File No: NA/462

Date: January 1997

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Reactive Black 2506-MS

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Reactive Black 2506-MS

1. APPLICANT

Ciba-Geigy Australia Ltd of 235 Settlement Road THOMASTOWN VIC 3074 has submitted a standard notification statement in support of their application for an assessment certificate for 'Reactive Black 2506-MS'.

2. IDENTITY OF THE CHEMICAL

Reactive Black 2506-MS 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:	FAT 45168/A
Trade Name:	the notified chemical will be marketed as a component of the dye Cibacron Navy PG; this will be available in both powdered and liquid forms
Molecular Weight:	approximately 1 000 (free acid)
Method of Detection and Determination:	Ultra violet (UV)/visible spectroscopy; infrared spectroscopy; nuclear magnetic resonance spectroscopy

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	black-blue powder
Melting Point:	no melting point; decomposes above 240°C
Specific Gravity:	1.7 at 21.5°C (pycnometer)
Vapour Pressure:	8×10^{-23} Pa at 25°C (estimated)
Water Solubility:	367 g/L at 25°C (flask method)

Fat Solubility:	0.11 mg/100 g at 37°C
pH:	6.5 - 7.5 at 1 g/L
Partition Co-efficient (n-octanol/water):	log P_{ow} < -2 (estimated - see comments below)
Hydrolysis as a Function of pH:	$T_{1/2}$ at pH 4.0 = 100 days at 25°C $T_{1/2}$ at pH 7.0 > 1 year at 25°C $T_{1/2}$ at pH 9.0 > I year at 25°C (these values are estimated - see comments below)
Adsorption/Desorption:	not provided
Dissociation Constant:	not provided

Particle size:

< 0.37 μm	2.81%
0.37 - 0.78 μm	2.76%
0.78 - 1.61 μm	6.90%
1.61 - 3.20 μm	17.80%
3.20 - 6.41 μm	33.82%
6.41 - 12.45 μm	21.96%
12.45 - 25.53 μm	9.33%
25.53 - 63.00 μm	4.62%
> 63.00 μm	0.00%

Surface Tension:	58.8 mN/m at 21.8°C (notified chemical dissolved in water at a concentration of 1.0 g/L)
Flash Point:	not provided
Flammability Limits:	not flammable
Autoignition Temperature:	347°C
Explosive Properties:	not explosive
Reactivity/Stability:	not an oxidising agent

Comments on Physico-Chemical Properties

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.

At pH 7 and 9, hydrolysis rates were less than 10% after 5 days at 50°C, and no further testing was conducted. This was not the case at pH 4, and hydrolysis testing was conducted at 50, 60 and 70°C. Regression analysis was used to extrapolate a hydrolysis half-life of around 100 days at 25°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, and the value for log P_{ow} of -4.2 was obtained by calculation using the Leo-Hansch method. 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 (log P_{ow}) to be less than -2. It is accepted 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. It is expected that the chemical will bind to positively charged substances such as clay particles, but would only be expected to bind to organic matter where cations are involved (1).

No dissociation constant was provided for the chemical. It would be expected to fully dissociate in water.

The notified chemical is expected to show some surface activity. By definition (EEC Directive 92/69), a chemical has surface activity when the surface tension is less than 60 mN/m (2).

4. PURITY OF THE CHEMICAL

Degree of Purity: > 60%

Classification of Impurities: no health hazard classification of the impurities was provided by the notifier

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured or reformulated in Australia. It will be imported in a ready to use form, as a component of the dye Cibacron Navy PG. The liquid form of the end use product will contain Reactive Black 2506-MS at a concentration of less than 20% and the powdered form will contain Reactive Black 2506-MS at a concentration of greater than 50%. These end use products will be used for the colouration of cellulose textiles, using printing methods.

The notifier states that the notified chemical is expected to replace older reactive dyes on the market, which in general have lower rates of fixation. The improved solubility of the notified substance means that the co-solvent, caprolactam, is no longer required as a component of the end use product.

