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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

FAT 40'530/A

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

FAT 40'530/A

1. APPLICANT

Ciba-Geigy Australia Ltd of 235 Settlement Road THOMASTOWN Victoria 3074 has submitted a standard notification statement with their application for an assessment certificate for FAT 40'530/A.

2. IDENTITY OF THE CHEMICAL

Fat 40'530/A is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, chemical abstract service number, molecular and structural formulae, spectral data, exact purity, use and volume have been exempted from publication in the Full Public Report and the Summary Report.

Other Names:	FAT 40'530/A Reactive Navy DER 7850 (50.2% of the notified chemical together with known coloured, unknown coloured, known uncoloured and unknown uncoloured by-products)
Trade Name:	Cibacron Navy LS-G (notified chemical, by-products, stabilising agents, inhibitors and other additives)
Method of Detection and Determination:	the notified chemical is identified by nuclear magnetic resonance (NMR) and infrared (IR) spectroscopy and quantitatively determined by ultraviolet (UV/Vis) spectral analysis

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	violet to blue black powder
Odour:	no odour
Melting Point:	does not melt but decomposes at > 230°C
Density:	1 790 kg/m^3 at 23°C
Vapour Pressure:	3.6 x 10^{-37} kPa at 25°C

Water Solubility:	> 500 g/L at 20°C
Fat Solubility:	< 0.48 mg/L in octanol
Surface Tension:	49.5 mN/m at 19.5°C
Partition Co-efficient (n-octanol/water) log P_{ow}:	log P_{ow}<-2.0 at 20°C
Hydrolysis as a Function of pH:	$T_{1/2}$ pH 4 at 25°C = > 365 days $T_{1/2}$ pH 7 at 25°C = >365days $T_{1/2}$ pH 9 at 25ºC = 107 days (estimated)
Vinylation as a Function of pH:	$T_{1/2}$ pH 4 at 25°C = >365 days $T_{1/2}$ pH 7 at 25°C = 9.8 days $T_{1/2}$ pH 9 at 25ºC = 14.8 days (estimated)
Adsorption/Desorption:	not determined
Dissociation Constant:	-SO_3H range from pKa > -8.3 to -0.2 phenols pKa = 6.9 and 7.0
Flash Point:	not applicable
Flammability Limits:	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:	> 430°C
Explosive Properties:	None
Reactivity/Stability:	not considered an oxidising substance
Particle Size Distribution:	7.71% particles $\leq$ 24.42 μm

Comments on Physico-Chemical Data:

Tests were performed according to EEC/OECD test guidelines at facilities complying with OECD Principles of Good Laboratory Practice. The vapour pressure was determined from the calculated boiling point using the Modified Watson Correlation. The notified chemical is not volatile.

Vinylation of the ethyl sulphate groups to the vinylated products will occur under environmental pH ranges. This is an intermediate stage before hydrolysis. The rates given above at 25°C were evaluated using the Arrhenius equation from rates determined at 50°C.

The partition coefficient (log P_{ow}) was estimated to be less than - 6.0 by calculation using the saturation concentration of the notified chemical in pure solvents. The results obtained by the preliminary partitioning experiment showed that log P_{OW} lies outside the range determinable by the flask shaking method and no further testing was performed. Therefore, the notifier estimated the partition coefficient to be log P_{OW} less than -2. The EPA accepts that the log P_{ow} 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 anticipates that the notified chemical is likely to bind/adsorb to common soils. The EPA expects that the chemical will bind to positively charged substances such as clay particles. However, binding of the chemical to organic matter is questioned by the EPA, which considers that such binding would occur only where cations are involved (1).

The molecular structure of the free acid of the notified chemical was used as the basis for the estimation of the dissociation behaviour. The acid dissociation constants were estimated to be in the range from pK_a -8 to pK_a 18. The notified chemical contains sulphate functionalities that will be expected to completely dissociate under environmental conditions. The phenols may or may not dissociate depending on pH.

