File No: NA/377

Date: April 1996

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Reactive Red DER 7650 FAT 45'169/A

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989,* and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Human Services and Health.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, Worksafe Australia, 92-94 Parramatta Road, Camperdown NSW 2050, between the hours of 10.00 a.m. and 12.00 noon and 2.00 p.m. and 4.00 p.m. each week day except on public holidays.

For Enquiries please contact the Administration Coordinator at:

Street Address: 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA
Telephone: (61) (02) 577-9466 **FAX (61) (02) 577-9465**

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Reactive Red DER 7650 FAT 45’169/A

1. APPLICANT

Ciba-Geigy Australia Pty Ltd of 235 Settlement Road THOMASTOWN VIC 3074 has submitted a standard notification statement in support of their application for an assessment certificate for the chemical, Reactive Red DER 7650 FAT 45’169/A.

2. IDENTITY OF THE CHEMICAL

Reactive Red DER 7650 FAT 45’169/A 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 have been exempted from publication in the Full Public Report and the Summary Report.

Trade names:	Reactive Red DER 7650 FAT 45’169/A (notified chemical) Cibacron Red LS-B (imported substance containing 73% crude dyestuff)
Method of detection and determination:	the compound can be quantified by UV-Vis spectroscopy at 550 nm; impurities and residual starting material can be separated, identified and quantified by HPLC
Spectral data:	examples of UV-Visible, infrared (IR) and proton nuclear magnetic resonance (NMR) spectra for a sample of FAT 45'169/A were included in the submission

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	dark red powder (imported product)
Odour:	none (imported product)
Melting point:	does not melt; the compound decomposes at > 230°C
Boiling point:	1150°C theoretical (Meissner's method)

Density:	1.74 g/cm^3 at 22°C (Gas Pycnometer)
Vapour pressure:	3 x 10^{-50} kPa at 25°C (calculated - modified Watson correlation)
Surface tension:	58.3 mN/m at 21.5°C (OECD Ring Tensiometer method)
Water solubility:	155 g/L (+/- 9 g/L) at 18°C (Flask method EEC Directive 92/69 A.6 OECD Test Guideline 105)
Fat solubility:	< 4.4 x 10^{-4} g/kg of standard fat simulant HB307 at 37°C (limit of detection; EEC Directive 84/449 A.7 OECD Test Guideline 116)
Partition co-efficient (n-octanol/water):	log P_{ow} < -2 (calculated)
Hydrolysis as a function of pH:	pH 4, half life = 5.4 days at 25°C pH 7, half life = 4.7 years at 25°C pH 9, half life = 29 days at 25°C (calculated by Arrhenius equation)
Adsorption/Desorption:	not determined
Dissociation constant:	not determined
Flash point:	not flammable
Flammability limits:	not flammable
Autoignition temperature:	non-auto-flammable when tested between 22°C and 400°C
Explosive properties:	no explosive properties when subjected to flame, shock or friction
Reactivity/Stability:	stable under normal conditions; may decompose at elevated temperatures

Particle size distribution:

mass %	*range in µm*
0.41%	< 0.36
0.09%	0.36 - 0.75
38.91%	< 63
29.48%	63 - 100
27.33%	100 - 200
4.28%	> 200

Comments on physico-chemical properties

Reactive Red DER 7650 FAT 45'169/A is a surfactant (by EEC definition, a chemical has surface activity when the surface tension is less than 60 mN/m (1)).

Adsorption/desorption and dissociation constants were not determined. The high water solubility, low P_{ow}, and low fat solubility would tend to indicate low absorption. Adsorption of this material to substrates is discussed further under the Environmental Fate section below.

Hydrolysis data at 25°C was calculated by the notifier by the Arrhenius equation from data at pH 4.0, 7.0 and 9.0 over a range of temperatures. The measured half-life values for the compound were: 80 hours at 30°C and 14 hours at 50°C (pH 4); 45 days at 50°C, 89 hours at 70°C and 27 hours at 80°C (pH 7); and 82 hours at 50°C, 25 hours at 60°C and 18 hours at 70°C (pH 9). The compound is more stable at neutral to slightly alkaline pH and relatively less stable to hydrolysis in acidic conditions. The half-lives of 5.4 days (pH 4) and 29 days (pH 9) at 25°C are considered relatively fast, with the half-life of 4.7 years at 25°C (pH 7) very slow.

The partition coefficient result was outside the limit accessible by the flask method and was determined by calculation using the Leo-Hansch method. Strictly speaking this parameter is only meaningful for substances that do not dissociate in water and are not surface active and these properties render this value unreliable.