Import volumes are expected to increase to up to 6 tonnes of the notified chemical per year by the fifth year.

6. OCCUPATIONAL EXPOSURE

Exposure of transport and storage workers would occur only in the event of accidental spillage.

Dermal, inhalational and ocular exposure may occur during the repacking of dye products containing the notified chemical. Workers may be exposed to significant levels of the notified chemical unless adequate protective measures are taken. The protective measures used at the notifier's sites include addition of an anti-dusting agent to the powdered form of the end use product. In addition, repacking processes will be conducted in a booth in which flow air is drawn away from the operators at a rate which ensures capture of particulates released to air. The notifier states that under the conditions employed, workplace air monitoring studies have shown that levels of dye in the breathing zone are undetectable.

Dyeing processes involve the pumping of approximately 50 kg of the imported product from the intermediate bulk containers (IBCs) directly into the printing paste blending vessel to make 500 kg of printing paste. The notified chemical is present in the printing paste at less than 5%. During transfer, dermal exposure may occur when workers are connecting and disconnecting hoses. Eye contact would be limited to accidents. The notifier states that in rare cases, the non-dusting powdered end use product may be used. In this case, inhalational, dermal and ocular exposure may occur during transfer of the product from 30 kg containers into a weighing container and manual transfer to a closed paste blending vessel. The powder would then be dispersed into the paste using high speed stirring.

Minimal worker exposure is expected during the automatic pumping of the coloured printing paste to an automated printing machine. Large bolts of cloth to be printed will be passed through the printing machine. After printing, the cloth is steamed immediately 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 only during equipment cleaning or

repair.

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

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

7. PUBLIC EXPOSURE

Public exposure to the notified chemical following an accident is unlikely, in view of the quality accredited transport services and the recommended clean up and disposal measures.

Public exposure is also unlikely to occur as a result of dyeing processes, disposal of trace residues in empty packages or discharge of dyehouse effluent.

Significant public exposure to garments dyed with the notified chemical will occur. Cellulosic fibres dyed with the notified chemical will be used in the production of ladies outerware fabrics, decorative fabrics, bathroom and beachware fabrics and bedlinen. The notified chemical will be bound to tightly to the fibres, however, and leaching should be negligible.

8. ENVIRONMENTAL EXPOSURE

Release

After a printing run, residual paste containing the notified chemical is hosed off the screens, purged from pipelines and blending vessels. The notifier estimates around 5% of the paste is either recycled to the next batch of paste, or is lost to the effluent system. This will account for around 300 kg per annum of notified chemical.

The bulk of the notified chemical 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 notified chemical undergoes a chemical change involving chemical bonding with hydroxy groups on the cellulose fibres.

Fixation rates for the notified chemical are around 88%. Further minor releases can be expected from accidental spillage and minor repacking operations. Previous experience suggests this volume will be less than 0.1% of the import volume. A breakdown of releases is provided below:

Import volume: up to 6 000 kg

	Release (%)	*Volume (kg)*
Accidental spills; reformulation	0.1	6
Cleaning of residual printing plates	5	300
Unfixed notified chemical	12	720
TOTAL	**17.1**	**1 026**

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

Fate

Dyes normally released in water as effluent from the dyehouse are expected to be the major source of environmental exposure to the notified chemical. It is unclear whether some of the notified chemical in the effluent will be in the hydrolysed form, although this could be expected due to the temperatures at which dye fixation is conducted.

The notified chemical may either partition to sediment or stay in the aqueous compartment. Hobbs (3) reports that reactive dyes have been found not to adsorb 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 notified chemical will produce oxides of carbon, nitrogen and sulfur, together with 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.

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 a cation-adsorption mechanism (1). Another possible route of entry of the notified chemical 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.

