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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Reactive Blue 244

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Reactive Blue 244

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 'Reactive Blue 244'.

2. IDENTITY OF THE CHEMICAL

Reactive Blue 244 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data and details of exact import volume have been exempted from publication in the Full Public Report and the Summary Report.

Other Names:	Cibacron Blue B Formazane Blue BG 2913 FAT 40'368/B
Trade Name:	Cibacron Blue P-B Powder (> 60% notified dye) Cibacron Blue P-B Liquid (< 40% notified dye)
Molecular Weight:	< 1 000 (free acid)
Method of Detection and Determination:	infrared (IR), ultraviolet/visible (UV/Vis) and nuclear magnetic resonance (NMR) spectra

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	the notified chemical is a blue powder
Boiling Point:	> 300°C [EEC L251/A1 - Capillary method, liquid bath (1)]
pH:	6.0 at 352 g/L

Specific Gravity:	1.72 at 23°C [EEC 84/449 A3 - 'Air comparison pycnometer method (1)]
Vapour Pressure:	not determined
Water Solubility:	> 300 g/L at 25°C [OECD TG 105 'flask method' (2)]
Partition Co-efficient (n-octanol/water):	log P_{ow} < -4.0 at pH 6.7 and 25°C [OECD TG 107 'shake flask' (2)]
Hydrolysis as a Function of pH:	$T_{1/2}$ at pH 4.0 = 897 hours at 25°C (estimated) $T_{1/2}$ at pH 7.0 > 1 year at 25°C (estimated) $T_{1/2}$ at pH 9.0 > 1 year at 25°C (estimated) [OECD TG 111 (2)]
Adsorption/Desorption:	not determined
Dissociation Constant:	not determined
Fat Solubility:	< 0.1 mg/100 g fat at 37°C
Particle Size:	< 2 μm 0.1% (w/w) > 12 97.0% > 16 87.5% > 24 62.4% > 32 38.4% > 48 9.5% > 64 7.3% > 96 2.1% median of mass distribution = 28.2 μm OECD method 110 (2) could not be used for this test
Surface Tension:	71.9 - 72.1 mN/m at 1.0 g/L and 20°C 55.9 - 63.1 mN/m at 10.0 g/L and 20°C
Flash Point:	not highly flammable
Flammability Limits:	not highly flammable
Autoignition Temperature:	275°C
Explosive Properties:	not explosive
Reactivity/Stability:	not oxidising; considered stable under conditions of intended use

Comments on Physico-Chemical Properties

The physico-chemical properties were determined for FAT 40'368/A. This dye has the same structure as the notified chemical, but has a free copper content of approximately 4%. A revised manufacturing procedure results in FAT 40'368/B having a free copper content of less than 0.3%. It is accepted that the supplied physico-chemical properties of FAT 40'368/A will be very similar to those of the notified chemical, FAT 40'368/B.

Tests were performed according to EEC/OECD test guidelines (1, 2).

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 should be negligible, as it is noted that the dye is a high molecular weight, organic tetrasodium salt and that similar dyestuffs previously submitted by the notifier exhibited very low (calculated) vapour pressures.

The notified chemical forms a paste at 1 000 g/L. The test report indicates that water solubility up to 352 g/L was attained.

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 and 25°C, the half-life was determined to be 897 hours (approximately 37 days).

The results obtained by the preliminary partitioning experiment showed that log K_{ow}, determined to be less than -4.0, lies outside the range determinable by the flask shaking method, and no further testing was performed. The log partition coefficient was therefore estimated to be approximately -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 agreed that the log P will be very 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, although it is expected that the chemical will 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 notifier claims that since the notified chemical contains sulfonate groups, the dissociation for this group would be around 2.5 (based on benzene sulfonic acid).

The notified chemical contains sulfonic acid functionalities that will be expected to remain completely dissociated under typical 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 (1).

The notified chemical is relatively insoluble in fat.

4. PURITY OF THE CHEMICAL

Degree of Purity: > 50%

Classification of Impurities: no health hazard classification of the impurities was provided by the notifier; toxicity tests were carried out on a substance which is structurally identical to the notified chemical, but which had a higher free copper content; this substance contained impurities when tested; these results 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 two dye products; Cibacron Blue P-B Powder (> 60% notified dye) and Cibacron Blue P-B Liquid (< 40% notified dye). Import volumes will be roughly 50% powder form and 50% liquid form. These dyes will be used for printing and continuous dyeing processes.

