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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Reactive Red 202

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Reactive Red 202

1. APPLICANT

Tomen Australia Ltd, Melbourne Branch of Level 50 Rialto, 525 Collins Street, MELBOURNE, VIC 3000 has submitted a standard notification statement in support of their application for an assessment certificate for Reactive Red 202.

2. IDENTITY OF THE CHEMICAL

The notifier has applied that the chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, and details of exact import volume to be exempted from publication in the Full Public Report and the Summary Report.

Other Name:	Reactive Red 202
Trade Name:	Sumifix Supra Rubine E-FX Gran

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	odourless, dark reddish powder
Melting Point:	decomposes without melting at temperatures exceeding 264°C
Specific Gravity:	1.71 at 20°C
Vapour Pressure:	2×10^{-27} kPa at 25°C (calculated)
Water Solubility:	> 852 $g.L^{-1}$ at 20°C
Partition Co-efficient (n-octanol/water):	log P_{ow} < -5.8 (see comments below)

Hydrolysis as a Function of pH:	ester component: $t_{1/2}$ = 206 hours (pH 7, 25°C) $t_{1/2}$ < 2.4 hours (pH 9, 50°C) vinyl component: $t_{1/2}$ = 38 226 hours (pH 9, 25°C) $t_{1/2}$ = 111 hours (pH 9, 60°C) hydroxy component stable (see comments below)
Adsorption/Desorption:	not determined (see comments below)
Dissociation Constant:	not determined
Flash Point:	not determined
Flammability Limits:	not determined
Autoignition Temperature:	> 260°C
Explosive Properties:	none
Reactivity/Stability:	the notified chemical was stable under normal conditions but incompatible with oxidizing agents
Surface Tension:	71.7 $mN.m^{-1}$ (20°C, 998 $mg.L^{-1}$)
Fat Solubility:	< 5.3 X 10^{-4} mg.100 g $solvent^{-1}$ (37°C)

Particle size:

<25 μm	0.03%
25-38 μm	0.00%
38-68 μm	0.21%
68-106 μm	3.49%
106-125 μm	3.71%
125-150 μm	12%
150-250 μm	71.39%
250-500 μm	9.17%
>500 μm	0.00%

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD Test Guidelines (1) at facilities complying with OECD Principles of Good Laboratory Practice.

The dyestuff was dissolved in water up to a concentration of 852 $g.L^{-1}$. At higher concentrations, lumps appeared in the mixtures. The concentrations of the three main components of the dyestuff were determined to be greater than 20.1, 27.8 and 532.2 $g.L^{-1}$ for the hydroxy, the vinyl and the ester components, respectively.

The rates of hydrolysis were determined for the three main dyestuff components. The ester component was found to be hydrolytically stable at pH 4, and

hydrolytically unstable at pH 7 and 9. The vinyl component is hydrolytically stable at pH 4 and 7, and hydrolytically unstable at pH 9 (at higher temperatures), whilst the hydroxy component is hydrolytically stable at pH 4, 7 and 9.

As the notified chemical is protonated and not a pure substance, the partition coefficient could not be determined using the shake flask or HPLC methods. Therefore, the partition coefficient was estimated from the n-octanol and the water solubilities. The log partition coefficient (log P_{OW}) of each component is less than -5.7, -5.7 and -5.8 for the hydroxy, the vinyl and the ester components, respectively.

The dyestuff has a very high water solubility, and a very high hydrophilicity, as demonstrated by the estimated log P_{OW} of less than -5.8. As such, the notifier claims that, by direct comparison with the log P_{OW}, the log K_{OC} can be considered to be low. The notified chemical is not expected to adsorb to soil or sediment, and most likely will be highly mobile.

The notified chemical is a multi-sulfonated aromatic azo compound. The notifier claims that although it has various ionisable substitutes, its dissociation property should be determined by the three aromatic sulfonic acid groups. It is expected that the dyestuff would be fully ionised in the expected environmental pH range of 4 to 9.

The notified chemical is not expected to be surface active. By definition, a chemical has surface activity when the surface tension is less than 60 $mN.m^{-1}$ (2).

