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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Monoazo Yellow BG 3247

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For Enquiries please contact the Administration Coordinator at:

Street Address: 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA
Telephone: (61) (02) 9577-9466 FAX (61) (02) 9577-9465

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Monoazo Yellow BG 3247

1. APPLICANT

Ciba Specialty Chemicals Australia Pty Ltd of 235 Settlement Road THOMASTOWN VIC 3074 has submitted a standard notification statement in support of their application for an assessment certificate for 'Monoazo Yellow BG 3247'.

2. IDENTITY OF THE CHEMICAL

Monoazo Yellow BG 3247 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data and details of exact import volume have been exempted from publication in the Full Public Report and the Summary Report.

Other Names:	FAT 40400/A Reactive Yellow 181
Trade Name:	the notified chemical will be marketed as a component of the dye Cibacron Yellow P-2RN; this will be available in both powdered and liquid forms
Molecular Weight:	< 1 000 (sodium salt)
Method of Detection and Determination:	ultraviolet/visible spectroscopy; infrared spectroscopy; nuclear magnetic resonance spectroscopy

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	the notified dye is a dark red powder
Melting Point:	> 300°C (OECD TG 102 - Capillary method, liquid bath (1))
Specific Gravity:	1.76 at 22°C (EEC 84/449 A3 - air comparison pycnometer method (2))

Vapour Pressure:	not measured, expected to be very low
Water Solubility:	> 300 g/L at 20°C (OECD TG 105 flask method (1))
Fat Solubility:	< 0.05 mg/100 g fat at 37°C (OECD TG 116 (1))
Partition Co-efficient (n-octanol/water):	log P_{ow} < -10 (estimated) (OECD TG 117 (1))
Hydrolysis as a Function of pH:	$T_{1/2}$ at pH 4.0: 163 days at 25°C $T_{1/2}$ at pH 7.0: longer than 1 year at 25°C $T_{1/2}$ at pH 9.0: longer than 1 year at 25°C (OECD TG 111 (1))
Adsorption/Desorption:	not determined
Dissociation Constant:	not determined

Particle size:

< 40 μm	2%
40 - 100 μm	8%
100 - 200 μm	23%
200 - 400 μm	21%
400 - 800 μm	26%
800 - 1 000 μm	11%
1 000-2 000 μm	2%
< 2 000 μm	4%

Surface Tension:	69.0 - 61.1 mN/m at 20°C at 1.0 g/L 43.1 - 38.9 mN/m at 20°C at 10 g/L (OECD TG 115 (1))
Flash Point:	not provided
Flammability Limits:	not flammable (can be ignited, flame does not spread)
Autoignition Temperature:	none to 400°C
Explosive Properties:	non-explosive
Reactivity/Stability:	not an oxidising agent
Fat Solubility:	< 0.05 mg/100g at 37°C

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines (1, 2) at facilities complying with OECD Principles of Good Laboratory Practice.

Vapour pressure was not determined, though the notifier expects that it will be very low. This is in agreement with similar dyestuffs previously submitted by the notifier that exhibited very low (calculated) vapour pressures. Also, the notified chemical is a high molecular weight, organic trisodium salt.

Preliminary testing revealed that at 50°C the hydrolysis of the notified chemical was less than 10% at pH 7 and 9. Hence, it has a half-life period longer than one year at 25°C at pH 7 and 9. At pH 4 at 25°C, the half-life was determined to be 3 910 hours (or 163 days). The hydrolysis products are unclear from the hydrolysis test report.

The results obtained by the preliminary partitioning experiment showed that log P_{OW} lies outside the range determinable by the flask shaking method and no further testing was performed. Therefore, the partition coefficient (log P_{OW}) was estimated to be below -10.0 by calculation using the computer model CLOGP (Release 3.42). The model is based on the formal fragmentation of the molecule into suitable substructures for which reliable log P_{OW} increments are known. The high water solubility should ensure that the log P_{OW} will be low.

Adsorption/desorption data were not provided. High water solubility and a low partition coefficient would normally indicate low affinity for soil or sediment. The notifier has indicated that some binding of the notified chemical to common soils is possible, but expects the chemical to remain relatively mobile in groundwater. It is expected that the chemical will bind to positively charged substances such as clay particles. However, the binding of the chemical to organic matter is questionable since such binding is only likely to occur only where cations are involved (3).