Less than 5 tonnes of the notified chemical will be imported each year for the first five years.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported as a component of dye products which will be supplied in both liquid and powdered form. The liquid form will be supplied in 600 kg intermediate bulk containers (IBCs) and the powdered form will be imported in 30 kg lined cardboard containers. Exposure of transport and storage workers is expected to occur only in the unlikely event of an accident or leaking packaging.

Some repackaging of the powdered form of the dyes 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. An anti-dusting agent is included in the final dye product and previous notifications for powdered dyes of this type have stated that repacking processes will be conducted in a booth in which air flow is drawn away from the operators at a rate which ensures capture of particulates. The notifier has also previously 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.

The notified chemical will be used in printing and pad dyeing processes. Workers may be exposed to the notified dye during the preparation of printing paste and pad liquor. Both processes involve pumping the liquid form of the dye from the IBCs directly into a blending vessel where other components are added to make the printing paste or pad liquor. During transfer, dermal exposure may occur when workers are connecting and disconnecting hoses. Eye contact would be limited to accidents. The non-dusting powdered end use product may also be used in printing or pad dyeing operations. Inhalational, dermal and ocular exposure may occur during transfer of this product from the cardboard containers into a weighing container and manual transfer to a closed blending vessel. The powder is then immediately wetted and dispersed using high speed stirring.

During printing processes, 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 between 120 and 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. The notifier states that minimal worker exposure to dye containing the notified chemical is likely to occur during equipment cleaning or repair.

There is also minimal opportunity for workers to be exposed to the notified chemical during continuous dyeing processes, as this process is largely automated. Some dermal exposure may occur when the cloth is initially threaded through the pad trough, although the notifier states that the trough is normally empty at the start of a run. Once dyed, the cloth passes to a heating chamber or steamer and is washed off and dried. The operator does not come into contact with the impregnated cloth (which will be wet with pad liquor) unless there is an interruption of the process.

Some exposure may also occur during cleaning processes, although the notifier states that these are also largely automated.

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

7. PUBLIC EXPOSURE

The potential for public exposure to Reactive Blue 244 arising from transport, re-packing and industrial dyeing processes is assessed as being very low.

The public will make contact with fabrics dyed with Reactive Blue 244, some of which will be used in the manufacture of clothing. However, the notifier states that the dye will be fixed strongly to the fibre substrate and does not anticipate any significant transfer to the skin. Hence, the extent of public exposure to the notified chemical from this source should be very low. Furthermore, the notified dye's fastness to washing and drycleaning is claimed to be high and hence negligible

exposure should occur from cleansing liquors.

8. ENVIRONMENTAL EXPOSURE

The dye has an average fixation performance of 75 to 95%, though a test report to justify this claim was not provided. The notifier claims that the full fixation test report is no longer available and added that the fixation figure is a conservative one based on the fact that the laboratory standard is not always achieved, with losses occurring in the preparation and clean up of printing pastes.

The notifier anticipates that the dyestuff will be used at two dyehouses only, located in Sydney and Hobart. Usage in country areas is not expected.

Release

The bulk of the dye will become chemically fixed to the cellulose textiles, and in this state is not expected to impact on the environment. The results of fastness performance tests show that a high order of fastness rating 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, 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

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 copper and sodium salts in the ash with 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 11 mg O_2/g. The chemical oxygen demand (COD) was determined to be 641 mg/g O_2. The dye was found to be not readily biodegradable in the OECD 301A Test for ready biodegradability (modified AFNOR-Test) (2). 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. 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} approximately -10.6), very high water solubility of the substance (> 300 g/L), low fat solubility (< 0.1 mg/100 g) and relatively high molecular weight. Hydrophilic dyes with log K_{ow} less than 3 have been shown not to bioaccumulate (6). Therefore, bioaccumulation of the notified polymer is not expected (7, 8).

