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May 2005

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Red TZ 5271

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba Specialty Chemicals (ABN: 97 005 061 469)
235 Settlement Rd
THOMASTOWN VIC 3074

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:

Spectral data
Purity
Identity of impurities
Identity of Additives/Adjuvants
% Weight of Additives/Adjuvants
Manufacture/import volume
Number of sites of use

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
EU 577954

2. IDENTITY OF CHEMICAL

The notified chemical is comprised of two main components, A and B. These components are reaction products described by a single chemical name and CAS Number but different structural formulae as indicated below.

CHEMICAL NAME
2-naphthalenesulfonic acid, 7-amino-4-hydroxy-8-[[2-sulfo-4-[[2-(sulfooxy)ethyl]sulfonyl]phenyl] azo]-, potassium sodium salt, coupled with diazotised 2-[(4-amino-5-methoxy-2-methylphenyl)sulfonyl]ethyl hydrogen sulfate

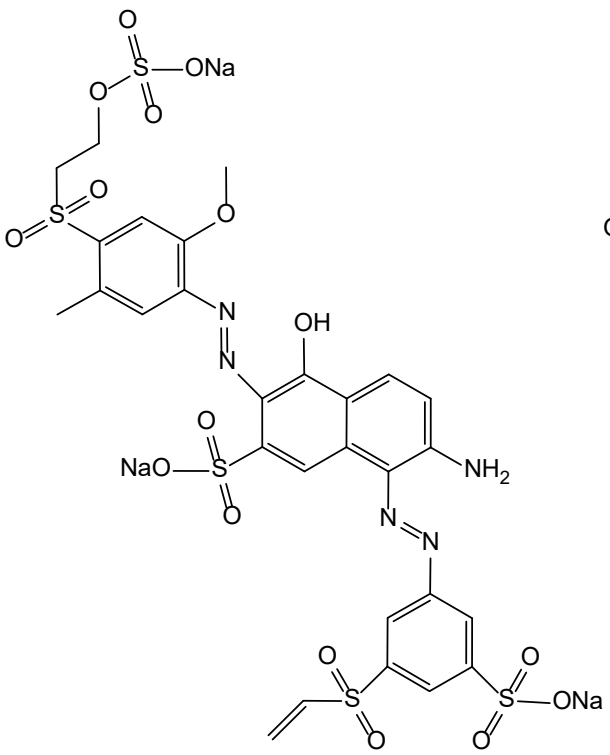
OTHER NAME(S)
FAT 40`812/A

MARKETING NAME(S)
<20% component of Cibacron Super Black R.

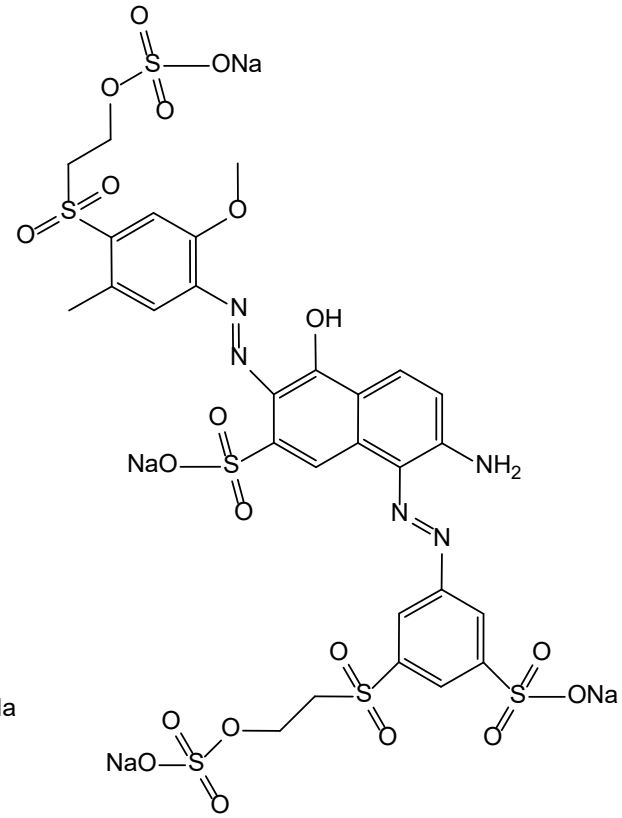
CAS NUMBER
577954-20-2

MOLECULAR FORMULA
Main component A: $C_{28}H_{24}K_{0.4}N_5Na_{2.6}O_{16}S_5$
Main component B: $C_{28}H_{25}K_{0.5}N_5Na_{3.5}O_{20}S_6$

STRUCTURAL FORMULA



Main component A



Main component B

Structures are shown as the sodium salts. Potassium may be substituted at the ratios indicated in the molecular formula.

MOLECULAR WEIGHT
Main component A: 922.23
Main component B: 1044.43

METHODS OF DETECTION AND DETERMINATION

METHODS	^{1}H Nuclear Magnetic Resonance Spectroscopy UV/visible Spectroscopy Infrared Spectroscopy
TEST FACILITY	(RCC Ltd, 2003a)

3. COMPOSITION

DEGREE OF PURITY
<60% (sum of two main components)

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported in 30 kg polyethylene lined cardboard kegs.

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

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

USE
Dye for cellulosic textiles, for use in dyehouses only.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney or Melbourne.

TRANSPORTATION AND PACKAGING
The notified chemical will be imported as a <20% component of Cibacron Super Black R in 30 kg cardboard containers with polyethylene lining, which are designed for international travel.

5.2. Operation description

The notified chemical will be imported in a commercial form as a granular solid, which will be dissolved in warm water to produce the dye solutions. Most imported dye will be sold as received, although a small amount may be repacked into smaller containers as samples or for use in mill trials. If required, repackaging will take place at the importer's facility.

The dyes will be used in several dyehouses nationally. At the customer facilities, the granular dye will be weighed, and on average 2.5 kg of dye will be poured through a hatch into the dyeing vat. The dye is mixed with approximately 500 L of water in the enclosed vat to prepare the dye solution. The dye containing the notified chemical will be used on approximately 50 days per year. Small samples of the dye solution will be removed for quality control testing.