The vapour pressure was calculated by the modified Watson correlation as the value was below the measurement range of the gas saturation method. The vapour pressure was also calculated from the decomposition temperature as < 1.2 Pa at 25°C.

The dye is a sodium salt of aromatic sulphonic acids which also contains basic and aromatic nitrogens. The functional groups present are expected to have typical acidity and basicity.

4. PURITY OF THE CHEMICAL

Degree of purity: 58.4% (calculated as sodium salt)

Impurities:

Chemical	*Weight %*
Identified Organic Impurities	
identified coloured by-product R2	3.8%
identified coloured by-product R3	0.8%
identified coloured by-product R4	4.3%
Unidentified Organic Impurities	
coloured by-products	17.4%
uncoloured by-products	0.7%
Inorganic Impurities	
calcium fluoride	0.2%
sodium chloride	0.2%
sodium sulfate	< 0.2%
sodium phosphate	3.4%
water	10.7%

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia but will be imported as a component of the dye preparation, Cibacron Red LS-B, at between 3 to 5 tonnes in the first year, rising to 8 to 10 tonnes by year 5.

Reactive Red DER 7650 FAT 45'169/A will be used in the colouration of cellulose textiles by the exhaust dyeing method. The notifier has provided evidence that the substance exhibits approximately 89% fixation using the exhaust dyeing technique.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported in the product Cibacron Red LS-B (containing 73% crude dyestuff). The imported product will arrive in 30 kg sealed cardboard containers with antistatic polyethylene linings and will be transported by road to the importer's premises in Melbourne and Sydney. The imported product will be distributed to approximately 8 dyehouses within Australia. In some cases repacking into smaller containers will be conducted before distribution.

Exposure of transport and storage workers will result only in the event of accidental spillage. Workers involved in repacking may be exposed to significant levels of chemical depending on the method used. Usual practice at importer's warehouse is for repacking to be conducted in a booth in which flow air is drawn away from the operators.

The notifier anticipates that at each site, during each shift, two operators will be involved in weighing and mixing the imported product and two operators will run the dyeing machine. Imported product will be scooped from 30 kg containers into a weighing container and manually transfered to a closed mixing tank (where it will be dissolved using high speed stirring at 90°C). Dissolved dye will be metered from the mixing tank to a closed dyeing vessel. In most cases the transfer will be automatically controlled. Cloth to be treated will be added to the dyeing vessel by the operators. Once the dyeing process is complete, unfixed dye will be removed from the textile using a boiling, soapy bath in the dyeing vessel.

The weighing area will be ventilated and operators involved in weighing and mixing operations will be required to wear overalls, protective gloves and glasses as well as respiratory protection. Operators using the exhaust dyeing machine will be required to wear gloves and safety glasses.

Laboratory workers may be exposed to the chemical during sampling and analysis. Workers involved in cleaning operations are not expected to be exposed to significant amounts of the notified chemical as they will not enter the dyeing vessel. Approximately once a week the dyeing vessel will be 'boiled out' with caustic soda and hydrosulfide.

7. PUBLIC EXPOSURE

The notified chemical will be imported into Australia in 30 kg cardboard containers and the majority onsold directly to dyehouses with a small proportion repacked before distribution. The compound will be imported as Cibacron Red LS-B containing 73% of the crude dyestuff, and the imported volume will rise from 3 tonne in the first year to about 10 tonne per annum by 1999. The notified chemical will be used to colour cellulose textiles and will be covalently bound to the fibre. Consequently there will be significant public contact with the notified chemical in this fixed form. Minor public exposure to the undiluted notified chemical may result from accidental spillage during transport and storage, and during formulation. Disposal of the chemical after accidental spillage will be carried out by a licensed waste disposal contractor to approved landfills.

8. ENVIRONMENTAL EXPOSURE

Release

Small amounts of the dye may be lost to the environment in a powder form from ventilation of dusts to the air and through spills during transit, at the warehouse or at the dyehouse. Such spills can be easily contained, collected and disposed of to landfill. All clean-up of spills and disposal should be in accordance with instructions on the Material Safety Data Sheet (MSDS).

Any residues that are wetted down are expected to dissolve due to the high water solubility and, as the reactive dye, should react by nucleophilic substitution and bind covalently to suitable sites in soils and sediments due to the high affinity to substrates. Waste dye that may arise from cleaning of ventilation filters or containers will be disposed of to approved landfill or may be incinerated as appropriate.

