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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

REACTIVE BLUE TZ 3926

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

REACTIVE BLUE TZ 3926

1. APPLICANT

Ciba-Geigy Australia Ltd of 235 Settlement Road THOMASTOWN Victoria 3074 has submitted a standard notification for assessment of Reactive Blue TZ 3926.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, Reactive Blue TZ 3926, is considered to be non-hazardous. Therefore, the details relating to exempt information have been exempted from publication in the Full Public Report and the Summary Report.

2. IDENTITY OF THE CHEMICAL

Other names: Reactive Blue TZ 3926, FAT 45'171/A

Trade name: Cibacron Blue LS-3R (product containing FAT 45'171/A)

Method of detection and determination:

Reactive Blue TZ 3926, may be detected by UV/VIS, IR spectroscopy and NMR spectra. Assay and by-products by HPLC with VIS detection. Determination of the impurities may be performed by atomic absorption spectroscopy, differential pulse polarography, ion chromatography and flame ionisation analysis.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: violet powder

Odour: no odour

Melting Point: >400°C

Density: 0.61 g/cm @ 23°C

Vapour Pressure: estimated 6 x 10^{-35}Pa at 25°C

Water Solubility: 122 g/L at 18°C

Fat Solubility: not given for FAT45'171/A (Reactive Blue TZ 3926); following result is for FAT41'016/A the unmethylated homologue of the notified chemical. <0.1 mg/100 g @ 37°C

Surface Tension: 60.3 $mN.m^{-1}$ at 25.3 °C

Partition Co-efficient (n-octanol/water) log P_{ow}: log P_{ow}<-2.0

Hydrolysis as a function of pH: not given for FAT45'171/A (Reactive Blue TZ 3926); following results are for FAT41'016/A the unmethylated homologue of the notified chemical.
$T_{1/2}$ pH 4 at 25°C = <1 day
$T_{1/2}$ pH 7 at 25°C = >1day<1 year
$T_{1/2}$ pH 9 at 25°C = >1 day<1 year (estimated)

Adsorption/Desorption: not provided

Dissociation Constant:

not given for FAT45'171/A (Reactive Blue TZ 3926); following results are for FAT41'016/A

R-SO_3: -2.5 > pK_a > -3.0 (4x acidic)

Ph-NH-Ph is ~ 0.8 (2x basic)

Tr-NH-CH_2: pK_a < 2.0 (2x basic)

(Spectrophotometric technique according to Albert and Serjeant (1))

Flash Point: not applicable

Flammability Limits: not given for FAT45'171/A (Reactive Blue TZ 3926); following results are for FAT41'016/A; not highly flammable; could not be ignited.

Combustion Products: not provided

Pyrolysis Products: not provided

Decomposition Temperature:	not provided
Decomposition Products:	not provided
Autoignition Temperature:	>400°C
Explosive Properties:	none
Reactivity/Stability:	not considered an oxidising substance

Particle size distribution: range -

<0.35µm	**0.03%**	
0.35-0.74µm	0.09%	
0.74-1.52µm	0.18%	
1.52-3.02µm	0.39%	
3.02-6.04µm	0.86%	
6.04-11.74µm	1.93%	
1.74-24.08µm	4.24%	
24.08-63.00µm	11.41%	
<63µm	**19.13%**	
63-100µm	25.21%	
100-200µm	37.34%	
200-400µm	15.34%	
>400µm	3.00%	
mean -120µm (derived from cumulative distribution graph)		

Comments on missing physico-chemical data:

This section contains information on the substance FAT 45'171/A, together with complementary information on FAT 41'016/A. The notified substance is the methyl derivative of FAT 41'016/A.

The partition coefficient using the saturation concentration of the dye in pure solvents was estimated to be log P_{ow} < -6.0. Calculations using the Leo-Hansch method estimated it to be log P_{ow} < -5.3. However, the experimental and calculation results obtained for the partition coefficient lie outside the range accessible by the flask shaking method of the OECD 107 test, thus it was estimated to be log P_{ow} < -2.0.

