File No: NA/498

Date: June 1997

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Monoazo Red SR 6947

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Monoazo Red SR 6947

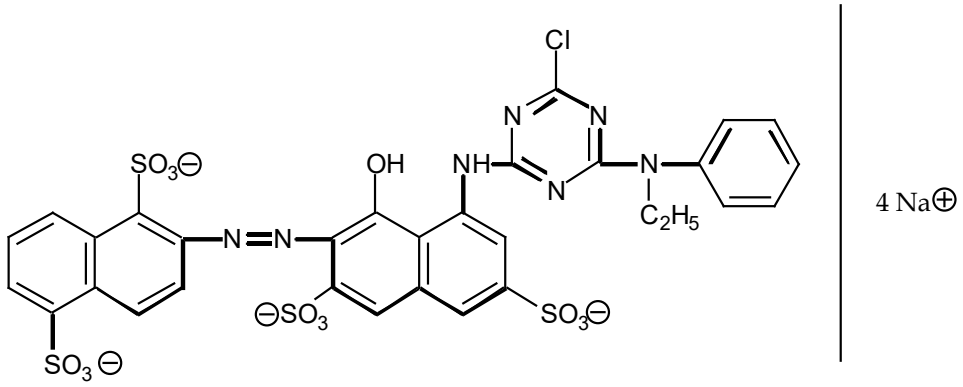
1. APPLICANT

Ciba Specialty Chemicals Pty Limited of 235 Settlement Road THOMASTOWN VIC 3074 has submitted a standard notification statement in support of their application for an assessment certificate for 'tetrasodium 5-[4-chloro-6-(N-ethylanilino)-1,3,5-triazin-2-ylamino]-4-hydroxy-3-(1,5-disulfonaphthalene-2-ylazo) naphthalene-2,7-disulfonate'; hereafter referred to as Monoazo Red SR 6947. No requests for exempt information were made by the notifiers and the assessment report for the notified chemical is published here in its entirety.

2. IDENTITY OF THE CHEMICAL

Chemical Name:	tetrasodium 5-[4-chloro-6-(N-ethylanilino)-1,3,5-triazin-2-ylamino]-4-hydroxy-3-(1,5-disulfonaphthalene-2-ylazo) naphthalene-2,7-disulfonate
Chemical Abstracts Service (CAS) Registry No.:	130201-57-9
Other Names:	1,5-naphthalenedisulfonic acid, 2-[[8-[[4-chloro-6-(ethylphenylamino)-1,3,5-triazin-2-yl]amino]-1-hydroxy-3,6-disulfo-2-naphthalenyl]azo-, tetrasodium salt FAT 40'406/A Cibacron Red SR 6947 Monoazo Red SR 6947
Trade Name:	Cibacron Red P-4B 33% liquid (product containing notified dye at a concentration of 20.7%) Cibacron Red P-4B (powder form containing the notified dye at a concentration of 64.5%)
Molecular Formula:	$C_{31}H_{24}ClN_7O_{13}S_4.4Na$

Structural Formula:



Molecular Weight:	954.22
Method of Detection and Determination:	infrared (IR), ultraviolet/visible (UV/Vis) and nuclear magnetic resonance (NMR) spectra; high performance liquid chromatography
Spectral Data:	IR, UV/Vis and NMR spectra were provided for the notified dye; major characteristic peaks were found in the IR spectrum at: 980, 1 040, 1 200, 1 380, and 2 820 - 2 980 cm^{-1}

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	the notified dye is a dark red powder
Melting Point:	> 300°C (OECD TG 102 - capillary method, liquid bath (1))
Specific Gravity:	1.75 at 22°C (EEC 84/449 A3 - air comparison pycnometer method (2))
Vapour Pressure:	not determined
Water Solubility:	> 300 g/L at 20°C (pH 7.3) (OECD TG 105 'flask method' (1))
Partition Co-efficient (n-octanol/water):	log P_{ow} < -10.6 (calculated) (OECD TG 117 (1))
Hydrolysis as a Function of pH:	$T_{1/2}$ at pH 4.0: 2000.7 hours (estimated) $T_{1/2}$ at pH 7.0: longer than 1 year (estimated) $T_{1/2}$ at pH 9.0: longer than 1 year (estimated) (OECD TG 111 (1))
Adsorption/Desorption:	not determined