The dye solution will be transferred through an enclosed system to a tank, and then dispensed into an enclosed dyeing machine. Over 80% of the dye is bound covalently to the substrate, and then excess dye is washed off, and the textile is dried.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Weighing, dissolving and transfer	6-12	15 minutes/day	60-120 days/year
Dyeing and fixing	6-12	4-8 hours	60-120 days/year
Repacking	2	15 minutes/day	1-2 days/year
Warehouse workers	3-6	15 minutes/day	60-120 days/year

Exposure Details
During transport and storage, workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached. Should a spill occur, the granules are expected to be dampened and placed in suitable correctly labelled containers for recovery and disposal in accordance with instructions contained in the MSDS and disposed of in accordance with Local, State or Federal government regulations.

During the weighing out, dyeing and fixing process, the workers handle the dyestuff as granules or in solution largely in a closed system. Weighing out is conducted in a purpose-designed dispensary under local exhaust ventilation and the dye is added to the blending vessel also under local exhaust ventilation. Workers may be exposed to the dust, although the product contains an antidusting additive,

and the notifier has advised that the product containing the notified chemical has a particle size ranging from 150 and 350 microns, indicating that there will be little chance of inhalation exposure. The most probable route of exposure to the aqueous solution (~1 g/L notified chemical) will be dermal with little exposure to aerosols. Over 80% of the dye is bound covalently to the substrate, and then excess dye is washed off, and the textile is dried. During processing, the material is taken up on beams or trucks so that no manual handling of textile impregnated with wet dye is necessary.

Following the dyeing and fixing steps, the excess dye is washed off. Due to the covalent linkage of the dye to the substrate it is not envisioned that there will be any exposure to the free chemical following the washing steps.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Since the notified chemical will not be manufactured locally, there will be no environmental exposure associated with this process in Australia. Repacking of the dye (less than 100 kg per year) may take place, however, release from the process is expected to be negligible.

RELEASE OF CHEMICAL FROM USE

Nearly all of the dye containing the notified chemical will be removed from the import container liners by shaking and less that 1 kg of the chemical per annum will remain as residue. Given the potential for recovery and reuse and the high unit cost of the dyestuff the waste due to spills is expected by the notifier to be less than 6 kg per annum. Dissolution of the dye takes place in an enclosed vat and the dye is pumped through a closed system to the dyeing machine, therefore, release of the chemical is not expected at this stage.

The dye will be used to colour cellulosic textiles by the exhaust dyeing method. Once the dye is adsorbed and diffused into the fibre matrix it reacts with active sites on the substrate producing strong covalent bonds. The fabric is then dried and steamed to fix the dye to cellulose and then the unreacted dye is washed off. Fixation data provided by the notifier indicates that the fixation rate of the notified chemical to be 83%. The notified chemical adsorbed to the fabric with the dye will not be released to the environment. The rinsate generated via fabric rinsing should contain up to 17% of the notified chemical imported. This will represent the major route of environmental exposure (up to 850 kg of notified chemical per annum based on the maximum import volume).

The dye washed off the fabric will be discharged to the dyehouse effluent system, where cationic flocculation will be used to remove the anionic dyestuff. The treated effluent containing traces of the notified chemical will be disposed of to the sewer.

The dye will be used in a small number of dyehouses and is not expected to be used in country dyehouses.

5.5. Disposal

Any solid waste generated at the dyehouse including the residue in empty import containers will be disposed of as chemical waste according to the MSDS instructions. Incineration is recommended due to the high water solubility of the notified chemical.

5.6. Public exposure

The product containing the notified chemical will only be available to industrial end users. Once the cloth is dyed it will be washed to remove unfixed dye. Products which may be dyed include domestic textiles used for apparel, sheeting and other uses. There is no evidence of bleeding of the dye from dyed cloth. Therefore public exposure to the dyed product is significant whereas exposure to the chemical is not likely to be significant. No public exposure to the notified chemical is expected during repackaging or disposal of industrial waste water.

There is a chance of public exposure due to rupture of containers in an accident. The MSDS for the product advises that any spill should be contained and collected for later disposal in accordance with Government regulations. Public exposure through importation and transportation is therefore

negligible.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Dark red-brownish powder. The imported dyestuff, Cibacron Black Super R, is in the form of black granules.

Melting Point >400°C

METHOD OECD TG 102 Melting Point/Melting Range.
EC Directive EEC A.1 Melting/Freezing Temperature.
Remarks Determined with a differential scanning calorimeter. Between 50°C and 200°C a poorly defined endothermic heat effect was observed. An exothermic reaction was observed at about 250°C. At the completion of the experiment, the sample had lost about 23-24% of its mass with a black carbonised residue remaining.
TEST FACILITY (RCC Ltd, 2003b)

Density 1766 kg/m^3 at 19.5°C

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive EEC A.3 Relative Density.
Remarks Determined with a gas comparison pycnometer.
TEST FACILITY (RCC Ltd, 2003c)

Vapour Pressure $<2 \times 10^{-27}$ kPa at 25°C

METHOD OECD TG 104 Vapour Pressure and EC Directive 92/69 Vapour Pressure.
Remarks The vapour pressure of expected to be low due to its ionic form. The vapour pressure of the acidic form of the dye was estimated using the Modified Watson Correlation as described in the OECD guideline based on the calculated boiling point (>758°C).
TEST FACILITY RCC Ltd (2003d)

Water Solubility ≥419 g/L at 20°C

METHOD OECD TG 105 Water Solubility and EC Directive 92/69/EEC A.6 Water Solubility (Simplified Flask Method).
Remarks As a preliminary study in accordance with guideline, about 4 g of the notified chemical was added to 6 mL of water and stirred for 23 hours at room temperature. The resulting solution was centrifuged and the filtered supernatant was analysed by HPLC.

Due to the dark red colour and high viscosity of the solution, it was not possible to determine if complete dissolution of the notified chemical occurred at concentrations greater than that described above. The water solubility may therefore be higher than determined in this study. Based on the high solubility exhibited in this preliminary study and the high viscosity of the solution, a main test as described in the OECD guideline was not performed.