The notified chemical contains sulphonic acid functionalities that will be expected to completely dissociate under environmental conditions.

The notified chemical is not expected to be surface active at a concentration of 1 g/L. However, at higher concentrations, surface activity is likely to increase. By definition, a chemical has surface activity when the surface tension is less than 60 mN/m (2).

4. PURITY OF THE CHEMICAL

Degree of Purity: > 80%

Classification of Impurities: no health hazard classification of the impurities was provided by the notifier; toxicity test carried out on the notified dye, which contain the impurities, when tested are summarised in section 9 of this report

Additives/Adjuvants: commercial liquid product contains non-hazardous adjuvants (below 1%) to improve application

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured or reformulated in Australia. It will be imported in a ready to use form, as a component of the dye Cibacron Yellow P-2RN. The liquid form of the end use product will contain Monoazo Yellow BG 3247 at a concentration of less than 30% and the powdered form will contain Monoazo Yellow BG 3247 at a concentration of greater than 60%.

These end use products will be used for the colouration of cellulose textiles, using printing or exhaust dyeing methods in city dyehouses only. The notifier states that the notified chemical is expected to replace older reactive dyes on the market, which in general have lower rates of fixation. Import volumes are expected to increase to up to six tonnes of the notified chemical per year by the fifth year.

6. OCCUPATIONAL EXPOSURE

The notified dye will be imported mainly in liquid form, in 600 kg Industrial Bulk Containers (IBC). A smaller quantity of the powder commercial form will be imported in 30 kg polythene lined cardboard kegs. Exposure of transport and storage workers would occur only in the event of accidental spillage.

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

Dyeing processes involve the pumping of approximately 50 kg of the imported product from the IBC directly into the printing paste blending vessel to make 500 kg of printing paste. The notified chemical is present in the printing paste at less than 5%. During transfer, dermal exposure may occur when workers are connecting and

disconnecting hoses. Eye contact would be limited to accidents.

In the case of preparation of dye from the powdered form of the notified dye, inhalational, dermal and ocular exposure may occur during transfer of the product from 30 kg containers into a weighing container and manual transfer to a closed paste blending vessel. The powder would then be dispersed into the paste using high speed stirring.

Minimal worker exposure is expected during the automatic pumping of the coloured printing paste to an automated printing machine. Large bolts of cloth to be printed will be passed through the printing machine. After printing, the cloth is steamed immediately to fix the dye to the cellulose. The cloth is then washed in a continuous multi-tank and dried. The notifier states that worker exposure to dye containing the notified chemical is likely to occur only during equipment cleaning or repair. Such exposure will be minimal.

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

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

7. PUBLIC EXPOSURE

The imported product containing the notified chemical will not be sold to the public. Public exposure to the notified chemical during storage, distribution and industrial dyeing processes is expected to be negligible. There will be widespread public contact with fibres which are dyed with the notified chemical. However, because the dye will be chemically bonded to the cellulose fibres, public exposure from dyed cellulose textiles is expected to be negligible. The high fastness performance (80%) of the dye indicates that a small amount of dye will be discharged in the dyeing house effluent. Following treatment in waste water plants, very small amounts of the notified chemical will be disposed of to receiving waters. Sludges at the treatment plants will be disposed of by incineration or to secured landfill. Therefore, public exposure from disposal should be minimal.

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 high order of 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. 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 to be a maximum of 0.1% based on previous similar notifications by the notifier).

Fate

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 (4) 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 and potential mobility of the material. Incineration of the dye will produce oxides of carbon, nitrogen and sulfur, together with sodium salts in the ash and a small amount of hydrogen chloride. Disposal by landfill will be at a secured site, so the risk of leaching to the water table is significantly reduced.

The biochemical oxygen demand (BOD) of the dye was tested and the five day study showed the BOD_5 was 0 mg/g O_2. The chemical oxygen demand (COD) was determined to be 773 mg/g O_2. The dye was found to be not readily biodegradable (expressed as percentage elimination, biodegradation amounted to 0% at the end of the 28-day exposure to micro-organisms from a domestic waste water treatment plant) in the OECD 301A Test for ready biodegradability (modified AFNOR Test). No inhibition on the activity of the bacteria was observed in this test. The dye's inherent biodegradability was not measured.