Dissociation Constant:	not determined
Fat Solubility:	< 0.05 mg/100 g fat at 37°C (OECD TG 116 (1))
Particle Size:	< 20 μm 2% (w/w) > 20 98% > 40 60% > 63 46% > 100 26% > 200 3% > 400 0.3% median of mass distribution (width) 56 μm OECD method 110 could not be used for this test, as the range of particle sizes was too great
Surface Tension:	66.3 - 66.4 mN/m at 1.0 g/L and 20°C 55.1 - 55.4 mN/m at 10.0 g/L and 20°C (OECD TG 115- Wilhelmy plate method (1))
Flash Point:	not flammable
Flammability Limits:	not flammable
Autoignition Temperature:	self-ignition at 350°C
Explosive Properties:	non-explosive
Reactivity/Stability:	not an oxidising agent

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines (1, 2) at facilities complying with OECD Principles of Good Laboratory Practice.

No melting point was detected below 573 K.

Vapour pressure was not determined, though the notifier expects that it will be negligible. It is agreed that the vapour pressure is expected to be negligible, given that the notified chemical is a high molecular weight, organic tetrasodium salt. It is also noted that similar dyestuffs previously submitted by the notifier exhibited very low (calculated) vapour pressures.

Preliminary testing revealed that at 50°C the hydrolysis of the notified chemical was less than 10% at pH 7 and 9. Hence, it has a half-life period longer than one year at 25°C at pH 7 and 9. At pH 4 at 25°C, the half-life was determined to be 2000.7 hours (approximately 83 days).

The results obtained by the preliminary partitioning experiment showed that log K_{ow} lies outside the range determinable by the flask shaking method and no further testing was performed. Therefore, the log partition coefficient was estimated to be less than -10.6 by calculation using the computer model CLOGP (Release 3.42). The model is based on the formal fragmentation of the molecule into suitable substructures for which reliable log P increments are known. It is accepted that the log P will be low due to the high water solubility.

Adsorption/desorption data were not provided. High water solubility and a low partition coefficient would normally indicate low affinity for soil or sediment. The notifier has indicated that some binding of the notified chemical to common soils is possible, though expects the chemical to remain relatively mobile in groundwater. It is expected that the chemical will bind to positively charged substances such as clay particles. However, binding of the chemical to organic matter is unlikely (3).

The notified chemical contains sulfonic acid functionalities that will be expected to remain completely dissociated under environmental conditions.

The notified chemical is not expected to be surface active at a concentration of 1 g/L. However, at higher concentrations, surface activity is likely to increase. By definition, a chemical has surface activity when the surface tension is less than 60 mN/m (2).

4. PURITY OF THE CHEMICAL

Degree of Purity: 58 - 70% (typical concentration 64.6%)

Impurity	*CAS Number*	*% Weight*
known coloured by-products	–	16.3
unknown coloured by-products	–	4.5
unknown, uncoloured by-products	–	0.7
sodium sulfate	7757-82-6	0.5
disodium hydrogenphosphate	10028-24-7	2.4
water	7732-18-5	7.2
total impurities		31.6

The notified dye was also screened for the presence of unsulfonated, primary, aromatic amines, which were not detected at the threshold of the method (10 mg/kg).

Classification of Impurities: no health hazard classification of the impurities was provided by the notifier; toxicity tests carried out on the notified dye (which contained the above mentioned impurities when tested) are summarised in section 9 of this report

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified dye will not be manufactured in Australia. It will be imported as a component of the end use products, Cibacron Red P-4B 33% liquid (product

containing notified dye at a concentration of 20.7%) and Cibacron Red P-4B (powder form containing the notified dye at a concentration of 64.5%). These end use products will be used for the colouration of cellulose textiles using printing methods.