Based on the results the notified chemical is readily soluble (Mensink *et al.* 1995).
TEST FACILITY RCC Ltd (2003e)

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$*
4	50	>1 year

7	25	212 hours
	50	7 hours
9	25	<1 day

Remarks

No further testing was undertaken at pH 4, as the notified chemical was stable at 50°C, nor at pH 9 where it was found to be very unstable.

At pH 7.0, the notified chemical retention time peak of approximately 10 minutes increased, and a second peak at a retention time of approximately 11 minutes decreased simultaneously. Consequently the hydrolysis behaviour of the peak area sum was followed. As the test substance was not stable at pH 7.0, further testing was performed at higher temperatures to calculate the rate constant and the half-life at 25°C.

TEST FACILITY

RCC Ltd (2003f)

Partition Coefficient (n-octanol/water) log P_{ow} = <-5.5 at 20°C

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks Preliminary tests indicated a partition coefficient below –2, therefore a main test could not be conducted. A log P_{ow} value was estimated using the preliminary solubility data in n-octanol and in water. Solubility in n-octanol is <1.2012 µg/ml, which is the limit of detection for the assay.

The low log P_{ow} is consistent with the high water solubility indicating a low affinity for the organic phase and component of soils and sediments.
TEST FACILITY RCC Ltd (2003e)

Adsorption/Desorption log K_{oc}<1.32 (K_{oc}<21)

METHOD OECD TG 121 Estimation of the Adsorption Coefficient (Koc) on Soil and Sewage Sludge using High Performance Liquid Chromatography (HPLC)
HPLC screening method. Method C19 of Commission Directive 2001/59 EC (which constitutes Annex V of Council Directive 67/548/EEC).
Remarks Six reference substances with known log K_{oc} values were used. The test substance eluted well before the first substance, ie. phenol.

The low K_{oc} value is consistent with the high water solubility of the notified chemical and indicates that its mobility in soil as being very high and it will not be adsorbed by organic carbon in soil.
TEST FACILITY RCC Ltd (2003g)

Dissociation Constant pKa (approximate)
11.23, -0.48, -1.45, -3.9

Remarks The pKa values were estimated using the software LogD Solubility Suite v.7.0 (ACD labs, 2003). The notified chemical will be dissociated over the environmental pH range.
TEST FACILITY RCC Ltd (2003h)

Particle Size

METHOD European commission, Directorate General XII-JRC, Science Research and Development-Joint Research Centre. “Particle Size Distribution, Fibre length and Diameter Distribution” Guidance Document, ECB/TM/February 1996.

Range (µm)	*Mass (%)*
<10	8.13
10-20	11.67
20-40	28.27
40-60	20.09
60-100	21.44
100-200	10.38
>200	0.02

Remarks Determined using laser diffraction method.
Mass Median Diameter = 41.8 µm.
Inhalable fraction: 89.6%
Respirable fraction: 8.13%
TEST FACILITY (RCC Ltd, 2003i)

Octanol Solubility <1.2 mg/L octanol at 37°C

Remarks The octanol solubility was derived from the results generated during the partition coefficient test.
TEST FACILITY RCC Ltd (2003e)

Surface Tension 75.3 mN/m at 21°C.

METHOD	OECD TG 115 Surface Tension of Aqueous Solutions. EC Directive 92/69/EEC A.5 Surface Tension.
Remarks	The surface tension of an aqueous solution (at a concentration of about 0.1%) was measured with a Krüss K8 tensiometer using the ring method.
TEST FACILITY	RCC Ltd (2003j)

Flash Point Not determined.

Flammability Limits Not flammable.

METHOD	EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks	The test sample could not be ignited with a flame from a gas burner.
TEST FACILITY	(RCC Ltd, 2003k)

Autoignition Temperature 342°C

METHOD	92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks	A large exothermic reaction (max temperature measured during reaction was 505.9°C) was observed when the sample temperature reached ~350°C.
TEST FACILITY	(RCC Ltd, 2003l)

Explosive Properties Not explosive.

METHOD	EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks	Negative by thermal stress, shock and friction.
TEST FACILITY	(Institute of Safety and Security, 2003)

Oxidising Properties Not oxidising.

Remarks	Based on UN recommendation criteria and on the oxygen balance, the notified chemical is non-oxidising and expected to be stable under normal environmental conditions.
TEST FACILITY	(RCC Ltd, 2003m)

Reactivity Expected to be stable under normal environmental conditions.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 >2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 >2000 mg/kg bw	low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	non-irritating
Rabbit, sensitisation, local lymph node assay	evidence of sensitisation
Rat, repeat dose oral gavage toxicity – 28 days.	NOAEL = 50 mg/kg/day bw
Genotoxicity – bacterial reverse mutation	mutagenic
Genotoxicity – in vitro mammalian chromosome abberation test	genotoxic
Genotoxicity – in vitro mammalian gene mutation test	non genotoxic
Genotoxicity – in vivo mammalian erythrocyte micronucleus test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 96/54/EEC B.1 tris Acute Oral Toxicity – Acute Toxic Class Method.

Species/Strain	Rat/HanBrl: WIST (SPF)
Vehicle	Purified water.
Remarks - Method	No deviations from protocol.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3/F	2000	0
II	3/F	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity	There were no deaths or test substance related clinical signs or remarkable body weight changes during the study period.
Effects in Organs	Macroscopic examination upon necroscopy revealed no remarkable findings.
Remarks - Results	None.

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

TEST FACILITY (RCC Ltd, 2003n)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Notified chemical.

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

Species/Strain	Rat/HanBrl: WIST (SPF)
Vehicle	Purified water.
Type of dressing	Semi-occlusive.
Remarks - Method	No deviations from protocol.

RESULTS

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

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	There were no test-related signs of toxicity, although light red discolouration was seen on the treated skin that persisted for 11-15 days.
Signs of Toxicity - Systemic	There were no deaths or test-substance related clinical signs. Two females showed a loss of body weight (0.5% and 0.6%) between days 1 and 8, and another female lost 0.3% body weight between day 8 and the end of the observation period. The body weights of all other animals were within the normal range.
Effects in Organs	Macroscopic examination upon necroscopy revealed no remarkable findings.
Remarks - Results	None.

