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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

TRISAZO BLUE DK 2039

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

TRISAZO BLUE DK 2039

1. APPLICANT

Ciba-Geigy Australia Ltd of 235 Settlement Road, Thomastown, VIC 3074 has submitted a standard notification with their application for an assessment certificate for Trisazo Blue DK 2039.

2. IDENTITY OF THE CHEMICAL

Trisazo Blue DK 2039 is likely to be hazardous due to its potential as a skin sensitiser. However, for commercial reasons the chemical name, CAS number, molecular and structural formulae, exact molecular weight and exact import volume have been exempted from publication in the Full Public Report and the Summary Report. The conditions of this being permitted are:

- A descriptive generic name be used to identify the substance in public reports and the MSDS,
- The relevant employee unions shall be informed of the conditions of use of Trisazo Blue DK 2039,
- The full chemical name shall be provided to any health professionals in the case of a legitimate need where exposure to the chemical may involve a health risk,
- The full chemical name shall be provided to those on site who are using the chemical and to those who are involved in planning for safe use, etc. in the case of a legitimate need,
- The Director of NICNAS will release the full chemical name etc in the case of a request from a medical practitioner,
- Confidentiality will expire after a 3 year period,
- The chemical be identified as a skin sensitiser in the Health Effects Section of the MSDS, and that reference to its assessment by NICNAS be made on the MSDS,
- These conditions shall be published in the Chemical Gazette.

Other names: FAT 40'361/C
Trisazo Blue DK 2039
C. I. Direct Blue 301

Trade name: Pergasol Blue R Liquid (contains 12.5% of the notified chemical)

Molecular weight : < 1000

Method of detection and determination:

The notified chemical can be identified by UV/Vis, IR and NMR spectra

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Black/brown powder
Odour:	Odourless
Melting Point:	None to 300°C
Density:	1690 kg/m^3 at 22°C
Vapour Pressure:	Not determined (the notified chemical is a solid substance with high melting point and molecular weight.
Water Solubility:	> 150 g/L at 20°C
Fat Solubility:	0.04 mg/100g fat simulant at 37°C
Partition Co-efficient (n-octanol/water) log P_{ow}:	log P_{ow} < -4.9 (Flask shaking method; concentration determined by spectrophotometry OECD TG 107) log Pow < -13 (by calculation for principal isomer, OECD TG 117 Annex/EEC A800 using the combined method
Hydrolysis as a function of pH:	pH 4: stable at 50°C pH 7: stable at 50 °C pH 9: stable at 50 °C Half life > 1 year at 25°C
Adsorption/Desorption:	Not determined
Dissociation Constant pKa**:**	As a lithium/sodium salt the dye is expected to be highly dissociated
Flash Point:	Not applicable
Flammability Limits:	Not highly flammable - could be ignited but flame would not spread
Autoignition Temperature:	Self-ignition at 370°C

Explosive Properties:	Not explosive - neither by thermal nor mechanical stress (shock and friction)
Reactivity:	With regard to thermal stability in air - no thermal effect up to 150°C either with or without air.

Particle size distribution:

> 500µm	0.3%
> 400µm	1%
> 200µm	13%
> 100µm	59%
> 63µm	82%
> 40µm	95%

Median of mass Distribution (width) = 120µm

Comments on physico-chemical properties

Although highly soluble, the dye is expected to have superior fixation properties to paper that will resist leaching by water. The fixation properties have been evaluated by colorimetric tests. Product fastness tests have also been carried out, with the dye resistant to extraction in water, and some resistance with sulphuric acid, sodium carbonate solution, water/ethanol and bleaching agents.

The experimental log P_{OW} lies outside the range of accuracy of the OECD 107 test. Thus, a calculation was performed on the principal isomer. The calculation was based on evaluating contributions from substructures within the molecule with Fujita-Hansch-π, Rekker and Hansch-Leo fragment constants as appropriate, to give a value of 3.4 minus four formal charge contributions (–3 each) from the sulphonate groups.

The notifier has commented that the dye is not expected to be surface active. The high water solubility, low logP_{ow} and low fat solubility are contra-indications of affinity to soil/sediment and organic matter.