Although the dye is not readily biodegradable, the potential for bioaccumulation is low due to the low calculated partition coefficient (log P_{OW} < -10.0), very high water solubility of the substance and low fat solubility (0.05 mg./100g). Hydrophilic dyes with log P_{OW} of less than 3 have been shown not to bioaccumulate (5). Also, biological membranes are not permeable to chemicals of very large molecular size and therefore bioaccumulation of the notified chemical is not expected (6, 7).

Residues that persist after sewage treatment will enter marine environments in solution (from city waste water treatment systems). While azo dyes are generally stable under aerobic conditions, they are susceptible to reductive degradation under anaerobic conditions characteristic of sediment (5). Also, highly sulphonated azo dyes have been shown to sorb to sediment through an anion-adsorption mechanism (3). 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 (3). 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.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Monazo Yellow BG 3247

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5 000 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	mild sensitiser	(12)

9.1.1 Oral Toxicity (8)

Species/strain:	rat/Han: WISTAR (SPF)
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	oral gavage; in bi-distilled water
Clinical observations:	diarrhoea was noted in all animals on day one only, no other clinical observations
Mortality:	none
Morphological findings:	none
Test method:	similar to OECD guidelines (1)
LD_{50}:	> 5 000 mg/kg
Result:	the notified dye was of very low acute oral toxicity in a limit test in rats

9.1.2 Dermal Toxicity (9)

Species/strain:	rats/Han:WISTAR (SPF)
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	single dermal application of 2 000 mg/kg test substance; site was covered by semi-occlusive dressing for 24 hours

Clinical observations:	no signs of systemic toxicity ;scales and yellow discolouration of the skin persisted in all animals throughout test period
Mortality:	none
Morphological findings:	none
Test method:	similar to OECD guidelines (1)
LD_{50}:	> 2 000 mg/kg
Result:	the notified dye was of low acute dermal toxicity in a limit test in rats

9.1.3 Inhalation Toxicity

Not performed. The notifier states that the end use product containing the notified dye will be supplied predominantly in the liquid form. The powdered form of the end use product will contain anti-dusting agents.

9.1.4 Skin Irritation (10)

Species/strain:	rabbit/New Zealand White (SPF)
Number/sex of animals:	2 males; 1 female
Observation period:	72 hours
Method of administration:	0.5 g of test substance was applied to a 6 cm^2 area of intact dorsal skin; test site was covered with semi-occlusive dressing for 4 hours; site was irrigated with lukewarm water once dressing removed; skin reactions were assessed at 1, 24, 48 and 72 hours after removal of the dressing and scored according to the method of Draize (13)
Draize scores (13)*:*	there were no Draize scores greater than 0; yellow discolouration of the skin occurred at all time points in all animals; no other abnormal changes were noted in the animals at any of the time points
Test method:	similar to OECD guidelines (1)
Result:	the notified dye was a not an irritant to rabbit skin

9.1.5 Eye Irritation (11)

Species/strain:	rabbit/New Zealand white (SPF)
Number/sex of animals:	1 male; 2 females
Observation period:	72 hours
Method of administration:	0.1 g of test substance was instilled into the conjunctival sac of one eye; untreated eye served as a control
Comments:	all animals had eye irritation scores score of 0 at all times after application; the eyelashes of all animals were yellow coloured at 1, 24 and 48 hours
Test method:	similar to OECD guidelines (1)
Result:	the notified chemical was a not an irritant in rabbit eyes

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): bi-distilled water (1:1 (v/v)) - 0.1 mL of 5% concentration of test material in saline - 0.1 mL of 5% concentration of test material in FCA:saline (1:1 (v/v)) Day 7: occluded application of 15% concentration of test material in saline for 48 hours
Challenge procedure:	Day 14: occluded application of 10% solution of test material in saline for 24 hours

Challenge outcome:

Challenge concentration	Test animals		Control animals	
	24 hours*	48 hours*	24 hours	48 hours
10%	2/20#	2/20	0/10	0/10

* time after patch removal
\# no of animals responding

Test method: similar to OECD guidelines (1)

Result: 10% of animals showed mild sensitisation up to 48 hours; the notified chemical has mild potential for skin sensitisation in guinea pigs but the response is below the 15% Worksafe threshold for classification as a skin sensitiser at the concentrations tested