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

TEST FACILITY (RCC Ltd, 2003o)

7.3. Acute toxicity – inhalation

Data not provided.

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Purified water.
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No deviations from protocol.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	0		0
Oedema	0	0	0	0		0

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

Remarks - Results	Red staining visible in all animals up to 10 days after treatment did not preclude Draize score determination.

CONCLUSION The notified chemical is non-irritating to the skin.

TEST FACILITY (RCC Ltd, 2003p)

7.5. Irritation – eye

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	21 days
Remarks - Method	Observation period was extended to 21 days due to red staining of the eye. This staining did not preclude Draize score determination.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.67	0.33	1.00	1	72 hours	0
Conjunctiva: chemosis	0.33	0.00	0.33	2	24 hours	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	0	0	0

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

Remarks - Results: Red staining of the eye persisted for the entire study, i.e. 21 days.

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

TEST FACILITY: (RCC Ltd, 2003q)

7.6. Skin sensitisation

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 429 Skin Sensitisation – Local Lymph Node Assay.

Species/Strain	Mouse / CBA/CaOlaHsd
Vehicle	70% ethanol
Signs of Irritation	Slight ear swelling observed in all mice treated with 10% and 25% notified chemical. From day 2, all mice in Group 4 excreted purple urine.
Remarks - Method	A non-standard vehicle (ethanol) was used but is not expected to affect the interpretation of the results. The testing laboratory has performed tests on a number of different vehicles and has determined that 70% ethanol is the best choice of vehicle for hydrophilic substances, mainly based on a low background Stimulation Index (SI) when compared to untreated animals (RCC Ltd, 2002). 25% was the highest achievable concentration of the notified chemical in the vehicle (ethanol).

RESULTS

Group	*Number and Sex of Animals*	*Dose %*	*DPM Per lymph node*	*Stimulation Index*
I	4	0	381	--
II	4	5	710	1.9
III	4	10	1189	3.1
IV	4	25	801	2.1

Remarks - Results	The notified chemical is classified as a sensitiser, as an SI value greater than 3 was seen. A clear dose response correlation was not observed, however the notifier agrees that classification as a skin sensitiser is appropriate. EC3 = 9.6 % (w/v) (Estimated concentration for an SI of 3)
CONCLUSION	There was evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	(RCC Ltd, 2003r)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/HanBrl:WIST
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	Purified water
Remarks - Method	No deviations from protocol.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	10/sex	0	0
II (low dose)	5/sex	50	0
III (mid dose)	5/sex	200	0
IV (high dose)	10/sex	1000	0
V (control recovery)	10/sex	0	0
VI (high dose recovery)	10/sex	1000	0

Mortality and Time to Death

No mortality was observed during the treatment or recovery phases.

Clinical Observations

The mean body weights and mean body weight gain of high-dose males were lower than those of control males throughout the treatment period. Also, the mean body weights of mid-dose males were lower than control males towards the end of the treatment period, on days 22 and 28. These differences are considered to be a possible effect of the notified chemical. Similar deviations were not seen in female rats.

Dark red fecal discolouration was observed in both sexes after day 2 in the high dose group and after day 4 in the mid dose group. This discolouration continued for the first two days of the recovery period.

A dose-related discolouration of the urine was noted after 4 weeks treatment in all animals in the mid- and high-dose groups. The urinary discoloration was reversible after the recovery period.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Urinary protein was significantly elevated in both males and females in the high-dose group as compared with controls.

A range of other effects were seen, and were not considered to be toxicologically significant as they were not dose related, only occurred in the high dose recovery groups or were within the range of historical controls.

Effects in Organs

Reddish discolouration of the kidneys, intestinal tract, urinary bladder and mesentery lymph nodes were observed in the high dose group.

Small amounts of red/brown, granular to vesicular pigment (without any tissue reaction) was observed in the cytoplasm of renal tubulus cells in high-dose animals, and a reduced amount in high-dose recovery animals.

Remarks – Results

Toxicologically relevant observations were a decrease in the mean body weight and mean body weight gain for mid- and high-dose males, an increase in urinary protein in high-dose animals, and small amounts of granular pigment in the kidneys of high-dose animals.b

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 50 mg/kg bw/day in this study, based on deviations in body weight and body weight gain for higher doses. No NOEL could be established due to the staining properties of the notified chemical.

TEST FACILITY (RCC Ltd, 2003s)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Test 1: plate incorporation test Test 2: pre-incubation test
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA100, TA98 *E. coli*: WP2*uvr*A
Metabolic Activation System	S9 fraction from Phenobarbital/β-naphthoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 33-5000 µg/plate b) Without metabolic activation: 33-5000 µg/plate
Vehicle	Deionised water
Remarks - Method	No significant protocol deviations.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	None.	None.	None.	negative
Test 2	None.	None.	None.	positive (WP2*uvr*A)
Present				
Test 1	None.	≥ 2500 µg/plate (TA 1535)	None.	negative
Test 2	None.	None.	None.	positive (WP2*uvr*A)

Remarks - Results

No treatment related substantial increase in numbers of revertant colonies was seen in any of the four *S. typhimurium* strains used.

At the highest concentration (5000 µg/plate), the threshold of revertant *E. coli* WP2*uvr*A colonies was exceeded in Test 2, the pre-incubation test, with or without metabolic activation. A confirmatory experiment verified this result without metabolic activation, and with metabolic activation there was evidence of higher mutation frequencies with increasing concentration, in the range below the generally acknowledged border of

biological relevance. No evidence of mutagenicity was seen in the plate incorporation test for this strain.

A minor toxic effect was noted in strain TA 1535 at 2500 μg/plate in the presence of metabolic activation in Test 2.

Negative controls were similar to historical values. Positive controls confirmed the sensitivity of the test system.

CONCLUSION The notified chemical was weakly mutagenic to bacteria under the conditions of the test.

TEST FACILITY (RCC Ltd, 2003t)

7.9.1 Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.