During the dyeing process the bulk of the dye will become chemically bound to fibre and in this state is not expected to have an impact on the environment. The major source of loss to the environment will be the release of the dye in dyehouse effluent following the washing of dye fabrics to free it of the unfixed dyestuff. Fabric dyed with the notified substance may be disposed of to landfill.

Fate

The highest environmental exposure of the notified material will be from unfixed residue released into dyehouse effluent after washing the fabric free of unfixed dye. This is expected to be in two forms, the first as unreacted, reactive dye and the second as the hydrolysed derivative. This second form is expected to predominate and will have none of the characteristics of the reactive dye (2). In the hydrolysed form, the dye has the properties of an acid dye with low affinity to fibres or substrates.

In sewage treatment works, unfixed reactive dye may be removed by degradation or sorption to sludge. While azo dyes are generally not biodegraded under aerobic conditions they are susceptible to reductive degradation under anaerobic conditions such as those found in sewage, sediments and soils (3). While reactive dyes, in general, have been found not to adsorb to sludge in model systems (4) studies of highly sulphonated bis(azo) dyes have shown that these chemicals sorb to sediments (4,5) particularly to strongly silty sand and weak sandy loam. The notified dye is of this type and is expected to bind in its non-hydrolysed, reactive form.

Hydrolysed dye has a low affinity to substrates and adsorption to sewage sludge is low, generally between 0-30% (2) and is expected to remain in the aquatic compartment. Complete removal requires a combination of other treatment processes such as chemical and enzymatic (biological) reduction. This reduction leads to amino sulphonic acid which exhibits low toxicity.

Dyestuff can also enter the sediment as a precipitate of the calcium salt. Several calcium salts of sulphonic dyes are known to be insoluble at modest concentrations

(4). No significant increase in the dissolved concentration is predicted over time and residues that are bound to sediment are expected to undergo limited, slow reductive degradation.

Biodegradability tests indicate no significant degradation of the dyestuff. Ready biodegradation was assessed using a 28 day modified OECD screening test according to EEC Directive 92/69 EEC C.4-B 1992 and OECD Test Guideline No. 301 E 1992 and indicated that the material was nondegradable showing -4% DOC removal after 28 days. Inherent biodegradability was determined using a 28 day Zahn-Wellens/EMPA test according to EEC Directive 87/302/EEC 1987 and OECD Test Guideline No. 302 B 1992 and the compound was found to be practically nondegradable, with between -2 to 7% DOC removal after 28 days. The dyestuff is classified as practically nondegradable.

Due to the high water solubility, poor biodegradation and the poor binding of the dyestuff in its hydrolysed form it is likely that significant quantities will remain in the aquatic compartment.

Bioaccumulation of the dyestuff is not expected due to the high water solubility, low partition coefficient and low fat solubility. Reactive dyes and their hydrolysed derivatives are highly hydrophilic due to a high degree of sulphonation. They are strong electrolytes and are almost completely dissociated at all acidity ranges in aqueous solutions. The notified material is also of large molecular size and is unlikely to cross biological membranes during exposure.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Reactive Red DER 7650 FAT 45'169/A

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2000 mg/kg	(6)
acute dermal toxicity	rat	LD_{50} > 2000 mg/kg	(7)
skin irritation	rabbit	non-irritant	(8)
eye irritation	rabbit	non-irritant	(9)
skin sensitisation	guinea pig	not a sensitiser	(10)

9.1.1 Oral Toxicity (6)

Species/strain:	rats, Wistar
Number/sex of animals:	5 male, 5 female
Observation period:	15 days
Method of administration:	the test substance was administered as a single oral (gavage) dose of 2000 mg/kg (10 ml/kg)
Clinical observations:	ruffled fur in all animals (5 hours), sedation and hunched posture in 1 female rat only (5 hours)
Mortality:	nil
Morphological findings:	nil
Test method:	based on OECD Guidelines for Testing Chemicals (11)
LD_{50}:	> 2000 mg/kg
Result:	low oral toxicity

9.1.2 Dermal Toxicity (7)

Species/strain:	rat, Wistar
Number/sex of animals:	5 male, 5 female
Observation period:	15 days
Method of administration:	a single application of test substance at a dose of 2000 mg/kg (4.0 ml/kg) was applied to the clipped back of each animal (≥ 10% of total body surface) and covered with a semi-occlusive dressing; the dressing was removed 24 hours later and the treatment area washed with lukewarm tap water
Clinical observations:	no clinical signs of systemic toxicity were noted during the study
Mortality:	nil
Morphological findings:	nil

Test method:	based on OECD Guidelines for Testing Chemicals (11)
LD_{50}:	> 2000 mg/kg
Result:	low dermal toxicity

9.1.3 Acute Inhalation Toxicity

No inhalation toxicity study was available. The applicant claims that the notified chemical will be used with an antidusting agent which will reduce the risk of exposure to dust. This is acceptable.