4. PURITY OF THE CHEMICAL

Degree of Purity: < 100%

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. It 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 (50.2%) is Cibacron Navy LS-G High Concentration. It will be used to dye textiles. The proposed import volume is 3-7 tonnes in the first year rising to 10-14 tonnes per year in the fifth year. Approximateley 8 main and 4 minor specialised dyehouses will use the product containing the notified chemical.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported in ready-to-use form. It will be packed in approved sturdy receptacles, in sealed cardboard containers with antistatic polyethylene lining. From the wharf the notified chemical containing the dye will be transported by road to a warehouse

There is potential for exposure during transport and handling only in the event of an accident.

The dye will be distributed to dyehouses in the same packaging as it was imported. Some limited repackaging for the purpose of supplying samples or materials for mill trials may be required. It is estimated that a maximum of two people will repack less than 100 kg of the dye each year in “down-flow” booths, where the air flow is away from the operators (in these facilities, the capture velocity for particulates is exceeded, so that the exposure approaches zero). Exposure to the notified chemical will be limited to less than 10 days per year for 15-20 minutes each day.

In the dyehouse, dye is weighed, added to a blending vessel and transfered to a dyeing apparatus. Primary occupational exposure to the notified chemical containing the dye is during batching operations. The dye is dissolved in an open vat (blending vessel) generally without local exhaust exreaction, before it is (approximately 500 L), pumped to a tank from which it is dispensed to a dyeing machine. These dyeing processes all occur in an closed system. 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.

It is estimated that 12 dyehouses will use the notified chemical, 8 main and 4 minor. 12 employees have the potential to be exposed in each of these dyehouses. It is estimated that potentially 144 Australian employees are likely to be exposed.

The worst case exposure of an employee to the noitified substance has been modelled by the notifier and is estimated at 0.0017 mg/kg bw/day for dye-weighers. This assumes weighing of five 2.0 kg measures/day a year. The greatest potential for exposure in the workplace is during the weighing and dissolution process.

7. PUBLIC EXPOSURE

The potential for public exposure to the notified chemical during dyeing operations is considered to be negligible.

Extensive public contact will occur with fabrics dyed with the notified chemical, but at this stage the notified chemical containing the dye will be irreversibly bonded to the fibre. The potential for absorption of the notified chemical will be further reduced by its high molecular weight of 1 706. Exposure from dyed fabrics is therefore anticipated to be negligible.

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 high order of fastness rating is achieved in all cases. 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. 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 by the EPA at 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 normally released in water as effluent from the dyehouse is expected to be the major environmental exposure. It is unclear whether some of the dye in the effluent will be in the vinylated or hydrolysed form. The dye may either partition to sediment or stay in the aqueous compartment. Hobbs (3) 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 of the material. Incineration of the dye will produce oxides of carbon, nitrogen and sulfur, together with sodium salts in the ash. Disposal by landfill will be at a secured site, so the risk of leaching to the water table is significantly reduced.

The biochemical oxygen demand (BOD) of the dye was tested and the five day study showed the BOD_5 was 7.5 mg O_2/g. The dye was found to be not readily biodegradable (expressed as percentage removal, biodegradation amounted to 4% at the end of the 28-day exposure to micro-organisms from a domestic waste water treatment plant) in the OECD 301E Test for ready biodegradability. It was found to be slightly inherently biodegradable (expressed as percentage removal, biodegradation amounted to 14% by the end of the 28-day exposure period) in the Zahn-Wellens/EMPA Test (OECD 302B) for inherent biodegradability.

Although the dye is not readily biodegradable, the potential for bioaccumulation is low due to the low calculated partition coefficient (log P_{ow} < -2.0) and very high water solubility of the substance. Hydrophilic dyes with log P_{ow} < 3 have been shown not to bioaccumulate (4). Also, biological membranes are not permeable to chemicals of

very large molecular size and therefore bioaccumulation of the notified polymer is not expected (5,6).