Cell Type/Cell Line	Chinese hamster V79 cells
Metabolic Activation System	S9 fraction from Phenobarbital/β-naphthoflavone induced rat liver
Vehicle	Deionised water
Remarks - Method	No significant protocol deviations. At test item concentration 500 μg/mL with metabolic activation, 200 metaphase plates were scored instead of the usual 100.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	250, 500*, 1000*, 1500*, 2000, 2500	4 h	18 h
Present			
Test 1	125*, 250*, 500*, 750, 1000, 1500	4 h	18 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	2500 μg/mL	1500 μg/mL	≥2500 μg/mL	+ (≥500 μg/mL)
Present				
Test 1	1250 μg/mL	500 μg/mL	≥1250 μg/mL	+ (at 500 μg/mL)

Remarks - Results In the absence of metabolic activation, the chromosomal aberration rates were statistically significantly increased after treatment with 500 and 1500 μg/mL as compared to the corresponding solvent control, and additionally the response after treatment with 1500 μg/mL was considered biologically relevant as the level clearly exceeded historical control levels.

In the presence of metabolic activation, the number of structural chromosomal aberrations slightly exceeded the historical control range. In addition, there was a dose-response correlation in the number of cells carrying chromosomal aberrations at lower concentrations than 500 μg/mL (1.0%, 1.5% and 4.3% at 125, 250 and 500 μg/mL).

There was no biologically relevant increase in the occurrence of polyploid metaphases.

EMA and CPA were used as positive controls and showed distinct increases in cells with structural chromosomal aberrations.

CONCLUSION The notified chemical was clastogenic to Chinese hamster V79 cells treated *in vitro* under the conditions of the test.

TEST FACILITY (RCC Ltd, 2003u)

7.9.2 Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 476 In vitro Mammalian Cell Gene Mutation Test.
EC Directive 2000/32/EC B.17 Mutagenicity - In vitro Mammalian Cell Gene Mutation Test.

Cell Type/Cell Line	Chinese hamster V79 cells
Metabolic Activation System	S9 fraction from Phenobarbital/β-naphthoflavone induced rat liver.
Vehicle	Deionised water
Remarks - Method	No significant protocol deviations.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Test 1	75, 150, 300, 450, 600 μg/mL	4 h	7 days	15 days
Test 2	50, 100, 200, 400, 600 μg/mL	24 h	7 days	15 days
Present				
Test 1	150, 300, 600, 1200, 2400 μg/mL	4 h	7 days	15 days

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥156.3 μg/mL	≥300 μg/mL	None.	negative
Test 2	≥625 μg/mL	None.	None.	negative
Present				
Test 1	≥625 μg/mL	≥1200 μg/mL	None.	negative

Remarks - Results It is unclear why reduced cytotoxicity is seen in Test 2, in the absence of metabolic activity and may, therefore, represent a dosing error. The pre-test showed relevant toxic effects in the absence of metabolic activity above 156.3 μg/mL, which is consistent with the cytotoxicity in Test 1.

EMA and DMBA were used as positive controls and showed distinct increases in cells with structural chromosomal aberrations.

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

TEST FACILITY (RCC Ltd, 2003v)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE Notified chemical

METHOD OECD TG 474 Mammalian Erythrocyte Micronucleus Test.

Species/Strain	Mouse/NMRI
Route of Administration	Oral – gavage

Vehicle	Deionised water
Remarks - Method	No significant protocol deviations.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	6/sex	-	24 h
II (low dose)	6/sex	500 mg/kg bw	24 h
III (mid dose)	6/sex	1000 mg/kg bw	24 h
IV (high dose)	12/sex	2000 mg/kg bw	6 @ 24 h / 6 @ 48 h
V (positive control, CP)	6/sex	10 mg/kg bw	24 h

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity	The high dose (2000 mg/kg bw) reached the limit dose for a test substance known to be of low acute toxicity via the administration route for the micronucleus study. There were no deaths or test substance related clinical findings or remarkable body weight changes during the study.
Genotoxic Effects	The test substance did not exert cytotoxic effects on the bone marrow as indicated by unchanged polychromatic to normochromatic erythrocyte (PCE:NCE) ratios in treated animals compared to controls.
Remarks - Results	After treatment with the test item the number of PCEs was not significantly different from the mean value, indicating that the chemical did not exert any cytotoxic effects on the bone marrow.

CONCLUSION The notified chemical did not induce micronuclei under the conditions of this *in vivo* erythrocyte micronucleus test.

TEST FACILITY (RCC Ltd, 2003w)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 A Ready Biodegradability: DOC Die-Away Test.
Inoculum	Activated sludge collected from a communal wastewater treatment plant.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Dissolved organic carbon (DOC)
Remarks - Method	The test substance concentration used was 36.6 mg DOC/L. In addition to the test sample, inoculum and procedural (37.3 mg DOC/L D(+) – Glucose as reference substance), abiotic sterile and inhibition control samples were measured.

RESULTS

Test substance		*D(+) – Glucose*	
Day	*% degradation*	*Day*	*% degradation*
1	3	1	16
3	7	3	95
7	1	7	93
10	3	10	96
14	4	14	95
21	4	21	96
28	2	28	98

Remarks - Results	The inhibition control attained 50% degradation after 14 days confirming that the test substance was not inhibitory to activated sludge bacteria under the test conditions and that the degradation of the reference substance was not inhibited by the presence of the test substance. Degradation of the reference substance confirmed the suitability of the inoculum and validity of test conditions.
CONCLUSION	The test substance cannot be considered to be readily biodegradable according to the OECD criteria.
TEST FACILITY	Solvias (2003a)

8.1.2. Inherent biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 302B Zahn-Wellens Test and Commission Directive 87/302/EEC Part C.
Inoculum	Activated sludge collected from a communal wastewater treatment plant.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Dissolved organic carbon (DOC)
Remarks – Method	In addition to the test substance (153.6 and 154.5 mg DOC/L), blank samples and samples containing a reference substance (diethylene glycol at 158.2 and 153.4 mg DOC/L) were measured.

RESULTS

Test substance			*<Reference Substance>*	
Day	*% Degradation*		*Day*	*% Degradation*
	Vessel 1	*Vessel 2*		
2	1	1	2	4
6	1	2	6	50
9	2	3	9	93
14	6	7	14	100
19	9	6	19	100
27	10	8	27	-
28	12	9	28	-

Remarks – Results: The test substance attained 10% degradation by 28 days. Degradation of the reference substance (more than 70% after 14 days) indicates the viability of the culture and test conditions.