Adsorption/desorption data was not provided. High water solubility and low partition coefficient would normally indicate a low affinity for soil or sediment. The notifier has indicated that adsorption to common soil would be strong. This is questioned by the EPA and would only be the case where there is a co-ordination to soil cations.

It is expected that the dye will not be surface active. By EEC definition, a chemical has surface activity when the surface tension is less than 60 $mN.m^{-1}$ (EEC Directive 92/69, A.5. "Surface Tension" (1992)).

Information on combustion products, pyrolysis products and decomposition temperature were not provided by the notifier. It should be noted that the substance could not be ignited. Flash point is not applicable to solids.

4. PURITY OF THE CHEMICAL

Degree of purity: 76.2%

Toxic or hazardous impurity:

Chemical name:	sodium fluoride
CAS No.:	7681-49-4
Weight percentage:	0.5%
Toxic properties:	harmful when inhaled; harmful if concentration exceeds 3% (2)

Impurities of unknown toxicity:

Unidentified organic byproduct 3.4%
(Unknown coloured by-products 3.3% and unknown uncoloured 0.1%)

Non-hazardous impurity/impurities (> 1% by weight):

sodium phosphate	CAS7558-79-4	5.0%
water		6.6%

Uncomplexed copper was found to be 323 mg/kg.

Additive/Adjuvant: anti-dusting agent, only included in commercial version

5. INDUSTRIAL USE

The notified chemical will be imported into Australia as a violet powder in a ready-to-use form containing an anti dusting agent. The imported product containing the notified chemical (>60%) is Cibacron Blue LS-3R. It will be used to colour cellulosic fibres by the exhaust dyeing method. The chemical is said to exhibit approximately 80% level of fixation using this technique.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported as the commercial form in approved sturdy receptacles. This contains the hazardous impurity sodium fluoride which is considered harmful by inhalation, in contact with skin and if swallowed. The cut-off point for this harmful classification is 3% (as sodium fluoride in the product) (2). In FAT 45'171/A (Reactive Blue TZ 3926) sodium fluoride is at a concentration of 0.5% therefore the harmful categorisation is not applicable to the commercial product containing Reactive Blue TZ 3926.

The dye will be distributed to dyehouses in the same packaging as it was imported. Some repackaging for the purpose of supplying samples or materials for mill trials may be required. This is expected to be minimal and will occur in "down-flow" booths where the air flow is away from the operators.

The notified chemical is imported and supplied in the commercial form which contains anti-dusting agents. Dyehouse exposure to the powdered form, prior to incorporation in solution, will be minimised by local exhaust ventilation and where this is inadequate the use of personnel protective equipment.

It is estimated that potentially 144 Australian employees are likely to be exposed in dyehouses utilising the dye formulation containing Reactive Blue TZ 3926.

The worst case exposure of an employee to the notified substance has been modelled by the notifier and is estimated at 0.0015 mg/kg bw/day for dye-weighers. This assumes weighing of five 2.0 kg measures/day for 67 days a year. The greatest potential for exposure in the workplace is during the weighing and dissolution processes.

The steps involved in the textile dying process are weighing, addition of the dye to the blending vessels and transferring of the dye mixture to the dyeing equipment. The dye is dissolved in a vat before it is pumped to a tank from which it is dispensed to the dye machine. These processes all occur in closed systems. The fabric is fed into the dye machine and following dyeing is washed free of unfixed dye and dried. Exposure of workers during the dyeing process is not expected.

The Material Safety Data Sheet (MSDS) states that at a minimum dyehouse staff handling the notified chemical should wear impervious gloves, glasses/face shields, overalls and where ventilation is inadequate, suitable respiratory protective masks.