The probable environmental fate of water soluble azo dyes is biotransformation or aqueous photolysis, since the compounds are non-volatile, are resistant to hydrolysis (> 365 days for the notified chemical at 25°C, pH 7) and should not partition strongly to sediments (4). Humic materials in natural water have been shown to strongly accelerate the photodecomposition of azodyes, probably because of oxidation by singlet oxygen or oxyradicals present in waters exposed to sunlight (4).

The notified chemical was found to be not readily biodegradable in the OECD 301E Test, with 1-5% biodegradation observed at the end of the 28-day exposure period.

Additionally, the notified chemical was found to be practically non-biodegradable in

an inherent biodegradability test (28 day Zahn-Wellens/EMPA Test). Between 2 and 7% DOC removal occurred after the 28 day exposure period to microorganisms from a domestic waste water treatment plant.

Although the notified chemical 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 Pow < 3 have been shown not to bioaccumulate (5). Also, biological membranes are not permeable to chemicals of large molecular size and therefore bioaccumulation of the notified polymer is not expected (6,7).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Reactive Black 2506-MS

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 000 mg/kg	(8)
acute dermal toxicity	rat	LD_{50} > 2 000 mg/kg	(9)
skin irritation	rabbit	non-irritant	(10)
eye irritation	rabbit	slight irritant	(11)
skin sensitisation	guinea pig	non-sensitising	(12)

9.1.1 Oral Toxicity (8)

Species/strain:	rat/HanIbm: WIST (SPF)
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	gavage; test substance was dissolved in bi-distilled water
Clinical observations:	one female had a hunched posture on day 1
Mortality:	none
Morphological findings:	none
Test method:	according to OECD guidelines (13)
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical was of low acute oral toxicity in a limit test in rats

9.1.2 Dermal Toxicity (9)

Species/strain:	rats/HanIbm:WIST (SPF)
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	single dermal application of 2 000 mg/kg test substance; site was covered by semi-occlusive dressing for 24 hours
Clinical observations:	blue discolouration of the skin persisted throughout test period; minimal weight loss in two females during the first week was attributed to the semi-occlusive dressing
Mortality:	none
Morphological findings:	none
Test method:	according to OECD guidelines (13)
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical was of low acute dermal toxicity in rats

9.1.3 Inhalation Toxicity

not performed

9.1.4 Skin Irritation (10)

Species/strain:	rabbit
Number/sex of animals:	1 male; 2 females
Observation period:	72 hours
Method of administration:	0.5 g of test substance was applied to a 6 cm^2 area of intact dorsal skin; test site was covered with semi-occlusive dressing for 4 hours; site was irrigated with lukewarm water once dressing removed; skin reactions were assessed at 1, 24, 48 and 72 hours after removal of the dressing and scored according to the method of Draize (14)

Draize scores:	erythema could not be assessed at the 1 and 24 hour time points due to blue discolouration of the skin; no other abnormal changes were noted in the animals at any of the time points; there were no Draize scores greater than 0
Test method:	according to OECD guidelines (13)
Result:	the notified chemical was a non-irritant to rabbit skin

9.1.5 Eye Irritation (11)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	1 male; 2 females
Observation period:	72 hours
Method of administration:	0.1 g of test substance was instilled into the conjunctival sac of one eye; untreated eye served as a control
Comments:	the hairs around the lid of all animals were deep blue coloured at 1, 24 and 48 hours; all animals had a score of 1 for conjunctival redness and chemosis 1 hour time after application; one animal had a Draize score of 1 for conjunctival redness and chemosis 24 hours after application; all other eye irritation scores were 0
Test method:	according to OECD guidelines (13)
Result:	the notified chemical was a slight eye irritant in rabbits

9.1.6 Skin Sensitisation (12)

Species/strain:	guinea pig/albino
Number of animals:	30 females; 10 control, 20 test

Induction procedure:

Day 1: 3 pairs of intradermal injections:
- 0.1 mL Freunds Complete Adjuvant (FCA):saline (1:1 (v/v))
- 0.1 mL of 5% concentration of test material in bi-distilled water
- 0.1 mL of 5% concentration of test material in FCA:saline (1:1 (v/v))