The results also showed that adsorption of the test substance to sludge after 3 hours is 1% and therefore, the total elimination (adsorption and degradation) after 28 days was considered to be 11%.

CONCLUSION: As the biodegradation level did not exceed 20%, the test substance cannot be considered to be inherently biodegradable.

TEST FACILITY: Solvias (2003b)

8.1.3. Bioaccumulation

No bioaccumulation data were provided. However, the bioaccumulation potential of the notified chemical is low due to its high water solubility and the low lipid solubility and log P_{ow}.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 203 Fish, Acute Toxicity Test and EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - Static

Species: Zebrafish (*Danio rerio*)
Exposure Period: 96 hours
Auxiliary Solvent: None
Water Hardness: 160 mg $CaCO_3$/L
Analytical Monitoring: Samples of test solution were analysed by liquid chromatography.
Remarks – Method: Based on the results of a range finding test (no mortalities at 100 mg/L) a limit test was performed at a nominal test concentration of 100 mg/L.

Oxygen content (97 to 101% in control and 96 to 100% in the test substance solutions), pH (7.8 to 8.2 in control and 7.9 to 8.3 in test solutions) and temperature (23.1 to 23.4°C in control and 22.3 to 23.2°C test solutions) were all satisfactorily maintained.

RESULTS

LC50: >100 mg/L at 96 hours.
NOEC (or LOEC): 100 mg/L at 96 hours (only concentration tested).
Remarks – Results: No precipitation was observed in the test solution throughout the study period. No mortalities or sub-lethal effects were observed in the control or test media. Analysis of the test media showed the measured test concentrations to be in the range of 103 to 110% of the nominal level.

CONCLUSION: The notified chemical is practically non-toxic to fish.

TEST FACILITY Solvias (2003c)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test and EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - Static

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	231 mg $CaCO_3$/L
Analytical Monitoring	Samples of test solution were analysed by liquid chromatography.
Remarks - Method	Five concentrations were tested based on preliminary test results. Oxygen content (96% in control and 96 to 98% in the test substance solutions), pH (8.0 in control and 7.6 to 8 in the test solutions) and temperature (19.9 to 20.2°C in control and 20.3 to 20.4°C test solutions) were satisfactorily maintained.

RESULTS

Concentration mg/L Nominal	*Number of D. magna*	*% Immobilised*	
		24 h	*48 h*
Control	20	0	0
4.3	20	0	0
9.4	20	0	0
21	20	0	0
45	20	0	0
100	20	0	0

LC50	>100 mg/L at 48 hours
NOEC (or LOEC)	>100 mg/L at 48 hours (highest concentration tested)
Remarks - Results	Precipitation of the test substance was not mentioned in the report but would be unlikely. Analysis of the test media showed the measured test concentrations to be in the range of 105 to 107% of the nominal level throughout the test period.

CONCLUSION The notified chemical is practically non-toxic to aquatic invertebrates.

TEST FACILITY Solvias (2003d)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test and EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 0.32, 1.0, 3.2, 10, 32 and 100 mg/L (based on preliminary test results).
Auxiliary Solvent	None
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	Samples were analysed by HPLC.
Remarks - Method	The pH of the control solutions ranged from 7.9 (at the start) to 8.7 (at test termination) while that of the exposure solutions ranged from 7.8 to

7.9 (at the start) and from 8.1 to 9.0 (at test termination). The test temperature was maintained at 24°C.

RESULTS

	Biomass		*Growth*	
	EbC50 (95% CL) mg/L (0-72 h)	*NOEC mg/L*	*ErC50 (95% CL) mg/L (0-72 h)*	*NOEC mg/L*
Part A - Test solutions (coloured)	17 (9.7-36)	1.0	>100	1.0
Part B - Algae in test water with no test substance (reduced light due to coloured test media above)	26 (20-36)	-	>100	-

Remarks - Results

Analysis of the test media showed the mean measured test concentrations varied from 83 to 116% of the nominal values. All the test media were coloured red with greater intensity as the concentration increased.

The EC values in Part A of the test were higher than the corresponding values in Part B and only a part of the growth inhibition was caused by the reduced light effect. Based on the results for the highest test concentration the report stated that a real toxic effect of the test substance could not be excluded at that concentration.

CONCLUSION

Based on the test results (growth) the notified chemical may be harmful to algae. However, this result should be interpreted with caution due to the light absorbing effects of the test solutions as mentioned above.

TEST FACILITY

RCC (2003x)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 209 Activated Sludge, Respiration Inhibition Test.
EC Directive 67/548/EEC L 133 Part C

Inoculum: Activated sludge obtained from a communal sewage treatment plant.
Exposure Period: 3 hours
Concentration Range: Nominal: 26, 64, 160, 400 and 1000 mg/L
Remarks – Method: Test concentrations of the reference substance (3,5-dichlorophenol) were 7.5, 15 and 30 mg/L.

RESULTS

IC50: >1000 mg/L
NOEC: 1000 mg/L (highest concentration tested)
Remarks – Results: No significant effect on respiration was observed at any of the test concentrations used (< 10% inhibition of the respiration rate). The IC50 of the reference substance was 10.3 mg/L, thus validating the test.

CONCLUSION

The notified chemical does not inhibit the respiration of activated sludge. This is also supported by the results observed in the biodegradation test (summarised in 8.1.1).