Projected import volumes are as follows:

	Import Volume (tonnes)		
Year	***Notified Dye***	***Product***	
		Liquid	***Powder***
1	2-4	10-12	0.2-0.3
2	3-5	12-15	0.3-0.5
3	3-5	15-16	0.3-0.5
4	3-5	15-16	0.3-0.5
5	4-6	16-20	0.3-0.5

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported mainly in liquid form, in 600 kg intermediate bulk containers (IBCs). There will also be a small amount of the powdered form imported in 30 kg containers. Exposure of transport and storage workers is expected to occur only in the event of accidental spillage.

Minimal repackaging of the notified chemical may be carried out by the notifier. Dermal, inhalational and ocular exposure may occur during repacking of dye products containing the notified chemical. Workers may be intermittently exposed to significant levels of the notified chemical unless adequate protective measures are taken. Exposure times are expected to be up to 20 minutes per day, 10 days per year. The protective measures used at the notifier's sites include addition of an anti-dusting agent to the powdered form of the end use product. In addition, repacking processes will be conducted in a booth in which flow air is drawn away from the operators at a rate which ensures capture of particulates released to air. In previous notifications for dyes of this type, the notifier has stated that under the conditions employed at the notifier's site, workplace air monitoring studies have shown that levels of dye in the breathing zone are undetectable.

Dyeing processes involve the pumping of approximately 50 kg of the imported product from the IBCs directly into the printing paste blending vessel to make 500 kg of printing paste. The notified dye is present in the printing paste at approximately 2.3%. During transfer, dermal exposure may occur when workers are connecting and disconnecting hoses. Eye contact would be limited to accidents. The notifier states that in some cases, the non-dusting powdered end use product may be used. In this case, inhalational, dermal and ocular exposure may occur during transfer of the product from 30 kg containers into a weighing container and manual transfer to a closed paste blending vessel. The powder is then immediately wetted and dispersed into the paste using high speed stirring.

Minimal worker exposure is expected during the automatic pumping of the coloured printing paste to an automated printing machine. Large bolts of cloth to be printed will be passed through the printing machine. After printing the cloth is heated to 120-

130°C to dry the dye, and is then steamed to fix the dye to the cellulose. The cloth is then washed in a continuous multi-tank and dried. Workers will be exposed to the notified chemical for a maximum of 1 hour per shift, if they were involved with all stages of the mixing, printing and washing off processes.

The notifier states that minimal worker exposure to dye containing the notified chemical is likely to occur during equipment cleaning or repair.

Dermal exposure will be the main route of exposure for laboratory workers who may be exposed to the notified chemical during sampling and analysis. Inhalational and ocular exposure may also occur if quality control or product development work is carried out on the powdered form of the end-use dye.

Workers may also come into contact with dry fabrics coloured by the notified chemical during packaging or manufacturing.

7. PUBLIC EXPOSURE

The notified dye will be used to colour cellulosic textiles for apparel and sheeting purposes. Approximately 80% of the dye is fixed by the printing technique.

The notifier has indicated that the dye is strongly bound to the textiles after the completion of the colouring process. However, small quantities of the dye will be released, and dermal exposure could occur following contact with the dyed textiles, or during washing. The amount of dye released from the textiles is expected to be minimal and should therefore pose a negligible hazard to the public.

Minor public exposure may result from disposal of the unused notified chemical, or accidental spillage of dye products during transport and storage. However, adequate measures are described by the notifier to minimise the risk of public exposure during disposal, or in the event of accidental spillage.

8. ENVIRONMENTAL EXPOSURE

Release

The bulk of the dye will become chemically fixed to the cellulosic textiles, and in this state is not expected to impact on the environment. The result of fastness performance tests shows that a good order of fastness should be achieved. After application to fabrics, the dye undergoes a chemical change involving chemical bonding with hydroxy groups on the cellulose fibres.