The solubility of each component of the dyestuff was determined in standard fat to be less than $3.0x10^{-4}$ $mg.100\ g^{-1}$, $3.9x10^{-4}$ $mg.100\ g^{-1}$ and $5.3x10^{-4}$ $mg.100\ g^{-1}$ respectively for the hydroxy, the vinyl and the ester component at 37.0°C, indicating very low fat solubility.

The majority (greater than 80%) of the notified chemical has particle size between 150 to 500 μm and only less than 0.03% is of less than 25 μm. It can be predicted that the population of respirable size (less than 7 μm) will be minimal.

4. PURITY OF THE CHEMICAL

Degree of Purity: > 60%

Toxic or Hazardous Impurities:

Chemical name: Reactive Red 202 (vinyl)

Weight percentage: < 10%

CAS No.: not allocated

Chemical name:	Reactive Red 202 (hydroxy)
Weight percentage:	< 10%
CAS No.:	not allocated

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical is a reactive dyestuff used for dyeing cellulose fibres. The notified chemical is formulated as granules. No reformulation of the product will take place in Australia, as the product will be used directly. Less than ten tonnes of the notified chemical will be imported per annum for the first five years.

6. OCCUPATIONAL EXPOSURE

This chemical will be imported in recyclable cardboard boxes with polyethylene inner bags. The size of the cardboard box is approximately 39x39x39 cm containing 20 kg dyestuff. Occupational exposure during transportation and storage will only occur in the event of an accident.

Workers with direct exposure to the dyestuff will be the dye weighers and mixers. Reactive Red 202 will be scooped from a dyestuff box into a weighing dish then added to a mixing vessel with a mechanical stirrer, to which water is added. The weighing will be under local dust extraction and the mixing vessel is covered with a lid during stirring. The prepared solution is used for dyeing and printing of cellulose fibre.

The dye machine operators will load fabric into dye machines manually. After staining, fabric will be washed free of unfixed dye and dried. Approximately 80% of the dye is irreversibly fixed to the fabric. The processes are operated mechanically. Therefore the dye machine operators would have limited exposure to the notified chemical.

The dye weighers and mixers are most likely to be exposed to the notified chemical. The most likely route of exposure would be dermal contamination. The vapour pressure of the notified chemical is low so inhalation of vapour is not likely. A small proportion of fine particles is in the range for inspirable dust, so some exposure via inhalation may occur. NOHSC has established an exposure standard (10 $mg.m^{-3}$) for inspirable dust.

7. PUBLIC EXPOSURE

Public exposure during distribution to dyehouses is considered unlikely. In the event of a transport accident, spills are to be contained and collected by vacuum or

wetted down, adsorbed onto sawdust or sand and swept up. The contaminated area is then to be washed down.

At the dyehouses, unbound dye is likely to be partly retained in sediment in the dyehouse effluent system, with the remaining dye released into the sewerage system. Empty containers are to be disposed of by landfill. The potential for public exposure to Reactive Red 202 during dyeing operations is considered to be negligible.

Extensive public contact will occur with fabrics dyed with the notified chemical, but at this stage Reactive Red 202 will be irreversibly bonded to the fibre. Potential for absorption of Reactive Red 202 will be further reduced by its high molecular weight of greater than 1 000 and negligible fat solubility. Exposure from dyed fabrics is therefore anticipated to be negligible.

8. ENVIRONMENTAL EXPOSURE

Release

The bulk of the dye will become chemically fixed to the cellulosic textiles, and in this state is not expected to impact on the environment.

Considerable release is expected as a consequence of incomplete fixation of the dye. The notifier indicates that fixation of the new dye to cotton textiles is only between 60 and 80%, and a test report provided gave 77% fixation. Thus, assuming a maximum annual use of 10 tonnes of new dye, it is possible that up to 4 tonnes will be released into the sewage systems with the effluent discharged from the dye houses. The notifier claims that effluent from all of the dyehouses will be treated at the Western Treatment Plant (Werribee Farm).

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

Fate

Most of the notified chemical will be fixed to cotton textiles as a dye. The fate of the dye will consequently be that of the material to which it is applied, and this would most likely be incinerated or placed into landfill. The notifier indicates that incineration is the preferred method for disposal/destruction of the new dye. Incineration of the dye will produce oxides of carbon, nitrogen and sulfur, together with sodium salts in the ash.