Residues that persist after sewage treatment will enter freshwater or marine environments in solution. While azo dyes are generally stable under aerobic conditions, they are susceptible to reductive degradation under anaerobic conditions characteristic of sediment (4). Also, highly sulphonated *bis*(azo) dyes have been shown to sorb to sediment through an anion-adsorption mechanism (1). Another possible route of entry of the dye to the sediment is by the precipitation of its calcium salts, as several calcium salts of sulphonic dyes are known to be insoluble at modest concentrations (1). Degradation of such dyes in sediment water systems proceeded with a half-life of 2-16 days. Accordingly, no significant increase in dissolved concentrations over time is predicted, while residues bound to sediment are expected to undergo reductive degradation.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of FAT 45'530/A

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} >2000 mg/kg	(7)
acute dermal toxicity	rat	LD_{50}>2000 mg/kg	(8)
skin Irritation	rabbit	non-irritant	(9)
eye irritation	rabbit	slight irritant	(10)
skin sensitisation	guinea-pig	mild sensitiser	(11)

9.1.1 Oral Toxicity (7)

Species/strain:	rat (HanIbm); WIST (SPF)
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration (vehicle):	gavage (distilled water)
Clinical observations:	no clinical signs noted
Mortality:	no deaths
Morphological findings:	diarrhea was observed on test days 3 to 5 and 2 to 5 in four males and all females
Test Method:	OECD guidelines for testing of chemicals (27)
LD_{50}:	> 2000 mg/kg

Result	low oral toxicity in rats

9.1.2 Dermal Toxicity (8)

Species/strain:	rat (HanIbm) WIST (SPF)
Number/sex of animals:	5 /sex
Observation period:	14 days
Method of administration (vehicle):	distilled water
Clinical observations:	blue skin
Mortality:	no deaths
Morphological findings:	no deviations from normal morphology were found
Test Method:	OECD guidelines for testing of chemicals (27)
LD_{50}*:*	> 2000 mg/kg
Result	low dermal toxicity in rats

9.1.4 Skin Irritation (9)

Species/strain	young adult 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.
Test Method:	OECD guidelines for testing of chemicals (27)
Result:	not irritant to rabbit skin

9.1.5 Eye Irritation (10)

Species/strain:

young adult New Zealand White rabbits

Number of animals:

1 male/2 females

Method of administration:

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

Draize (12) Scores

Animal	Time after instillation			
	1 hour	1 day	2 days	3 days
CORNEA:	opacity area	opacity area	opacity area	opacity area
1	3	0	0	0
2	1	0	0	0
3	2	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	- 4	- 1	0 1	0 0
2	- 1	0 1	0 1	0 0
3	3 2	2 1	0 1	0 0

[a] redness [b] chemosis

Test Method:

OECD guidelines for testing of chemicals (27)

Result:

slight irritant

9.1.6 Skin Sensitisation (11)

9.1.6.1 Test 1

Species/strain:

Himalayan spotted guinea-pig

Number of animals:

20 in test group, female guinea-pigs/10 in control groups

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: 50% notified chemical in distilled water; control group distilled water only

Challenge at day 22: test and control group 1, 50% notified chemical in distilled water and distilled water only.

Re-challenge at day 29: test and control group 2, 15 and 25% notified chemical in distilled water

The Challenge Outcome:

Challenge Concentration	***24 hrs***		***48hrs***	
	test	***control***	***test***	***control***
0%	0/20	0/10	0/20	0/10
25%	14/20	*4/10	13/20	4/10

* 50% concentration of FAT'530/A showed an irritancy potential of 40% on the control group 1. A second challenge was performed with two lower concentrations, 15% and 25% on the same test group but using a new control group (control group 2)

Re-challenge Concentration	***24 hrs***		***48hrs***	
	test	***control***	***test***	***control***
0%	3/20	0/10	0/20	0/10
25%	7/20	0/10	6/20	0/10

Test Method: Directive 92/69/EEC (5) test B6 (27)

Result: skin sensitiser in the guinea

9.1.6.2 Test 2 (13)

Species/strain: Himalayan spotted guinea pig

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: 50% notified chemical in distilled water; control group: distilled water only

Challenge at day 22: test and control group 1, 50% notified chemical in distilled water and distilled water only.

