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NATIONAL INDUSTRIAL CHEMICALS
NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Disazo Violet DK 2123

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Disazo Violet DK 2123

1. APPLICANT

Ciba-Geigy Australia Ltd, 140 Bungaree Road, Pendle Hill, NSW, 2145.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data porvided, Disazo Violet DK 2123 is considered to be non-hazardous. Therefore, the following details have been exempted from publication: the chemical name, CAS No., molecular formula, structural formula, molecular weight and spectral data to be exempt from publication.

Other name(s): F.A.T 11'011/D
Direct Violet 9

Trade name(s): Pergasol Violet BN Liquid

Methods of detection and determination:

High Pressure liquid chromatography (HPLC), thin-layer chromatography (TLC), Gas chromatography (GC), atomic absorption spectroscopy and volumetry (barium acetate).
Method details were not submitted.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:

Disazo Violet DK 2123 is a deep violet, honey-like viscous liquid.

Glass-transition temperature: -17°C

Specific Gravity/Density: 1181 kg/m^3 at 70°C

Dynamic Viscosity: 56,000 mPa.s (50°C) at shear rate 8.35 - 47.1 s^{-1}
6,900 mPa.s (70°C) at shear rate 19.0 - 359 s^{-1}

Surface Tension:
(aqueous solution, 20°C, Wilhelmy plate method)
48.6 - 47.2 mN/m at 10.0 g/L
71.0 - 70.0 mN/m at 0.01 g/L

Vapour Pressure: < 4.0 x 10-4 Pa at 25°C
(Balance method)

Water Solubility: > 380 g/L at 20°C

Fat Solubility: < 0.46 mg/100g fat at 37°C

Partition Co-efficient: log P_{OW} = -2.13 at pH 6.7 and 25°C
(n-octanol/water)

Hydrolysis as a function of pH: Half-life > 1 year at pH 4, 7 and 9 at 25°C.

Adsorption/Desorption: Not determined

Dissociation Constant: Not determined

Flash Point: Negative to 105°C

Flammability Limits: Not determined

Pyrolysis products: Not determined

Autoignition Temperature: 425°C

Explosive Properties: Negative

Reactivity/Stability: Stable up to 150°C

Particle size distribution: Not relevant

Comments on physicochemical properties:

Soil adsorption-desorption: Given the low level of entry of the substance into the soil and its stated improved fixation

properties the test was considered unnecessary. This test was not required for notification to EEC. As noted below strong adsorption to sediment may be expected.

Dissociation constant: The high water solubility of the dye, its formulation involving a counter ion and two sulphonate groups indicates a high degree of dissociation. This was not measured as the test not required for notification to EEC.

4. PURITY OF THE CHEMICAL

Main component:	60-90%
Desmophen (excess counter-ion):	< 10%
Known coloured component:	< 10%
Known uncoloured component:	< 10%
Unknown coloured components:	1%
Unknown uncoloured component:	< 1%
Water:	5-10%
Unsulphonated, primary aromatic amines:	< 0.001%
Additives/Adjuvants:	None

5. INDUSTRIAL USES

Disazo Violet DK 2123 will be manufactured overseas and imported into Australia. The chemical will be used solely in the colouration of paper and tissue products. Disazo Violet DK 2123 is a desmophen (rather than sodium) salt of the existing dye, Direct Violet 9, which, with the assistance of sodium chloride or sulphate in the dye bath, has a high affinity to cellulose fibres. Direct dyes are dissimilar to reactive dyes which contain groups capable of reacting with the hydroxyl or amino groups in cellulose, wool and other substrates to form covalent bonds (Reference 2). It is anticipated that Disazo Violet DK 2123 will largely replace an existing product, Direct Violet 9. The import volume is estimated to be >1 tonne per year for the first 5 years.

6. PUBLIC AND OCCUPATIONAL EXPOSURE

Disazo Violet DK 2123 will be imported. The product will be transported from the point of entry by road or ship (to Tasmania) in 800 litre containers (type not specified). Under normal conditions, spillage from these containers will be unlikely.