9.1.4 Skin Irritation (10)

Species/strain:	New Zealand White rabbits
Number/sex of animals:	1 male, 2 females
Observation period:	72 hours
Method of administration:	a single application of 0.5 g of undiluted test substance was applied to the shaved right flank of each animal (test site approximately 6 cm^2) and the test site was covered with a gauze patch; a gauze patch applied to the shaved left flank of each animal served as control

Draize scores (12):

	Time after decontamination							
	1 hour		***1 day***		***2 days***		***3 days***	
Animal	***e[a]***	***o[b]***	***e[a]***	***o[b]***	***e[a]***	***o[b]***	***e[a]***	***o[b]***
1	0[i]	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0

[i] see Attachment 1 for Draize scales
[a] erythema [b] oedema

Test method:	based on OECD Guidelines for Testing Chemicals (11)
Result:	non-irritant

9.1.5 Eye Irritation (9)

Species/strain: rabbits, New Zealand White

Number/sex of animals: 1 male, 2 females

Observation period: 3 days

Method of administration: 0.1 g of test substance was placed into the conjunctival sac of the left eye of each animal; eyes remained unrinsed for the duration of the study

Draize scores (12):

	Time after instillation							
Animal	***1 hour***		***1 day***		***2 days***		***3 days***	
Cornea	***o[a]***		***o[a]***		***o[a]***		***o[a]***	
1	0[i]		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[b]***	***c[c]***	***r[b]***	***c[c]***	***r[b]***	***c[c]***	***r[b]***	***c[c]***
1	-*	2	-	1	1	1	0	0
2	-	2	-	2	1	1	0	0
3	-	1	0	0	0	0	0	0

[i] see Attachment 1 for Draize scales

[a] opacity [b] redness [c] chemosis

* could not be assessed due to violet staining of the conjunctivae

Test method: based on OECD Guidelines for Testing Chemicals (11)

Result: non-irritant

9.1.6 Skin Sensitisation (10)

Species/strain: Himalayan spotted guinea pigs

Number of animals: 30 males (10 control, 20 test)

Induction procedure: test animals were injected (0.1 ml per injection) in the left and right side of the shaved neck with 1:1 v/v mixture of Freund's Complete Adjuvant and physiological saline (1:1 FCA/saline), 5% test substance in bi-distilled water or 5% test substance in a mixture of 1:1 FCA/saline; control animals were injected in the same manner with bi-distilled water substituted for the test substance; 7 days later the test area was massaged with 10% sodium-lauryl sulfate; the following day the trunk of each test animal was covered with a patch containing 25% test substance in physiological saline (control animals received physiological saline alone)

Challenge procedure: 21 days after induction both test and control animals were tested with 15% test substance in physiological saline on one flank and vehicle alone on the opposite flank

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hrs****	***48 hrs****	***24 hrs***	***48 hrs***
15%	0/20**	0/20	0/10	0/10

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

Test method: based on OECD Guidelines for Testing Chemicals (11) and the Maximisation procedure of Magnusson and Kligman (13)

Result: not found to be a sensitiser

9.2 Repeated Dose Toxicity (14)

Species/strain:	rats, Wistar
Number/sex:	35 male, 35 female
Method of administration:	the test substance in bi-distilled water was administered by gavage
Dose/Duration of administration:	5 animals of each sex were given 0, 10, 50, 200 or 1000 mg/kg test substance for 28 days and sacrificed thereafter; an additional 5 animals of each sex were given 0 or 1000 mg/kg test substance for 28 days and sacrificed after a 14 day recovery period
Mortality:	nil
Clinical signs of toxicity:	nil except for general body discolouration in the high dose group
Clinical chemistry/Haematology:	there were no test substance related effects on haematogy or urinalysis; animals in the high dose group showed increased creatinine, uric acid and phospholipid levels in addition to slight increase in total cholesterol
Opthalmoscopic examinations:	no abnormal findings
Necropsy findings/Histopathology:	high dose rats of both sexes showed nephrotoxicity in the form of increased renal cortical tubular basophilia and degeneration as well as increased severity of tubular hyaline droplets in males and red tubular droplets in females; high dose animals also showed kidney effects at the end of the 14 day recovery period; 2 high dose male rats showed clusters of foamy macrophages containing red pigment droplets in the lungs (this effect remained in one of the animals after the recovery period); animals dosed with 200 mg/kg showed discolouration of the kidneys and the mesenteric lymph nodes; no abnormal findings were noted in animals dosed at 10 or 50 mg/kg
Test method:	based on OECD Guidelines for Testing Chemicals (11)