The major environmental exposure to dye will come from effluent discharge from dyehouses and waste water treatment systems. This release will consist mainly of the hydrolysed derivative (4). Other releases will be limited to traces remaining from repacking operations and clean-up of any spills, and from trace residues in empty packaging (estimated to be a maximum of 0.1% based on previous similar notifications by the notifier).

All clean up of spills and disposal of empty packaging should be carried out according to the Material Safety Data Sheet (MSDS).

Fate

The dye, including the hydrolysed derivative, normally released in water as effluent from the dyehouse is expected to be the major environmental exposure. The dye may either partition to sediment or stay in the aqueous compartment. Hobbs (5) reports that reactive dyes have been found not to absorb to sludge in model systems. Any dye that binds to the sludge during the waste treatment process would be disposed of through incineration or landfill. Incineration is the preferred option because of the high water solubility and potential mobility of the material. Incineration of the dye will produce oxides of carbon, nitrogen and sulfur, together with sodium salts in the ash and a small amount of hydrogen chloride. Disposal by landfill will be at a secured site, so the risk of leaching to the water table is significantly reduced.

Residues that persist after sewage treatment will enter marine environments in solution (from city waste water treatment systems). While azo dyes are generally stable under aerobic conditions, they are susceptible to reductive degradation under anaerobic conditions characteristic of sediment (6). Also, highly sulfonated azo dyes have been shown to sorb to sediment through an anion-adsorption mechanism (3). Degradation of such dyes in sediment water systems proceeded with a half-life of 2 to 16 days. Accordingly, no significant increase in dissolved concentrations over time is predicted, while residues bound to sediment are expected to undergo reductive degradation.

The biochemical oxygen demand (BOD) of the dye was tested and the five day study showed the BOD_5 was 0 mg O_2/g. The chemical oxygen demand (COD) was determined to be 923 mg/g O_2. The dye was found to be not readily biodegradable (expressed as percentage elimination of organic carbon, biodegradation amounted to 0% at the end of the 28 day exposure to micro-organisms from a domestic sewage treatment plant) in the OECD 301A Test for ready biodegradability (modified AFNOR-Test (1)). No inhibition on the activity of the bacteria was observed in this test, which is consistent with the findings of the Activated Sludge - Respiration Inhibition Test (see Environmental Effects Section below). The dye's inherent biodegradability was not measured.

Although the dye is not readily biodegradable, the potential for bioaccumulation is low due to the low calculated partition coefficient (log K_{ow} < -10.6), very high water solubility of the substance (> 300 g/L) and low fat solubility (< 0.05 mg/100 g). Hydrophilic dyes with log K_{ow} less than 3 have been shown not to bioaccumulate (6). Also, biological membranes are not permeable to chemicals of very large molecular size and therefore bioaccumulation of the notified polymer is not expected (7, 8).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Monoazo Red SR 6947

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 000 mg/kg	(9)
acute dermal toxicity	rat	LD_{50} > 2 000 mg/kg	(10)
skin irritation	rabbit	non-irritant	(11)
eye irritation	rabbit	slight irritant	(12)
skin sensitisation	guinea pig	moderate sensitiser	(13)

9.1.1 Oral Toxicity (9)

Species/strain:	rat/WIST (SPF)
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	gavage; vehicle was polyethylene glycol
Clinical observations:	diarrhoea was noted in all animals on day 1
Mortality:	none
Morphological findings:	none
Test method:	similar to OECD guidelines (1)
LD_{50}:	> 2 000 mg/kg
Result:	the notified dye exhibited low oral toxicity in a limit test in rats

9.1.2 Dermal Toxicity (10)

Species/strain:	rat/WIST (SPF)
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	vehicle was polyethylene glycol; single dermal dose of 2 000 mg/kg of test substance was applied to an intact skin site; site covered with semi occlusive dressing; dressing removed after 24 hours and site washed with lukewarm water
Clinical observations:	the skin of all animals was discoloured at the test site for the whole of the study period; there were no signs of systemic toxicity
Mortality:	none
Morphological findings:	none
Test method:	similar to OECD guidelines (1)
LD_{50}:	> 2 000 mg/kg
Result:	the notified dye exhibited low acute dermal toxicity in a limit test in rats

9.1.3 Inhalation Toxicity

Not performed. The notifier states that the end use product containing the notified dye will be supplied predominantly in the liquid form. The powdered form of the end use product will contain anti-dusting agents.

