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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Reactive Green DER 7766 (FAT 40521/A)

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Reactive Green DER 7766 (FAT 40521/A)

1. APPLICANT

Ciba-Geigy Australia Ltd of 235 Settlement Road THOMASTOWN 3074 has submitted a standard notification statement in support of an application for an assessment certificate for Reactive Green DER 7766 (FAT 40521/A).

2. IDENTITY OF THE CHEMICAL

Reactive Green DER 7766 (FAT 40521/A) is not considered to be hazardous based on the nature of the dye and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data and the full identity of all components of the notified dye have been exempted from publication in the Full Public Report and the Summary Report.

Other names:	azo dye (generic name)
Trade name:	Reactive Green DER 7766 (FAT 40521/A) Cibacron Green LS-3B (product containing notified dye)
Method of detection and determination:	physical testing; infrared spectroscopy; UV-visible absorption spectra; nuclear magnetic resonance (NMR) spectroscopy

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	dark blue powder at 20°C
Melting point:	> 300°C (at 760 mm Hg)
Specific gravity:	1.78
Vapour pressure:	1.9×10^{-41} kPa at 25°C (calculated)
Water solubility:	> 424 g/L at 20°C

Partition co-efficient (n-octanol/water):	log K_{ow} < -2 (calculated; see comments below)
Hydrolysis as a function of pH:	$T_{1/2}$ at pH 4.0 = 133 days (estimated) $T_{1/2}$ at pH 7.0 = 4.5 days $T_{1/2}$ at pH 9.0 = 1.0 day
Adsorption/desorption:	not performed; anticipated that the notified dye will bind/absorb to positively charged substances such as clay particles or organic matter, given the ionic nature of the main component
Dissociation constant:	the pK_a values calculated for each of the acidic protons in the molecular structure of the main component ranged from -8.4 to 6.9
Particle size:	< 10 μm: 12.5% 10 μm - 36 μm: 37.5% 36 μm-100 μm: 41.4% > 100 μm: 8.6%
Surface Tension:	62.2 mN/m at 19.8°C (notified dye dissolved in water)
Flash point:	notified dye is not flammable
Flammability limits:	notified dye is not flammable
Autoignition temperature:	318°C
Explosive properties:	not explosive
Reactivity/stability:	considered stable under conditions of intended use

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 vapour pressure was calculated from the calculated boiling point using the Modified Watson Correlation.

It is unclear from the hydrolysis test report what the hydrolysis products will be, as they have not been stated by the notifier. However, under basic conditions it is likely that the chlorine on the main component of the dye will be substituted to form the hydroxyl phenol group.

The partition coefficient was estimated to be less than -6.2 by calculation using the

saturation concentration of the notified dye in pure solvents. However, the results obtained by the preliminary partitioning experiment has shown that log P_{ow} lies outside the range accessible by the flask shaking method. Therefore the log P_{ow} was estimated to be less than -2.

Adsorption/desorption data were not provided. High water solubility and low partition coefficient would normally indicate low affinity for soil or sediment. The notifier anticipates that the notified dye is likely to bind/adsorb to the positively charged substances such as clay particles or organic matter given the ionic nature of the main component of the dye. The latter is questioned by the EPA and would only be the case where there is a co-ordination to soil cations.

It is expected that the dye will not be surface active. By EEC definition (EEC Directive 92/69), a chemical has surface activity when the surface tension is less than 60 mN/m (2).

4. PURITY OF THE CHEMICAL

Degree of purity:

the notified dye consists of more than 50 known and unknown components, as determined by high performance liquid chromatography (3)

the notified dye was also screened for the presence of inorganic ions, a carboxylic acid and water; the CAS number provided by the notifier covers all of the described dye components

unsulfonated aromatic amines were screened for, but not detected at the threshold of the method (10 mg/kg) (3)

5. USE, VOLUME AND FORMULATION

Reactive Green DER 7766 (FAT 40521/A) will not be manufactured in Australia. The notified dye will be imported as a component of Cibacron Green LS-3B, which will be used for the colouration of cellulose textiles by the exhaust dyeing method. The concentration of Reactive Green DER 7766 (FAT 40521/A) in the end use product (Cibacron Green LS-3B) will be less than 90%.