The dye normally released in water as effluent from the dyehouse is expected to be the major environmental exposure. The dye may either partition to sediment or stay in the aqueous compartment. Hobbs (3) reports that reactive dyes have been found not to absorb to sludge in model systems, thus the majority is expected to remain in the aquatic compartment. Any dye that does bind 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 and

potential mobility of the chemical.

The notified dye is not readily biodegradable, with only 1 to 4% degradation achieved after 28 days in the Modified Sturm test (EEC Dir C.4-C) (4). However in a landfill, the notified substance or its degradation products would be expected to undergo slow decomposition through the biological and abiotic processes operative in these facilities. Depending on the ambient oxidative conditions, the notified chemical would be destroyed, producing methane, ammonia, and sulphides (reducing environment) or water and oxides of carbon and nitrogen (aerobic environment). The contained sulfur would in all probability eventually be oxidised to sulphate.

Although the dye is not readily biodegradable, the potential for bioaccumulation is very low due to the low calculated partition coefficient (log P_{OW} less than -5.8), very high water solubility (greater than 852 $g.L^{-1}$) and low fat solubility (less than $5.3x10^{-4}$ mg.100 g $solvent^{-1}$) (5). Hydrophilic dyes with log P_{OW} less than 3 have been shown not to bioaccumulate (6). Also, biological membranes are not permeable to chemicals of very large molecular size (7).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Reactive Red 202

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5 000 $mg.kg^{-1}$	(8)
acute dermal toxicity	rat	LD_{50} > 2 000 $mg.kg^{-1}$	(9)
skin irritation	rabbit	not a skin irritant	(10)
eye irritation	rabbit	a slight eye irritant	(10)
skin sensitisation	guinea pig	a moderate skin sensitiser	(11)

9.1.1 Oral Toxicity (8)

Species/strain:	rat/Crj:CD (SD)
Number/sex of animals:	2 test groups of 5/sex
Observation period:	14 days
Method of administration:	the notified chemical was suspended in 0.5% methylcellulose aqueous solution and given by gavage at 2 000 and 5 000 $mg.kg^{-1}$
Clinical observations:	no signs of systemic toxicity were observed

Mortality:	nil
Morphological findings:	no abnormal changes related to the treatment
Test method:	similar to OECD Guidelines (1)
LD_{50}:	> 5 000 $mg.kg^{-1}$
Result:	the notified chemical was of low acute oral toxicity in rats

9.1.2 Dermal Toxicity (9)

Species/strain:	rat/Crj:CD (SD)
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	the notified chemical was suspended in 0.5% methylcellulose aqueous solution and applied to skin at 2 000 $mg.kg^{-1}$ for 24 hours
Clinical observations:	no signs of systemic toxicity
Mortality:	nil
Morphological findings:	no abnormal changes related to the treatment
Test method:	similar to OECD Guidelines (1)
LD_{50}:	> 2 000 $mg.kg^{-1}$
Result:	the notified chemical was of low acute dermal toxicity in rats

9.1.3 Inhalation Toxicity

Not determined.

9.1.4 Skin Irritation (10)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 2 males, 1 female

Observation period: 72 hours

Method of administration: the notified chemical (0.5 g) was applied to intact skin with an occlusive tape for 4 hours

Test method: similar to OECD Guidelines (1)

Result: Draize scores (12) were zero for erythema and edema in all the animals up to 72 hours; the notified chemical is not a skin irritant in rabbits

9.1.5 Eye Irritation (10)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 2 males, 1 female

Observation period: 4 days

Method of administration: the notified chemical (0.1 g solid) was applied in conjunctival sac of one eye of each rabbit, the untreated eye served as a control

Draize (12) scores:

	Time after instillation											
Animal	**1 day**			**2 days**			**3 days**			**4 days**		
Conjunctiva	**r[a]**	**c[b]**	**d[c]**	**r[a]**	**c[b]**	**d[c]**	**r[a]**	**c[b]**	**d[c]**	**r[a]**	**c[b]**	**d[c]**
1	1	1	1	1	0	0	1	0	0	0	0	0
2	1	1	0	1	0	0	1	0	0	0	0	0
3	1	1	0	1	0	0	1	0	0	0	0	0