7. PUBLIC EXPOSURE

The notified chemical will be imported as a >60% component of a ready-to-use powder (Cibacron Blue LS-3R), and will usually be distributed from one warehouse to the customer's dyehouses without repackaging. A small quantity of the powder may be re-packed in "downflow" booths to supply samples for trials. Public exposure during distribution to dyehouses is considered unlikely. In the event of a transport accident, spills are to be contained and collected by vacuum or wetted down and

swept up. The contaminated area is then to be washed and covered with dry absorbent.

The potential for public exposure to Reactive Blue TZ 3926 during dyeing operations is considered to be negligible.

Extensive public contact will occur with fabrics dyed with the notified chemical, but at this stage Reactive Blue TZ 3926 will be irreversibly bonded to the fibre. The potential for absorption of Reactive Blue TZ 3926 will be further reduced by its high molecular weight of 1462. Exposure from dyed fabrics is therefore anticipated to be negligible.

8. ENVIRONMENTAL EXPOSURE

- Release

The bulk of the dye will become 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 high order of fastness rating is achieved in all cases.

The major release of the dye will come from the discharge of dyehouse effluent and waste water treatment systems. Other releases will be limited to traces remaining from any clean-up of any spills, repacking operations and trace residues in empty packaging.

All clean up of spills and disposal of empty packaging should be carried out according to the MSDS. Information relating to the proper emptying of drums before disposal will be highlighted in the MSDS for the commercial form of the substance.

- Fate

The dye normally released in water as effluent from the dyehouse is expected to be the major environmental release. The dye may either partition to sediment or stay in the aqueous compartment. Any dye that binds to the sludge during the waste treatment process would be disposed of through incineration or landfill. Incineration is the preferred disposal route because of the high water solubility of the material. Incineration of the dye will produce oxides of carbon, nitrogen and sulphur. There could also be some acidic fluorine combustion products in the absence of strong halide receptors. Disposal by landfill should be done at a secured site, so the risk of leaching to the water table is significantly reduced.

The biological oxygen demand (BOD) of the dye was tested and the five day study showed the BOD_5 is 0 mgO_2/g. The dye was found to be not readily biodegradable (0% after 28 days) in the OECD 301A test for ready biodegradability and not inherently biodegradable (5.6% after 28 days) in the modified Zahn-Wellens test (OECD TG: 302B), but did not inhibit bacteria. Although the dye is not readily biodegradable, the potential for bioaccumulation is low due to the low partition

coefficient (log P_{ow} < -2.0) and low lipid solubility (< 0.1 mg/100 g @ 37 ^{o}C) of the substance.

Residues that survive sewage treatment will enter freshwater or marine environments in solution. The low biodegradability and stability to hydrolysis coupled with the high water solubility suggest the compound may persist for long periods in the aquatic compartment. However, the dye would quickly become diluted to levels well below that likely to be toxic to aquatic organisms. Sorption to soils/sediments is not expected as reactive dyes show poor binding and are not absorbed (3).

9. EVALUATION OF TOXICOLOGICAL DATA

Results of acute dermal studies, skin and eye irritation studies and repeated dose toxicity were not supplied by the notifier for Reactive Blue TZ 3926. The notifier in support of the application provided results of these studies using the unmethylated homologue of the notified chemical, this chemical is known as FAT 41'016/A.

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Reactive Blue TZ 3926, (FAT 45'171/A).

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	>2000LD_{50} mg/kg	(4)
Acute dermal toxicity	Rat	*>2000LD_{50} mg/kg	(5)
Skin Irritation	Rabbit	*Non-irritant	(6)
Eye irritation	Rabbit	*Non-irritant	(8)
Skin sensitisation	Guinea-pig	non-sensitising	(9)

*Results not available for FAT 45'171/A (Reactive Blue TZ 3926), these results are for FAT 41'016/A.

9.1.1 Oral Toxicity (4)

Species/strain: rat (HanIbm)

Number/sex of animals: 5 female/5male

Observation period: 14 days

Method of administration (vehicle): gavage (distilled water)

Clinical observations: no clinical signs noted

Mortality: no deaths

Morphological findings: no deviations from normal morphology were found in all animals.