9.1.4 Skin Irritation (11)

Species/strain:	rabbit/NZW (SPF)
Number/sex of animals:	1 male; 2 female
Observation period:	72 hours
Method of administration:	0.5 g of the test substance was moistened with bi-distilled water and applied to a 6 cm^2 intact dorsal skin site; skin covered by gauze and semi-occlusive dressing for 4 hours; site washed with lukewarm water after dressing removed; observations made at 1 hour, 1, 2

	and 3 days after removal of dressing and scored according to the method of Draize (14)
Draize scores (14):	there were no Draize scores above zero; discolouration of the skin at the test site was noted for all animals at all time points; this colouration did not preclude the assessment of any irritant response
Test method:	similar to OECD guidelines (1)
Result:	the notified dye was not an irritant to rabbit skin

9.1.5 Eye Irritation (12)

Species/strain:	rabbit/NZW (SPF)
Number/sex of animals:	2 male; 1 female
Observation period:	72 hours
Method of administration:	0.1 g of the test material was placed in the conjunctival sac of the left eye of each animal; right eye served as control
Draize scores (14) of unirrigated eyes:	all animals had slight chemosis 1 hour after treatment, this had cleared by the 24 hour reading (one animal) and by the 48 hour time point (remaining 2 animals); all other Draize scores were zero
Test method:	similar to OECD guidelines (1)
Result:	the notified chemical was a slight eye irritant in rabbits

9.1.6 Skin Sensitisation (13)

Species/strain:	guinea pig/GOHI (SPF)
Number of animals:	30 females
Induction procedure:	Day 1: 3 pairs of intradermal injections: - 0.1 mL Freund's complete adjuvant (FCA): physiological saline (1:1(v/v))

- 0.1 mL of 5% concentration of test material in physiological saline

- 0.1 mL of 5% concentration of test material in FCA: physiological saline(1:1 (v/v))

Day 7: test area treated with 10% (w/w) sodium lauryl sulfate in petrolatum oil

Day 8: occluded application of filter paper soaked in test material (25% in vaseline) for 48 hours

Challenge procedure: Day 22: occluded application of filter paper soaked in test material (25% in vaseline) for 24 hours

Rechallenge procedure: Day 36: occluded application of filter paper soaked in test material (10% in vaseline and 25% in vaseline) for 24 hours

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
25%	9/19**	7/19	0/10	0/10

Rechallenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
10%	1/19**	1/19	0/10	0/10
25%	7/19	7/19	0/10	0/10

* time after patch removal
** number of animals exhibiting positive response (1 animal from the test group was killed during the study for ethical reasons.)

Test method: similar to OECD guidelines (1)

Result: the notified dye is a moderate skin sensitiser in guinea pigs

9.2 Repeated Dose Toxicity (15)

Species/strain:	rat/WIST (SPF)
Number/sex of animals:	30/sex; control and high dose groups: 10/sex low and mid dose groups: 5/sex
Method of administration:	gavage; vehicle was polyethylene glycol
Dose/Study duration::	dose levels were based on the results of a 5 day range finding study in rats (16) test material administered daily for a total of 28 days: control: 0 mg/kg/day low dose: 50 mg/kg/day mid dose: 200 mg/kg/day high dose: 1 000 mg/kg/day all animals were sacrificed at the end of the treatment period, with the exception of 5 animals from control and high dose groups, which were maintained for an additional 2 week recovery period before sacrifice
Clinical observations:	male rats of the mid dose group consumed statistically more food than respective controls on treatment days 15 to 28; female rats in the high dose group consumed less food during the treatment free period; these differences were considered to be incidental and of normal pattern for rats of this strain and age all treated animals showed signs of slight diarrhoea throughout the treatment period; discolouration of the faeces in animals of the mid and high dose groups was also noted throughout the treatment period a slightly lower overnight urinary output and lower urine specific gravity was noted in males from the high dose group; a lower specific gravity was also noted for females of this group; urine discolouration was also noted for both sexes in the high dose group; at the end of the treatment free period the specific gravity was found to be comparable to the controls, however lower urine output and discolouration were still evident

