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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Reactive Orange TZ3931

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Reactive Orange TZ3931

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 Orange TZ3931'.

2. IDENTITY OF THE CHEMICAL

Reactive Orange TZ3931 is considered to be hazardous based on the nature of the chemical and the data provided. However, for commercial reasons, the chemical name, CAS number, molecular and structural formulae, molecular weight, methods of detection and determination, estimated import volumes and number of sites at which the chemical will be used have been granted exemption from publication in the Full Public Report and the Summary Report on the following basis:

- A descriptive generic name**,** tetraazo bis (fluortriazine) tetrasulfonic acid derivative, sodium salt, shall used to identify the substance in public reports and the Material Safety Data Sheet (MSDS),

- The relevant employee unions shall be informed of the conditions of use of Reactive Orange TZ3931,

- The full chemical name shall be provided to any health professionals in the case of a legitimate need where exposure to the chemical may involve a health risk,

- The full chemical name shall be provided to those on site who are using the chemical and to those who are involved in planning for safe use, etc. in the case of a legitimate need,

- The Director of NICNAS will release the full chemical name etc in the case of a request from a medical practitioner,

- Confidentiality will expire after a 3 year period,

- The chemical be identified as a sensitiser in the Health Effects Section of the MSDS, and that reference to its assessment by NICNAS be made on the MSDS,

These conditions shall be published in the Chemical Gazette.

Generic Name:	tetraazo bis (fluorotriazine) tetrasulfonic acid derivative, sodium salt
Other Names:	FAT 45163/A
Trade Name:	Reactive Orange LS-BR
Molecular Weight:	> 1 000 (free acid)
Method of Detection and Determination:	appropriate methods include: physical testing; infrared (IR) spectroscopy; ultraviolet/visible (UV/Vis) spectroscopy; nuclear magnetic resonance (NMR) spectroscopy

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	red-brown powder
Melting Point:	> 300°C
Specific Gravity:	1 630 kg/m^3 at 22.5°C (pycnometer)
Vapour Pressure:	1.5x10^{-32} Pa at 25°C (estimated - Modified Watson Correlation)
Water Solubility:	> 65.2 g/L at 20°C (see comments below)
Fat Solubility:	< 0.04 mg/100 g at 37°C
Partition Co-efficient (n-octanol/water):	log P_{ow} < -4.3 (calculated)
Hydrolysis as a Function of pH:	$T_{1/2}$ at pH 7.0 = 3.5 years at 25°C (calculated) $T_{1/2}$ at pH 9.0 = 10 weeks and 3 days at 25°C (calculated)
Adsorption/Desorption:	not provided
Dissociation Constant:	pK_a = 6.14 at 20°C
Flash Point:	not flammable
Particle Size:	< 10 μm 0.50%

10 - 20 μm	1.50%
20 - 50 μm	4.65%
50 - 63 μm	1.60%
63 - 250 μm	47.30%
> 250 μm	44.50%

Surface Tension: 72.4 mN/m at 20°C (0.974 g/L solution)

Flammability Limits: not flammable

Autoignition Temperature: not autoflammable

Explosive Properties: not explosive

Reactivity/Stability: notified chemical is considered stable under conditions of intended use

Comments on Physico-Chemical Properties

The vapour pressure was determined from the calculated boiling point using the Modified Watson Correlation. The notified chemical is not volatile.

The solubility of the notified chemical was reported to be 65.2 g/L. The notifier indicates that solubility could be higher than this, because the chemical forms a paste at a concentration of 500 g/L, meaning it is not possible to use a five-fold saturation concentration as required by the EEC method followed. The solubility of the main component in water was determined to be 70.11 g/L during determination of the partition co-efficient.

Hydrolysis testing was carried out at pH 7 and pH 9 only. The hydrolysis 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 from the quotient of the n-octanol and water solubility, due to the flask shaking and high performance liquid chromatography (HPLC) methods not being applicable. The reported estimated partition co-efficient of log P_{ow} less than -4.3 is that of the main component of the notified chemical.

Adsorption/desorption data were not provided. High water solubility and a low partitior coefficient would normally indicate low affinity for soil or sediment. The chemical may bind to positively charged substances such as clay particles.

By definition (EEC Directive 92/69) (1), a chemical has surface activity when the surface tension is less than 60 mN/m. The notified chemical is therefore not considered surface active.