Day 7: test area treated with 10% sodium lauryl sulfate in *paraffinum perliquidim*

Day 8: occluded application of 25% concentration of test material in bi-distilled water for 48 hours

Challenge procedure:

Day 22: occluded application of 25% solution of test material in bi-distilled water for 24 hours

Challenge outcome:

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

* time after patch removal

** number of animals exhibiting positive response (one of the animals in the test group was found dead on test day 24 - at necropsy reddish discolouration of the lungs and abdominal cavity containing blood and blood clots were observed)

Test method: according to OECD guidelines (13)

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

9.2 Repeated Dose Toxicity (15)

Species/strain: rat/HanIbm:WIST (SPF)

Number/sex of animals: 30/sex; control and high dose groups: 10/sex low and mid dose groups: 5/sex

Method of administration: gavage

Dose/Study duration:	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 the control and high dose groups, which were maintained for an additional 2 week recovery period before sacrifice
Clinical observations:	blue colouring of the faeces was observed in all animals; food consumption increased in males and females of the high dose group during the third and fourth week of treatment
Clinical chemistry/Haematology	**Haematology:** changes in several haematological parameters in animals in the mid and high dose groups were considered to be treatment related; these suggested methaemoglobinemia with an increase in haematopoietic activity, indicated by the increase in reticulocytes these findings were reversed at the end of the treatment free period **Clinical biochemistry:** there were a number of slight to marked substance-related effects noted in animals in of the mid and high dose groups; these included blue discolouration of the plasma and effects on a number of other parameters, particularly increases in the uric acid and total bilirubin levels part of the increase in total bilirubin may have been related to a greater erythrocyte turnover (ie haemoglobin liberation) as a result of methaemoglobinemia; other changes suggested metabolic adaptations; it was considered, however, that the findings were due to in part to interference by the test article in the metabolite assays these parameters were found to be reversed

	at the end of the treatment-free period, with the following exceptions: slightly increased uric acid and total bilirubin level; light blue colouration of the plasma (both sexes, high dose group); slightly increased phosphorous level (females, high dose group); these findings were considered to be test substance-related **Urinalysis:** at termination of the treatment free period there were no changes which were considered of toxicological importance; changes which had been noted were reversed by the end of the treatment free period, with the exception of a yellow-grey discolouration of the urine and a slight increase in urine bilirubin in both sexes in the high dose group
Macroscopic findings and Histopathology:	**Organ weights, organ to body weight and organ to brain weight rations** no treatment related effects noted **Macroscopic and microscopic findings** bluish kidney discolouration was observed in all animals of the mid and high dose groups; this was reversed at the end of the treatment free period extramedullary splenic haematopoiesis was observed at the end of the treatment period in 2 males and 1 female in the high dose group and in 1 male each of the control and high dose groups after recovery
Test method:	according to OECD guidelines (13)
Result:	the findings of this 28 day subacute toxicity study indicate that treatment with the notified chemical at high doses induces methaemoglobinemia with an increase in haematopoietic activity; corresponding with histopathological findings of slightly increased splenic extramedullary haematopoiesis; these effects were largely reversed by the end of the recovery period

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (16)

Strains:	*Salmonella typhimurium* TA 1535, TA 1537, TA 98, TA 100 and *Escherichia coli* strains WP2 and WP2*uvrA*
Concentration range:	33.3, 100, 333, 1 000, 2 500 and 5 000 μg/plate
Test method:	according to OECD guidelines (13)
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

9.3.2 Chromosome Aberration Assay in chinese hamster V79 cells (17)

Dosing schedule:	without S9 mix: 100 - 2000 μg/mL - treatment time 18 hours and 28 hours with S9 mix: 300 - 5 000 μg/mL - treatment time 4 hours for all treatment groups, cells were prepared 18 hours and 28 hours after the start of treatment and scored for structural chromosomal aberrations
Test method:	according to OECD guidelines (13)
Result:	the notified chemical did not induce structural chromosomal aberrations in chinese hamster V79 cells, in either the presence or absence of metabolic activation