TEST FACILITY

Solvias (2003e)

8.3. Chemical oxygen demand (COD)

TEST SUBSTANCE	Notified chemical
METHOD	DIN 38409 – H 41-1 (1980) Commission Directive 92/69/EEC Annex L 383 A, C6
Reaction Mixture	Potassium dichromate in a strong sulfuric acid medium with silver sulfate as a catalyst
Exposure Period	2 hours
Auxiliary Solvent	None
Analytical Monitoring	The residual potassium dichromate was determined by titration with ferrous ammonium sulfate.
Remarks – Method	The reaction mixture was boiled with the test substance under reflux for 2 hours at 148 ± 3°C. A solution of potassium hydrogen phthalate (at 0.17 g/L) was used as the reference item.
RESULTS	
Remarks – Results	The test was considered valid since the COD of the reference substance (196 mg O_2/L) was 200 ± 8 mg O_2/L.
CONCLUSION	The COD of the test substance was 838 mg O_2/g.
TEST FACILITY	Solvias (2003f)

8.4. Biochemical oxygen demand (BOD_5)

TEST SUBSTANCE	Notified chemical
METHOD	ISO 5815 Second Edition – 1989-08-01 – Static
Inoculum	Filtered seeding water from a communal wastewater treatment plant.
Exposure Period	5 days
Auxiliary Solvent	None
Analytical Monitoring	DOC
Remarks – Method	The test substance was incubated in dark in completely filled and stoppered bottles at 20.0°C for 5 days. Eight concentrations from 6.4 to 818.2 mg/L were used. D(+)-glucose (150.2 mg) and L-glutamic acid (150.4 mg) per L of distilled water was used as the reference substance.
RESULTS	
Remarks – Results	The test was considered valid since the BOD_5 of the reference substance (188 mg O_2/L) was between 180 and 230 mg O_2/L.
CONCLUSION	The BOD_5 of the test substance was 0 mg O_2/g. This result supports the lack of ready and inherent biodegradation as reported in test results summarised under Section 8.1.
TEST FACILITY	Solvias (2003g)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The low K_{oc} value and the inherent biodegradability test results indicate that the test substance is not likely to adsorb to sludge. However, cationic effluent flocculation is expected to effectively precipitate the notified chemical. The solids containing the chemical would be disposed of through incineration or as chemical waste along with other solid waste (due to spills, leaks and container residues) from the dyehouse. Incineration is the preferred option because of the high water solubility and potential mobility of the notified chemical. Incineration of the sludge or waste containing the notified chemical will produce oxides of carbon and other main elements and metal salts in the ash.

If the dye containing the notified chemical is disposed of to landfill the residues may be mobile. Although the notified chemical cannot be considered as readily biodegradable it would degrade very slowly via biotic and abiotic processes. Disposal to landfill if any, will be as chemical waste, therefore, the risk of leaching to the water table is significantly reduced. The fate of the dye and the notified chemical bound to fabrics would be the same as that of the fabrics. The fabrics may be disposed of to landfill, where the notified chemical would remain inert.

The notifier indicates that a conservative assumption that 50% of the dyestuff is retained in the dyehouse effluent sludge or removed through other mechanisms in the community sewage treatment plants (STPs) can be made. The notified chemical released to the communal sewer via the dyehouse effluent discharge will be its major environmental exposure. The dye containing the notified chemical will be used in a small number of city dyehouses only. However, based on the typical use of the dye expected per day, worst-case predicted environmental concentration (PEC) values are estimated for two city dyehouses.

Calculation Factor	City Dye House 1 (High volume STP discharge)	City Dye House 2
Typical use of notified chemical expected per day (over 60 days per year)	33 kg	
Weight of fabric dyed per day	4000 kg	
Quantity of water used including wash-off water (at 100 L/kg)	400,000 L	
Weight of notified chemical lost per day in wash-off (at a fixation rate of 83%)	5.61 kg	
Concentration of notified chemical in washwater	14.0 mg/L	
Concentration after dilution in dyehouse by other washwaters at 1 part dye-specific washwater with 6.25 parts of dyehouse effluent (2.5 ML effluent per day)	1.93 mg/L	
Concentration after dilution in STP at 1 part of dyehouse effluent with 100 parts of STP discharge (for Dyehouse 1) - Assumes none removed in sludge	0.02 mg/L	
Concentration after dilution in STP at 1 part of dyehouse effluent with 50 parts of STP discharge (for Dyehouse 2) - Assumes none removed in sludge		0.04 mg/L
Dilution factor in receiving water	Nil (River) 1:10 (Ocean)	Nil (River) 1:10 (Ocean)
Concentration after dilution in receiving waters (PEC in aquatic environment)	0.02 mg/L (River) 0.002 mg/L (Ocean)	0.04 mg/L (River) 0.004 mg/L (Ocean)

The potential for bioaccumulation is low due to the very high water solubility, high molecular weight, the low lipid solubility and log K_{ow} of the notified chemical.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests are listed below. The most sensitive species were algae with 72 hour E_bC50 value of 17 mg/L.

Organism	*Duration*	*End Point*	*mg/L*
Fish	96 h	LC_{50}	>100
Daphnia	48 h	EC_{50}	>100
Algae	0-72 h	E_bC_{50}	17
		E_rC_{50}	>100

A predicted no effect concentration (PNEC - aquatic ecosystems) of 0.17 mg/L has been derived by dividing the end point of 17 mg/L by a worst-case scenario uncertainty (safety) factor of 100 (as toxicity data are available for three trophic levels). As mentioned under section 8.2.3, the algae toxicity results should be interpreted with caution as they contain an element of apparent toxicity caused by reduced light.

Location	PEC*(mg/L)	PNEC (mg/L)	Risk Quotient (RQ)*
Dyehouse 1			
Inland River	0.02	0.17	0.12
Ocean outfall	0.002	0.17	0.01
Dyehouse 2			
Inland River	0.04	0.17	0.24
Ocean outfall	0.004	0.17	0.02

* The worst-case PEC and the RQ values calculated assuming the notified chemical is not removed during the wastewater treatment at the dyehouses or the STP process.

The resulting risk quotient (RQ = PEC/PNEC) values for the aquatic environment, assuming that the chemical is not removed in the dyehouse treatment facility or at communal STP, are all below 1 for both freshwater and marine water, indicating no immediate concern to the aquatic compartment. Further, a large part of the notified chemical can be expected to be removed by flocculation in the dyehouse treatment facility and adsorbed to sludge in the STPs considerably reducing the PEC and the risk quotients.

Based on the proposed use pattern the notified chemical is not expected to pose an unacceptable risk to the health of aquatic life.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

During transport and storage, workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached. Should a spill occur, the granules are expected to be dampened and placed in suitable correctly labelled containers.