The anticipated annual import volumes are as follows:

		Year		
		1	2-3	4-5
Import Volume (tonnes)	***Product***	< 6	< 10	< 15
	Notified Dye	< 5.4	< 9	< 13.5

6. OCCUPATIONAL EXPOSURE

The notified dye will be imported at a concentration of less than 90% in the product Cibacron Green LS-3B in 30 kg cardboard containers with antistatic polyethylene lining. Waterside, warehouse and transport workers are unlikely to come into contact with the notified dye except in the event of an accident or leaking packaging.

There may be minimal repacking of the dye by the notifier. Inhalational, dermal and ocular exposure may occur when workers are weighing and repackaging the pure powdered dye. 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, and the notifier states that there will also be ventilation in the weighing area which will prevent a build up of dye dust. However, approximately 90% of the particles fall within the size range considered inspirable by the International Organisation for Standardisation (cited in (4)). Only 6% of the particles would be, however, considered fine enough to enter the lower regions of the respiratory tract (cited in (4)).

The notifier states that the product will be used exclusively for exhaust dyeing processes. Workers will initially weigh the product, using a scoop to transfer it from the 30 kg box to a weighing container. The potential for inhalational exposure at this stage is moderate, as 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. The notifier states that the expected duration of exposure to the notified dye in liquid form is 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 product containing the notified dye will not be available to the public directly. Minimal public exposure can be expected during the transport of the notified dye or products containing it, although the notified dye could be wind dispersed despite the inclusion of anti-dusting agents.

The level of public exposure due to dust formation during repackaging by the importer or mixing prior to use in the dye houses is low, due to the inclusion of anti-dusting agents in the product.

Widespread and prolonged contact by the public with textiles dyed with the product can be expected, particularly if those textiles are manufactured into clothing or bedding.

8. ENVIRONMENTAL EXPOSURE

Release

The bulk of the dye will become fixed to the cellulose textiles, and in this state is not expected to impact on the environment. The result of fastness performance tests shows that a high order of fastness rating is achieved in all cases.

The major release of the dye will come from the discharge of dyehouse effluent and waste water treatment systems. Other releases will be limited to traces remaining from clean-up of any spills, repacking operations and trace residues in empty packaging (estimated at a maximum of 0.1%).

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

Fate

The dye normally released in water as effluent from the dyehouse is expected to be the major environmental release. The dye in the effluent is expected to be mainly in the hydrolysed form. The dye may either partition to sediment or stay in the aqueous compartment. Any dye that binds to the sludge during the waste treatment process would be disposed of through incineration or landfill. Incineration is the preferred disposal route 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. There could also be some acidic chlorine combustion products. Disposal by landfill should be carried out at a secured site, so the risk of leaching to the water table is significantly reduced.

The biological oxygen demand (BOD) of the dye was tested and the five day study showed the BOD_5 is 0 mg O_2/g. The dye was found to be slightly biodegradable (12.7% after 28 days) in the OECD 301A Test (1) for ready biodegradability, but it did not inhibit bacteria. Although the dye is only slightly biodegradable, the potential for bioaccumulation is low due to the low partition coefficient (log P_{ow} < -2.0) and high water solubility of the substance.

Residues that survive sewage treatment will enter freshwater or marine environments in solution where the dye would quickly become diluted to levels well below that likely to be toxic to aquatic organisms. Azo dyes are generally stable under aerobic conditions, but are susceptible to reductive degradation under anaerobic conditions characteristic of sediment (5). Also, highly sulphonated *bis*(azo) dyes have been shown to sorb to sediment (6). 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

(7). 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. However, apart from precipitation as the calcium salt, the hydrophilic nature of the notified dye and its sulphonated metabolites should limit the affinity for soil and sediment and thus the dye should remain in the aquatic compartment.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Reactive Green DER 7766 (FAT 40521/A)

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	non-irritant	(11)
skin sensitisation	guinea pig	non-sensitising	(12)

9.1.1 Oral Toxicity (8)

Species/strain:	rat/Wistar
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	gavage; test substance was dissolved in distilled water
Clinical observations:	none
Mortality:	none
Morphological findings:	none
Test method:	according to OECD guidelines (1)
LD_{50}:	> 2 000 mg/kg

