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May 2005

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Orange DER 8638

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

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
Italy

2. IDENTITY OF CHEMICAL

The notified chemical is comprised of three main components, A, B and C. These components are reaction products described by a single chemical name and CAS Number but different structural formulae as indicated below. Components A and B differ from component C by the vinylation of one or the other sulfato group.

CHEMICAL NAME
disodium 3,5-diamino-2-[(2-sulfophenyl)azo]benzoate, reaction products with diazotised 2-[(4-aminophenyl)sufonyl]ethyl hydrogen sulfate, sodium salts

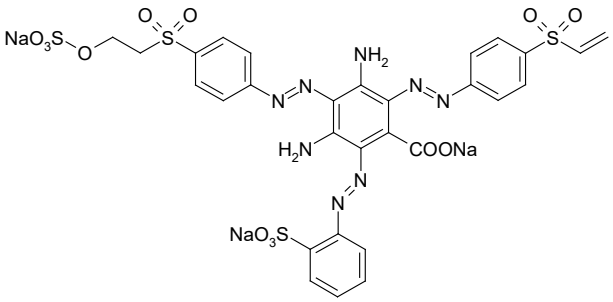
OTHER NAME(S)
FAT 40'810/A

MARKETING NAME(S)
Component of Cibacron Super Black R (<20%) and Cibacron Super Black G (<20%).

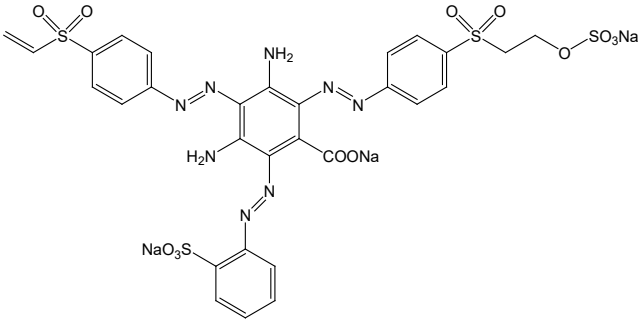
CAS NUMBER
481066-69-7

MOLECULAR FORMULA
A, B: $C_{29}H_{23}N_8Na_3O_{13}S_4$
C: $C_{29}H_{24}N_8Na_4O_{17}S_5$

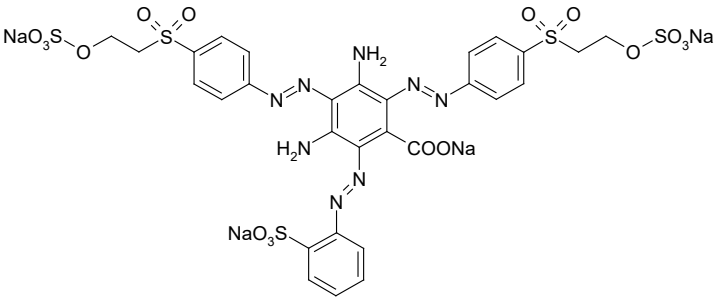
STRUCTURAL FORMULA



Compound A



Compound B



Compound C

MOLECULAR WEIGHT
A, B: 888.78
C: 1008.84

METHODS OF DETECTION AND DETERMINATION

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

3. COMPOSITION

DEGREE OF PURITY
60-80% (sum of three 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 component of Cibacron Super Black R and G 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 has 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 is in the form of black granules.

Melting Point >400 °C

METHOD OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/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 1660 kg/m^3 at 19.5ºC

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks Determined with a gas comparison pycnometer.
TEST FACILITY (RCC Ltd, 2003c)

Vapour Pressure <6.6×10^{-28} kPa at 25ºC

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69 Vapour Pressure.
Remarks Calculated from the expected boiling point (>758°C) using the Modified Watson Correlation as described in OECD TG 104 and EC Directive 92/69.
TEST FACILITY (RCC Ltd, 2003d)

Water Solubility 224 g/L at 20ºC

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks About 8 g of the test substance was added to 25 mL of water and shaken for 24, 48 and 72 hours at 30ºC prior to equilibrating for 24 hours at 24ºC. The resulting solution was centrifuged and the filtered supernatant was diluted in a 1:2000 ratio with water and analysed by HPLC.