The Challenge Outcome:

Challenge Concentration	***24 hrs***		***48hrs***	
	test	***control***	***test***	***control***
0%	0/20	0/10	0/20	0/10
25%	4/20	0/10	5/20	0/10

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

Result: mild sensitiser

9.2 Repeated Dose Toxicity (14)

Species/strain: Wistar rat HanIbm

Number/sex: 35/sex

Method of administration (vehicle): distilled water

Dose/ Duration of administration: 0, 10, 50, 200, 1000 mg/kg/day for 28 days to a total of 70 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 treatment-related clinical signs of toxicity observed in any of the animal

2. Clinical Chemistry/Haematology

The treatment had a slight influence on the haematology/clinical chemistry profiles with a significant increase in methemoglobin and uric acid concentrations, as well as low total bilirubin in high dose animals (1000 mg/kg). An increase in the total protein content in the high dose group males were noted. After the recovery period the levels of methemoglobin, uric acid and total bilirubin in high dose groups were comparable to that of the controls with the exception of the total protein concentration in the males. Also the urine discolouration was no longer evident, except in two males in the high dose group.

3. Necropsy Findings/ Histopathology
Kidney weight and kidney/body weight ratios were higher in animals treated at 200 and 100 mg/kg/day, but were comparable to the control groups after the recovery period.

In 1000 mg/kg/day dose group, adverese tubular changes were noted at minimal to moderate severity in all males and at minimal to slight severity in all females. This was also accompanied by an increase in hyaline droplet formation in males, and minimal to slight degree of lipofuscin-like tubular pigment in females. At recovery adverse tubular changes were persistant at a slightly reduced level.

Test Method: OECD guidelines for testing of chemicals No. 407, Directive EEC 84/449 Test B7

Result: treatment related persistant effects (at 1 000 mg/kg/day) observed in the kidney

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assays (15)

Strains: *Salmonella typhimurium* TA 1535, TA 1537, TA 98 and TA100
Escherichia coli WP2 and WP2 uvrA

Concentration range: 33.3 - 5 000 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 (27)

Result:	in one experiment, a dose dependent enhancement factors of strains WP2 and WP2 *uvrA* exceeded the limit of 2.0 at concentrations of 2 500 μg/plate in the presence of metabolic activation, in the duplicate experiment the limit was nearly exceeded under same conditions; weakly mutagenic with metabolic activation

9.3.2 *In Vitro* cytogenetic assay in Chinese hamster V79 cells (16)

Dose levels:	
Experiment 1	18h: 3, 10, 30 μg/ml 28h: 100μg/ml (without metabolic activation) 18h: 30, 50, 100 μg/ml (with metabolic activation)
Experiment 2	18h: 100, 300, 500μg/ml 28h: 500μg/ml (without metabolic activation 18h: 50, 100, 300 μg/ml 28h: 500 μg/ml
Experiment 3	18h: 100, 500, 500μg/ml 28h: 500μg/ml (without metabolic activation 18h: 100, 300, 500 μg/ml 28h: 400 μg/ml
Metabolic activation:	rat liver S9
Test Method:	84/449/EEC Test B10 (27)
Toxicologically significant observations:	in experiment 3, in the absence of metabolic activation, toxicity was observed with 1000 μg/ml (28 h interval; 27.8%) and 800 μg/ml (28 h interval; 53.3%); in experiment 3 in the presence of metabolic activation toxicity was observed with 500 μg/ml (18 h interval; 16.1%)

	at other dose levels there were no significant reduction in mitotic index to infer toxicity
Result:	the notified chemical showed clastogenic effects in Chinese hamster V79 cells *in vitro* with metabolic activation