Mortality:	one control animal died during blood sampling immediately prior to scheduled necropsy
Clinical chemistry/Haematology:	changes in haematological parameters in females from the high dose group suggested slight anaemia; these findings were not supported by other changes which would suggest increased erythropoietic activity; these changes were also within the range of the historical control data; this finding was reversed at the end of the treatment free period there were a number of slight changes in clinical biochemical parameters in high dose group animals; these were considered to be of metabolic nature, and of limited toxicological relevance, with the exception of the higher bilirubin concentration, which was thought to be related to interference of the test article with the assay procedure; these findings were reversed at the end of the treatment free period
Ophthalmology:	one female from the high dose group was found to have a corneal ulcer toward the end of the treatment-free period; this was thought to be spontaneous and not related to the test substance
Histopathology:	some differences were noted in absolute and relative organ weights in animals of both sexes from the high dose group the kidneys of animals from the high dose group were discoloured; renal tubular vacuolation was noted in males and females from the high dose group (at the end of both the treatment and recovery periods); the vacuoles contained pigment thought to be the test substance; an increase in renal tubular basophilia was noted mainly in male recovery animals; this suggested that the presence of the pigment for long periods may cause some degeneration; kidneys of animals in low and mid dose groups were indistinguishable from controls
Test method:	similar to OECD guidelines (1)

Result:	the findings of this 28 day oral repeat dose toxicity study indicate that treatment of rats with the notified chemical at the high dose (1 000 mg/kg/day) induces a number of changes in the kidneys, suggestive of organ toxicity

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (17)

Strains:	*Salmonella typhimurium* TA 1535, TA 1537, TA 1538, TA 98 and TA 100
Concentration range:	experiment 1: 10, 100, 333, 1 000 and 5 000 μg/plate experiment 2: 100, 333, 1 000, 2 500 and 5 000 μg/plate vehicle was water; assays were carried out in the presence or absence of rat liver S9 fraction
Test method:	similar to OECD Guidelines (1)
Result:	the notified chemical was not mutagenic in the bacterial strains tested in the presence or absence of metabolic activation provided by rat liver S9 fraction; concurrent positive controls demonstrated the sensitivity of the assay

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (18)

Species/strain:	mouse/NMRI
Number and sex of animals:	42/sex
Doses:	4 000 mg/kg; vehicle was distilled water; animals were sacrificed 24, 48 or 72 hours after treatment
Method of administration:	gavage
Test method:	similar to OECD guidelines (1)

Result: the notified dye did not induce a significant increase in micronuclei in mouse bone marrow cells when orally administered at a dose which induced slight toxic effects in the test animals

9.4 Overall Assessment of Toxicological Data

The notified dye exhibited low acute oral and dermal toxicity in rats (LD_{50} > 2 000 mg/kg for both studies). Inhalation toxicity tests were not performed. The notified dye was not a skin irritant in rabbits, but was a slight eye irritant in the same species. A guinea pig maximisation test showed the notified chemical to be a moderate skin sensitiser.

A repeat dose (28 day) oral toxicity study showed effects on the kidneys when the dye was administered at high doses (1 000 mg/kg/day), which were suggestive of organ toxicity.

The notified chemical was not mutagenic in bacteria and did not cause chromosome damage in mouse bone marrow cells *in vivo*.