Result:	target organ for toxicity is the kidney; toxic dose is not low enough to classify the chemical as hazardous (15)

9.3 Genotoxicity

9.3.1 Salmonella typhimurium and Escherichia coli Reverse Mutation Assay (16)

Strains:	*Salmonella* strains TA 98, TA 100, TA 1535 and TA 1537; *Escherichia* strains WP2 and WP2 uvrA
Concentration range:	0, 33.3, 100.0, 333.3, 1000.0, 2500.0 and 5000.0 µg/plate
Test method:	based on OECD Guidelines for Testing Chemicals (9)
Result:	non-mutagenic (in all strains there were no increases in revertant colonies at any dose level)

9.3.2 *In Vitro* Cytogenetic Assay in Chinese Hamster V79 cells (17)

Metabolic activation:	rat liver S9 mix	
Experiment 1 doses:	without S9	18h: 10, 30, 100 µg/ml 28h: 100 µg/ml
	with S9	18h: 30, 100, 300 µg/ml 28h: 300 µg/ml
Experiment 2 doses:	without S9	18h: 30, 100, 300 µg/ml 28h: 300 µg/ml
	with S9	18h: 30, 100, 300 µg/ml 28h: 300 µg/ml
Test method:	based on OECD Guidelines for Testing Chemicals (11)	
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 has low acute oral and dermal toxicity in the rat, is non-irritating to rabbit skin and eye and was shown to be non-sensitising to guinea pig skin. Based on these results the chemical is also expected to have low acute inhalation toxicity. Repeated exposure of the rat by the oral route for 28 days showed cumulative effects in the kidney, however all toxic effects were observed at doses at or above 200 mg/kg/day. The chemical showed no mutagenic activity in *Salmonella typhimurium* or *Escherichia coli* and showed no clastogenicity 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* (15).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Ecotoxicity studies were carried out using the notified material (~60% pure) dissolved in water. Actual concentrations of the test solution, where measured, varied from 83% to 136.5% of nominal concentrations. All results reported by the notifier were of nominal concentrations. Results of ecotoxicological tests supplied by the notifier are summarised below.

Ecotoxicological test results supplied by the notifier

Organism	***Test***	***Result***
Rainbow trout (*Oncorhynchus mykiss*)	acute semi-static 96 hours	NOEC and LC_0 > 100 mg/L LC_{50} > 100 mg/L
Daphnia magna	acute immobilisation	NOEC and EC_0 32 mg/L over 48 hours EC_{50} > 100 mg/L over 48 hours
algae (*Scenedesmus subspicatus*)	growth inhibition	NOEC (growth) 10 mg/L LOEC (growth) 21 mg/L EC_{50} (growth) 140 mg/L NOEC (biomass) 4.6 mg/L LOEC (biomass) 10 mg/L EC_{50} (biomass) 40 mg/L
aerobic waste water bacteria	respiration	EC_{50} > 100 mg/L
earthworms (*Eisenia foetida*)	acute 14 day	14 day NOEL > 1000 mg/kg 14 day LC_{50} > 1000 mg/kg

Acute toxicity tests on fish were carried out according to Commission Directive 92/69/EEC, Annex Part C.1 1992 and OECD Guideline for Testing of Chemicals,

Section 2, No. 203. Nominal concentrations of the test substance ranged from 4.6 to 100 mg/L. Test solutions with concentrations of 46 and 100 mg/L were too intensely coloured to observe fish during the 96 hour period. Fish exposed to these concentrations for 96 hours were removed to control water at the end of the test for observation. For all fish there was no observed intoxication and no deaths resulted. The 96 hour NOEC, LOEC, LLC and LC_{50} values are reported as 100 mg/L (nominal) but are expected to be in excess of this level.