9. EVALUATION OF TOXICOLOGICAL DATA

The following toxicological studies were carried out on FAT 40'368/A, which has the same structure as the notified chemical, but has a free copper content of approximately 4%. FAT 40'368/B (the form of the notified chemical which will be imported) has a free copper content of less than 0.3%.

9.1 Acute Toxicity

Summary of the acute toxicity of FAT 40'368/A

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} = 2 620 mg/kg (combined sexes)	(9)
acute dermal toxicity	rat	LD_{50} > 2 000 mg/kg	(10)
skin irritation	rabbit	slight irritant	(11)
eye irritation	rabbit	slight irritant	(12)
skin sensitisation	guinea pig	non-sensitiser	(13)

9.1.1 Oral Toxicity (9)

Species/strain: rat/Wistar

Number/sex of animals: 15/sex

Observation period: 15 days

Method of administration: gavage; vehicle was distilled water; due to the high mortality rate at the initial dose level (5 000 mg/kg), the dosing regimen was as follows:

Dose (mg/kg)	*Number Treated M/F*
2 000	5/5
3 000	5/5
5 000	5/5

Clinical observations: deaths which occurred were preceded by the following symptoms: sedation, dyspnoea, ataxia, hunched or ventral body posture, ruffled fur and bluish coloured extremities; clinical observations noted in survivors also included a number of the above effects

Mortality: all deaths occurred by day 3; see table below for details

Dose mg/kg	*Mortality (males)*	*Mortality (females)*
2 000	0/5	1/5
3 000	3/5	5/5
5 000	5/5	5/5

Morphological findings: no remarkable findings were noted in animals which were necropsied at the end of the study;

	general, bluish discolouration was noted in animals that died during the study (no further details were provided in the report)
Test method:	similar to OECD guidelines (2)
LD_{50} (combined sexes):	2 620 mg/kg; calculated using the Logit-Estimation model
Result:	the notified dye was of low acute oral toxicity in rats

9.1.2 Dermal Toxicity (10)

Species/strain:	rat/Wistar
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	single dermal dose of 2 000 mg/kg of test substance was applied to an intact skin site; vehicle was distilled water; site covered with occlusive dressing; dressing removed after 24 hours and site washed with lukewarm water
Clinical observations:	the application area was discoloured
Mortality:	none
Morphological findings:	none
Test method:	similar to OECD guidelines (2)
LD_{50}:	> 2 000 mg/kg
Result:	the notified dye is of low acute dermal toxicity in rats

9.1.3 Inhalation Toxicity

Not performed. The notifier states that the powdered product containing the notified dye will also contain anti-dusting agents, which will reduce the potential for exposure by this route.

9.1.4 Skin Irritation (11)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	2 males/1 female
Observation period:	72 hours
Method of administration:	0.5 g of the test substance was moistened with distilled water and applied to an 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):	one animal had slight erythema at the one hour reading which persisted through to the 48 hour timepoint; all other Draize scores were zero
Test method:	similar to OECD guidelines (2)
Result:	the notified chemical was a slight skin irritant in rabbits

9.1.5 Eye Irritation (12)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	2 males/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:	one animal had slight conjunctival redness and the remaining 2 animals had slight chemosis at the one hour time point; these effects had cleared by the 48 hour timepoint; a large amount of discharge and discolouration of the eye were noted at the one hour time point
Test method:	similar to OECD guidelines (2)

Result: the notified dye was a slight eye irritant in rabbits

9.1.6 Skin Sensitisation (13)

Species/strain: guinea pig/Dunkin-Hartley albino

Number of animals: 15/sex

Induction procedure:

Day 1: 3 pairs of intradermal injections:
- 0.1 mL Freund's complete adjuvant (FCA): distilled water (1:1(v/v))
- 0.1 mL of 5% concentration of test material in distilled water
- 0.1 mL of 5% concentration of test material in FCA: distilled water (1:1 (v/v))

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

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

Comments: two animals (1 control and 1 test) died spontaneously during the study

Challenge outcome:

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

* time after patch removal
** number of animals exhibiting positive response

Test method: similar to OECD guidelines (2)