4. PURITY OF THE CHEMICAL

Degree of purity: Typical: 45%
Range: 40-50%

A number of coloured and uncoloured homologues and by-products together with water at < 10% make up the remainder.

Additives/Adjuvants: Stabilisers, inhibitors and other additives may be added at the formulation stage but not in the notifed substance.

5. INDUSTRIAL USE

The notified chemical is an imported dye expected to replace other dyes currently in the marketplace, as it has a better rate of fixation (97-98%). The dye will be used to colour paper and tissue paper.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported in ready-to-sell packages at a rate of < 10 tonnes per year for the first five years as an aqueous solution at a concentration of < 60%. These will be in the form of collapsible storage containers. A polypropylene receptacle with cock holds the liquid, which is supported in a steel frame. An inclined floor ensures complete emptying. After emptying, the steel frame may be "collapsed" to 40% of the original volume to allow for more efficient transport. Each container may hold 770 L (800 kg net). Some re-packaging (no reformulation) may occur for supply of samples or material for mill trials, which will occur at the notifier's premises. This will be done in 65 L HDPE containers or 200 L poly-lined steel drums (closed head).

The dilution of the dye takes place in a covered tank and the dye concentrate is transferred to the tank through lines controlled by a metering pump. The lines are connected by dry break couplings. The dilute dye solution is pumped through a closed system to the pulper. The machine operators do not need to come in contact with the solution. Following the beater, refiner and machine chest operations, the pulp dispersion is further refined before mixing with backwater from the paper papermaking machine. Adjustment to the dye concentration takes place by continous on-line dosing of the mixed flow. The dye is fixed to the paper fibres during calendering and drying.

Occupational exposure potential is primarily a potential for those operators connecting and disconnecting delivery/transfer hoses in paper mills. The number of establishments in Australia (sites) expected to use the product is up to 6 customers.

For the worst-case estimate of exposure, the most optimistic sales quantity has been used. It is expected that up to a total of 30 people in the Australian workforce would handle the substance. These include machine operators and laboratory technicians. The workers will handle the dyestuff in solution and in closed machine systems.

A further 15 workers would handle paper dyed with the notified substance during manufacture and a further 10 workers would be involved with finisihing processes (reeling, cutting, packaging).

The nature and possible duration of exposure of the workers to the notified chemical is as follows:

Operation	*Maximum no. of workers potentially exposed*	*Type of exposure*	*Maximum duration of exposure*	
			hr/day	*days/year*
Repacking	4	dermal	1	12
Dilution	30	dermal	0.5	24
Paper making	54	dermal (wet paper) dermal (dilute dye) inhalation (aerosol)	1 0.5 not significant	15(dark shade) 12
Leak/spill clean-up	3-7	dermal	-	
Finishing	60	dermal inhalation (paper dust)	not significant not significant	

7. PUBLIC EXPOSURE

The public will not be exposed to the chemical during its importation and use in papermills. The dyestuff strongly binds to paper, and will not be used on paper which will contact food, hence public exposure to the chemical in dyed paper will be negligible.

8. ENVIRONMENTAL EXPOSURE

. Release

The bulk of the dye will become chemically bound to paper fibres, and in this state is not expected to impact on the environment. Due to its high water solubility and its use in dyeing, however, the major potential loss to the environment is from the dye being released into the papermill effluent system (i.e. the papermill biological effluent treatment works or the community Sewage Treatment Plant).

The addition of dye to the paper is an efficient process. The current dye represents an improvement on other dyes due to its high affinity for paper fibres. Assessment of fixation has been carried out by colorimetric methods based on depth of shade. These indicate that at light shades 98% of dye and the dark shades 97% of the dye will be exhausted. Recovery of lost dyestuff occurs through the mill effluent system from which it is recovered through a "save all" (1 - 1.5%) and clarifier (0.25 - 0.4 %, which removes paper sludge, to which dye is absorbed) leaving 0.75 - 1.1% dye entering waste water from the mill. Addition of flocculant to the clarifier can also reduce this final amount by up to 80%.