Based on the toxicological studies provided by the notifier, Monoazo Red SR 6947 would be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (19), based on skin sensitising effects.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were performed in compliance with OECD/EEC Test Methods (1, 2) and according to OECD Principles of Good Laboratory Practice.

Test	***Species***	***Results (Nominal)***
Acute Toxicity (Static Test) (OECD TG 203 (1))	Zebra Fish (*Brachydanio rerio*)	96 hour LC_{50} > 1 000 mg/L
Acute Toxicity - Immobilisation Test (Static Test) (OECD TG 202 (1))	Water Flea (*Daphnia magna*)	48 hour NOEC = 125 mg/L 48 hour EC_{50} = 420.5 mg/L
Growth Inhibition - Growth (μ) & Biomass (b) (Static Test) (OECD TG 201 (1))	Green Algae (*Scenedesmus subspicatus*)	72 hour E_bC_{50} = 27.6 mg/L 72 hour $E_\mu C_{50}$ = 1 193 mg/L
Respiration Inhibition (OECD 209 (1))	Activated Sludge - Aerobic Waste Water Bacteria	3 h IC_{50} > 100 mg/L

Tests determined that the test media concentrations were all sufficiently stable.

Although not reported, test media were most probably slightly to strongly coloured by the test substance at even low concentrations.

The ecotoxicity data for the substance shows that the dye is practically non-toxic to the zebra fish and water flea. At all test concentrations (down to 100 mg/L), a slight change in the swimming behaviour of the test fish was observed.

Since the test solution is intensely coloured deleterious effects can be caused by the interception of light (shading effect) necessary for algal growth. However, a modified growth inhibition test (to differentiate between a real toxic effect of the notified chemical or an effect caused by shading) was not performed.

It should be noted that for environmental purposes, growth inhibition, whether due to chemical or physical factors, is still of relevance. Algistatic effects may still lead to an undesirable environmental impact if exposure is continuous. Thus, the notified chemical can be considered as slightly toxic to algae.

The notified chemical showed practically no toxic effects to the respiration rate of aerobic waste water bacteria in the respiration test, with a 3 hour IC_{50} greater than 100 mg/L.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the dye, when fixed to the cellulosic fibre, is rated as negligible.

The notifier has specified that a limited number of dyehouses (three) in city areas will be using the notified dye, thus the environmental hazard has been determined for metropolitan based dyehouses, one in Sydney and the other in Hobart. No usage in country dyehouses is expected. The application method is by printing of a printing paste and fixation followed by wash-off. The predicted environmental concentration (PEC) is estimated in the table below.

These calculations assume that no dye is removed in treatment of the different waste effluents and represent the worst case scenario for dyehouses, ie sewage treatment plants provide the lowest dilution. The typical use of dye per day figure was supplied by the notifier and is claimed to be the expected maximum useable for any one day's printing as estimated for the fifth year after introduction.

Calculation Factor	*Sydney Dyehouse*	*Hobart Dyehouse*
typical use of dyestuff expected per day (over 120 days in a year)	50 kg	50 kg
amount of Active (notified chemical) in 33% commercial product	11.5 kg	11.5 kg
weight of cloth printed per day	4 000 kg	4 000 kg
weight of active lost - due to wash-off (10%) and unfixed residues (fixation 72%)	4.37 kg	4.37 kg
quantity of water used including wash-off water (@ 100 L/kg)	400 000 L	400 000 L
effluent concentration in dye-specific wash-water	10.93 mg/L	10.93 mg/L
dilution factor in dyehouse by other wash-waters	1:6.25 (2.5 ML/day effluent)	1:6.25 (2.5 ML/day effluent)
influent concentration	1.75 mg/L	1.75 mg/L
dilution factor in sewage treatment plant	1:250	1:50
concentration balance in effluent from sewage treatment plant	6.99 μg/L	0.03 mg/L
dilution factor in receiving waters	1:10 (ocean)	1:3 (estuarine/river)
PEC in receiving waters	0.70 μg/L (0.70 ppb)	0.012 mg/L (11.7 ppb)
safety factor for exposure to most sensitive aquatic organism, algae (E_bC_{50} = 27.6 mg/L)	39 470	2 350

These calculations show that the exposure to fish, daphnia and algae is at levels unlikely to cause any significant effect. Dye concentrations greater than 1 ppm can give rise to intensely coloured effluent that is unacceptable to waste water authorities (5, 20). Therefore, at higher release rates, there is still unlikely to be any significant effect on algae.