Result: the notified dye was not a skin sensitiser in guinea pigs

9.2 Repeated Dose Toxicity (15)

Species/strain:	rat/Wistar
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 distilled water
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:	all animals in the high dose group showed discoloured faeces from day 20 until the end of the study slight rales were noted in one female from each of the low and mid dose groups at day 7 and day 21, respectively; this effect was not thought to be related to treatment with the test substance there were no statistically significant differences in food consumption in any of the treatment groups, when compared with controls statistically significant decreased body weights and body weight gain were observed in female animals in the high dose group from day 8 to the end of the treatment period
Mortality:	one female from the high dose group died after final blood collection
Clinical chemistry/Haematology	there were no toxicologically significant changes in haematological parameters

	animals from the high dose group had moderately increased creatinine levels and markedly increased uric acid levels at the end of the treatment period; these changes may suggest an effect of the test substance on renal function; these effects were found to be reversed at the end of the recovery period slight changes in other biochemical parameters in animals from the high dose group were thought to reflect hepatocellular changes, possibly due to an increased functional metabolic load; these changes had resolved by the end of the treatment free period, with the exception of albumin and total protein concentration in females, which remained decreased in comparison with controls
Urinalysis	a slight decrease in the overnight urinary output and a corresponding increase in urine specific gravity was noted in animals from the high dose group at termination of treatment; these findings may suggest some changes in relation to kidney function; these findings were reversed at the end of the treatment free period
Histopathology:	discolouration (principally of the kidneys and mesenteric lymph nodes) was noted in animals of the high dose group at the end of both the treatment and recovery periods congestion of the gastric mucosa was present in 4 males from the high dose group; this was considered an indication of an irritant effect of the test substance a moderate level of hyaline droplet formation was present in the proximal kidney tubules of 2 male rats in the high dose group; this was considered to be an indication of slight renal toxicity at the high dose level; this effect was no longer present at the end of the recovery period
Test method:	similar to OECD guidelines (2)

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 suggestive of slight kidney toxicity; these changes were largely reversed by the end of the recovery period

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:	10, 100, 333, 1 000 and 5 000 μg/plate assay was performed as two independent experiments; vehicle was bi-distilled water; assays were carried out in the presence or absence of rat liver S9 fraction
Test method:	similar to OECD guidelines (2)
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 Chromosome Aberration Assay in Chinese Hamster V79 Cells (18)

Dosing schedule:	a pre-test determined that the substance showed toxic effects at concentrations higher than 1.8 mg/mL without S9 fraction, and 0.8 mg/mL with S9 fraction present 7 hour fixation time: without S9 fraction: 1 mg/mL with S9 fraction: 0.6 mg/mL 18 hour fixation time: without S9 fraction: 0.1, 0.5, 1 mg/mL with S9 fraction: 0.05, 0.5, 0.7 mg/mL 28 hour fixation time: without S9 fraction: 1.3 mg/mL with S9 fraction: 0.70 mg/mL

	for all groups, the treatment interval was 4 hours; cells were fixed at 7, 18 and 28 hour timepoints and scored for structural chromosomal aberrations
Test method:	similar to OECD guidelines (2)
Result:	the notified dye induced structural chromosomal aberrations in Chinese Hamster V79 cells, in both the presence and absence of metabolic activation

9.3.3 Micronucleus Assay in the Bone Marrow Cells of the Mouse (19)

Species/strain:	mouse/NMRI
Number and sex of animals:	42/sex
Doses:	1 000 mg/kg (maximum tolerated dose (MTD) determined in a pre-experiment); vehicle was bi-distilled water; animals were sacrificed 24, 48 or 72 hours after treatment
Method of administration:	gavage
Test method:	similar to OECD guidelines (2)
Result:	the notified dye did not induce micronuclei in mouse bone marrow cells when orally administered the MTD

9.4 Overall Assessment of Toxicological Data

The combined oral LD_{50} for both sexes for the notified dye was found to be 2 620 mg/kg in rats. The dermal LD_{50} in rabbits was found to be greater than 2 000 mg/kg in a limit test. Inhalational toxicity studies were not performed. The notified dye was a slight skin and eye irritant in rabbits, and was found not to be a skin sensitiser in guinea pigs.

A 28-day repeat dose study showed that high doses (1 000 mg/kg/day) induced a number of changes suggestive of slight kidney toxicity.