Daphnia magna acute immobilisation tests were carried out according to Commission Directive 92/69/EEC, Annex Part C.2 1992 and OECD Guideline for Testing of Chemicals, Section 2, No. 202 1984. Nominal concentrations of the test substance ranged from 0.10 to 100 mg/L. The 48 hour NOEC and EC_0 values are reported as 32 mg/L (nominal) and the EC_{50} as > 100 mg/L (nominal). The 48 hour EC_{50} could not be calculated as only 25% of the organisms were immobilised at the highest tested concentration.

72 hour static algal growth inhibition tests on *Scenedesmus subspicatus* were carried out according to Commission Directive 92/69/EEC, Annex Part C.3 1992 and OECD Guideline for Testing of Chemicals, Section 2, No. 201 1984, modified to differentiate between toxic effects and indirect effects due to reduced light absorption. Nominal concentrations of the test substance ranged from 4.6 to 100 mg/L. The test was carried out in two parts, part A measured direct toxic effects and part B measured indirect (light) effects. Results from both parts of the test were nearly identical indicating that the results of the test were due to indirect effects only. It may be concluded from these tests that the test substance has no direct toxic effect on algae. Test results are based on nominal concentrations. Measured concentrations for the test substance ranged from 84.1% to 136.5% of the nominal concentration.

Acute toxicity tests (respiration) on aerobic waste water bacteria were carried out according to EEC Directive 87/302/EEC No. L 133 Part C and OECD Guideline for Testing of Chemicals No. 209 1984. Nominal concentrations of the test substance ranged from 3.2 to 100 mg/L. The test substance showed no inhibition on respiration rates over the range of test concentrations. The EC_{50} is therefore > 100 mg/L.

14 day acute toxicity tests were carried out on earthworms (*Eisenia foetida*) according to EEC Directive 87/302 No. L 133/118 and OECD Guideline for Testing of Chemicals No. 207 1984. Nominal concentrations of the test substance ranged from 0.1 to 1000 mg/kg. The test substance showed no toxic effects over the range of test concentrations. The EC_{50} is therefore determined to be > 1000 mg/kg. There was some measured loss of body weight in the test animals but this loss was not statistically significant. There were no abnormalities observed in the surviving worms.

The results show the dye to be practically non-toxic to fish, daphnids, aerobic bacteria and earthworms consistent with the high water solubility and high molecular weight of the substance. The surface activity of the dye did not appear to have a significant effect on aquatic organisms under the test conditions. The test compound is slightly toxic to algae growth. Since the test solution is intensely coloured,

algistatic effects are likely caused by absorption of light (shading effect) necessary for algae growth.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

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

The notifier has indicated the dye will be used at a limited number of dyehouses in both city and country locations in Australia and a fixation rate for the new dyestuff of 89% by the exhaust dyeing process. The environmental hazard has been calculated for dyehouses located at two general locations, one metropolitan based and the other country based, with calculations for the country location carried out for both high and low usage. The Predicted Environmental Concentration (PEC) is estimated below. These calculations assume no dye removed in the treatment of the different waste effluent. Higher levels may be approached in a country dyehouse during drought conditions.

Estimation of Predicted Environmental Concentration

Process or dilution factor	*City dyehouse*	*Country dyehouse - High Use*	*Country dyehouse - Low Use*
typical use of dye expected per day	30 kg	60 kg	10 kg
concentration in washwater (at a fixation rate of 89%)	3.3 kg	6.6 kg	1.1 kg
quantity of water used including wash-off water (at 75 L/kg)	150,000 L	150,000 L	75,000 L
effluent concentration in dye-specific wash-water	22 mg/L	44 mg/L	14.7 mg/L
dilution factor in dyehouse by other wash-waters	13:1 (2 ML/d effluent)	13:1 (2 ML/d effluent)	26:1 (2 ML/d effluent)
influent concentration	1.7 mg/L	3.3 mg/L	0.57 mg/L
dilution factor in sewage treatment plant	100:1	2:1	2:1
concentration balance in effluent from sewage treatment plant no removal of dye in sludge:	17 g/L	1.65 mg/L	0.285 mg/L
dilution factor in receiving waters	10:1	2:1	2:1
predicted environmental concentration in receiving waters no removal of dye in sludge:	1.70 µg/L	0.825 mg/L	0.143 mg/L
safety factor* for exposure of most sensitive aquatic organism (algae, *scenedesmus subspicatus*, for growth inhibition: E_bC_{50} = 40 mg/l)	> 1000	48.5	280

* THE safety factor is the EC_{50} divided by the highest PEC

The calculations in the above table assume that no dyestuff is retained in sludge (as shown for the study in reference 4) from the biological effluent treatment works and is a reasonable assumption given that unfixed dye is expected to predominantly exist as the hydrolysed form. Some dye, as the unhydrolysed reactive form, may be removed due to adsorption to organic sludge and possible complexation of the dye (4) but amounts are expected to be minimal.