Result:	the notified dye was of low oral toxicity in a limit test in rats

9.1.2 Dermal Toxicity (9)

Species/strain:	rat/Wistar
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	test substance was dissolved in distilled water and applied to one intact skin site on each animal; site covered with semi-occlusive dressing; dressing removed after 24 hours and skin washed with water
Clinical observations:	scales were noted on 5 males and 1 female from day 6 to the end of the study; blue discolouration of the skin was present for all animals for the duration of the study
Mortality:	none
Morphological findings:	none
Test method:	according to OECD guidelines (1)
LD_{50}:	> 2 000 mg/kg
Result:	the substance was of low acute dermal toxicity in rats

9.1.3 Inhalation Toxicity

Not performed

9.1.4 Skin Irritation (10)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	1 male; 2 females
Observation period:	72 hours

Method of administration:	0.5 g of the test substance was applied to a 6 cm^2 intact dorsal skin site; skin covered by gauze and semi-occlusive dressing for 4 hours; site washed with water after dressing was removed; observations made at 1 hour, 2, 3 and 4 days after removal of dressing and scored according to the method of Draize (13)
Test method:	according to OECD guidelines (1)
Result:	there were no Draize scores greater than 0; the test substance was found not to be irritating to intact rabbit skin

9.1.5 Eye Irritation (11)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	1 male; 2 females
Observation period:	72 hours
Method of administration:	0.1 g test substance was placed into the conjunctival sac of the left eye; right eye served as control
Comments:	vocalisation (approx 5 seconds) noted in one female after substance was applied; nictitating membrane of the treated eye of all animals was stained blue for the duration of the study; 2 animals had a score of 1 for conjunctival redness and chemosis at 24 hours; all scores were zero for the 48 and 72 hour readings
Test method:	according to OECD guidelines (1)
Result:	test material was a mild eye irritant in rabbits

9.1.6 Skin Sensitisation (12)

Species/strain: guinea pig/albino

Number of animals: 30 females; 10 control, 20 test

Induction procedure:

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

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

Day 8: occluded application of 30% concentration of test material in vaselinum album for 48 hours

Challenge procedure:

Day 22: occluded application of 30% solution of test material in vaselinum album for 24 hours

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hrs****	***48 hrs****	***24 hrs***	***48 hrs***
30%	2/20**	0/20	0/10	0/10

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

Test method: according to OECD guidelines (1)

Result: the test material was a mild skin sensitiser in guinea pigs

9.2 Repeated Dose Toxicity (14)

Species/strain: rat/Wistar

Number/sex of animals: 30/sex; Groups 1 and 4: 10/sex
Groups 2 and 3: 5/sex

Method of administration: gavage

Dose/study duration::	test material administered daily for a total of 28 days: Group 1: 0 mg/kg/day Group 2: 50 mg/kg/day Group 3: 200 mg/kg/day Group 4: 1 000 mg/kg/day All animals were sacrificed at the end of the treatment period, with the exception of 5 animals from Group 1 and Group 4, which were maintained for an additional 2 week recovery period before sacrifice
Mortality:	one female in the 1 000 mg/kg/day dose group died on the day of scheduled necropsy
Clinical observations:	none
Clinical chemistry/haematology	no changes of toxicological significance in haematology, urinalysis and clinical biochemistry; minor effects noted in animals in 1 000 mg/kg/day dose group at the end of the treatment period included: marginally increased reticulocyte count in males; marginally increased methaemoglobin concentration in females; slightly increased uric acid concentration in males and females; slightly decreased calcium and sodium concentration in males; slightly decreased potassium concentration in females; urine discolouration in group 3 and 4 animals; these findings were reversed by the end of the treatment-free recovery period
Necropsy findings:	no treatment related changes; black-brown discolouration of the kidneys attributed to discolouration by test substance
Histopathology:	no treatment related findings
Test method:	according to OECD guidelines (1)
Result:	no treatment-related findings noted at necropsy or during histopathology examination for both male and female rats when test substance was administered by gavage for a period of 28 days

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (15)

Strains:	*Salmonella typhimurium* TA 1535, TA 1537, TA 98, TA 100 and *Escherichia coli* strains *WP2* and *WP2uvrA*
Concentration range:	33.3, 100, 333, 1 000, 2 500 and 5 000 μg/plate
Test method:	according to OECD guidelines (1)
Result:	test material was not mutagenic in the bacterial strains tested in the presence or absence of metabolic activation provided by rat liver S9 fraction