The sludge (to which up to 50% of waste dye may be absorbed) may be further treated if the mill has a biological effluent treatment works, where chemical and biological degradation is carried out. Otherwise the solid waste is usually incinerated or passed to land fill.

. Environmental Chemistry and Fate

The biochemical oxygen demand (BOD) of the dye was tested and the five day study showed that the BOD_5 is 0 mgO_2/L.

The OECD TG 301A test for ready biodegradability was carried out, and found that the substance was not readily biodegradable (0% after 28 days), but did not inhibit bacteria.

The partition coefficient of the mixture has been determined as <–4 experimentally, and calculated as <–13 for the principal isomer. Although the dye is not readily biodegradable, the potential for bioaccumulation is low due to the low partition coefficient and low lipid solubility of the substance.

The dye normally released in water as effluent from the mill is expected to be the major environmental release. The dye may either partition to sediment or stay in the aqueous compartment; the two options are explored below.

Any dye that binds to sludge (e.g. at the mill) is expected to remain with the sludge, which would be disposed of by incineration or landfill. Instructions in the MSDS sheet show incineration to be the preferred method to reduce potential leaching of the compound into the environment.

Fate of Dye that Remains in Solution

After entering the sewage works, unfixed residues may be removed through degradation (chemical or biological) or sorption to sludge. Residues that survive sewage treatment will enter freshwater or marine environments in solution, where aerobic conditions are anticipated. The low biodegradability in aerobic conditions and stability to hydrolysis coupled with the high water solubility suggest the compound may persist for long periods in the aquatic compartment. However, as described below, the dye would be quickly diluted to levels described below that which are likely to be toxic to aquatic organisms.

Fate of Dye that Adsorbs to Sediment

The soil adsorption/desorption test was not performed. A fastness test to clay (Appendix B1, p 51, submission) showed poor affinity based on a "grey scale" assessment where dye and clay were stirred together, filtered and the filtrate examined. When paper/alum was added to the suspension, dye was retained with the paper/alum doped filtrate. Thus, dye is expected to fix to the paper, or stay in solution, in preference to clay. It is possible that the dye was binding to aluminum in the alum. Dyestuff could also enter sediment by precipitation of a calcium salt, as several calcium salts of sulphonic dyes are known to be insoluble at modest concentrations (1).

Whilst azo dyes are generally stable under aerobic conditions, highly sulphonated bis(azo) dyes have been shown to sorb to sediment, where they are susceptible to reductive degradation under the characteristically anaerobic conditions. (1) The surface tension suggests the notified dye to be borderline surface active material;[1]

[1] By EEC definition, a chemical has surface activity when the surface tension is less than 60 $mN.m^{-1}$.

the dye could also chelate to mineral sediment, containing such as Al^{3+}, Ca^{2+} etc. Once bound, the dye may reduce by cleavage of N=N bonds to yield the corresponding amine fragments. The sulfonate groups (rendering the groups soluble) will then reside on the napthyl fragments. Of the remaining aromatic amines from the principal isomer one is moderately toxic to fish (2) and another is presumably of the same order of toxicity. The anticipated concentration of the degradation products in the effluent is expected to be well below toxic levels and are therefore unlikely to pose a hazard to the aquatic environment.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of TRISAZO BLUE DK 2039

Test	*Species*	*Outcome*	*Reference*
Acute oral toxicity	Rat	LD_{50} >2000 mg/kg	(3)
Acute dermal toxicity	Rat	LD_{50} > 2000 mg/kg	(5)
Skin Irritation	Rabbit	Non-irritant	(6)
Eye irritation	Rabbit	Slight irritant	(8)
Skin sensitisation	Guinea pig	Non-sensitiser	(9)

9.1.1 Oral Toxicity (3)

Result:	LD_{50} > 2000 mg/kg, low oral toxicity in rats
Species/strain:	rat, Wistar Han (outbred, SPF-quality)
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	gavage (distilled water - application volume 10 mL/kg)
Clinical observations:	no clinical signs were observed
Mortality:	no deaths
Morphological findings:	macroscopic examination at terminal necropsy revealed no organ abnormalities in either males or females, except for discoloured lung (darkred) and discouloured kidneys (black) in one animal.
Test Method:	OECD Guidelines (4); EEC Directive 92/69 (5)