[1] see Attachment 1 for Draize scales
[a] redness [b] chemosis [c] discharge

Observation: Draize scores for cornea and iris were zero in all the animals; conjunctival observations revealed slight chemosis and redness for 1 and 3 days respectively; all changes were fully reversible within 4 days

Test method: similar to OECD Guidelines (1)

Result: the notified chemical was a slight eye irritant in rabbits

9.1.6 Skin Sensitisation (11)

Species/strain: guinea pig/Dunkin-Hartley

Number of animals: 20 males in test group; 10 males in negative control group

Induction procedure: 3 pairs of intradermal injections (0.05 mL per site in the scapular region) were given on day 1: Freund's complete adjuvant (FCA) with water (1:1); 5% notified chemical aqueous solution; and 5% notified chemical emulsion in FCA and water (1:1)

on day 8, a lint patch saturated with 0.4 g of 25% notified chemical in petrolatum was applied dermally to the injection sites for 48 hours

Challenge procedure: on day 22, a lint patch spread with 0.2 g of 25% notified chemical in petrolatum was applied topically to the right flank for 24 hours

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
25%	**5/20	7/20	0/10	0/10

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

Test method: similar to OECD Guidelines (1) (13)

Result: the notified chemical was a moderate skin sensitiser in guinea pigs

9.2 Repeated Dose Toxicity (14)

Species/strain:	rat/Crj:CD (SD)
Number/sex of animals:	5 test groups, each had 10/sex; additionally, 3 dosing groups (0, 300 and 1 000 $mg.kg^{-1}day^{-1}$) had 6/sex as recovery groups
Method of administration:	oral gavage
Dose/Study duration:	5 doses (0, 30, 100, 300 and 1 000 $mg.kg^{-1}day^{-1}$) were given by oral gavage daily for 28 days to males and for 29 days to females
Clinical observations:	no signs of systemic toxicity
Clinical chemistry/Haematology	no abnormal changes related to the treatment
Histopathology:	no abnormal changes related to the treatment
Test method:	similar to OECD Guideline (1)
Result:	the notified chemical showed no organ toxicity at dose up to 1 000 $mg.kg^{-1}.day^{-1}$ for 28 days in rats

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (15)

Strains:	*Salmonella typhimurium* TA 98, TA 100, TA 1535 and TA 1537
Concentration range:	50 to 5 000 μg per plate either with or without metabolic activation provided by rat liver S9
Test method:	similar to OECD Guidelines (1) (16)
Result:	the notified chemical was not mutagenic in bacteria under the test conditions

9.3.2 In vitro chromosomal aberration test (17)

Species/strain:	Chinese Hamster lung cells (CHL/IU)
Concentration range:	20 - 5 000 $\mu g.mL^{-1}$
Method of administration:	in the presence of rat liver drug-metabolising enzymes, the cells were treated with the notified chemical for 6 hours, and then cultured for further 13 and 18 hours in the absence of metabolic activation, the cells were treated with the notified chemical either by continuous treatment (24 and 48 hours) or by 6 hours pulse treatment (treated for 6 hours and harvest after 24 hours)
Test method:	similar to OECD Guidelines (1)
Result:	results were negative with metabolic activation and positive without metabolic activation; the notified chemical has a potential to induce chromosomal aberrations in CHL/IU in culture in the absence of metabolic activation system under the test conditions

9.4 Overall Assessment of Toxicological Data

Reactive Red 202 was of low acute oral (LD_{50} greater than 5 000 $mg.kg^{-1}$) and dermal (LD_{50} greater than 2 000 $mg.kg^{-1}$) toxicity in rats. It was a slight eye irritant, but not a skin irritant in rabbits. Reactive Red 202 is a moderate skin sensitiser in guinea pigs. In a 28 day study, rats treated at up to 1 000 $mg.kg^{-1}.day^{-1}$ exhibited no signs of systemic toxicity. In the presence or absence of metabolic activation, the chemical was not mutagenic in bacteria. It had the potential to induce chromosomal aberrations in the absence of metabolic activation in the *in vitro* mammalian cytogenetic test.