The notified dye was not mutagenic in bacteria, but did induce structural abnormalities in Chinese Hamster V79 cells *in vitro*. The notified dye did not induce chromosome damage in mouse bone marrow cells *in vivo.*

Based on the information summarised above, the notified chemical would not

be classified as hazardous according to *The Approved Criteria for Classifying Hazardous Substances* (20).

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 Practices.

The tests were performed on the notified chemical, FAT 40'368/B, which has less than 0.3% free copper.

Test	***Species***	***Results (Nominal)***
acute toxicity (static test) [OECD TG 203 (2)]	Zebra Fish (*Brachydanio rerio*)	96 hour NOEC $\geq$ 1 000 mg/L 96 hour LC_{50} > 1 000 mg/L
acute toxicity - immobilisation test (static test) [OECD TG 202 (2)]	Water Flea (*Daphnia magna*)	48 hour EC_{10} = 16.1 mg/L 48 hour EC_{50} = 75.3 mg/L
respiration inhibition [OECD 209 (2)]	Activated Sludge - Aerobic Waste Water Bacteria	3 hour IC_{50} > 100 mg/L

Test media concentrations were determined to be sufficiently stable. All test media, down to 95 mg/L of the test substance, were reported to be intensely coloured.

The ecotoxicity data for the substance shows that the dye is practically non-toxic to zebra fish. The substance shows slight toxicity to the water flea. 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.

An algal growth inhibition test has not been conducted on the notified chemical. The notifier justified this omission based on the relatively low Predicted Environmental Concentrations (PEC) (see Environmental Hazard Section below). They further claim that due to the "low copper level and knowledge of other tests on similar substances, only the 'light adsorption' by the dissolved colour would inhibit algal growth/reproduction".

Copper is known to be highly toxic to aquatic species. Toxic effects on saltwater algae has been observed at copper concentrations between 5 μg/L and 100 μg/L (21). Nitrogen fixation by blue-green algae was reduced by the addition of trace amounts of copper (22). However, copper toxicity is mitigated by increases in water hardness and dissolved oxygen, and in the presence of chelating agents, humic acid, amino acids and suspended solids (21, 22, 23). These processes remove copper from solution, thereby reducing its bioavailability (complexation forms less available forms of copper) (21, 24).

Since the test solution is intensely coloured, deleterious effects can be caused by the interception of light (shading effect) necessary for algal growth. However, 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.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

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

The notifier has specified that a limited number of dyehouses in city areas will be using the notified dye. Thus the environmental hazard has been determined for the two nominated metropolitan based dyehouses, one each in Sydney and 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 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 amount was supplied by the notifier and is claimed to be based on experience during the commercial evaluation of the product. The quantity used varies with printing design but would represent a typical highest use when the product was in regular use.

Calculation Factor	***Sydney Dyehouse***	***Hobart Dyehouse***
typical use of active expected per day (over 50 days in a year)	40 kg	40 kg
weight of active lost - due to wash-off, unfixed residues (fixation of 80%), and clean-up. total 25%.	10 kg	10 kg
dilution in dyehouse by other wash-waters	1.5 ML/day effluent	1 ML/day effluent
influent concentration	6.67 mg/L	10 mg/L
dilution factor in sewage treatment plant	1:250	1:50
conc. balance in effluent from sewage treatment plant	26.7 μg/L	0.2 mg/L
dilution factor in receiving waters	1:10 (ocean)	1:3 (estuarine/river)
PEC in receiving waters	2.67 μg/L (2.67 ppb)	0.07 mg/L (66.7 ppb)

It has been assumed in the calculations that no removal of the dye would take place during the wastewater treatment process. However, some of the dye would probably be removed due to the adsorption of the dye to the organic sludge and possible complexation of the dye (3). Therefore, the actual concentration in receiving waters is likely to be even lower than that calculated.

These calculations show that the exposure of fish and daphnia to these levels of the notified chemical is unlikely to cause any significant effects. At these proposed use rates, the notified chemical's PEC will be at levels that should not inhibit algal growth due to the shading effect. In any case, dye concentrations greater than 1 ppm can give rise to intensely coloured effluent that is unacceptable to waste water authorities (5, 25).