9.4 Overall Assessment of Toxicological Data

The notified chemical exhibited low acute oral and dermal toxicity in rats (LD_{50} > 2 000 mg/kg in both studies). Inhalational toxicity studies were not carried out, as the majority of the chemical will be imported as a component of a liquid dye formulation, and any powdered product to be imported will contain anti-dusting agents. The notified chemical was not a skin irritant in rabbits, but caused slight eye irritation in the same species. It was not a skin sensitiser when tested in guinea pigs.

A repeat dose 28 day oral toxicity study indicated that treatment with high doses of the notified chemical induces methaemoglobinemia with

corresponding increases in blood cell synthesis and immature red blood cells. These effects corresponded with histopathological findings showing slightly increased blood cell synthesis in the spleen. These effects were largely reversed, however, by the end of the recovery period.

No mutagenicity was observed in bacteria and no clastogenicity was observed in chinese hamster cells *in vitro*.

Based on the toxicological studies provided by the notifier, Reactive Black 2506-MS would not be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (18).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were carried out to OECD Test Methods (13).

Ecotoxicity Test Results

Test	***Species***	***Results (mg/L)***
Acute Toxicity (F; N)	Rainbow trout *(Oncorhynchus mykiss)*	96 hour LC_{50} > 100 mg/L
Immobilisation (S; N)	Water Flea *(Daphnia magna)*	48 hour EC_{50} > 100 mg/L
Growth Inhibition (see comments below) (S; N)	Algae *(Scenedesmus subspicatus)*	*Experiment A* 72h E_bC_{50} = 3.6 mg/L 72h $E\mu C_{50}$ = 20.8 mg/L *Experiment B* 72h E_bC_{50} = 7.5 mg/L 72h $E\mu C_{50}$ = 38.0 mg/L
Respiration Inhibition	Aerobic Waste Water Bacteria	IC_{50} > 100 mg/L
Acute Toxicity	Earthworms *(Eisenia foetida)*	LC_{50} > 1000 mg/kg

F = Flow through; S = Static; N = Nominal Concentration.

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

At all tested concentrations to fish, symptoms of intoxication could not be observed due to colouring of the test medium. After 96 hours, test fish were placed in control water for the observations of intoxication symptoms, but none were noted.

Daphnia testing resulted in 5% immobilisation in the 10 ppm and 46 ppm test solutions. This is not considered significant, as under the test guidelines, this level of

immobility is tolerated in the control solution. No other sub-lethal effects were observed. The test solutions were coloured as a result of the notified chemical at all solutions tested. A reproduction test was not performed, but due to the low toxicity observed in the immobilisation test, this is acceptable.

The notifier performed a modified algae growth test where two experiments were run simultaneously to determine the difference between the direct toxic effect of the notified chemical to algae, and the indirect effect to algae as a result of the notified chemical absorbing light.

In experiment A the notified chemical was included in the algal culture medium so effects on algae were due to both light and any direct chemical toxicity. In experiment B, the notified chemical 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 notified chemical) on the algae.

The results indicate that the main effect of the notified chemical on algae is due to the indirect effect of absorbing light, rather than a direct toxic effect. The notifier argues that the real toxic effect of the test substance amounted to, in maximum, about 32% of growth inhibition up to the highest test concentration of 100 ppm, and thus both the 72h E_bC_{50} and 72h $E\mu C_{50}$ are higher than 100 mg/L. While this may be technically correct, the demonstrated toxicity values of 72h E_bC_{50} = 3.6 ppm and 72h $E\mu C_{50}$ = 20.8 ppm will be used in environmental hazard calculations, as the notified chemical is moderately toxic to algae, whether the effect be direct or indirect.