4. PURITY OF THE CHEMICAL

Degree of Purity: above 50%

The identity and percentages of impurities remain confidential

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia but will be imported for as a component of the end-use dye Cibacron Orange LS-BR, for colouration of cellulose textiles.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported in 30 kg containers with an antistatic polyethylene lining. The dye will be transported to warehouses for minimal repacking and distribution to customers. Transport workers will be handling unopened drums and smaller packages of the dye, and are unlikely to be exposed to the notified chemical under normal circumstances.

Inhalational, dermal and ocular exposure may occur when workers are weighing and repackaging the pure powdered dye at the notifier's warehouses. The potential for inhalational exposure during these processes is moderate. Exposure will be minimised by anti-dusting agents, which are included as part of the final dye product. The notifier has stated in previous notifications for dyes of this type that there will be ventilation in the weighing area which will prevent a build up of dye dust. If a build up of dust does occur, less than 0.5% of the particles would be considered fine enough to enter the lower regions of the respiratory tract.

The notifier states that the product will only be used for the colouration of cellulose textiles using exhaust dyeing processes. Workers will initially weigh the product, using a scoop to transfer it from the 30 kg drum to a weighing container. The potential for inhalational exposure at this stage is moderate, for the reasons discussed in the preceding paragraph. Eye and dermal exposure may also occur.

After weighing, the product is then dissolved in water at 90°C using high speed mechanical stirring. The dye is then automatically metered to the enclosed dyeing vessel over a specified period. The pH of the dye and water mixture will be around 7. Unfixed dye is then removed from the textile in a boiling, soapy bath. Exposure to the notified dye should be limited to dermal contact once the dye is dissolved, although aerosol formation may occur at the mixing stage if the vessel is open, hence inhalational exposure may occur. Dermal exposure to the notified dye may also occur when operators are handling mixed dye liquors and during threading of textiles for dyeing. Based on information previously provided by the notifier, exposure to the notified dye in liquid form is expected to be only several minutes each hour.

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

7. PUBLIC EXPOSURE

The notified chemical will not be sold to the public, and no public exposure is expected to occur as a result of storage, distribution and dyeing processes. Public exposure resulting from disposal is also expected to be negligible.

Public exposure to the notified chemical may occur as a result of dermal contact with fabrics dyed with the notified chemical. The notifier stated that due to its colour value, the notified chemical will be used mainly for outerwear, which would minimise skin contact with the notified chemical.

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 relatively high 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. With consideration of fixation rates, import volumes and an estimated annual release of Cibacron Orange LS-BR through this mechanism could be in excess of 1 000 kg (an average of greater than 100 kg per annum per dyehouse).

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 applications by the notifier). All clean up of spills and disposal of empty packaging should be carried out according to the MSDS.

Fate

The dye normally released in water as effluent from the dyehouse is expected to be the major route of environmental exposure. Measured hydrolysis rates showed the chemical to have a half life of 8.3 hours at 90°C and pH 7, which are the conditions under which this dye is applied. Therefore, it would be expected that a reasonable proportion of the released dye would be in hydrolysed form.

The dye may either partition to cationic clay particles or stay in the aqueous compartment. Hobbs (2) 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.

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 (3). Also, highly sulphonated bis(azo) dyes have been shown to sorb to sediment through an anion-adsorption mechanism (4). 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 (4). 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 nonvolatile, resistant to hydrolysis (> 365 days for this dye at 25°C) and should not partition strongly to sediments (5). Humic materials in natural water have been shown to strongly accelerate the photodecomposition of azo dyes, probably because of oxidation by singlet oxygen or oxyradicals present in waters exposed to sunlight (5).

The dye was found to be not readily biodegradable. In the OECD 301E Test for ready biodegradability no biodegradation was observed at the end of the 28-day exposure period.

Although the dye is not readily biodegradable, the potential for bioaccumulation is low, due to the low calculated partition coefficient (log P_{ow} < -4.3) and high water solubility of the substance. Hydrophilic dyes with log P_{ow} below 3 have been shown not to bioaccumulate (3). Also, biological membranes are not permeable to chemicals of very 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 Orange TZ3931

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	sensitising	(12)

9.1.1 Oral Toxicity (8)

Species/strain:	rat/HabIbm: 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:	none
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:	rat/HabIbm: WIST (SPF)
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	single dose (2 000 mg/kg) applied to a clipped area of skin on back of animal and covered

	with a semi-occlusive dressing; dressing removed and skin washed with lukewarm water 24 hours after application
Clinical observations:	orange discolouration of the skin persisted throughout observation period; slight weight loss in one female 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 a limit test in rats