On the basis of submitted data, the notified chemical would not be classified as hazardous in accordance with NOHSC *Approved Criteria for Classifying Hazardous Substances* (18) in relation to acute lethal (oral, dermal) effects; irritation (eye, skin), and effects after repeated or prolonged exposure. However, the notified chemical would be classified as hazardous based on the skin sensitisation study presented in the submission.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier for dyestuff, containing Reactive Red 202 ester, vinyl and hydroxy components. Tests were performed according to OECD Test Guidelines at facilities complying with OECD Principles of Good Laboratory Practice.

Test	Species	Results (Nominal)	Reference
Acute Toxicity 96 h Semi-static	Carp *(Cyprinus carpio)*	LC_{50} > 1 000 $mg.L^{-1}$ NOEC = 1 000 $mg.L^{-1}$	(19)
Acute Immobilisation 48 h Static	Water Flea *(Daphnia magna)*	EC_{50} = 652 $mg.L^{-1}$ NOEC = 320 $mg.L^{-1}$	(20)
Chronic Toxicity 21 days Semi-static	Water Flea *(Daphnia magna)*	<u>Reproduction</u> EC_{50} = 22 $mg.L^{-1}$ NOEC = 6 $mg.L^{-1}$ <u>Parent Mortality</u> LC_{50} = 97 $mg.L^{-1}$ NOEC = 18 $mg.L^{-1}$	(21)
Growth Inhibition: Growth μ, Biomass b 72 h Static	Algae *(Scenedesmus subspicatus)*	$E\mu C_{50}$ > 100 $mg.L^{-1}$ NOEC(μ) = 4 $mg.L^{-1}$ EbC_5 = 32 $mg.L^{-1}$ NOEC(b) = 4 $mg.L^{-1}$	(22)
Respiration Inhibition 0.5 h	Aerobic Waste Water Bacteria	IC_{50} > 100 $mg.L^{-1}$ NOEC > 100 $mg.L^{-1}$	(23)

Fish

Based on the results of the range finding test, the final study was a limit test exposing carp to nominal concentrations of 1 000 $mg.L^{-1}$. The test media were renewed every 24 hours, with final test solutions clear red without precipitation.

The concentration of the total mixture remained greater than 90% during the 24 hour period of renewal. Results of analysis indicated that the concentration of Reactive Red 202 (ester) decreased but remained greater than 80% over 24 hours. The concentration of Reactive Red 202 (vinyl) increased almost proportionally to the decrease of the ester. This finding indicated that Reactive Red 202 (ester) is converted to Reactive Red 202 (vinyl).

During the 96 hour exposure period, no mortality of fish or any other effects were observed. In conclusion, the 96 h LC_{50} for carp indicates that the notified chemical is practically non-toxic to fish.

Aquatic Invertebrates

Acute
Daphnia were exposed to nominal concentrations ranging from 100 to 1 000 $mg.L^{-1}$ for 48 hours. After 48 hours, the relative concentrations of Reactive Red 202 (hydroxy) remained constant, whereas a “significant decrease” of the ester was observed, which was almost proportional to the increase of the vinyl.

Note that the rate of conversion was higher at lower concentrations. Apart from the conversion, the total concentration of the three components remained greater than 90%.

After 24 hours no significant immobilisation (10% and higher) was observed at any of the concentrations tested (one immobilised daphnid in one replicate at 560 $mg.L^{-1}$). After 48 hours of exposure, the total rate of immobilisation of daphnia was 85% at 1 000 $mg.L^{-1}$ and 40% at 560 $mg.L^{-1}$. No immobilisation of daphnia was observed at or below 320 $mg.L^{-1}$.

The 48 hour EC_{50} for the notified chemical (total mixture) was calculated by probit analysis to be 652 $mg.L^{-1}$ with a 95% confidence interval ranging from 578 to 776 $mg.L^{-1}$ when based on nominal concentrations. As such, the notified chemical can be expected to be practically non-toxic to aquatic invertebrates.