9.4 Overall Assessment of Toxicological Data

The notified chemical was of low acute oral toxicity via the oral and dermal routes in the rat with LD_{50} values of > 2 000 mg/kg for both routes of administration. It was a slight irritant to the eye and a non-irritant to the skin of rabbit. It was a slight skin sensitiser* in guinea pigs. When rats were treated orally with up to 1000 mg/kg/day dose group, treatment-induced nephrotoxicity was observed. These effects were not observed at dose levels of 50 and 200 mg/kg/day. FAT 40'530/A was found to be weakly mutagenic in vitro in Escherichia coli WP2 and WP2 uvrA and clastogenic in Chinese hamster V79 cells.

On the basis of submitted data, the notified chemical would not be classified as hazardous in accordance with the Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)] (Approved Criteria).

* In test 1, for contact sensitisation with FAT 40'530/A, the challenge concentration was 50% which was an irritant concentration since 40% of the control animals reacted with signs of skin irritation. To avoid skin irritant effects a lower concentration, 15%, was tested on the same test group but with a new control group. No reactions in the control group occured but 3 animals in the test group showed signs of skin sensitisation. A further concentration, 25% (non-irritant concentration), when tested on the same group of animals, 7 out of 20 tested (35%) reacted with chemosis and oedema with no effects observed in the controls. Based on these results, according to the 'Approved Criteria' FAT40"530/A should be classified hazardous. Since, a response of 30% of animals is considered positive for this type of test method. However, in a recent publication by Kligman etal (17) showed testing of several concentrations on the same animals by way of consecutive challenges may produce a hyperirritability status corresponding to the "angry back" syndrome in humans and by this mechanism leading to false positive responses. Based on these findings, the test was repeated (test 2) using new animals.

In test 2, 5 out of 20 animals (25%) reacted with signs of skin sensitisation. On the basis of these results FAT 405'530/A could only be considered a weak sensitiser producing a sensitisation rate of 25% in the maximisation test. The 35% response observed in test 1 was considered to be false positive value, on the basis of a hyperirritability produced by repeated testing of same animals.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies (Table 1) have been supplied by the notifier. The tests were carried out to OECD Test Methods.

Table 1: Ecotoxicity Test Results

Test	***Species***	***Results (Nominal)#***
Acute Toxicity (Semi-Static Test)	Rainbow Trout (*Oncorhynchus mykiss*)	96h NOEC 100 mg/L
Acute Toxicity - 48 hr Immobilisation (Static Test)	Water Flea (*Daphnia magna*)	48h EC_{50} 100 mg/L 48h NOEC 10 mg/L
Growth Inhibition$^{=}$ - Area (I_A) (= b, biomass) and Growth Rate (I_μ)	Algae (*Scenedesmus subspicatus*)	<u>Experiment A</u> 72h E_bC_{50} = 2.6 mg/L 72h $E\mu C_{50}$ = 15.8 mg/L <u>Experiment B</u> 72h $E\mu C_{50}$ = 2.1 mg/L 72h $E\mu C_{50}$ = 18.4 mg/L
Respiration Inhibition	Aerobic Waste Water Bacteria	30 min EC_{50} 100 mg/L

Algae results based on measured concentrations - see text for more details.

† This test was modified to differentiate between a reduced growth of algae due to real toxic effects of the notified chemical on the algal cells (Experiment A) and that due to an indirect effect only, namely a reduced algal growth by light absorption in coloured test solutions (Experiment B) - see text for more details.