Test Method:	OECD guidelines for testing of chemicals No.401; Directive 92/69/EEC Test B1
LD_{50}:	>2000 mg/kg
Result	low oral toxicity in rats

9.1.2 Dermal Toxicity (5)

Species/strain:	rat (HanIbm)
Number/sex of animals:	5 male/5 female
Observation period:	14 days
Method of administration (vehicle):	distilled water
Clinical observations:	blue/black skin
Mortality:	no deaths
Morphological findings:	no deviations from normal morphology were found
Test Method:	OECD guidelines for testing of chemicals No 402; Directive 84/449/EEC Test B3
LD_{50}:	>2000 mg/kg
Result	low dermal toxicity in rats

9.1.4 Skin Irritation (6)

Species/strain	New Zealand White rabbit
Number/sex of animals:	1 male/2 female
Method of administration:	a gauze patch bearing 0.5g of the test article was applied to the right shaved flank of each animal for four hours. A control gauze patch was applied to the contralateral flank.

Draize (7) Scores[i] *(refer to endnote)*

Animal	Time after decontamination			
	60 min	1 day	2 days	3 days
ERYTHEMA				
1	0	0	0	0
2	1	1	0	0
3	1	1	0	0
OEDEMA				
1	0	0	0	0
2	0	0	0	0
3	0	0	0	0

Test Method: OECD guidelines for testing of chemicals No. 404; Directive 84/449/EEC Test B4.

Result: not irritant to rabbit skin

9.1.5 Eye Irritation (8)

N.B. results of test carried out on FAT 41'016/A, unmethylated homologue of FAT 45'171/A (Reactive Blue TZ 3926).

Species/strain: New Zealand White rabbits

Number of animals: 3

Method of administration: 0.1 g of test substance was placed in the conjunctival sac of the left eye of each animal.

Draize (7) Scores[ii] *(refer to endnote)*

Animal	Time after instillation			
	1 hour	1 day	2 days	3 days
CORNEA:	opacity area	opacity area	opacity area	opacity area
1	0	0	0	0
2	0	0	0	0
3	0	0	0	0
IRIS				
1	0	0	0	0
2	0	0	0	0
3	0	0	0	0
CONJUNCTIVA	r[a] c[b]	r[a] c[b]	r[a] c[b]	r[a] c[b]
1	1 0	0 0	0 0	0 0
2	1 1	0 0	0 0	0 0
3	1 1	0 0	0 0	0 0

[a] redness [b] chemosis

Test Method: OECD guidelines for testing of chemicals No. 405; Directive 84/449/EEC Test B5

Result: non-irritant

9.1.6 Skin Sensitisation (9)

Species/strain: Himalayan spotted

Number of animals: 20 in test group, female guinea pigs/10 in control groups (Ibm: GOHI)

Induction at day 1: test group: injections of adjuvant/saline mixture 1:1 (v/v); 5% notified chemical in distilled water; 5% notified chemical in the adjuvant/saline mixture. Control group: injections of adjuvant/saline mixture 1:1 (v/v); distilled water; adjuvant/saline 1:1 (v:v) mixture with distilled water(w/w) 1:1.

Induction at day 8: test group: Topical: 25% notified chemical in distilled water. Control group: distilled water only.

Challenge at day 22: test and control group, 25% notified chemical in distilled water and distilled water only.

Results:

Challenge Concentration	24 hrs		48hrs	
	test	control	test	control
0%	0/10	0/10	0/10	0/10
25%	0/20	0/20	0/20	0/20

Test Method: Directive 92/69/EEC (5) test B6

Result: non-sensitiser

9.2 Repeated Dose Toxicity (10)

N.B. results of test carried out on FAT 41'016/A, unmethylated homologue of FAT 45'171/A (Reactive Blue TZ 3926).

Species/strain: Wistar rat HanIbm

Number/sex: 30 males/30 females

Method of administration (vehicle): distilled water

Dose/ Duration of administration:	0, 50, 200, 1000 mg/kg/day for 28 days to a total of 60 rats followed by a 14 day recovery period. (20 in control, 10 at 50, 10 at 200 and 20 at 1000 mg/kg/day).