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)*	*$t_{½}$ <hours or days>*
4	25ºC	>1 year
7	25ºC	<1 day
9	25ºC	<1 day

Remarks No further testing was done at pH 4 as the test substance was stable at 50°C and at

pH 7 and 9 where it was found to be very unstable with more than 50% hydrolysed after 24 h.

TEST FACILITY (RCC Ltd, 2003f)

Partition Coefficient (n-octanol/water) log Pow = <-4.5 at 20ºC

METHOD OECD TG 107 Partition Coefficient (n-octanol/water).
OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks Preliminary tests indicated a partition coefficient far below –2, therefore a main test could not be conducted. Log Pow was estimated using the preliminary solubility data in n-octanol and in water. Solubility in n-octanol is <6.416 mg/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, 2003g)

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, 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 will not be adsorbed by organic carbon in soil.

TEST FACILITY (RCC Ltd, 2003h)

Dissociation Constant pKa (approximate)
2.4, -1.3, -3.8, -3.9, -6

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, 2003i)

Particle Size

METHOD OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Range (μm)	*Mass (%)*
<10	77.18
10-20	19.86
20-40	2.96
40-60	0
60-100	0
100-200	0
>200	0

Remarks Determined using laser diffraction method.
Mass Median Diameter = 5.7 μm
Inhalable fraction: 100%
Respirable fraction: 77%

TEST FACILITY (RCC Ltd, 2003g)

Surface Tension 71.4 mN/m at 20.2ºC

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. The results indicate that the notified chemical is not a surface active agent.
TEST FACILITY	(RCC Ltd, 2003h)

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, 2003i)

Autoignition Temperature 300ºC

METHOD	92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks	A large exothermic reaction (max temperature measured during reaction was 495ºC) was observed when the sample temperature reached ~260ºC.
TEST FACILITY	(RCC Ltd, 2003j)

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)

Oxidizing Properties

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, 2003k)

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	limited evidence of sensitisation
Rat, repeat dose oral gavage toxicity – 28 days.	NOAEL 200 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosomal aberration test	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 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.

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

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3/F	2000	0
II	3/M	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, 2003l)

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 significant protocol deviations.

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 all 15 days of the test.
Signs of Toxicity - Systemic	There were no deaths or test-substance related clinical signs. Two females showed a loss of body weight (0.3% and 6.2%) between days 1 and 8. 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, 2003m)

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 significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	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, 2003n)

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	0.33	0.67	0.33	1	48 hours	0
Conjunctiva: chemosis	0	0	0	1	1 hour	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.

The NOHSC *Approved Criteria for Classifying Hazardous Substances* states that 'Ocular lesions are also severe if the substance or preparation causes irreversible colouration of the eyes'. Thus, the notified chemical is classed as R36 based on irreversible colouration.

TEST FACILITY: (RCC Ltd, 2003o)

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% (v/v) ethanol in water.
Signs of Irritation: Slight ear swelling observed in mice in Group 3 and Group 4 on days 3 and 4.
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).

10% was the highest technically achievable concentration in this vehicle.

RESULTS

Group	*Number and Sex of Animals*	*Dose %*	*DPM Per lymph node*	*Stimulation Index*
I	4	0	521	--
II	4	2.5	1275	2.4
III	4	5	1328	2.5
IV	4	10	1339	2.6

Remarks - Results: SI values of over 3 result in the test item being regarded as a sensitiser. Thus the notified chemical is not classed as a sensitiser, regardless of the increase in SI and dose-response relationship.

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

TEST FACILITY: (RCC Ltd, 2003p)

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 significant protocol deviations.

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
Slightly to moderately dark faeces was seen for animals in groups 3 and 4, from days 5 to 24. This was considered to be a passive effect of the test item.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
The mean level of leukocytes (urinalysis) was increased in males treated with 1000 mg/kg/day after four weeks of treatment.

The mean levels of sodium excretion were increased in males treated with 200 mg/kg/day and in both sexes treated with 1000 mg/kg/day after four weeks of treatment.

Effects in Organs

No test substance related findings.

Remarks – Results
Various statistically significant changes were observed for the laboratory findings but were thought not to be treatment related because there was no dose response relationship or the change occurred in one sex only or the change occurred only in recovery animals..

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 200 mg/kg bw/day in this study, based on the increased level of leukocytes (urinalysis) in males treated with 1000 mg/kg/day. No NOEL could be established due to the staining properties of the notified chemical.