The above calculation for a country dyehouse at high usage is based on a final depth of shade of 2.0% which the notifier has indicated is typical for red dyed cloth. When the red reactive dye is used as a component in trichromatic dyeing a more typical depth of shade is expected to be as low as 0.5%. Based on this figure the highest PEC for the dye into receiving waters would be 0.21 mg/L for country dyehouses at high use levels.

Based on the above calculations exposure to fish, *daphnia sp*. and aerobic bacteria will be at levels unlikely to cause any significant effect. Although the algae species tested is considered by the USA EPA to be insensitive (17) the growth inhibition effect of the dye on algae was shown to be a function of decreased light intensity or a change in the light quality reaching the algae in the coloured medium and relevant. Dye concentrations > 1 ppm can give rise to intensely coloured effluent unacceptable to waste water authorities (4). The dye in unlikely to have any significant effect on algae.

The dyes high water solubility suggests that once released to waterways, dilution is expected to rapidly reduce the environmental concentration to undetectable levels. The substance is not expected to reach the terrestrial compartment to any significant level or to have any impact on terrestrial (soil) organisms.

A MSDS has been provided and contains warnings in regard to protection of the environment, containment and disposal of spillage.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The hazards associated with the notified chemical are low. Based on the toxicological data provided, Reactive Red DER 7650 FAT 45'169/A is not classed as hazardous according to Worksafe Australia criteria (15). It is expected to have low acute toxicity, be neither irritating nor sensitising to the skin and non-irritating to the eyes. It is also expected to have no mutagenic potential. The chemical has a low vapour pressure, is non-flammable and has a high decomposition temperature (> 230°C). It also has a low partition coefficient and high molecular weight therefore dermal absorption should be low. Although the chemical was not found to be sensitising to the skin, cases of respiratory sensitisation have been observed with reactive dyes and care should be taken to avoid inhalation.

There is a limited amount of handling of the dye due to the use of closed systems. Workers involved in sampling, repackaging, weighing and mixing of the imported product will be potentially exposed to chemical powder via the dermal and inhalational routes. Transport and storage workers may also be exposed by these routes in the event of accidental spills.

The notifier states that the imported product will be treated to minimise dust formation by the addition of a dusting agent. While it is conceivable that spilt product may be ground to a fine dust during use, the overall exposure by inhalation should be low as only 0.5% of the undusted chemical has a particle size in the respirable range. Exposure by the inhalation route will be further minimised by the use of local exhaust ventilation during weighing processes and down draft air systems and a booth during repackaging if necessary. Coupled with the low expected acute inhalation toxicity (based on animal toxicity by other routes), the risks to workers by inhalation should be low. Any possible risks associated with respiratory sensitisation should also be low when the chemical is used in the proposed manner.

As all operators will be required to wear protective clothing, gloves and glasses, dermal exposure during the above operations should also be low under normal use situations. Exposure during the dyeing process is not anticipated.

The chemical will be incorporated into cellulose textiles as a covalently bound dye and therefore public exposure will be significant. The notified substance may conceivably be bleached or lost from the textiles during extreme treatments, but given the normal manner of washing and wearing clothing made from cellulose textiles, the substance is unlikely to pose a significant health risk. The potential for minor public exposure to more concentrated chemical exists during reformulation, transport and disposal of chemical if accidentally spilt. This is minimised by the recommended practices during formulation, storage and transportation.

13. RECOMMENDATIONS

To minimise environmental exposure to Reactive Red DER 7650 FAT 45'169/A, it is recommended that for rural dyehouses, under conditions of limited water availability, that dyehouse effluent be monitored. At high dyeshades, concentrations may approach 1 ppm and monitoring is recommended to ensure receiving waters are not coloured.