The primary possibility of high exposure to the notified chemical is at the time of weighing out and addition to the blending vessel. The commercial form containing the notified chemical is granular, and the notifier has stated that the particle sizes are 150-350 microns, and thus inspiration is unlikely. Weighing out from the imported cartons occurs in a purpose designed dispensary under local exhaust ventilation. Addition of the dye to the blending vessel also occurs under the influence of local exhaust ventilation. Once the dye has been dissolved, there is no further chance of inhalation.

The most probable route of exposure to the aqueous solution will be dermal. When handling the dyes, workers wear elbow-length PVC gloves, safety glasses/faceshield and protective overalls. During dyeing, the dye is transported in closed systems, and material is taken up on beams or trucks, so that no manual handling of wet dye is necessary. There is the possibility of worker exposure if the dyeing machine has to be opened in the case of malfunction, in which case eye protection, gloves and overalls would be worn.

There is little chance of exposure to the dye after fixation to the fabric. The fabric is washed free of un-fixed dye and dried. The dye forms covalent bonds to the fabric, and is not likely to be bioavailable.

The notifier provided a worst-case estimate of exposure of dyehouse workers to the notified chemical. This includes exposure, both through inhalation and dermal exposure, during weighing and dying under worst case conditions and in the absence of engineering methods and PPE. Under these conditions, workers would be exposed to 0.005 mg/kg bw/day.

UK HSE EASE software estimate of exposure for weighing, dissolving and transfer workers based on the following assumptions:

0.33 mg/day (dermal)
0.026 mg/day (inhalation)

Total Dosage assuming 70 kg average worker bodyweight : 0.005 mg/kg/day body weight

NOAEL from 28-day repeat dose oral toxicity study in rats: 50 mg/kg/day body weight

MOE (Margin of Exposure): 10,000

Laboratory workers will be exposed to small quantities of the notified chemical for short periods. The exposure could occur in a variety of ways. Exhaust ventilation and personal protective equipment should be available as required.

The notifier states that repackaging of the notified chemical is unlikely. If repacking is required, trained re-pack operators will work in down-flow booths with airflow that exceeds the capture velocity for particulates, which minimises exposure.

9.2.2. Public health – exposure assessment

The notified chemical is a component in a dye product used only by industrial users. Public exposure is therefore limited to dermal contact with dyed material. In such material the dye is fixed to the cloth and is generally not biologically available.

9.2.3. Human health – effects assessment

The notified chemical is a dark red-brownish powder, with 77% of particles in the respirable fraction. However, the commercial form of the notified chemical contains anti-dusting agents and is in the form of granules with a size of 150-350 microns. The chemical is highly hydrophilic (log P_{ow} < -5.5), and this, coupled with the high MW (>900 for the majority of components) indicates that the permeability coefficient through the skin can be reasonably estimated at < 10^{-6} cm/min (EPA, 1992).

The notified chemical was of low acute oral toxicity (LD_{50} > 2000 mg/kg) and low acute dermal toxicity (LD_{50} > 2000 mg/kg) in rats. It was non-irritating to rabbit skin and non-irritating to the eye of rabbits, although it did cause persistent staining of skin and the conjunctiva. Although no acute inhalation studies have been conducted, the notified chemical is not expected to be an inhalation hazard based upon its low vapour pressure and the granular form of the dyestuff.

In a bacterial point mutation study, evidence of mutagenicity was observed in *E. coli*, while no substantial increase in the number of revertant colonies was seen in any of the *S. typhimurium* strains used. In an *in vitro* chromosomal aberration study, evidence of clastogenicity was found in the presence of metabolic activation at concentrations above 500 µg/mL, and a strong dose-response correlation in the number of cells carrying chromosomal aberrations at concentrations between 125 µg/mL and 500 µg/mL. On the basis of these positive results, further testing was carried out, and the results indicated that the substance did not support genotoxicity. Both an *in vitro* Mammalian Cell Gene Mutation Test and an *in vivo* erythrocyte micronucleus test indicated that the notified chemical was not genotoxic.

In a 28-day repeat dose oral study, lower mean body weights and mean body weight gain values were noted for males at 200 mg/kg bw/day and 1000 mg/kg bw/day and thus a NOAEL of 50

mg/kg/day was established in the study.

There was evidence of sensitisation in a mouse Local Lymph Node Assay at a concentration of 10%, with a stimulation index of 3.1 at that concentration. There was also ear swelling observed in all animals at 10% or 25% concentration. The EC3 was determined to be 9.6%. Due to this result, the notified chemical is classed as R43: May cause sensitisation by skin contact.

9.2.4. Occupational health and safety – risk characterisation

The risk of adverse effects arising from exposure to the notified chemical is low, due to the largely enclosed and automated operations in the dyeing process. Where there is a chance of exposure such as during transfer and weighing, the suggested engineering controls and PPE will greatly reduce the likelihood of exposure.

9.2.5. Public health – risk characterisation

The risk of adverse effects on the general public is negligible, as the only exposure will be to dye that is covalently linked to textiles. Test data supplied by the notifier indicates that the dye has excellent fastness properties.

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 NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

R43: May cause sensitisation by skin contact

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.

For the environment, the notified chemical is classified as Chronic III – harmful to aquatic life with long lasting effects.

	Hazard category	*Hazard statement*
Skin sensitiser	1	May cause allergic skin reaction
Eye irritation (based on persistent staining)	2A	Causes serious eye irritation

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratios the chemical is not considered to pose a risk to the environment.

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 as a dye for cellulosic textiles, used in dyehouses only.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical and products containing the notified chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). They are published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified chemical and products containing the notified chemical provided by the notifier were in accordance with the NOHSC *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 NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - 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

Health Surveillance

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

1. Sensitised workers should be advised not to further handling the notified chemical.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - a downdraft weighing booth or efficient local exhaust ventilation should be used during operations involving handling the dyestuff.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - face shield or safety goggles
  - respiratory protection while handling the notified chemical in granular form
  - protective gloves
  - industrial clothing

  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

Disposal

- The notified chemical waste and contaminated packaging should be disposed of as chemical waste to an approved waste disposal facility in accordance with federal, state and local regulations. Incineration is recommended.

Emergency procedures

- Spills should be handled by dampening granules and scooping into marked containers for disposal as chemical waste in accordance with federal, state and local regulations.

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(2) of the Act:
- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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