9.2 Repeated Dose Toxicity (14)

Species/strain: rat/Han:WISTAR (SPF)

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

Method of administration: gavage

Dose/Study duration: test material administered daily for a total of 28 days:

control: 0 mg/kg/day
low dose: 50 mg/kg/day
mid dose: 200 mg/kg/day
high dose: 1 000 mg/kg/day

all animals were sacrificed at the end of the treatment period, with the exception of 5 animals from the control and high dose groups, which were maintained for an additional 2 week recovery period before sacrifice

Clinical observations: deep yellow urine in 5 out of 10 of the 1 000 mg/kg rats, colour returned to normal during recovery period; no other treatment related clinical signs

high dose (1 000 mg/kg) rats showed a slight increase in liver and heart weights during the

	treatment period in males but declined during the recovery period, variation in female heart and liver weight occurred during treatment but was not related to dose or sustained for the entire treatment period
Macroscopic findings and Histopathology:	no treatment related changes
Test method:	similar to OECD guidelines (1)
Result:	no treatment related toxicity observed

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (15)

Strains:	*Salmonella typhimurium* TA 1535, TA 1537, TA 1538, TA 98, TA 100
Concentration range:	10, 100, 333.3, 1 000, and 5 000 μg/plate
Test method:	similar to OECD guidelines (1)
Result:	the notified dye 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 Micronucleus Assay in the Bone Marrow Cells of the Mouse (16)

Species/strain:	mice/NMRI
Number and sex of animals:	5/5
Doses:	5 000 mg/kg
Method of administration:	oral gavage; 3 treatments 24 hours apart
Test method:	similar to OECD guidelines (1)
Result:	the notified dye did not induce an increase in micronuclei in mouse bone marrow cells

9.3.3 Chromosomal Aberration Assay in Chinese hamster V79 cells (17)

Dosing schedule:	with and without S9 mix for 4 hours:
	5 000 μg/mL - cells were prepared

	after 7 and 28 hours 500, 4 000, 5 000 μg/mL - cells were prepared after 18 hours
	all doses and times were scored for structural chromosomal aberrations
Test method:	according to OECD guidelines (1)
Result:	treatment related decreased mitotic index occurred in 5 000 μg/mL treated cells at 7 hours and 28 hours with and without S9 mix; at 18 hours treatment related toxicity occurred only in the S9 treated high dose group; 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 chemical exhibited low acute oral and dermal toxicity in rats (LD_{50} > 5 000 mg/kg in both studies). Inhalational toxicity studies were not performed. The notified chemical was not a skin or eye irritant in rabbits. It showed mild skin sensitising potential when tested in guinea pigs but the response at the concentrations tested was below the level for classification as a skin sensitiser according to the Worksafe *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) (18).

A repeat dose 28 day oral toxicity study in rats indicated no treatment related toxic effects.

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

Based on the toxicological studies provided by the notifier, Monoazo Yellow BG 3247 would not be classified as hazardous according to the Approved Criteria (18).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were performed in compliance with OECD/EEC Test Methods (1, 2) and according to OECD Principles of Good Laboratory Practices.

Test	Species	Results (Nominal)
Acute Toxicity (Static Test) (OECD TG 203)	Zebra Fish (*Brachydanio rerio*)	96 h LC_{50} > 1 000 mg/L
Acute Toxicity - Immobilisation Test (Static Test) (OECD TG 202)	Water Flea (*Daphnia magna*)	48 h NOEC > 1 000 mg/L
Growth Inhibition - Growth (μ) & Biomass (b) (Static Test) (OECD TG 201 ▪)	Green Algae (*Scenedesmus subspicatus*)	<u>Experiment A</u> 72 h E_bC_{50} = 15.2 mg/L 72 h $E_\mu C_{50}$ = 206 mg/L[#] 72 h LOEC(μ) = 3.2 mg/L <u>Experiment B</u> 72 h E_bC_{50} = 11.3 mg/L 72 h $E_\mu C_{50}$ = 331 mg/L[#]
Respiration Inhibition (OECD 209)	Activated Sludge Aerobic Waste Water Bacteria	3 h IC_{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 chemical 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).

[#] The $E_\mu C_{50}$ value was calculated by extrapolation; 50% inhibition in growth rate was not observed in any of the tested concentrations.