Toxicologically Significant Observations:

1. Clinical
No clinical signs of toxicity observed in any of the animals.

2. Clinical Chemistry/Haematology
The treatment had no influence on the haematology profile apart from a significant increase in bilirubin concentrations in high dose animals. The authors claim that the high bilirubin readings are due to the dye colour causing spectral interference; no tests were performed to test the theory. After the recovery period the levels of bilirubin in the control and high dose groups were comparable. There was discolouration of the urine which was reversible within the two week recovery period.

3. Necropsy Findings/ Histopathology
A minimal and reversible effect was found in the highest dose group of males. Weights of the following organs differed from the controls: kidney, liver, pituitary and heart weights. A minimal and reversible effect was found with lower ovary weight in the high dose female group compared to the controls.

Test Method:	OECD guidelines for testing of chemicals No. 407, Directive EEC 84/449 Test B7
Result:	No treatment related irreversible effects

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assays (11)

Strains:	*Salmonella typhimurium* TA 1535, TA 1537, TA 98 and TA100 *Escherichia coli* WP2 and WP2 uvrA
Concentration range:	33.3 - 5000 μg/ plate, with and without the addition of rat liver post mitochondrial supernatant (S9 fraction) as an extrinsic metabolic activation system.
Test Method:	OECD guidelines for testing of chemicals No. 471, Section 4; Directive EEC 92/69, L 383 A.
Result:	In both experiment, with and without metabolic activation, on the strains tested,

induction of gene mutations by base pair changes or frameshifts did not occur.

9.3.2 *In Vitro* cytogenetic assay in Chinese hamster V79 cells (12)

Dose levels: 18h: 30, 300, 800μg/ml (without metabolic activation)
28h: 600μg/ml

Experiments were repeated with identical doses except the 18h 800μg/ml was replaced with 600μg/ml.

18h: 300, 1000, 2500μg/ml (with metabolic activation)
28h: 2500μg/ml

Experiments were repeated with identical doses except the18h 2500μg/ml was replaced with 2000μg/ml and the 28h 2500μg/ml replaced with 2000μg/ml.

Metabolic activation: rat liver S9

Test Method: 84/449/EEC Test B10

Result: The notified chemical did not exert a clastogenic effect in Chinese hamster ovary cells *in vitro*.

9.4 Overall Assessment of Toxicological Data

The notified chemical Reactive Blue TZ 3926 was of low acute oral toxicity to rats (LD_{50}>2000 mg/kg) and was not a skin sensitiser in guinea pigs. Assays for mutagenicity were performed with the notified chemical in *Salmonella typhimurium* and *Escherichia coli* over a concentration range of 33.3 - 5000 μg/plate. Negative results were obtained in the presence and absence of metabolic activation. The notified chemical also displayed no clastogenic activity in cultured Chinese hamster V79 cells at concentrations of up to 2500 μg/ml with metabolic activation and 800 μg/ml without metabolic activation.

Supporting toxicological data was provided by the notifier from studies undertaken on the unmethylated homologue of FAT 45'171/A (Reactive Blue TZ 3926), FAT 41'016/A. This chemical was found to have low dermal toxicity to rats (LD_{50}>2000 mg/kg) and was not a skin or eye irritant to rabbits. However FAT 41'016/A elicited dermal erythema in 2/3 rabbits which resolved 2 days post application, and also caused conjunctival redness and chemosis in 2 and 3/3 rabbits, respectively, which reversed 24 hr post treatment.

In a 28-day repeat oral dose study in rats (with 14-day recovery) at 0, 50, 200 and 1000 mg/kg/day, FAT 41'016/A caused a reversible discolouration of the urine, increase in serum bilirubin concentration and depression in ovarian weight among animals receiving the high dose. No deaths or clinical signs of toxicity were observed. Other than staining of some internal organs, there were considered to have been no treatment-related effects at 50 or 200 mg/kg/day.