Chronic
The duration of the study was 21 days and the test solutions were renewed every two days. Analytical data showed that the concentrations of the total mixture of the chemical were greater than 90% of nominal at all test concentrations, except at 6 $mg.L^{-1}$ where concentrations were between 80 and 90%.

During the exposure period, a test concentration related mortality was recorded with a total of 10% mortality at 18 $mg.L^{-1}$, 40% at 60 $mg.L^{-1}$, 50% at 176 $mg.L^{-1}$ and 100% at 600 $mg.L^{-1}$, resulting in an LC_{50} of 97 $mg.L^{-1}$ (probit analysis). No mortality was recorded at 6 $mg.L^{-1}$ and in the control. The parental daphnids exposed to 600 $mg.L^{-1}$ did not develop eggs in the brood pouch before they all had died after 8 days. Daphnids exposed to 176 $mg.L^{-1}$ developed eggs from day 9, but these did not develop to living offspring. A similar but slightly less severe result was observed at 60 $mg.L^{-1}$.

Test results indicate that the notified chemical is at worst, very slightly toxic to aquatic invertebrates under chronic exposure conditions (24). The overall LOEC and NOEC were calculated to be 18 $mg.L^{-1}$ and 6 $mg.L^{-1}$, respectively.

Algae

After a range finding test, Reactive Red 202 was exposed to exponentially growing algal cultures for 72 hours, at concentrations ranging from 0.8 to 100 $mg.L^{-1}$. The concentration of the total mixture remained greater than and equal to 90% during the 72 hour test period.

Inhibition of cell growth (biomass b) increased with increasing concentrations of the notified chemical from 4 $mg.L^{-1}$ upwards, resulting in 79% inhibition at 100 $mg.L^{-1}$. Growth rate (μ) reduced with increasing concentrations of the notified chemical from 9 $mg.L^{-1}$ upwards. The average response remained just below 50% at 100 $mg.L^{-1}$. Statistically significant 'cell growth' and 'reduction of growth' rate was found at test concentrations of 9 $mg.L^{-1}$ and higher.

The notifier claims that the effect on algal growth may have been at least partially caused by the absorption of light owing to the colour of the test solutions, i.e.

deleterious effects can be caused by the interception of light (shading effect) necessary for algal growth. The notified chemical is a red dyestuff which may have interfered with the wave lengths necessary for normal algal growth (from ca. 360 to 480 nm).

Nonetheless, it should be noted that for environmental purposes, growth inhibition, whether due to chemical or physical factors, is of relevance. Algistatic effects may lead to an undesirable environmental impact if exposure is continuous. Thus, the notified chemical can be considered as slightly toxic to algae.

Microbes

No significant inhibition (greater than 10%) in the respiration rate of the sludge was recorded at 100 $mg.L^{-1}$. After 0.5 hours, 8 and 3% inhibition of oxygen consumption was recorded. The IC_{50} result indicates that the notified chemical is practically non-toxic to aerobic waste water bacteria. However, over periods of exposure greater than 0.5 hours, the toxicity could increase.

Conclusions

Considering ecotoxicity test results, the dyestuff can be considered practically non-toxic to fish, aquatic invertebrates (acute and chronic exposure) and aerobic waste water bacteria. The slightly toxic rating to algae is most probably due to deleterious effects caused by the interception of light (shading effect).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

A limited number of dyehouses in one region will be using the notified dye. The notifier has indicated that the six dyehouses will use approximately 50 kg per day, with a total combined daily effluent output of 12 ML. Thus, the environmental hazard has been determined for the combined Melbourne based dyehouses with waste water treatment at Werribee Farm.

The Predicted Environmental Concentration (PEC) is estimated below. These calculations assume that minimum fixation occurs (60%), no dye is removed in treatment of the different waste effluents and represents the worst case scenario for dyehouses.