Test media at the lowest concentration tested (nominally 0.32 mg/L) were slightly coloured by the notified chemical. This may have hampered observations. For fish and algae, the notified chemical was found to be sufficiently stable during the test periods, ranging from 94% to 113% of the nominal values. Therefore, results given in Table 1 are related to nominal concentrations. The mean measured concentrations in the algae test varied in the range from 72% to 100% of nominal. Therefore, the results in Table 1 are based on the mean measured test substance concentrations.

The ecotoxicity data for the substance shows that the dye is practically non-toxic to rainbow trout and water flea, which is consistent with the high water solubility and high molecular weight of the chemical.

The company performed a modified algae growth test. In one experiment (Experiment B), the dye was not incorporated in the algal culture medium, but was interpolated between the light source and the culture dish; this allows assessment of the effect of light quality and quantity (due to the dye) on the algae. In the second experiment (Experiment A), the dye is actually included in the algal culture medium; the effects on algae here will be due to both light and any direct chemical toxicity.

Impacts on algal growth were measured as 'percentage inhibition area' (under the growth curve) (I_A) (= b, biomass) and 'percentage inhibition growth rate' (I_μ) (= μ, length). No significant differences were reported between Experiments A and B for both I_A and I_μ, implying that the effects on growth (at concentrations at and above 0.10 mg/L) were due only to changes in the quality or quantity of light.

The notified chemical was found to slightly inhibit the respiration rate of aerobic waste water bacteria (in activated sludge) in the range from 1.7% to 3.5% when exposed to test article concentrations of 3.2 to 100 mg/L (OECD TG: 209). The 30 min-EC_{50} is reported as 100 mg/L.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the dye, when fixed to the cellulosic fibre, is rated as negligible. In determining this, the following was considered:

- the notifier has specified that a limited number of specialised dyehouses (approximately eight main and four minor) in city and country areas will be using the notified chemical in a dye formulation;
- the environmental hazard has been determined for three dyehouses located in two general locations, one metropolitan based dyehouse and the other country based; and
- two examples of dye usage were given for country dyehouses.

The Predicted Environmental Concentration (PEC) is estimated below in Table 2. These calculations assume that no dye is removed in treatment of the different waste effluents, and it represents the worst case scenario for dyehouses, *ie* with the lowest dilution during waste treatment and in receiving waters. A 3% depth of shade was used for the dyeing rate (the maximum dye rate as stated by the notifier).

Table 2: Predicted Environmental Concentration (PEC)

Calculation Factor	***City Dyehouse***	***Country Dyehouse - High Dye Use***	***Country Dyehouse - Low Dye Use***
Typical use of dye expected per day	75.0 kg	60.0 kg	30.0 kg
Conc. in wastewater (fixation rate 88%)	9.0 kg	7.2 kg	3.6 kg
Quantity of water used incl. wash-off water (@ 100 L/kg[1])	250 000 L	200 000 L	100 000 L
Effluent conc. in dye-specific wash-water	36 mg/L	36 mg/L	36 mg/L
Dilution factor in dyehouse by other wash-waters	1:10 (2.5 ML/day effluent)	1:10 (2 ML/day effluent)	1:20 (2 - 4 ML/day effluent)
Influent concentration	3.6 mg/L	3.6 mg/L	1.8 mg/L
Dilution factor in sewage treatment plant	1:100	1:2	1:2
Conc. balance in effluent from sewage treatment plant	0.036 mg/L	1.8 mg/L	0.9 mg/L
Dilution factor in receiving waters	1:10 (to ocean outfall)	1:2 (to river outfall)	1:2 (to river outfall)
PEC in receiving waters	3.6 mg/L[1] (3.6 ppb)	0.9 mg/L (0.9 ppm)	0.45 mg/L (0.45 ppm)
Safety factor for exposure to most sensitive aquatic organism, Algae (72h E_bC_{50} = 2.1 mg/L)	583	2.3	4.7

It has been assumed in the calculations in Table 2 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 (1). Dye would normally be applied only at 0.5% depth of shade. Therefore, due to these factors, the actual concentration in receiving waters is likely to be significantly lower than that calculated. (The PEC in receiving waters for a country dyehouse with high usage using a 0.5% depth of shade is 0.15 mg/L, with a safety factor > 14 for algae.)