TEST FACILITY (RCC Ltd, 2003q)

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*: WP2uvrA
Metabolic Activation System	S9 fraction from Phenobarbital/β-naphthoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 312.5-5000 µg/plate b) Without metabolic activation: 312.5-5000 µg/plate
Vehicle	DMSO
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.	negative
Present				
Test 1	None.	None.	None.	negative
Test 2	None.	None.	None.	negative

Remarks - Results No substantial increases in numbers of revertant colonies were seen in any of the bacterial strains used.

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

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

TEST FACILITY (RCC Ltd, 2003r)

7.9 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

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	125, 250, 500, 750*, 1000*, 1500*	4 h	18 h
Test 2	250*, 500*, 750*, 1000, 1500, 2000	18 h	18 h
Test 3	250*, 500, 750, 1000	28 h	28 h
Present			
Test 1	25, 50*, 100*, 150*, 200, 300	4 h	18 h
Test 2	25, 50, 100*, 150*, 200*, 300	4 h	28 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	≥1250 μg/mL	None.	≥1000 μg/mL	None.
Test 2	≥1250 μg/mL (24 h exposure)	≥1000 μg/mL	≥1000 μg/mL	Yes. (750 μg/mL)
Test 3	≥1250 μg/mL (24 h exposure)	≥500 μg/mL	≥750μg/mL	None.
Present				
Test 1	≥312.5 μg/mL	≥200 μg/mL	≥200 μg/mL	None.
Test 2	≥312.5 μg/mL	≥200 μg/mL	None.	Yes. (200 μg/mL)

Remarks - Results	There was a strong sub-significant dose-response correlation in the number of cells carrying chromosomal aberrations at lower concentrations than 750 μg/mL in test 2 without metabolic activation (0.5%, 2.5% and 7.0% at 250, 500 and 750 μg/mL, respectively). EMS 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, 2003s)

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	The relative humidity ranged between 30-76%, and not between 30-70% as described in the study plan

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 b.w.	24 h
III (mid dose)	6/sex	1000 mg/kg b.w.	24 h
IV (high dose)	12/sex	2000 mg/kg b.w.	6 @ 24 h / 6 @ 48 h
V (positive control, CPA)	6/sex	10 mg/kg b.w.	24 h

CPA=cyclophosphamide.

RESULTS	
Doses Producing Toxicity	The high dose (2000 mg/kg b.w.) reached the limit dose for a non-toxic test substance. 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. CPA was used as the positive control and showed distinct increases in cells with structural chromosomal aberrations.
CONCLUSION	The notified chemical was not clastogenic under the conditions of this micronucleus test.
TEST FACILITY	(RCC Ltd, 2003t)

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 notified chemical concentration used was 36.9 mg DOC/L. In addition to the test sample, Inoculum, Procedural (37.0 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	42
3	6	3	92
7	4	7	94
10	2	10	93
14	6	14	97
21	3	21	95
28	2	28	96

Remarks - Results	The inhibition control attained 52% degradation after 14 days confirming that the notified chemical was not inhibitory to activated sludge bacteria under the test conditions and that the degradation of reference substance was not inhibited by the presence of the notified chemical. Degradation of the reference substance confirmed the suitability of the inoculum and validity of test conditions.
CONCLUSION	The notified chemical 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 notified chemical (148.7 and 147.2 mg DOC/L), blank samples and samples containing a reference substance (diethylene glycol at 151.6 and 155.8 mg DOC/L) were measured.

RESULTS

Test substance			*<Reference Substance>*	
Day	*% Degradation*		*Day*	*% Degradation*
	Vessel 1	*Vessel 2*		
2	0	0	2	10
5	2	1	5	51
7	3	0	7	98
9	3	0	9	100
12	8	4	12	98
16	6	6	16	98
19	9	7	19	-
21	10	4	21	-
23	11	7	23	-
27	13	9	27	-
28	15	10	28	-

Remarks – Results

The notified chemical attained 13% 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 notified chemical to sludge after 3 hours is 0% and therefore, the total elimination (adsorption and degradation) after 28 days was considered to be 12%.

CONCLUSION

As the biodegradation level did not exceed 20%, the notified chemical cannot be considered to be inherently biodegradable.