The dye contains uncomplexed copper at a concentration of approximately 0.3%. Similar calculations to those shown above give a concentration of copper in effluent from the dyehouses entering the sewage treatment works (STW) at 20 μg/L (Sydney) and 30 μg/L (Hobart). Typical background concentrations of copper in domestic wastewater of Australian cities ranges from 90 to 200 μg/L (26). After treatment at the STW, the concentration of copper entering receiving waters due to the Sydney dyehouse is 8 ng/L (8 ppt) and due to the Hobart dyehouse is 0.2 μg/L (0.2 ppb). However, this assumes that no copper is removed during the waste water treatment processes, where in fact 50% is typically removed by primary treatment and 85% typically removed by primary plus secondary treatments (26). The ANZECC Water Quality Guidelines (21) indicate that concentrations of copper in fresh water should not exceed 2 to 5 μg/L (depending on the water hardness) and 5 μg/L in marine waters. Therefore, copper concentrations entering the aquatic environment due to the use of the notified dyestuff will be at levels that should not pose a significant hazard in the environment or add significantly to background levels.

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, warehouse and transport workers is negligible, as exposure to the notified chemical will only occur in the event of accident or leaking packaging.

The notified chemical will be imported as a component of both liquid and powdered dye formulations and some repackaging of the powdered form of the dye may occur. There is a low occupational health risk posed to workers who may be involved in handling powdered dye products containing Reactive Blue 244. While there is potential for exposure to the notified chemical via inhalation, less than 3% of the particles would be considered respirable (criteria quoted in (27)) and an anti-dusting agent is used in the dye preparation. In addition, 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.

If dermal exposure to the notified chemical occurs, the molecular weight (< 1 000) would not preclude absorption. The pH values for the notified chemical and the final dye products in solution indicates that they are unlikely to cause corrosive effects,

although animal data indicates that the notified chemical may cause slight skin irritation if exposure occurs. Workers may also experience slight eye irritation if exposure occurs. Reactive Blue 244 was not a skin sensitiser in guinea pigs. As inhalation toxicity data are not available for the notified chemical and as there is potential for exposure by inhalation, exposure should be kept to a minimum.

The occupational health risk for workers handling the notified chemical in liquid or paste form during printing or pad dyeing processes is also low. Based on data previously supplied by the notifier for dyes of this type, dyeing processes are largely automated and the concentration of the notified chemical is relatively low. The main route of exposure is expected to be dermal. The chemical may be a slight irritant if skin or eye contact occurs. Results from animal studies indicated that the chemical is unlikely to be a sensitiser if workers are dermally exposed.

A repeat dose 28-day oral toxicity study indicated that treatment with high doses (1 000 mg/kg/day) of the notified chemical induces a number of changes suggestive of slight kidney toxicity. It is unlikely that these effects will occur as a result of workplace exposure, however, 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 potential for public exposure to Reactive Blue 244 arising from transport, repacking and industrial dyeing processes is very low. Widespread public dermal contact will occur with fabric dyed with the notified chemical. However, the dye will be fixed strongly to the substrate and should not be available for systemic absorption.

The use pattern outlined by the notifier and the toxicological data provided suggests that Reactive Blue 244 presents a low public health hazard.

13. RECOMMENDATIONS

To minimise occupational exposure to Reactive Blue 244 the following guidelines and precautions should be observed:

- It is good work practice to wear industrial clothing which conforms to the specifications detailed in Australian Standard (AS) 2919 (28) and occupational footwear which conforms to Australian and New Zealand Standard (AS/NZS) 2210 (29) to minimise exposure when handling any industrial chemical;

- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly and 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 chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (30).

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 chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise.

Secondary notification under Section 64 of the Act will be required if the method of use changes in such a way as to greatly increase the environmental exposure of the notified chemical, or if additional information becomes available on adverse environmental effects of the chemical. This includes if the notifier wishes to import the notified dyestuff with an increased free copper concentration, eg FAT 40'368/A with 4% free copper. In this case an algal toxicity test will be required. In addition, this notification is very site specific. Therefore, secondary notification may also be required if the notified dyestuff is used at another dyehouse with different waste water treatment procedures to those indicated in this notification.

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