9.3.2 Chromosome Aberration Assay in Chinese Hamster V79 Cells (16)

Dosing schedule:	without S9 mix: 30 - 300 μg/mL - treatment time 18 hours and 28 hours with S9 mix: 300 - 5 000 μg/mL - treatment time 4 hours For all treatment groups, cells were prepared 18 hours and 28 hours after the start of treatment and scored for structural chromosomal aberrations
Test method:	according to OECD guidelines (1)
Result:	the notified dye 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 dye exhibited low acute toxicity when administered orally (LD_{50} > 2 000 mg/kg) and dermally (LD_{50} > 2 000 mg/kg) to rats. Inhalation toxicity tests were not performed, as the notifier states that an anti-dusting agent is incorporated into products containing the notified dye. The dye was found not to be a skin irritant, but was found to be a mild eye irritant in rabbits. When tested in guinea pigs, Reactive Green DER 7766 (FAT 40521/A) was a mild skin sensitiser.

There were no treatment related changes noted in rats when the test substance was

administered by gavage for a period of 28 days, and although minor changes in some haematology and urinalysis parameters were noted in animals from the highest dose group, these were reversed by the end of a 2 week period without treatment. No mutagenicity was observed in bacteria and no clastogenicity was observed in Chinese hamster cells *in vitro*.

Based on the animal data summarised above, Reactive Green DER 7766 (FAT 40521/A) would not be classified as hazardous according to Worksafe's *Approved Criteria for Classifying Hazardous Substances* (17).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

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

Summary of the environmental toxicity of Reactive Green DER 7766 (FAT 40521/A)

Test	***Species***	***Result (nominal)***
Acute Toxicity	Rainbow Trout	96h NOEC & EC_0 48 mg/L
Acute Immobilisation	*Daphnia magna*	48h NOEC & EC_0 75 mg/L
Growth Inhibition (growth and biomass)*	Green algae *(Scenedesmus subspicatus)*	Experiment A NOEC = 0.32 mg/L Experiment B NOEC = < 0.32 mg/L
Respiration Inhibition	Aerobic Waste Water Bacteria	EC_{50} > 100 mg/L

*The method of this test was modified to differentiate between a reduced growth of algae due to real toxic effects of the notified dye on the algal cells (Experiment A) or due to an indirect effect, a reduced algal growth by light absorption in coloured test solutions (Experiment B).

Due to the instability of the notified dye, possibly due to hydrolytic degradation, the reported biological results are related to the nominal test concentrations and to the mean measured values, calculated over all measurements during the test periods. Test media of a nominal concentration of 1 mg/L were strongly coloured by the notified dye.

The ecotoxicity data for the substance shows that the dye is slightly toxic to Rainbow Trout and *Daphnia magna*. Due to the intense colouration of the test media, no remarkable observations were made concerning the behaviour of the fish. The 96 hour LOEC and the 96 hour LC_{50} for the fish species and the 48 hour LOEC and the 48 hr EC_{50} for the daphnia were clearly higher than the nominal 100 mg/L, however these values have not been quantified.

The modified growth inhibition test showed that there was almost the same growth inhibition of *Scenedesmus subspicatus* when the algae grew in test water without the test substance, but with reduced light intensities, which simulated the filter effect of the coloured test media. As the test solution is intensely coloured, deleterious effects can be caused by the interception of light (shading effect). Therefore, the real toxic effect of the notified dye can be excluded up to at least the highest tested

concentration of 49 mg/L (nominal 100 mg/L), making the notified dye slightly toxic to algae.

The notified dye showed practically no toxic effects to the respiration rate of aerobic waste water bacteria in the respiration test, with an EC_{50} > 100 mg/L.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

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

The notifier has specified that a limited number of dyehouses in city and country areas will be using the notified dye. The environmental hazard has been determined for three dyehouses located in two general locations, one metropolitan based dyehouse and the other country based. Two examples of dye usage are given for country dyehouses. The Predicted Environmental Concentration (PEC) is estimated on the following page.

These calculations assume that no dye is removed in treatment of the different waste effluents and represent the worst case scenario for dyehouses. The typical use of dye per day amount was supplied by the notifier.

It has been assumed in the calculations that no removal of the dye would take place during the wastewater treatment process. However, some of the dye would probably be removed due to the adsorption of the dye to the organic sludge and possible complexation of the dye (7). Therefore, the actual concentration in receiving waters is likely to be lower than that calculated.