Test media, down to the lowest test concentration (nominal 1.0 mg/L), were slightly to strongly coloured by the test substance. Tests determined that the test media concentrations were all sufficiently stable.

The ecotoxicity data for the substance shows that the dye is practically non-toxic to the zebra fish and water flea. No abnormal responses of the fish were observed during testing.

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 under reduced light intensities by the filter effect of the coloured test media, to when the algae grew in directly in the test media with the dissolved test substance. Since the test solution is intensely coloured, deleterious effects can be caused by the interception of light (shading effect) necessary for algal growth. Therefore, the notifier claims that the real toxic effect of the notified chemical can be excluded up to at least the highest tested concentration of 100 mg/L.

However, it should be noted that for environmental purposes, growth inhibition, whether due to chemical or physical factors, is still of relevance. Algistatic effects may still lead to an undesirable environmental impact if exposure is continuous and therefore the calculated and determined EC_{50}'s for algae should not be disregarded. Thus, the notified chemical can be considered as slightly (bordering on moderately) toxic to algae.

The notified chemical showed practically no toxic effects to the respiration rate of aerobic waste water bacteria in the respiration test, with a 3 hour IC50 greater than 100 mg/L.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

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

The notifier has specified that a limited number of dyehouses (three) in city areas will be using the notified dye, thus the environmental hazard has been determined for a metropolitan based dyehouse. The Predicted Environmental Concentration (PEC) is estimated below.

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 and is claimed to be the expected maximum useable for any one days printing.

Predicted Environmental Concentration (PEC)

Calculation Factor	City Dyehouse
Typical use of dye expected per day (over 75 days in a year)	100 kg
Amount of Active (notified chemical) in 33% commercial product (@ 84% Active)	23.0 kg
Weight of Active Lost - due to wash-off and unfixed residues (fixation 80%)	5.35 kg
Quantity of water used including wash-off water (@ 100 L/kg)	400 000 L
Effluent concentration in dye-specific wash-water	13.4 mg/L
Dilution factor in dyehouse by other wash-waters	1:6.25 (2.5 ML/day effluent)
Influent concentration	1.85 mg/L
Dilution factor in sewage treatment plant	1:100
Conc. balance in effluent from sewage treatment plant	0.0185 mg/L
Dilution factor in receiving waters	1:10 (ocean)
PEC in receiving waters	1.85 μg/L (1.85 ppb)
Safety factor for exposure to most sensitive aquatic organism, Algae (E_bC_{50} = 11.3 mg/L)	6 125

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 (3). 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 is 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 greater than 1 ppm can give rise to intensely coloured effluent that is unacceptable to waste water authorities (3, 4, 19). 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 Material Safety Data Sheet (MSDS) is adequate to limit the environmental exposure and therefore limit the environmental effects.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

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

The majority of the notified chemical will be imported as a component of a liquid dye formulation. A small amount of repackaging the powdered form of the dye may occur, however, this will then be dispersed into a paste prior to dyeing. There is a low occupational health risk posed to the limited number of workers who may be involved in handling powdered dye products containing Monoazo Yellow BG 3247. Workers may be exposed to the notified chemical via dermal, inhalational and ocular routes. The notifier states that exposure to the notified chemical will be reduced by ventilation, which will be used while handling the dye in powdered form, and by the inclusion of an anti-dusting agent in the final dye product. Should dermal exposure occur, animal data indicates that the notified chemical is not likely to cause skin irritation.

Monoazo Yellow BG 3247 showed mild skin sensitising potential when tested in guinea pigs but the response was below the level for classification as a skin sensitiser according to the Approved Criteria. However, the notifier states on the MSDS that cases of sensitisation have been observed with other reactive dyes, therefore it is possible that a skin and/or respiratory sensitisation reaction may occur in susceptible workers. As inhalation toxicity data is not available for the notified chemical and as the potential for inhalational exposure to the notified chemical is moderate, exposure to the notified chemical should be kept to a minimum.

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

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

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

13. RECOMMENDATIONS

To minimise occupational exposure to Monoazo Yellow BG 3247 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 (20)and occupational footwear which conforms to Australian and New Zealand Standard (AS/NZS) 2210 (21) to minimise exposure when handling any industrial chemical;
- Impermeable gloves or mittens should conform to AS 2161(22);
- 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* (23).

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise.

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

16. REFERENCES

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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