The PEC calculations show that the exposure to fish and water flea is at levels unlikely to cause any significant effect, although levels are near those where significant inhibition of algal growth by the dye occured. This was due to a function of decreased light intensity or change in light quality reaching the algae in the coloured media. However, release of coloured effluent would generally be of concern to textile and dye manufacturing industries and waste water authorities (3,18). In any event, the dye's high solubility suggests that once released to the waterways, dilution would be expected to swiftly reduce the environmental concentration to undetectable 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.

It is noted that the notified chemical is surface active. However, significant effects are not expected in the environment due to the predicted low concentrations in the aquatic compartment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The toxicological profile of FAT 40’530/A suggests that it is unlikely to produce acute toxic effects upon ingestion and dermal contact. Although it is expected to be a slight eye irritant, is not expected to cause irritation to the skin. The notified chemical may be a slight skin sensitiser and is likely to be weakly genotoxic. The results of the sub-acute 28-day oral toxicity test suggest the notified chemical has the potential to cause renal damage on repeated and prolonged exposure. However, as organ toxicity in rats in this test was only observed at 1000 mg/kg/day, the notified chemical would not be classified as hazardous according to Approved Criteria.

The notified chemical is imported as a powder. The low particle size (2.87% < 11.91 μm) distribution of the notified chemical and use of an antidusting agent in the powder formulation is expected to minimise dust and hence exposure. This suggests that inhalational exposure is unlikely to occur. The use of local exhaust ventilation or the use respirators will further reduce exposure to dust. This suggests that inhalational exposure is unlikely to occur

When the dye is in aqueous solution, some skin contact is possible. Transfer from the blending vessel where the dye is dissolved to the dyebath is by pump. Thus the potential for spillage or splashing appears to be controlled. Dissolution of the dye in cold water is said to be instantaneous and mists are not formed during mixing.

The worst case occupational exposure has been modelled by the notifier and will be for dyeweighers. This would be at a maximum of 1.7 μg/kg bw/day. This is well below the level of 200 mg/kg/day which in the 28-day repeated dose rat study showed signs of chemical related toxicity.

Although the notified chemical should be regarded as a potential respiratory sensitiser, the risk of respiratory sensitisation would appear to be low given that the dye is in a non-dusting form and in the event of exposure minimising such exposures by the use of personal protective equipment. There is clearly a risk of slight skin sensitisation from the notified chemical and personal protective equipment as outlined below should be used.

The public will not be exposed to FAT 40'530/A during its importation and application to textiles by commercial dye-houses. The public will come into contact with the notified chemical containing only when handling retail fabrics. Since the notified chemical is irreversibly bound to textile fibres, has low potential for dermal absorption and is of low acute dermal toxicity, the notified chemical is unlikely to constitute a hazard to public health.

13. RECOMMENDATIONS

To minimise occupational and environmental exposure to the following guidelines and precautions should be observed:

- If engineering controls and work practices are not sufficient to reduce exposure to 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 (19) and should conform to AS/NZS 1716 (20).

    - Eye protection (chemical goggles or face shields) should be selected and fitted in accordance to AS 1336 (21) and used in accordance to AS/NZS 1716 (22).

    - Industrial clothing must conform to the specifications detailed in AS2919 (23).

    - Impervious industrial gloves should conform to the standards detailed in AS 2161 (24).

    - All occupational footwear should conform to AS/NZS 2210 (25).

- 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.

14. MATERIAL SAFETY DATA SHEET

The MSDS for FAT 40'530/A, was provided in Worksafe Australia format (26). This MSDS was provided by Ciba-Geigy Australia Ltd as part of the notification statement. The accuracy of this information remains the responsibility Ciba-Geigy Australia Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of FAT 40'530/A shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

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