9.1.2 Dermal Toxicity (5)

Result:	LD_{50} > 2000 mg/kg, low dermal toxicity in rats
Species/strain:	rat, Wistar Han (outbred, SPF-quality)
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	bi-distilled water (application volume 4 mL/kg)
Clinical observations:	the following local signs were observed: 2000 mg/kg: males/females - scales on the back and blue tinting of the skin; males had recovered after 11 observation days (scales) except blue skin which was observed till termination of test; females showed scales and blue skin until termination of the test.
Mortality:	no deaths
Morphological findings:	macroscopic examination at terminal necropsy revealed no organ abnormalities, however lungs were discoloured dark red in one animal
Body weights:	there was no effect on body weight in 7 animals but there was weight loss in 3 animals, probably related to the semi-occlusive dressing.
Test Method:	OECD Guidelines (4); EEC Directive 92/69 (5)

9.1.4 Skin Irritation (6)

Result:	non-irritant to the skin of rabbits; no erythema or oedema was observed in any rabbit any any time point (30-60 minutes, 1, 2 or 3 days after patch removal)
Species/strain:	rabbit, New Zealand White, (SPF-quality)
Number/sex of animals:	1 male, 2 females
Method of administration:	0.5g in bi-distilled water
Test Method:	OECD Guidelines (4); EEC Directive 92/69 (5)

9.1.5 Eye Irritation (8)

Result:	slight irritant to the rabbit eye; no corneal or iridal effects observed at 1h or 1, 2 or 3 days post-instillation; no conjunctival redness observed;

obvious swelling of the conjunctivae noted at 1h was slight at 1 day and resolved by day 2 post-instillation

Species/strain: rabbit, New Zealand White, (SPF-quality)

Number of animals: 1 Male, 2 Females

Method of administration: 0.1g of the test substance was placed into the conjunctival sac of the left eye of each animal

Test Method: OECD Guidelines (4); EEC Directive 92/69 (5)

9.1.6 Skin Sensitisation (9)

Result: non-sensitiser in guinea pigs; the test article was 12.5% of the notified chemical in aqueous solution containing 5% urea

Species/strain: Ibm: GOHI; SPF-quality guinea pig

Number of animals: 10 females (control)
20 females (test group)

Induction: three pairs of injections in the scapular region (0.1 mL) consisting of:

- Freund's complete adjuvant 50:50 with physiological saline
- the notified chemical, diluted to 5% with physiological saline
- the notified chemical diluted to 5% by emulsion in a 50:50 mixture of Freund's complete adjuvant and physiological saline;

the control group received the same injections without the notified chemical; epidermal induction was by occlusive dressing for 48 hours using a 50% solution of the notified chemical in physiological saline

Challenge: no response in any animal in control or test groups when challenged with the maximal non-irritant concentration of 25%

Test Method: OECD Guidelines (4); EEC Directive 84/449

9.2 Repeated Dose Toxicity (10)

Result: target organs: liver, kidney, spleen

Species/strain:	rat, Wistar Han (outbred, SPF-quality)
Total number of animals per group:	10 males, 10 females - control and high dose (500 mg/kg/day); 5 males, 5 females - low (20 mg/kg/day) and mid-dose (100 mg/kg/day); all animals dosed for 28 days and 5 males and 5 females in the control and high dose groups given a 14-day recovery period
Method of administration:	Trisazo Blue DK 2039 in bi-distilled water was administered daily by gavage
Clinical observations:	*s*ome clinical signs occurred in a small number of individuals of the high dose group (500 mg/kg); however these findings were regarded to provide no clear indication of toxicity
Clinical Chemistry/ Haematology	the following biochemical data were noted for the high dose group (500 mg/kg) after 4 weeks: -slightly increased urea concentration for both sexes, -slightly increased bilirubin concentration for males, -slightly increased triglyceride and phospholipid concentration for both sexes, -slightly decreased sodium concentration for males -slightly increased calcium concentration for females urinalysis data showed no changes of toxicological significance after 4 weeks of treatment nor at the end of the treatment-free recovery period; however, a slightly higher pH value, slight proteinuria and ketonuria, moderate to marked bilirubinuria, and marked urobilinogenuria was observed for both sexes of the high dose group (500 mg/kg) after 4 weeks; in addition, both sexes of the mid-dose group (100 mg/kg) indicated a light brown and both sexes of the high dose group a violet urine; these changes were no longer observed at termination of the treatment-free recovery period; it is assumed that these findings are false positives related to the blue nature of the test article, which gave a highly pigmented urine sample at the highest dose level, thereby causing a masking effect which interfered with the test procedure