The notified chemical was found not to inhibit the respiration rate of aerobic waste water bacteria (in activated sludge) when exposed to test article concentrations at 3.2 to 100 mg/L (OECD TG: 209)(13). The 30 minute-EC_{50} is reported as 100 mg/L.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified chemical will be used in up to 3 dye houses located in Sydney or Melbourne. As such, no predicted environmental concentration (PEC) will be calculated for a country dyehouse.

In determining the worst case PEC, the following assumptions are made:

- none of the notified chemical is removed through adsorption to sludge in dye house wash waters;
- up to 6 000 kg is imported, spread evenly over three dyehouses;
- dyeing operations are carried out on 75 days of the year (notifier's figures);
- 5% of the notified chemical is lost through residual paste being washed off screens, and cleaning of equipment.

- 12% of the notified chemical is lost through not being fixed to material.

Predicted Environmental Concentration (PEC)

Calculation Factor	*City Dyehouse*
Typical use of notified chemical expected per day	26.7 kg
Total release of 17% (see assumptions above)	4.54 kg
Influent concentration (Dyehouse generates 2.5 ML per day in effluent)	10.7 mg/L
Dilution factor in sewage treatment plant	1:100
Concentration balance in effluent from sewage treatment plant	0.11 mg/L
Dilution factor in receiving waters	1:10 (to ocean outfall)
PEC in receiving waters	11 μg/L (ppb)

The PEC calculated is two orders of magnitude lower than the most sensitive observed environmental effect which was a 72 hour E_bC_{50} of 3.6 ppm. While some of the notified chemical could reasonably be expected to be removed through adsorption or organic sludge, and possible complexation (1), it can be seen that use of this chemical in inland dyehouses, where dilution in municipal sewer systems and receiving waters will be far less, could result in a potential hazard for algae.

Exposure to fish and water flea is at levels unlikely to cause any significant effect, and the notified chemical's high solubility suggests that once released to the waterways, dilution would be expected to swiftly reduce the environmental concentration.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

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

The majority of the notified chemical will be imported as a component of a liquid dye formulation. A small amount of repackaging of a powdered form of the dye may occur, however, which will then be dispersed into a paste prior to dyeing. There is a low occupational health risk posed to the limited number of workers who may be involved in handling powdered dye products containing Reactive Black 2506-MS. Workers may be exposed to the notified chemical via dermal, inhalational and ocular routes. The notifier states that exposure to the notified chemical will be reduced by ventilation, which will be used while handling the dye in powdered form, and the inclusion of an anti-dusting agent in the final dye product. Should dermal exposure occur, animal data indicates that the notified chemical is not likely to cause skin irritation. Reactive Black 2506-MS was not a skin sensitiser in guinea pigs, however, the notifier states on the MSDS that cases of sensitisation have been observed with reactive dyes, therefore it is possible that a skin and/or respiratory sensitisation

reaction may occur in susceptible workers. Workers may also experience slight eye irritation if exposure occurs. As inhalational toxicity data is not available for the notified chemical and as the potential for inhalational exposure to the notified chemical is moderate, exposure to the notified chemical should be kept to a minimum and personal protective equipment should be worn where necessary to when engineering controls are inadequate.

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

A repeat dose 28 day oral toxicity study indicated that treatment with high doses of the notified chemical induces methaemoglobinemia with corresponding increases in red blood cell synthesis. These effects were largely reversed by the end of the recovery period. It is unlikely that these haematological effects will occur as a result of workplace exposure, however, as workplace 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.

There will be widespread public contact with the finished textiles from use of garments such as ladies' outerwear, decorative fabrics, bathroom and beachware fabrics and bed linen. However, because the notified chemical is bound tightly to the material, the potential for public exposure to the notified chemical during use of the garments is negligible. While public exposure to the notified chemical is possible following an accident, the likelihood is low in view of the quality accredited transport services and clean up and disposal protective measures.