9.1.3 Inhalation Toxicity

Not performed

9.1.4 Skin Irritation (10)

Species/strain:	rabbit/Chbb: NZW (SPF)
Number/sex of animals:	one male/two females
Observation period:	72 hours
Method of administration:	gauze patches bearing 0.5 g of the test substance were applied to a shaved area of the right flank of each animal; dressing removed after 4 hours
Draize scores:	orange discolouration of the skin persisted throughout the study; there were no Draize scores (14) greater than 0
Test method:	according to OECD guidelines (13)
Result:	the notified chemical was non-irritating to rabbit skin

9.1.5 Eye Irritation (11)

Species/strain:	rabbit/Chbb: NZW (SPF)
Number/sex of animals:	one male/two females
Observation period:	72 hours
Method of administration:	0.1 g of test substance placed in conjunctival sac of left eye of each animal; right eye served as control
Draize scores:	red discolouration of the skin and eyelid was noted throughout the study; all animals had a score of 1 for chemosis at the 1 hour reading, individual scores of 1 or 2 for conjunctival redness were noted up to and including the 48 hour reading; one animal had a score of 1 for conjunctival redness at the 72 hour reading; all other 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 pigs/Himalayan spotted
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 (w/w)) - 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 (w/w)) Day 7: test area treated with 10% sodium lauryl sulfate in *paraffinum perliquidim* Day 8: occluded application of 25% concentration of test material in *vaselinum album* for 48 hours

Challenge procedure: Day 22: occluded application of 25% solution of test material in *vaselinum album* for 24 hours

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
25%	4/20**	14/20	1/10	0/10

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

Test method: according to OECD guidelines (13)

Result: the notified chemical is 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 control and high dose groups, which were maintained for an additional 2 week recovery period before sacrifice

Clinical observations: no deaths occurred during the test period; there were no clinical signs of toxicity; differences in relative food consumption between control and test groups were not considered to be test related; retardation in weight gain was evident in males of the mid dose group and females of the high dose

	group
Clinical chemistry/Haematology	a number of minor statistically significant changes were noted in high dose animals: slightly lower erythrocyte count (females); slightly lower haemoglobin concentration and haematocrit (males and females); slightly higher reticulocyte count and increase in total bilirubin (males and females); small increase in middle reticulocyte fluorescence ratio (females); a light orange discolouration of the plasma was observed for all animals in the high dose group; these parameters were within the limits of historical control data and changes were reversed at the end of the treatment free period
Histopathology:	both sexes in the high dose group had vacuolation of the squamous epithelium of the limiting ridge; hyaline inclusions in the glandular epithelium and inflammatory cell infiltrate were also noted; 5 animals in the mid dose group and one in each of the control and low dose groups also exhibited signs of slight irritation of the gastric mucosa; these findings were reversed at the end of the treatment free period
Test method:	according to OECD guidelines (13)
Result:	these findings indicate that treatment with the notified chemical at high doses induces a greater turnover of circulating erythrocytes and stimulation of the reticulocyte pool during dosing; the increased total bilirubin suggests an increased rate of free bilirubin production as a result of a greater erythrocyte turnover; some irritation of the gastrointestinal tract also occurred after repeated oral administration of the notified chemical; all of the above effects were found to be reversed at the end of the 14 day treatment free 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 considered to be mutagenic in the bacterial strains tested in the presence or absence of metabolic activation provided by rat liver S9 fraction

9.3.2 Chromosomal Aberration Assay in Chinese Hamster V79 Cells (17)

Dosing schedule:	without S9 mix: 30 - 300 μg/mL - treatment time 18 hours and 28 hours with S9 mix: 30 - 500 μg/mL - treatment time 4 hours the concentration range in the experiments was limited by a precipitation of the test substance in the test medium which started at concentrations of 300 μg/mL 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 tests). Inhalational toxicity tests were not carried out by the notifier, as the dye containing the notified chemical will include an anti-dusting agent, which will minimise exposure by this route. Reactive Orange TZ3931 was non-irritating to rabbit skin, but was a slight eye irritant in

rabbits. The notified chemical was found to be a skin sensitiser in guinea pigs.

Repeated oral administration of high doses of Reactive Orange TZ3931 over a period of 28 days induced a higher turnover of circulating red blood cells and stimulation of the reticulocyte pool. An increase in total bilirubin suggested an increase in free bilirubin as a consequence of the greater erythrocyte turnover. Repeated oral administration also caused some irritation of the gastrointestinal tract. These findings were all reversed at the end of the 14 day recovery period.