there was a slight increase in the reticulocyte count and slight polychromatophilia for female rats of the high dose group (500 mg/kg) after 4 weeks; this may indicate a demand for new erythrocytes and a competent bone marrow.

Necropsy Findings/ Histopathology

at termination of the treatment period the following findings were observed:-

absolute liver, kidney and adrenal weights and/or their ratios to the body weight or brain weight were statistically significantly higher than the corresponding controls in both sexes of the high dose group (500 mg/kg); relative spleen weights were statistically significantly higher than controls in males of the high dose group; except for the liver to body weight ratios of females of the high dose group, all of these findings had returned to normal in recovery individuals; discolouration of the gastrointestinal tract was observed in mainly high dose animals, but there were no concomitant histological findings so that this should not be regarded as an expression of toxicity; the livers from high dose and recovery animals showed a slight increase in periportal mononuclear cell infiltration; there was an increase in the number of animals showing moderate hyaline droplet degeneration in the male kidneys in mid- (100 mg/kg) and and high (500 mg/kg) dose groups, which was not apparent in the recovery animals

Test Method: EEC Directive 92/69 (5)

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (11)

Result: negative

Comment: in two independent experiments, up to 5000 μg/ plate using strains TA 1535, TA 1537, TA 1538, TA 98 and TA 100, neither a significant and reproducible increase in revertants was found nor concentration-dependent enhancement of revertant numbers were found, either with or without liver microsomal activation; in the presence of metabolic activation, toxic effects were found in Salmonella TA 1537 at 1000 μg/ plate and at

5000μg/ plate as well as with TA 98 at 5000 μg/ plate.

Strains: *Salmonella typhimurium:* TA 1535, TA 1537, TA 1538, TA 98 and TA 100

Concentration range: 10.0, 100.0, 333.3, 1000.0 and 5000.0 μg/ plate

Test Method: OECD Guidelines (4), EEC directive 84/449 (5)

9.3.2 Chromosomal Aberration Assay in Chinese Hamster V79 Cells *In Vitro* (12)

Result: non-clastogenic

Comments: both with and without metabolic activation, no statistically relevant increases in the frequency of structurally aberrant cells, at any dose level at any time interval evaluated; the mitotic index was slightly depressed at high doses, compared to the solvent control; treatment with concentrations higher than 50 μg/ml (without S9 mix) and 1.0 μg/ml (with S9 mix) reduced the plating efficiency of the V79 cells; also the mitotic index was at least slightly reduced after treatment with the highest evaluated concentration at fixation intervals 7h (with and without S9 mix), 18h (with S9 mix) and 28h (without S9 mix); there was no relevant increase in cells with structural aberration after treatment with the test material at any fixation interval either without or with metabolic activation by S9 mix; appropriate reference mutagens were used as positive controls and showed distinct increases in cells with structural chromosome aberrations

Dose levels: the following dose levels were evaluated:

without S9 mix:	with S9 mix:
7h: 0.1 mg/mL	7h: 0.1 mg/mL
18h: 0.01, 0.03, 0.1mg/mL	18h: 0.01, 0.03, 0.1 0.1 mg/mL
28h: 0.5 mg/mL	28h: 0.1 mg/mL

Test Method: EEC directive 84/449 (5)