Predicted Environmental Concentration (PEC)

Calculation Factor	Combined Dyehouses
Approximate use of dye expected per day	50 kg
Amount of active (notified chemical) in commercial product (@ 80% active)	40 kg
Weight of active lost due to wash-off and unfixed residues (fixation 60-80%)	16 kg
Total combined effluent output	12 000 000 L
Influent concentration	1.33 $mg.L^{-1}$
Dilution factor in sewage treatment plants (> 500 ML treated per day)	1:42
Concentration balance in effluent from sewage treatment plant	0.03 $mg.L^{-1}$
Dilution factor in receiving waters	1:10 (ocean)
PEC in receiving waters	3.17 $\mu g.L^{-1}$ (3.17 ppb)
Safety factor for Algal NOEC of 4 $mg.L^{-1}$	1 260

These calculations show that the exposure to fish, daphnia and algae will be at levels unlikely to cause any significant effect. Dye concentrations greater than 1 ppm can give rise to intensely coloured effluent that is unacceptable to waste water authorities (3) (25). Therefore, it is unlikely that concentrations higher than this will enter natural aquatic systems.

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

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Reactive Red 202 has low oral and dermal toxicity, is not a skin irritant but is a slight eye irritant and a moderate skin sensitiser. In the 28-day repeat dose study, treated rats exhibited no signs of systemic toxicity. Reactive Red 202 was not genotoxic in an Ames test either with or without metabolic activation but did yield a positive result in an *in vitro* chromosomal aberration test using Chinese Hamster lung cells in the absence of metabolic activation. Reactive Red 202 would not be classified as hazardous in relation to acute lethal effects (oral and dermal), irritant

effects (skin and eye) or repeat dose toxicity according to NOHSC *Approved Criteria for Classifying Hazardous Substances (18)*, but would be classified as hazardous with respect to skin sensitisation. Reactive Red 202 warrants the risk phrase R43 (May cause sensitisation by skin contact). The chemical cut-off concentration requiring this phrase is greater than or equal to 1%.

The vapour pressure of the notified chemical is low. A small proportion of particles is within the inspirable size range, so exposure via inhalation is possible and dust mitigation processes are needed. The most likely route of exposure would be dermal contamination.

Occupational exposure during transportation and storage will only occur in the event of an accident. The dye weighers and mixers directly handle the notified chemical and could be contaminated during manually weighing and mixing procedures. Personal protective equipment (PPE) is necessary for weighers and mixers. The dye machine operators could be contaminated with the notified chemical while loading and unloading fabrics. A closed system is used for the dyeing process. Exposure is expected to be more controlled than that of the dye weighers and mixers, as the concentration of the notified chemical in the solution will be low and a closed mechanised process is used for dyeing and washing the dyed fabrics. PPE is considered to be necessary for the dye machine operators as the notified chemical is classified as a skin sensitiser. To minimise the generation of dust, exhaust ventilation should be maintained at workplaces. Employers are responsible for ensuring that the NOHSC exposure standard for inspirable dust of 10 $mg.m^{-3}$ is not exceeded.

Reactive Red 202 is a highly water soluble, reactive dyestuff. Following the commercial dying of fabrics, excess dye is readily removed from the fabric by water rinsing. Dye remaining on the fabric is irreversibly bonded and will not be bioavailable, thus exposure of the public to the dye will be negligible. Provided this chemical is not made available directly to the public for use in the home, public exposure and therefore public risk is negligible.

13. RECOMMENDATIONS

To minimise occupational exposure to Reactive Red 202 the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (26) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (27);
- Industrial clothing should conform to the specifications detailed in AS 2919 (28) and AS 3765.1 (28);
- Impermeable gloves or mittens should conform to AS 2161 (30);

- All occupational footwear should conform to AS/NZS 2210 (31);
- Respiratory protective device should confirm to AS/NZS 1715:1994;
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be 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.
- Reactive Red 202 warrants the risk phrase R43 (May cause sensitisation by skin contact). The chemical cut-off concentration requiring this phrase is greater than or equal to 1%.
- To minimise the generation of dust, exhaust ventilation should be maintained at workplaces. There is a NOHSC exposure standard for inspirable dust of 10 $mg.m^{-3}$. Employers are responsible for ensuring this exposure standard is not exceeded.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the product containing the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (32).