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

Based on the results of the animal studies summarised above, Reactive Orange TZ3931 would be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (18), on the basis of its skin sensitising effects.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

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

Test	*Species*	*Results (mg/L)*
Acute Toxicity (S; N)	Carp *(Cyprinus carpio*)	96 h LC_{50} > 100
Immobilisation (S; N)	Water Flea (*Daphnia magna*)	48 h EC_{50} > 100
Growth Inhibition (S; N)	Algae (*Scenedesmus subspicatus*)	72 h E_bC_{50} > 100
		72 h E_rC_{50} > 100
Respiration Inhibition	Aerobic Waste Water Bacteria	IC_{50} > 100

S=Static; N=Nominal Concentration.

One nominal concentration of 100 mg/L (ppm) was tested for the final fish study, with no mortalities recorded.

For the daphnia test, analysis of samples taken at the start of the final test revealed a mean actual concentration of 96.2 ppm (nominal = 100 ppm). After 48 hours the actual concentration had decreased significantly to mean concentrations of 53 ppm and 61 ppm in the test vessels. This was in contrast to the fish toxicity test, where the actual concentration was 95 ppm after 96 hours exposure. Precipitation and substance deposits were recorded after 24 and 48 hours during the test with daphnia, while this was not observed during the fish toxicity test. The presence of continuous aeration during the fish toxicity test will probably have prevented the deposition of the test substance, whereas the test solutions in the daphnia test remained undisturbed.

While the algae EC_{50} was greater than 100 ppm for both growth inhibition and growth rate, the notified chemical significantly inhibited cell growth at a concentration of 20 ppm and higher. For cell growth inhibition, the NOEC was 9 ppm, whereas it was 45 ppm for growth rate reduction. This apparent increased effect with respect to growth inhibition may be explained by colouring of the test solutions (particularly observed at higher concentrations) by the dye.

No significant inhibition in respiration rate of the sludge (<10%) was recorded up to the highest concentration of 101.2 ppm (EEC Directive 87/302, Part C).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The Predicted Environmental Concentration (PEC) is estimated below.
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 maximum dye use of 60 kg per day (as indicated by the notifier) has been assumed.

Predicted Environmental Concentration (PEC):

	City	***Country***
Dye use per day	60 kg	60 kg
Unfixed volume (fixation rate 83%)	10.1 kg	10.1 kg
Conc. after dilution in dyehouse (2 ML/day)	5 mg/L	5 mg/L
Dilution factor in sewage treatment plant	1:125	1:3
Concentration in sewage treatment plant	0.04 mg/L	1.7 mg/L
Dilution factor in receiving waters	1:10 (coast)	1:2 (inland)
PEC in receiving waters	**4.0 μg/L (ppb)**	**0.9 mg/L (ppm)**

While it has been assumed in the calculations that no removal of the dye would take place during the wastewater treatment process, some of the dye may be removed due to the adsorption of the dye to the organic sludge and possible complexation of the dye (4).

The PEC in receiving waters for a country dyehouse with high dye use is an order of magnitude less than the NOEC of 9 ppm for growth inhibition in algae, and at least three orders of magnitude lower than any of the reported EC_{50}/LC_{50} values obtained through ecotoxicity testing.

The only other source of environmental contamination is from accidental spills and disposal of packaging. The MSDS is adequate to limit the environmental exposure and therefore limit the environmental effects.

The environmental hazard of the chemical can be rated as low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

There is a negligible occupational health risk posed to workers who will be handling unopened containers of the notified dye, as exposure will only occur in the event of an accident or leaking packaging.

There is a moderate occupational health risk posed to workers involved in repacking Cibacron Orange LS-BR and those involved in weighing the dye prior to use in exhaust dyeing processes. Due to the powdered nature of the dye product, workers may be exposed to the notified dye via dermal, inhalational and ocular routes. The notifier has stated in previous notifications for reactive dyes that exposure to the dye 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. If dermal contact occurs, animal data indicates that the notified dye is not likely to cause skin irritation. However, results of a guinea pig skin sensitisation study indicate that the notified chemical has high allergic potency, and skin sensitisation may occur if workers are dermally exposed. Slight eye irritation may occur following ocular exposure. Workers should be aware that cases of respiratory sensitisation have also been observed with some reactive dyes and that a respiratory sensitisation reaction may occur in susceptible workers. As inhalational toxicity data is not available for the notified dye and as the potential for inhalational exposure to the notified dye is moderate, the level of dust in the workplace should be maintained at as low a concentration as possible and personal protective equipment should be worn where necessary to minimise exposure (see recommendations section).