To minimise occupational exposure to Reactive Red DER 7650 FAT 45'169/A the following guidelines and precautions should be observed:

- if engineering controls and work practices are insufficient to reduce exposure to Reactive Red DER 7650 FAT 45'169/A to a safe level, then the following personal protective equipment which conforms to Australian Standard (AS) or Australian/New Zealand Standard (AS/NZS) should be worn;

  the appropriate respiratory device should be selected and used in accordance with AS/NZS 1715 (19) and should comply with AS/NZS 1716 (20),

  eye protection should be selected and fitted in accordance with AS 1336 (21) to comply with AS/NZS 1337 (22),

  industrial clothing must conform to the specifications detailed in AS 2919 (23),

  industrial gloves or mittens should conform to AS 2161 (24),

  all occupational footwear should conform to AS/NZS 2210 (25);

- spillage of the notified chemical should be avoided;

- 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 Cibacron Red LS-B (containing the notified chemical) was provided in accordance with the *Code of Practice for the Preparation of a Material Safety Data Sheets* (26).

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act secondary notification of Reactive Red DER 7650 FAT 45'169/A 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

1. EEC Directive 92/69, A.5. *Surface Tension*,1992.

2. ETAD, Information Notice No.3, *Reactive Dyes: Mode of action and safe handling*.

3. Yen, C.P., Perenich, T.A. and Baughman, G.L., *Environmental Toxicology and Chemistry*, **10**, 1009-1017, 1991.

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

5. Weber, E.J., *Environmental Toxicology and Chemistry*, **10**, 609-618, 1991.

6. RCC Project 372835, *Acute Oral Toxicity Study with FAT 45'169/A in Rats*, RCC Research and Consulting Company Ltd, Itingen, Switzerland, 1994.

7. RCC Project 372846, *Acute Dermal Toxicity Study with FAT 45'169/A in Rats*, RCC Research and Consulting Company Ltd, Itingen, Switzerland, 1994.

8. RCC Project 372857, *Primary Skin Irritation Study with FAT 45'169/A in Rabbits (4-Hour Semi-Occlusive Applicaiton)*, RCC Research and Consulting Company Ltd, Itingen, Switzerland, 1994.

9. RCC Project 372868, *Primary Eye Irritation Study with FAT 45'169/A in Rabbits*, RCC Research and Consulting Company Ltd, Itingen, Switzerland, 1994.

10. RCC Project 372870, *Contact Hypersensitivity to FAT 45'169/A in Albino Guinea Pigs: Maximization Test*, RCC Research and Consulting Company Ltd, Itingen, Switzerland, 1994.

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

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

13. Magnusson, B. and Kligman, AM*, Allergic Contact Dermatitis in the Guinea-pig: Identification of Contact Allergens*. Thomas C.C., Springfield, Illinois, USA, 1970.

14. RCC Project 372881, *Subacute 28-Day Oral Toxicity (Gavage) Study with FAT 45'169/A in the Rat*, RCC Research and Consulting Company Ltd, Itingen, Switzerland, 1994.

15. National Occupational Health and Safety Commission, Approved Criteria for Classifying Hazardous Substances. Australian Government Publishing Service, Canberra, 1994.

16. RCC Project 372903, CCR Project 470601, *Salmonella typhimurium and Escherichia coli Reverse Mutation Assay with FAT 45'169/A*, RCC Research and Consulting Company Ltd, Itingen, Switzerland, 1994.

17. RCC Project 372914, CCR Project 470602, *Chromosome Aberration Assay in Chinese Hamster V79 Cells in vitro with FAT 45'169/A*, RCC Research and Consulting Company Ltd, Itingen, Switzerland, 1994.

18. USEPA, Environmental Effects Test Guidelines, *Algal acute toxicity test*, *EG-8*, 1982.

19. Standards Australia, Standards New Zealand, *Australian/New Zealand Standard 1715 - 1994 Selection, Use and Maintenance of Respiratory Protective Devices*, Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ., Wellington, New Zealand, 1994.

20. Standards Australia/ Standards New Zealand, *Australian/New Zealand Standard 1716 - 1991 Respiratory Protective Devices,* Standards Association of Australia Publ., Sydney, Australia, 1991.

21. Standards Australia, *Australian Standard 1336-1994, Recommended Practices for Eye Protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney, Australia, 1994.

22. Standards Australia, Standards New Zealand, *Australian/ New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand, 1992.

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

24. Standards Australia, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves*), Standards Association of Australia Publ., Sydney, Australia, 1978.

25. Standards Australia, Standards New Zealand, *Australian/ New Zealand Standard 2210 - 1994 Occupational Protective Footwear, Part 1: Guide to Selection, Care and Use. Part 2: Specifications,* Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand, 1994.

26. National Occupational Health and Safety Commission, G*uidance Note for the Completion of a Material Safety Data Sheet,* 2nd. edition, AGPS, Canberra, 1990.

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