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. Organisation for Economic Co-operation and Development. 1995-1996. *OECD Guidelines for the Testing of Chemicals on CD-Rom*. Paris: OECD
2. European Economic Community. 1992. *EEC Directive 92/69, Methods for the determination of toxicity*

3. Hobbs, S. 1988. *Industry category document: UK dye production and use in the textile industry*: Department of Environment (UK)

4. Koopmans, M. 1993. Determination of 'ready' biodegradability: carbon dioxide (CO2) evolution test (modified Sturm test) with Reactive Red 202. NOTOX B.V. The Netherlands

5. Connell, D. W. 1989. General characteristics of organic compounds which exhibit bioaccumulation. In *Bioaccumulation of Xenobiotic Compounds*, ed. D. W. Connell. Boca Raton: CRC Press

6. Yen, C. P., Perenich, T. A., Baughman, G. L. 1991. Fate of Commercial Disperse Dyes in Sediments. *Environmental Toxicology and Chemistry* 10:1009-1017

7. Anliker, R., Moser, P., Poppinger, D. 1988. Bioaccumulation of dyestuffs and organic pigments in fish. Relationships to hydrophobicity and steric factors. *Chemosphere* 17:1631-1644

8. Kato, T. 1993. Acute oral toxicity study of Reactive Red 202 in rats: Sumitomo Chemical Co Ltd

9. Kato, T. 1993. Acute dermal toxicity study of Reactive Red 202 in rats: Sumitomo Chemical Co Ltd

10. Kato, T. 1992. Primary eye and skin irritation tests with Reactive Red 202 in rabbits: Sumitomo Chemical Co Ltd

11. Yoshitake, A. 1993. Skin sensitisation test of Reactive 202 in guinea pigs: Sumitomo Chemical Co Ltd

12. Draize, J. H. 1959. Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. *Association of Food and Drug Officials of the US* 49:2-56

13. Magnusson, B., Kligman, A. M. 1970. *Allergic Contact Dermatitis in the Guinea-pig: Identification of Contact Allergens,* Thomas, Springfield, Illinois.

14. Nishimoto, Y. 1993. 28-day oral toxicity study of Reactive Red 202 in rats: Sumitomo Chemical Co Ltd

15. Yoshitake, A. 1993. Reverse mutation test of Reactive Red 202 in bacterial system: Sumitomo Chemical Co Ltd

16. Ames, B. N., McCann, J., Yamasaki, E. 1975. Methods for detecting carcinogens and mutagens with the Salmonella/mammalian-microsome mutagenicity test. *Mutation Res.* 31:347-364

17. Yoshitake, A. 1993. in vitro chromosomal aberration test of Reactive Red 202 in Chinese Hamster lung cells (CHL/IU): Sumitomo Chemical Co Ltd

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

19. Bogers, M. 1993. 96 hours acute toxicity study in the carp with Reactive Red 202. NOTOX B.V., The Netherlands

20. Bogers, M. 1993. Acute toxicity study in *Daphnia magna* with Reactive Red 202. NOTOX B.V., The Netherlands

21. Bogers, M. 1996. *Daphnia magna,* Reproduction test with Reactive Red 202 (Semi-Static), Project 158862, NOTOX B.V., The Netherlands.

22. Bogers, M. 1993. *Scenedesmus subspicatus* fresh water algal growth inhibit test with Reactive Red 202. NOTOX B.V., The Netherlands

23. Koopmans, M. 1994. Activated sludge respiration inhibition test with Reactive Red 202. NOTOX B.V., The Netherlands

24. Mensink, B., Montforts, M., Wijkhuizen-Maslankiewicz, L., Tibosch, H., JBHJ, L. 1995. Manual for summarising and evaluation the environmental aspects of pesticides. Bilthoven, The Netherlands: National Institute of Public Health and Environmental Protection

25. Shu, H.-Y., Huang, C.-R. 1995. Degradation of commercial azo dyes using ozonisation and UV enhanced ozonisation process. *Chemosphere* 31:3813-3825

26. Standards Australia. 1994. *Australian Standard 1336-1994, Eye protection in the Industrial Environment*. Sydney: Standards Association of Australia

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

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

29. Standards Australia. 1990. *Australian Standard 3765.1-1990, Clothing for Protection against Hazardous Chemicals Part 1 Protection against General or Specific Chemicals*. Sydney: Standards Association of Australia

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

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

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

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