On the basis of submitted data, including that provided for the unmethylated homologue FAT 41'016/A, the chemical would not be classified as hazardous in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(1994)] with respect to oral or dermal toxicity, skin and eye irritation or skin sensitisation potential and is not a mutagen.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been provided by the notifier. The tests were carried out to OECD Test Methods.

Test	Species or biological test system	Result (Nominal)
Acute Toxicity	Zebra Fish	96h LC_{50} = 613 mg/L
Acute Toxicity	*Daphnia magna*	48h EC_{50} = 141.5 mg/L
Growth Inhibition	Green algae *Scenedesmus subspicatus*	72h EbC_{50} = 20 - 27 mg/L
Respiration Inhibition	Bacteria from activated sludge	3h IC_{50} = > 320 mg/L
Acute Toxicity	Earthworm *Eisenia foetida foetida*	14d LC_{50} > 1000 mg/L

The ecotoxicity data for the substance show that the dye is practically non-toxic to aquatic organisms, except algae, which shows a slight toxicity to growth. Since the test solution is intensely coloured, algistatic effects can be caused by interception of light (shading effect) necessary for algae growth. At concentration of 1000 mg/L a slight change in the swimming behaviour of the test fish could be observed. However, at this concentration the test solution would have been intensively coloured and this may have hampered observations.

There is no test report provided for the acute toxicity of the earthworm. The notifier included this information from the EC version of the MSDS.

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 in city and country will be using the notified dye. The environmental hazard has been determined for dyehouses located in two general locations, one metropolitan based dyehouse and

the other country based. The Predicted Environmental Concentration (PEC) is estimated below. These calculations assume that no dye is removed in treatment of the different waste effluents.

Predicted Environmental Concentration (PEC) Table

Calculation Factor	City Dyehouse	Country Dyehouse
Typical Use of Dye Expected Per Day	50.0 kg	20.0 kg
Conc. in Wastewater (Fixation Rate of 80%)	10.0 kg	4 kg
Quantity of Water Used Including Wash-off Water (at 100 $L.kg^{-1}$)	250,000 L	100,000 L
Effluent Concentration in Dye-specific Wash-water	40.0 mg/L	40 mg/L
Dilution Factor in Dyehouse by Other Wash-waters	10:1 (2.5 ML/day effluent)	10:1 (2 ML/day effluent)
Influent Concentration	4 mg/L	4 mg/L
Dilution Factor in Sewage Treatment Plant	1:100	1:2
Conc. Balance in Effluent From Sewage Treatment Plant	0.04 mg/L	2 mg/L
Dilution Factor in Receiving Waters	10:1 (ocean)	2:1 (river)
Conc. (PEC) in Receiving Waters	0.004 mg/L	1 mg/L

The above calculations represent the worst case scenario for dyehouses. A final depth of shade of 2.0% was used in the calculation of the PEC. The notifier stated that this was the likely maximum used by dyehouses, with the more typical depth of shade 0.5%. Therefore a more usual PEC for the dye into receiving waters will be 0.001 mg/L for metropolitan-based dyehouses and 0.25 mg/L for country based dyehouses. A maximum of 4.0% is given in the Colour Performance Test sheets, though this would occur only in very extreme cases as the final colour would be extremely dark.

It has also been assumed in the calculations that no removal of the dye would take place during the wastewater treatment process. 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 (13). Therefore the actual concentration to receiving waters is likely to be lower than that calculated.

These calculations show that the exposure to fish and daphnia is at levels unlikely to cause any significant effect. It was shown that the inhibition to algae growth caused by the dye was due more to the shadow effect rather than its toxicity. Dye

concentrations > 1 ppm can give rise to intensely coloured effluent which is unacceptable to waste water authorities (3). Therefore there is also unlikely to be any significant effect on algae.