The only other source of environmental contamination is from accidental spills and disposal of packaging. The MSDS is adequate to limit the environmental exposure and therefore limit the environmental effects.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The occupational health risk posed to waterside and transport workers is negligible, as exposure to the notified chemical will only occur in the event of accident or leaking packaging.

The majority of the notified dye will be imported as a component of a liquid dye formulation, although a small amount of repackaging of a powdered form of the dye may occur. There is a moderate occupational health risk posed to the limited number of workers who may be involved in handling powdered dye products containing Monoazo Red SR 6947. Workers may be exposed to the notified chemical via dermal, inhalational and ocular routes. The notifier states that exposure to the notified chemical will be reduced by ventilation, which will be used while handling the dye in powdered form, and the inclusion of an anti-dusting agent in the final dye product. Should dermal exposure occur, animal data indicates that the notified chemical may cause skin sensitisation. Monoazo Red SR 6947 is unlikely to cause skin irritation, however, workers may experience slight eye irritation if exposure occurs, based on the results of rabbit studies. As inhalation toxicity data is not available for the notified chemical and as the potential for exposure to the notified chemical by this route is moderate, exposure should be kept to a minimum. Personal protective equipment should be worn where necessary, for example when engineering controls are inadequate.

The occupational health risk for workers handling the notified chemical in liquid or paste form is low, as the dyeing processes are largely automated and the concentration of the notified chemical is low (approximately 2.3%). In addition, exposure times are expected to be relatively short. The main route of exposure is expected to be dermal, and the dye is not expected to be an irritant if skin contact occurs. As discussed above, skin sensitisation may occur in susceptible individuals. If accidental eye contact occurs, mild irritation may result.

A repeat dose 28 day oral toxicity study in the rat indicated that treatment with high doses of the notified chemical induces a number of kidney effects. However, it is unlikely that these renal effects will occur as a result of workplace exposure, as exposures are expected to be low.

There is a negligible health risk for workers handling dry, dyed textiles during packaging or manufacturing, as the notified chemical will be irreversibly bound to the fabric.

The notified dye will be used to colour cellulosic textiles used for apparel and sheeting and minimal amounts may be released from the textiles during wearing and washing. The chemical is a dermal sensitising agent and a slight ocular irritant. However, despite the possibility of dermal and ocular exposure to the notified chemical, the amount which is bio-available will be minimal, and therefore should pose negligible public health risk. The potential for minor public exposure exists during transport and disposal of the notified chemical, which is minimised by the notifier's recommended practices.

Based on the toxicity profile and the anticipated exposure of the public to the notified dye, it is unlikely that Monoazo Red SR 6947 will pose a significant risk to public health when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to Monoazo Red SR 6947 the following guidelines and precautions should be observed:

- Industrial clothing should conform to the specifications detailed in Australian Standard (AS) 2919 (21);
- Impermeable gloves or mittens should conform to AS 2161 (22);
- All occupational footwear should conform to Australian/New Zealand Standard (AS/NZS) 2210 (23);
- If engineering controls are inadequate to minimise inhalational exposure when handling powdered dye products containing the notified chemical, a mask which conforms to AS/NZS 1715-1994: *Use and Maintenance of Respiratory Protective Devices* (24) and AS/NZS 1716-1991: *Respiratory Protective Devices* (25) should be worn;
- Spillage of products containing the notified chemical should be avoided, spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for a product containing the notified dye was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (26).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified dye shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

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