9.4 Overall Assessment of Toxicological Data

Trisazo Blue DK 2039 was of low toxicity via the oral (LD_{50} > 2000 mg/kg) and dermal (LD_{50} > 2000 mg/kg) routes in the rat. It was a non-irritant to the skin and a slight irritant to the eye in rabbits. It was not a skin sensitiser in guinea pigs. Trisazo Blue DK 2039 was found to be non-mutagenic *in vitro* to *Salmonella typhimurium* strains TA 1535, TA 1537, TA 1538, TA 98 and TA 100 and was also found to be

non-clastogenic *in vitro* in chinese hamster V79 cells. A twenty-eight-day oral repeat dose study in rats indicated that the target organs are the liver and kidneys. A further potential target organ may be the spleen.

On the basis of submitted data, the notified chemical would not be classified as hazardous in accordance with Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (14) in relation to acute lethal effects (oral, dermal) ; severe effects after repeated or prolonged exposure (oral route) or irritant effects (skin, eye). Although the skin sensitisation test supplied demonstrated that the notified chemical was not a skin sensitiser, the test article used was a 12.5% aqueous solution. According to the notifier the pure chemical was found to be a skin sensitiser in another test and would, therefore, be classified as hazardous in relation to sensitising effects (skin) in accordance with Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances.*

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been provided.

Test	***Species***	***Result***
Acute Toxicity	Zebra fish	96h LC_{50} = 490 mg/L NOEC = 325 mg/L
Acute Toxicity	*Daphnia magna*	48h EC_{50} = 328 mg/L NOEC = 79 mg/L
Growth inhibition	Bacteria from activated sludge	3h IC_{50} > 100 mg/L

The acute toxicity to Zebra fish was carried out according to OECD 203 as a static test, with concentrations of aqueous Trisazo Blue DK 2039 solutions of 100, 178, 316, 562 and 1000 ppm and a control. The LC_{50} values were calculated from the resulting data according to the Spearman-Karber and the Probit methods. No abnormal responses of the fish were observed, however, at the higher concentrations tested the visibility due to the dye would have been extremely poor, and may have hampered observations.

For daphnia magna, the immobilization tests were carried out according to OECD 202, Part 1 at both 24 and 48 hrs. The tests showed the dye to be slightly toxic to daphnids (US EPA guideline 540/9-85-005). The range of concentrations tested were 3.906, 15.625, 62.5, 250 and 1000 mg/L solutions. At 1000 mg/L, the dark-blue colour was such that precipitation may have occurred, but was not noticed. The 24 h and 48 h EC_{50} values were separately calculated using the Logitt model.

As the substance colours water, the algal growth inhibition test was considered unreliable in such circumstances, and was not performed. However, it should be noted that for environmental purposes, growth inhibition, whether due to chemical or physical factors, is still of relevance. An assumed NOEC of 5 mg/L is made in the calulation of the PEC, based on information from a previous Ciba-Geigy dye submission, NA/305 (file no. 95/4182).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The Predicted Environmental Concentration is estimated below.

Process or dilution factor	***City paper mill***		***Country paper mill***	
	Light coloured paper (98% fixation)	Dark coloured paper (97% fixation)	Light coloured paper (98% fixation)	Dark coloured paper (97% fixation)
Typical dye use per day	3.75 kg	15 kg	3.75 kg	15 kg
Quantity in backwater	0.075 kg	0.45 kg	0.075 kg	0.45 kg
Backwater flow rate per day	2, 000,000 L	2,000,000 L	2,000,000 L	2,000,000 L
Dye concentration in backwater before "save all" and clarifier steps	0.0375 mg/L	0.225 mg/L	0.0375 mg/L	0.225 mg/L
Dye concentration after "save-all" and clarifier steps	0.019 mg/L	0.113 mg/L	0.019 mg/L	0.113 mg/L
Dilution factor with other effluent from other papermaking machine in mill	(a) 1:3	(a) 1:3	(a) 1:3	(a) 1:3
Dilution factor in sewage treatment plant	(b) 1:10	(b) 1:10	(b) 1:3	(b)1:3
Dye concentration in recieving waters assuming "save all" and clarifying steps and dilution	(a) + (b): 0.63ppb (b) only: 1.9 ppb	(a) + (b): 3.76 ppb (b) only: 11.3 ppb	(a)+(b): 2.11 ppb (b) only: 6.33 ppb	(a)+(b): 12.55 ppb (b) only: 37.7 ppb
Dye concentration direct to sewer from mill	(a) + (b):1.25 ppb (b) only: 3.75 ppb	(a) + (b): 7.5 ppb (b) only: 22.5 ppb	(a) + (b): 4.17 ppb (b) only: 12.5 ppb	(a) + (b): 25 ppb (b) only: 75 ppb
Safety factor for Algae	263 – 7937	44 – 1330	263 – 2370	44 – 398

