
City Q - River:	0.90	2.9	0.310
City Q - Ocean:	0.09	2.9	0.031
Country Q – River	2.50	2.9	0.862
Country Q – Ocean	0.25	2.9	0.086
City Q - River:	0.80	2.9	0.276
City Q - Ocean:	0.08	2.9	0.028
Country Q – River	60.00	2.9	20.690
Country Q – Ocean	6.00	2.9	2.069

The Q values for all of the exposure scenarios presented above by the notifier are less than 1, indicating that the proposed use patterns and volumes are unlikely to pose an unacceptable risk to the aquatic environment. However, the Q value for the release from a country dye-house into a river scenario (0.862) is relatively close to 1, despite the mitigation employed in deriving the PEC.

Using the exposure scenarios calculated by DTEWRs standard methodology (Environment Australia (2003)), it can be seen that a significant risk to the aquatic environment exists when the proposed volume (5 tonne per year) is released to a small country STP. Even if this is only 25% or 10% (as assumed by the notifier), the Q remains unacceptable at 7.25 and 2.90 respectively. While the calculations are somewhat conservative, further mitigation is not possible. Therefore, use where release of effluent is to a country sewer is not supported until further information on the actual fixation rate is supplied.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical is imported at a concentration of 40% in 20 L plastic pails or 25 L jerrycans and added manually to dye baths at a final concentration of < 5%. As the chemical is classified as corrosive and skin sensitising according to the Approved Criteria, workers adding the imported solution to the dye bath are expected to be wearing full face and eye protection and chemically resistant gloves and clothing (including footwear). In these circumstances dermal exposure should not normally occur provided personal protective equipment is correctly washed and maintained. The notified chemical has a (predicted) low vapour pressure so inhalation exposure would be limited to aerosols formed during addition of the imported solution to the dye bath. Exposure to these aerosols is controlled by the use of local exhaust ventilation in addition to the PPE.

In the dye bath, exposure to the notified chemical is limited by its concentration of 5% (maximum) and the final process of dyeing textiles is enclosed so that dermal or ocular exposure should not normally occur in this situation. However, dyeing of air filters can occur in unsealed baths so that accidental exposure could conceivably occur and PPE will be required to control this exposure.

Cleaning and maintenance of the machines will occur by or following washing with water. Therefore any residues in the machines would be very dilute. A majority of the notified chemical is released during washing, following water treatment, to the sewer and exposure to workers would be to a very dilute aqueous solution if it occurs at all.

Although spraying of the notified chemical onto the substrate in diluted form is not intended at this time a possible scenario was submitted by the notifier. The workers could potentially spray the notified chemical at a maximum of 5% in the dye bath under local exhaust ventilation to minimise spray drift.

9.2.2. Public health – exposure assessment

The main means of exposure to the public will be in the final products ie in socks. In this case the small amount of chemical bound to the textile should not migrate and should not therefore be bioavailable.

9.2.3. Human health – effects assessment

Based on the toxicological data provided the notified chemical is unlikely to be acutely toxic via the oral route (LD50 > 2000 mg/kg bw). Dermal acute toxicity could not be conducted as the notified chemical is corrosive as indicated by the test for skin irritation in rabbits. The notified chemical was a skin sensitiser in guinea pigs and therefore potentially could elicit allergic dermatitis. Severe effects in a 90-day repeat dose oral toxicity study in rats were not observed and therefore the notified chemical is not classified as hazardous on this basis. The notified chemical was not mutagenic in bacteria, exhibited sporadic non-dose related increases in chromosomal aberrations in Chinese hamster V79 cells in vitro and exhibited equivocal responses in an in vitro mouse lymphoma forward mutation system. On balance the notified chemical is likely to be weakly genotoxic at most and would require more extensive testing in the mouse lymphoma system to decide if the responses seen were true positives.

Based on the available data, the notified chemical is classified as a hazardous substance in accordance with the *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004) and assigned the risk phrases R34 Causes burns and R43 May cause sensitisation by skin contact.

9.2.4. Occupational health and safety – risk characterisation

The fact that the notified chemical is corrosive to skin and is sensitising means workers are at risk of these effects while manually pouring the imported solution containing the notified chemical into dye baths. Therefore, adequate protective clothing and footwear, full face shields and chemically resistant gloves and clothing are required to control exposure during this operation while workers are in the vicinity of the dye bath. If PPE is used in this way and properly cleaned and maintained, the risk of burns or allergic dermatitis should be low. Under these circumstances, given that local exhaust ventilation is employed, the risk of respiratory irritation and (possible) respiratory sensitisation from exposure to aerosols should also be controlled.

Once the notified chemical is blended in the dye liquor at a maximum concentration of 1.4% the risk of irritation or allergic dermatitis should be low where the system is enclosed such as when dyeing textiles. Dye baths used for dyeing air filters can be unsealed in which case there is still potential for skin sensitisation from accidental exposure although exposure should be intermittent at most and the risk of allergic dermatitis would be low. The risk of these health effects during disposal of the dye liquor, cleaning or washing the machines is limited by the dilution of the notified chemical and the limited likely exposure.

Application of dye liquour to air filters can be via spraying with potential for exposure to aerosols. However spraying should be conducted in a designated area where provision is made

for capture of overspray and volatiles. Under these conditions the risk of sensitisation should be low.

Once the chemical is applied to the substrate it is chemically bound and should not migrate. Therefore, there should be no risk of irritation or sensitisation for people handling filters or textiles after passing through the pad mangle and on to further processing.

9.2.5. Public health – risk characterisation

The main means of exposure to the public will be in the final products ie in socks. In this case the small amount of chemical bound to the textile should not migrate (the notifier states the fixation rate is 98%) and should not therefore cause adverse health effects.

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

10.1. Hazard classification

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

R34: Causes burns
R43: May cause sensitisation by skin contact

and

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

	Hazard category	***Hazard statement***
Health		
Corrosion	Category 1	Corrosive
Sensitisation	Category 2	Sensitiser
Environment	Acute Category 1	Very toxic to aquatic life.

10.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern and proposed import volume for city use only.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is High Concern to occupational health and safety under the conditions of the occupational settings described necessitating the use of adequate PPE. The risk is acceptable provided adequate controls are in place.

10.3.2. Public health

There is No Significant Concern to public health when used as described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product to be imported containing the notified chemical provided by the notifier was in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). 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 product to be imported containing the notified chemical provided by the notifier was in accordance with the *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the health hazard classification for the notified chemical:
  - R34 Causes burns
  - R43 May cause sensitisation by skin contact

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥ 1%: R43 May cause sensitisation by skin contact
  - 5% ≤ concentration < 10%: R36 Irritating to eyes; R38 Irritating to skin
  -
  - ≥ 10% R34 Causes burns
    R41 Risk of serious eye damage (assumed for chemicals assigned R34)

- The notified chemical should be classified as follows under the ADG Code:
  - Class 8, Packing Group II

- Suppliers should label the notified chemical as a Class 8 dangerous good with the signal word Corrosive and the risk and safety phrases listed above.

Health Surveillance

- As the notified chemical is a skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:
  - Local exhaust ventilation should be used during addition of the notified chemical to the dye bath

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Full face shield, chemical resistant gloves (nitrile, neoprene), protective clothing and footwear

  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 *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 end-user dye-houses for release of the notified chemical to the environment:
  - No release to country sewers.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment, collection and subsequent safe disposal.

12.1. Secondary notification

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

(1) Under Section 64(1) of the Act; if
- the notified chemical is to be released to country sewers

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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