TEST FACILITY

Solvias (2003b)

8.1.2. 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	178 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 (96 to 101% in control and 96 to 100% in the test substance solutions), pH (7.8 to 8.2 in control and 8.1 to 8.3 in test solutions) and temperature (21.5 to 22.3°C in control and 21.6 to 22.2°C test solutions) were all satisfactorily maintained.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	0	7	0	0	0	0	0
100	96 - 92	7	0	0	0	0	0

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 92 to 96% 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	*Number of D. magna*	*% Immobilised*	
Nominal		*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	3

EC50	>100 mg/L at 48 hours
NOEC	45 mg/L at 48 hours (highest concentration tested without effects)
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 116% of the nominal level throughout the test period. Only 15% immobilisation was observed at the

highest test concentration. Hence, the EC50 is greater than 100 mg/L.

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	Not reported.
Analytical Monitoring	Samples were analysed by HPLC.
Remarks - Method	The test method was modified to characterise the effect of growth inhibition caused by reduced light intensities in the coloured test solutions. Parallel tests were conducted in which the test organisms were exposed to concentrations of the test substance (Experiment A) and to light filtered through solutions of the test material (Experiment B). The pH of the exposure solutions ranged from 8.0 (at the start) to 9.6 (at test termination). The test temperature was maintained at 23°C.

RESULTS

Experiment A

Biomass		*Growth*	
EbC50 (95% CL) mg/L (0-72 h)	*NOEC mg/L*	*ErC50 (95% CL) mg/L (0-72 h)*	*NOEC mg/L*
46 (22-188)	10	>100	100

Experiment B

Biomass		*Growth*	
EbC50 (95% CL) mg/L (0-72 h)	*NOEC mg/L*	*ErC50 (95% CL) mg/L (0-72 h)*	*NOEC mg/L*
44 (19-277)	-	>100	100

Remarks - Results Analysis of the test media showed the mean measured test concentrations varied from 93 to 110% of the nominal values. All the test media were coloured with greater intensity as the concentration increased.

The EC values in Experiment A of the test were similar to the corresponding values in Experiment B, indicating that the growth inhibition was caused by the reduced light effect resulting from the coloured nature of the chemical.

CONCLUSION The notified chemical is slightly toxic to algae. The toxic effect results from the highly coloured nature of the chemical reducing the light available to the algae.

TEST FACILITY (RCC Ltd, 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 11.5 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 sulphuric acid medium with silver sulphate as a catalyst.
Exposure Period	2 hours.
Auxiliary Solvent	None.
Analytical Monitoring	The residual potassium dichromate determined by titration with ferrous ammonium sulphate.
Remarks – Method	The reaction mixture was boiled with the test substance under reflux for 2 hours at 148 ± 3°C. A solution of potassium hydrogenphthalate (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 (203 mg O_2/L) was 200 ± 8 mg O_2/L.
CONCLUSION	The COD of the test substance was 896 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 6.6 to 840.6 mg/L were used. D(+)-Glucose (150.2 mg) and L-Glutamic acid (150.4 mg) per 1 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 (205 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.

Release of the notified chemical 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 (one discharging into a large sewage treatment works and the other into a small sewage treatment works) assuming no partitioning to sludge within the sewage treatment works.

Process or Dilution Factor	City Dye House 1 (High volume STP discharge)	City Dye House 2 (Low volume STP discharge)
Typical notified chemical use expected per day	28 kg	28 kg
Quantity in wash water (at a fixation rate of 83%)	4.76 kg	4.76 kg
Typical daily volume of dye wash-water effluent	400,000 L	400,000 L
Concentration in dye wash water	11.9 mg/L	11.9 mg/L
Typical daily volume of dye house wash-water effluent	2,900,000 L	2,900,000 L
Concentration in dye house effluent	1.64 mg/L	1.64 mg/L
Dilution factor in sewage treatment plant	1:100	1:10
Concentration in effluent from sewage treatment plant	16.4 µg/L	164 µg/L
Predicted environmental concentrations (PECs) in receiving waters		
Ocean (Dilution Factor 1:10)		
PEC	1.6 µg/L	16 µg/L
River (Dilution Factor 1:1)		
PEC	16 µg/L	164 µg/L

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 46 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}	46
		E_rC_{50}	>100

A predicted no effect concentration (PNEC - aquatic ecosystems) of 0.46 mg/L has been derived by dividing the end point of 46 mg/L by a worst-case scenario uncertainty (safety) factor of 100 (as toxicity data are available for three trophic levels).