Safety factor for *Daphnia magna*	5, 600 – 124, 921	6, 960 – 20, 931	5, 600 – 37, 299	5, 600 – 6, 271

Safety factor = NOEC/Dye concentration

The above calculations represent a range of manufacturing environments; effluent from city-based mills is potentially more dilute than that from country mills, where the mill may be the major source of industrial effluent. Additionally, drought situations may effect the dilution levels in country sewage.

The range of safety factors for Daphnia magna and algae has been calculated from:

Worst case: effluent, after clarification and "save all" steps, is released directly into sewer undiluted;

Best case: effluent undergoes "save-all" and clarifier steps, is diluted by mill effluent by a factor of 3, then is diluted in the sewerage by a factor of 10.

The above calculations have not assumed any secondary clarifier or flocculation, which would be expected to further reduce the dye concentration in receiving waters.

Even in the worst scenario the safety margin is good for daphnids, and reasonable for algae.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is expected to exhibit low acute toxicity by the oral and dermal routes, is not likely to be a skin irritant and is not likely to be genotoxic. It may be a slight eye irritant and repeated or prolonged contact with the notified chemical has the potential to cause systemic effects. However, it should be noted that the notified chemical has a molecular weight > 500 and has a low fat solubility so it is predicted to be poorly absorbed across the skin. The notified chemical has been shown to be a skin sensitiser in its pure form. However, the report submitted with this notification, in which the test article was a 12.5% solution of the notified chemical in a formulation similar to that to be imported, suggested that Trisaso Blue DK 2039 was not a skin sensitiser. This does not prove that the formulation to be imported would not exhibit skin sensitisation as the concentration of the notified chemical in this formulation is considerably greater that 12.5%.

Occupational exposure during repacking at the notifier’s warehouse should be low since it involves simple transfer from one container to another and occurs intermittently.

Occupational exposure potential in paper mills is primarily for those workers connecting and disconnecting delivery/ transfer hoses in paper mills and is minimised by the use of dry break couplings. Once the concentrated dye is diluted, subsequent procedures are carried out in an enclosed system so that exposure to aqueous dye is expected to be minimal. There is some potential for exposure to an aerosol during ‘forming’. However, this is carried out in an isolated part of the plant and the concentration of the dye is low at this point.

Based on the fact that technical grade Trisaso Blue DK 2039 is a skin sensitiser it can be concluded that there may be a risk of skin sensitisation in some workers involved in repacking of the concentrated imported dye formulation, in transfer to the dilution tank and possibly in transfer of the diluted solution to the pulper. However, based on animal data, the risk of skin senstisation from the imported formulation may be considered to be low. No other adverse occupational health effects are expected under normal conditions of use, during transport and during disposal. The risk of adverse public health effects is expected to be negligible as exposure of the public is expected to be minimal.

13. RECOMMENDATIONS

To minimise occupational exposure to Trisazo Blue DK 2039 the following guidelines and precautions should be observed:

. During repacking of the concentrated dye formulation and during its dilution and transfer to the pulper personal protective equipment as described in Australian (AS) or Australian/New Zealand (AS/NZS) Standards as follows should be worn:

  - Eye protection should be selected and fitted in accordance with AS 1336 (15) and meet the requirements of AS/NZS 1337 (16);

  - Impermeable gloves should conform to AS 2161 (17);

  - Protective clothing should conform to AS 2919 (18);

  - Protective footwear should conform to AS/NZS 2210 (19).