The results of a 28-day oral toxicity study suggest that there may be some effects on red blood cells and gastrointestinal irritation following repeated oral exposure to high doses of the notified chemical. These effects were found to be reversed after a 14 day treatment free period. However, the risk of these effects occurring following workplace exposure is low, given that adverse effects were only seen at high doses in the rat study and the workplace exposures are expected to be low.

The occupational health risk is reduced once the notified dye is dissolved in water, as the dyeing processes are largely automated and the maximum concentration of the notified chemical during the dyeing process is low (expected to be less than 1%). In addition, exposure times are expected to be short (several minutes per hour). The main route of exposure at this stage, however, is expected to be dermal. While the dye is not expected to be an irritant, sensitisation may occur following skin contact, even though the notified chemical will be at low concentrations (< 1%) by this stage of the process. If accidental eye contact occurs, mild irritation may result.

There is a negligible health risk for workers handling dry, dyed textiles during packaging or manufacturing, as the dye will be irreversibly bound to the fabric.

Public exposure to the notified chemical may occur as a result of dermal contact with fabrics dyed with the notified chemical. However, the notified chemical is fixed to the fabric fibres and dermal absorption of the notified chemical resulting from contact with the dyed fabrics is not expected to occur. The proposed use of the notified chemical is not expected to pose a significant hazard to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to Cibacron Orange LS-BR the following guidelines and precautions should be observed:

- Inhalational exposure to potentially harmful dusts should be kept to a minimum and respiratory protection (selected and fitted) according to Australian/New Zealand Standard (AS/NZS) 1715 (19) meeting the requirements of AS/NZS 1716 (20);
- Industrial clothing should conform to the specifications detailed in AS 2919 (21);
- Impermeable gloves or mittens should conform to AS 2161 (22);
- All occupational footwear should conform to AS/NZS 2210 (23);
- 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* (24).

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. No other specific conditions are prescribed.

16. REFERENCES

1. EEC Directive 92/69, A5 “Surface Tension” (1992)

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

3. 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.

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

5. 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.

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. Mahl, A. 1993, *Acute Oral Toxicity with FAT 45’ 163/A in Rats,* Project number 357996, data on file, RCC Group, Switzerland.

9. Mahl, A., Couch, C.N. 1993, *Acute Dermal Toxicity Study with FAT 45’163/A in Rats*, Project number 358007, data on file, RCC Group, Switzerland.

10. Arcelin, G. 1993, *Primary Skin Irritation with FAT 45’ 163/A in Rabbits*, Project number 358018, data on file, RCC Group, Switzerland.

11. Arcelin, G. 1993, *Primary Eye Irritation with FAT 45’ 163/A in Rabbits*, Project number 358020, data on file, RCC Group, Switzerland.

12. Arcelin, G. 1993, *Contact Hypersensitivity to FAT 45’ 163/A in Albino Guinea Pigs*, Project number 358031, 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,* vol. 49.

15. Dotti, A., Luetkemmeier, H., Biderman, K. and Wilson, J.Th. 1994, *Subacute 28-day Oral Toxicity (Gavage) Study with FAT 45’ 163/A in the Rat*, Project number 358053, data on file, RCC Group, Switzerland.

16. Poth, A. 1993, *Salmonella typhimurium and Escherichia coli Reverse Mutation Assay for Azo dyes with FAT 45'163/A,* Project number 436814, data on file, CCR Group, Germany.

17. Volkner, W. 1994, *Chromosome Aberration Assay in Chinese Hamster V79 Cells in vitro with FAT 45'163/A*, Project number 436825, data on file, CCR Group, 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/Standards New Zealand 1994, *Australian/New Zealand Standard 1715-1994, Selection, Use and Maintenance of Respiratory Protective Devices,* Standards Association of Australia, Sydney, Standards Association of New Zealand, Wellington.

20. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 1716-1994, Respiratory Protective Devices,* Standards Association of Australia Publ., Sydney, Standards Association of New Zealand, Wellington.

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

22. Standards Australia 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding electrical and medical gloves),* Standards Association of Australia, Sydney.

23. 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, Wellington.

24. 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