These calculations show that the exposure to fish and daphnia will be at levels unlikely to cause any significant effect. It was shown that the inhibition to algal growth caused by the dye was due more to the shadow effect rather than its toxicity. Dye concentrations > 1 ppm can give rise to intensely coloured effluent which is unacceptable to waste water authorities (18). Therefore, there is also unlikely to be any significant effect on algae.

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.

Predicted Environmental Concentration (PEC)

Calculation Factor	City Dyehouse	Country Dyehouse - High Dye Use	Country Dyehouse - Low Dye Use
Typical use of notified dye expected per day	30.0 kg	60.0 kg	10.0 kg
Amount of Active (at 70% Active dye components)	21.0 kg	42.0 kg	7.0 kg
Conc. in wastewater (fixation rate 82%)	3.78 kg	7.56 kg	1.26 kg
Quantity of water used incl. wash-off water (at 75 L/kg)	150 000 L	150 000 L	75 000 L
Effluent conc. in dye-specific wash-water	25.2 mg/L	50.4 mg/L	16.8 mg/L
Dilution factor in dyehouse by other wash-waters	1:13 (2 ML/day effluent)	1:13 (2 ML/day effluent)	1:26 (2 ML/day effluent)
Influent concentration	1.93 mg/L	3.87 mg/L	0.65 mg/L
Dilution factor in sewage treatment plant	1:100	1:2	1:2
Conc. balance in effluent from sewage treatment plant	0.0193 mg/L	1.935 mg/L	0.325 mg/L
Dilution factor in receiving waters	1:10 (ocean)	1:2 (river)	1:2 (river)
(PEC) in receiving waters	1.93 μg/L (1.93 ppb)	0.97 mg/L (0.97 ppm)	0.16 mg/L (0.16 ppm)

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, due to the low health hazard of the dye, and the fact that exposure will only occur in the event of an accident or leaking packaging.

There is a low occupational health risk posed to workers involved in repacking Cibacron Green LS-3B 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 states that exposure to the notified 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. Animal data indicates that the notified dye is not likely to cause skin irritation. However, cases of sensitisation have been observed with reactive dyes, and Reactive Green DER 7766 (FAT 40521/A) was a mild skin sensitiser in guinea pigs, so a sensitisation reaction may occur (possibly

skin and/or respiratory) in susceptible workers. Workers may also experience mild eye irritation if exposure occurs. 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 controlled according to Worksafe Australia's exposure standard for nuisance dusts (Time Weighted Average: 10 mg/m^3)(4) and personal protective equipment should be worn where necessary to further minimise exposure (see recommendations section).

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 dye during the dyeing process is approximately 0.2**%.** In addition, exposure times are expected to be short (several minutes per hour). The main route of exposure is expected to be dermal, and the dye is not expected to be an irritant if skin contact occurs. As discussed above, skin sensitisation may occur in susceptible individuals. If accidental eye contact occurs, mild irritation may result.

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.

In addition to being strongly bound to fabric fibres, the dye also has a high degree of fastness to washing and dry cleaning and, due to its colour value, is suitable predominantly for outerwear. As a consequence of these properties of the dye, significant transfer to the skin under normal circumstances is unlikely, and negligible residues are expected to be found in domestic washing water. Exposure of the public due to the repackaging and industrial end uses of the product is considered likely to be minimal, due to the inclusion of an anti dusting agent in the formulation. Reactive Green DER 7766 (FAT 40521/A) is considered to present a low public health risk, based on its likely use pattern and toxicological characteristics.

13. RECOMMENDATIONS

To minimise occupational exposure to Reactive Green DER 7766 (FAT 40521/A) the following guidelines and precautions should be observed:

- It is good work practice to wear industrial clothing which conforms to the specifications detailed in Australian Standard (AS) 2919 (19) and occupational footwear which conforms to Australian and New Zealand Standard (AS/NZS) 2210 (20) to minimise exposure when handling any industrial chemical;

- The Worksafe Australia document *Exposure Standards for Atmospheric Contaminants in the Occupational Environment: Guidance Note and National Exposure Standards* (4) should be used as a guide in the control of any nuisance dusts generated while handling Reactive Green DER 7766 (FAT 40521/A) in pure form;

- Spillage of the notified dye 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 dye was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (21).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified dye 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

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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