Based on the use pattern of the notified chemical, it is considered that it will not pose a significant hazard to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to Reactive Black 2506-MS 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 (19) and occupational footwear which conforms to Australian and New Zealand Standard (AS/NZS) 2210 (20) 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 the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (21).

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 shall be required if import volumes of the notified chemical increase to 10 tonnes per year, or if the notified chemical is to be used under different circumstances which may lead to increased environmental exposure, such as use in country dyehouses, or dyehouses discharging to inland water ways.

16. REFERENCES

1. Weber, E.J. 1991, 'Studies of benzidine-based dyes in sediment-water systems', *Environmental Toxicology & Chemistry* vol. 10, pp. 609-618.

2. EEC Directive 92/69, A5, 1992, *Surface Tension*

3. Hobbs, S. 1988, *Industry Category Document: UK Dye Production and Use in the Textile Industry*, UK Department of the Environment (CR36/38), July.

4. Hagg, W.R., Mill T. 1986, 'Direct and Indirect Photolysis of Water-Soluble Azodyes: Kinetic Measurements and Structure-Activity Relationships', *Environmental Toxicology and Chemistry,* vol. 6, pp. 359-369.

5. Yen, C.P., Perenich, T.A., Baughman, G.L. 1991, 'Fate of Commercial Disperse Dyes in Sediments', *Environmental Toxicology and Chemistry*, vol. 10, pp. 1009-1017.

6. Anliker, R., Moser P., Poppinger D. 1988, 'Bioaccumulation of dyestuffs and organic pigments in fish. Relationships to hydrophobicity and steric factors', *Chemosphere,* vol. 17, no. 8, pp. 1631-1644.

7. Gobas, F.A.P.C., Opperhuizen, A. Hutzinger, O. 1986, 'Bioconcentration of hydrophobic chemicals in fish: relationship with membrane permeation', *Environmental Toxicology and Chemistry,* vol. 5, pp. 637-646.

8. Crouch, C.N. 1994, *Acute Oral Toxicity Study With FAT45168/A In Rats,* Project Number 371777, data on file, RCC Group, Switzerland.

9. Crouch, C.N. 1994, *Acute Dermal Toxicity Study With FAT45168/A In Rats,* Project Number 371788, data on file, RCC Group, Switzerland.

10. Arcelin, G. 1994, *Primary Skin Irritation Study With FAT45168/A In Rabbits (4-hour Semi-Occlusive Application),* Project Number 371790, data on file, RCC Group, Switzerland.

11. Arcelin, G. 1994, *Primary Eye Irritation Study With FAT45168/A In Rabbits,* Report Number 371801, data on file, RCC Group, Switzerland.

12. Arcelin, G. 1994, *Contact Hypersensitivity to FAT45168/A In Albino Guinea Pigs Maximization Test,* Report Number 371812, data on file, RCC Group, Switzerland.

13. Organisation for Economic Co-operation and Development, *OECD Guidelines for Testing of Chemicals*, OECD, Paris.

14. Draize, J. H. 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US,* **49**.

15. Dotti, J.H. 1994, *Subacute 28-Day Oral Toxicity (Gavage) Study With FAT45168/A In The Rat,* Project Number 371823, data on file, RCC Group, Switzerland.

16. Poth, A. 1994, *Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay With FAT45168/A,* Project Number 467401, data on file, CCR, Germany.

17. Volkner, W. 1994, *Chromosome Abberation Assay In Chinese Hamster V79 Cells In Vitro With FAT45168/A,* Project Number 467402, data on file, CCR, Germany.

18. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(1994)], Australian Government Publishing Service, Canberra.

19. Standards Australia 1987, *Australian Standard 2919-1987, Industrial Clothing,* Standards Association of Australian Publ., Sydney.

20. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear,* Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.

21. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets* [NOHSC:2011(1994)], Australian Government Publishing Service, Canberra.

Attachment 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. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

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