9.1.3. Environment – risk characterisation

	Location	PEC* µg/L	PNEC µg/L	Risk Quotient (RQ)*
Dyehouse 1	Ocean outfall	1.6	460	0.003
	Inland River	16	460	0.035
Dyehouse 2	Ocean outfall	16	460	0.035
	Inland River	164	460	0.356

* 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. The endpoint is also derived from reduced light rather than chemical interaction. 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.

High levels of exposure to the notified chemical is possible at the time of weighing out and addition to the blending vessel. The commercial form containing the notified chemical is granular, with particle sizes of 150-350 microns; 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 controls and

PPE. Under these conditions, workers would be exposed to up to 0.006 mg/kg bw/day.

EASE (UK HSE, 1997) estimate of exposure assuming 100% absorption:
0.39 mg (dermal)
0.018 mg (inhalation)

Total dosage assuming 70 kg average worker bodyweight: 0.006 mg/kg bw/day.

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, re-pack operators will work in down flow booths with airflow that exceeds the capture velocity for particulates, which should minimise 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 notified chemical was slightly irritating to the eye, with conjunctival redness clearing by 48 hours. However, staining of the conjunctiva persisted until termination at 21 days. According to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2002), irreversible colouration of the eye is classed as a severe ocular lesion, and thus the notified chemical is classed as:

R41 – Risk of severe damage to eyes.

The notified chemical was of low acute oral toxicity (LD_{50} > 2000 mg/kg) and low dermal toxicity (LD_{50} > 2000 mg/kg) in rats. It was non-irritating to rabbit skin. 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.

There was limited evidence of sensitisation in the mouse Local Lymph Node Assay. Some ear swelling was observed, and the stimulation index (S.I.) was consistently high (2.4-2.6). However, the chemical is not classified as sensitising, according to the approved criteria for classifying hazardous substances (NOHSC, 2004), as the S.I. was not above 3.

In a 28-day repeat dose oral study, the mean level of leukocytes (urinalysis) was increased in males treated with 1000 mg/kg/day after four weeks of treatment. A NOAEL of 200 mg/kg/day was established in the study.

In a bacterial point mutation study, no evidence of mutagenicity was observed. In an in vitro chromosomal aberration study, evidence of clastogenicity was found in the presence of metabolic activation at concentrations above 200 µg/mL. The notified chemical was not clastogenic to mouse bone marrow under the conditions of this micronucleus test.

Based on the above results, the notified chemical is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

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 exposure.

There is likely to be some dermal exposure to the notified chemical, however, the only hazard associated with dermal exposure is persistent staining of the skin. In addition, products containing the notified chemical are likely to be classed as R43, and thus precautions will be in place to limit the level of dermal exposure.

The hazards of inhalation exposure to the notified chemical are unknown. However, the granular form of the product containing the notified chemical, and the PPE and engineering controls, including LEV when necessary, will largely prevent inhalation exposure.

Ocular exposure was identified as the most hazardous route for the notified chemical. However, exposure via this route is unlikely as eye protection will be worn. In addition, dye-house workers are likely to be experienced in handling chemicals which may cause persistent staining of the eye.

Chronic exposure is unlikely to present a high risk, due to the relatively low toxicity in the 28-day repeat dose study. In addition, there is likely to be low exposure, based on the suggested PPE and engineering controls.

Worst-case total chronic exposure: 0.006 mg/kg bw/day.
NOAEL from 28-day repeat dose oral toxicity study in rats: 200 mg/kg body weight.
MOE (Margin of Exposure): >30,000

9.2.5. Public health – risk characterisation

The risk of adverse effects to 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:

R41 – Risk of severe damage to eyes.
S39 – Wear eye/face protection.

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*
Eye irritation	2A	Causes serious eye irritation

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio the chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used as a dye for cellulosic textiles 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

CONTROL MEASURES

Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - R41 – Risk of severe damage to eyes.

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - 5% - 10%: R36 – Irritating to eyes
  - >10%: R41 – Risk of severe damage to eyes.

- Products containing more than [5%] notified chemical and available to the public must carry the following safety directions on the label:
  - S25 – Avoid contact with eyes
  - S26 – In case of contact with eyes. Rinse immediately with plenty of water and seek medical advice.
  - S22 – Do not breathe dust (where the product is in an inspirable form)

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 when handling products containing the notified chemical:
  - face shield or safety goggles
  - where local ventilation is insufficient, respiratory protection should be used 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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