The dye contains uncomplexed copper at a concentration of 0.0323%. Similar calculations as above gives a concentration of copper in receiving waters from a city dyehouse at 0.005 *u*g/L and country dyehouse at 1.615 *u*g/L. This assumes that no copper is removed during the dyeing and waste water treatment processes, where in fact 50% is typically removed by primary treatment and 85% typically removed by primary plus secondary treatments (14). Further, the typical dyeshade is 0.5%. Using these factors to re-calculate the concentration of copper in receiving waters from a country dyehouse gives 0.06 *u*g/L (for secondary treatment at 0.5% dyeshade). Concentrations of copper in fresh water should not exceed 2 - 5 *u*g/L, depending on the water hardness, with the concentration of copper not exceeding 5 *u*g/L in marine waters (15). At higher dyeshades, levels may be closer to these guidelines, and thus monitoring is recommended to ensure these are not breached.

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.

The dye is not likely to present a hazard to the environment when it is stored, transported and used in the typical manner. However it is recommended that for rural dyeing operation using this dye when higher than 0.5% dyeshades are used that levels of free copper are monitored in the dyehouse effluent.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is only imported in the commercial form which contains an anti-dusting agent. Where there is the possibility of exposure to the powdered dye local exhaust ventilation is typically used.

The worst case occupational exposure has been modelled by the notifier and will be for dyeweighers. This would be at a maximum of 0.0015 mg/kg bw/day. This is well below the NOAEL of 1000 mg/kg bw/day in the 28 day repeated dose study using rats. Overall, approximately 144 staff may be exposed during the weighing, dissolution and dyeing procedures in the dyeworks. Most of the dyeing process are in enclosed systems and direct contact by employees is further limited by personnel protective wear such as impervious gloves.

Public exposure to the dyestuff could occur through effluent discharges from the dyeworks, however this is unlikely. There is potential for widespread public contact with the notified chemical via dyed fabric, but negligible exposure is expected because Reactive Blue TZ 3926 will be bound irreversibly to fibre. The high molecular weight and low fat solubility will also minimise exposure. The notified chemical is therefore unlikely to constitute a hazard to public health.

13. RECOMMENDATIONS

To minimise occupational and environmental exposure to Reactive Blue TZ 3926 the following guidelines and precautions should be observed:

If engineering controls and work practices are not sufficient to reduce exposure a safe level the following personal protective equipment should be used:

. The appropriate respiratory device should be selected and used in accordance to Australian Standard/ New Zealand Standard (AS/ NZS) 1715 (16) and should conform to AS/NZS 1716 (17).

. Eye protection (chemical goggles or face shields) should be selected and fitted in accordance to AS 1336 (18) and used in accordance to AS/NZS 1716 (19).

. Industrial clothing must conform to the specifications detailed in AS2919 (20).

. Impervious industrial gloves should conform to the standards detailed in AS 2161 (21).

All occupational footwear should conform to AS/NZS 2210 (22).

The standard for nuisance dusts should be observed at all times.

Work practices should minimise the formation of dusts.

Ensure that good general exhaust ventilation is installed in areas where dust aerosols can be generated.

At all times avoid physical eye contact with unfixed dye or dyebath contents.

A copy of the MSDS should be easily accessible to employees.

For rural dyeing operations using this dye, levels of free copper should be monitored in the dyehouse effluent, when higher than 0.5% dyeshades are used.

14. MATERIAL SAFETY DATA SHEET

The MSDS for Reactive Blue TZ 3926, was provided in Worksafe Australia format (23).

This MSDS was provided by Ciba-Geigy Australia Ltd. as part of their notification statement. The accuracy of this information remains the responsibility of Ciba-Geigy Australia Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of Reactive Blue TZ 3926 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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[1] The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	rating	Oedema Formation	rating
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

[2] The Draize scale for evaluation of eye reactions is as follows:

CORNEA			
Opacity	**rating**	**Area of Cornea involved**	**rating**
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE					
Redness	**rating**	**Chemosis**	**rating**	**Discharge**	**rating**
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS	
Values	**rating**
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe

[ii]