. Good work practices should be implemented to avoid spillages and splashing;

. Good work practices should be implemented to minimise mists and aerosols;

. Good housekeeping and maintenance should be practised. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal in accordance with Local or State government regulations;

. The workplace should be well ventilated;

. Good personal hygiene should be observed; and

. A copy of the relevant Material Safety Data Sheet(s) (MSDS) should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The attached MSDS for Pergasol Blue R Liquid containing the notified chemical was provided in Worksafe Australia format (20).

This MSDS was provided by CIBA-GEIGY Australia Limited as part of their notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of CIBA-GEIGY Australia Limited.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of Trisazo Blue DK 2039 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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2. Vershueren, K 1983*, Handbook of Environmental Data on Organic Chemicals*, Second Edition Van Nostrand Reinhold Company, New York, p. 989.

3. Ullmann L, Althaus P, Janiak Th, Vogel O. 1990, *Acute Oral Toxicity Study with FAT 40'361/C in Rats*, RCC Project Number: 261898, data on file, Research & Consulting Company AG, Itingen.

4. Organisation for Economic Co-operation and Development, *OECD Guidelines for Testing of Chemicals*, OECD, Paris, France[2].

5. EEC Council Directive 84/449 and EEC Commission Directive 92/69 on the approximation of the laws, regulations and administration provisions relating of the classification, packaging and labelling of dangerous preparations, *Official Journal of the European Communities*, No. L251 (19 September 1984) and No. L383 (29 December 1992)[3].

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[2] The Guidelines relevant to the current notification are as follows:

- No. 401 Acute Oral Toxicity
- No. 402 Acute Dermal Toxicity
- No. 404 Acute Dermal Irritation/Corrosion
- No. 405 Acute Eye Irritation/Corrosion
- No. 406 Skin Sensitisation
- No. 407 Repeated Dose Oral Toxicity - Rodent: 28/14-Day
- No. 471 *S. typhimurium,* Reverse Mutation Assay
- No. 473 *In vitro* Mammalian Cytogenetic Test

[3] The tests specified in these directives relevant to the current notification are as follows:

- Test B1 Acute toxicity (oral)
- Test B3 Acute toxicity (dermal)
- Test B4 Acute toxicity (skin irritation)
- Test B5 Acute toxicity (eye irritation)
- Test B6 Skin sensitisation
- Test B7 Repeated dose (28 days) toxicity (oral)
- Test B10 Mutagenicity (*in vitro* mammalian cytogenetic test)

6. Ullmann L, Althaus P, Janiak Th, Vogel O. 1990, *Acute Dermal Toxicity Study with Fat 40'361/C in Rats*, RCC Project Number: 261900, data on file, Research & Consulting Company AG, Itingen.

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

9. Ullmann L, Porricello T, Janiak Th. 1990, *Primary Eye Irritation Study with FAT 40'361/C in Rabbits*, RCC Project No: 261911, data on file, Research & Consulting Company AG, Itingen.

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11. Ullmann L, Decker U, Althaus P, et al. 1990, *Subacute 28-day Oral Toxicity (Gavage) Study with FAT 40'361/C in the Rat*, RCC Project No: 261955, data on file, Research & Consulting Company AG, Itingen.

12. Timm A. 1990*, Salmonella Typhimurium Reverse Mutation Assay with FAT 40'361/C*, CCR Project No: 178211, CIBA-GEIGY AG, Basel, Switzerland.

13. Timm A. 1990, *Chromosome Aberration Assay in Chinese Hamster V79 Cells in vitro with FAT 40'361 /C*, CCR Project No: 178222, CIBA-GEIGY AG, Basel, Switzerland.

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

15. Standards Australia, 1994, *Australian Standard 1336-1994*, *Recommended Practices for Eye Protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney, 1982.

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

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

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

. Test B14 Mutagenicity (*Salmonella typhimurium* - reverse mutation assay)

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

20. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]*, AGPS, Canberra, Australia.

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. 1mm)	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 translu cent 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.	Disharge 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