The dye will be used in the paper industry at several sites situated at major cities and regional town centres. Under normal

conditions, worker exposure may occur during unpacking of transport containers and repacking for distribution; dispensing of the dye, handling of paper products during paper making, and during finishing operations, such as reeling, cutting and packaging. Potential exposure may also occur during clean-up and repair operations as a result of spillage from tanks or leakage from pumps and distribution lines. The main route of exposure is expected to be dermal. Formation of an aerosol of the dye is also possible.

The total number of workers exposed and the duration of exposure is presented in Table 1.

Table 1: Worker exposure

Operation	Max. No. of Workers	Route of Exposure	Max. Duration h/day	Days/Year
Repacking	4	Dermal	1	12
Dilution of dye	4	Dermal	1	45
Dispensing of diluted dye	35	Dermal	0.5	24
Paper Making				
Wet paper	63	Dermal	1	25
Clean-up	3	Dermal	0.5	12
Repairs	7	Dermal	0.5	12
Aerosol	14	Inhalational	Not significant	
Finishing	70	Dermal	Not significant	
		Inhalational (paper dust)	"	

Disposal of dyestuff will be by incineration or by secure landfill according to state and municipal regulations. Disposal of coloured paper will be by landfill or in water treatment sediments.

Disazo Violet DK 2123 will not be made available for home dyeing or paper-making.

7. ENVIRONMENTAL EXPOSURE

7.1 Release

Disazo Violet DK 2123 will be imported in containers (size not stated) and transported from point of entry to sites in Victoria and NSW where it will be diluted with water and repackaged in 800 litre containers as the sale product, Pergasol Violet BN. The product will be transported by road to all sites, except those in Tasmania where transport will be by ship. Bearing in mind the unlikely event of a major transport accident, spillages during product distribution is not expected. An estimate of disposal quantities was not provided, but it was not expected that significant quantities would need to be disposed. Disposal of unused dyestuff (container residues and spillages) will be by incineration or secure landfill.

7.2 Fate

Disazo Violet DK 2123 has a higher affinity (99% fixation) for pulp compared to Direct Violet 9, and hence will result in a lower quantity of unfixed dyestuff being passed to paper mill effluent and as such is not expected to impact on the environment. The dye is used in two processes, light (paper whitening) and medium paper colouration, which exhausts the dye content by 99% whilst still applying the appropriate level of colouration to the paper. The notifier indicates that an average of 2% of unfixed dyestuff, which makes allowances for late-dyeing and losses in start up and clean-up stages, passes to the paper mill effluent for recovery by "save-all" and "clarifier" processes. It is estimated that at least 50% of unfixed dye is recovered as a precipitate with treatment chemicals or attached to paper fines. The recovered dye is recycled to the paper machine or disposed off to landfill as solid waste. One site will be involved in the medium colouration of paper on 10 days of the year and, given the colouration process, would be expected to discharge a higher concentration of unfixed residues as a higher level (1 kg dye/tonne pulp vs 0.02 kg dye/tonne pulp) of dye is used.

Unfixed residues from dyeing operations will enter the aquatic environment following three scenarios dependent upon the site of the paper mill. Unfixed residues will be pumped directly to the sea or to a lake, be filtered and clarified before discharge to the sea or to a river or be subjected to primary and secondary

treatment at Latrobe Water and Sewerage Authority plant before discharge (3). The mode of unfixed dye release from the Sydney and Melbourne sites is unclear.

Discharge of unfixed and unrecovered dye directly or via clarification to sea will result in a large dilution process to insignificant levels. Discharge of unfixed dye to a lake (a coastal lagoon) will result in increasing levels of dye with time, moderated only by periodic flushing to open sea (3). In a largely stagnant lagoon binding of discharged dye to sediment may allow anaerobic degradation to occur. Azo dyes are generally stable under aerobic conditions, but are susceptible to reductive degradation under the anaerobic conditions characteristic of sediment (4). Although hydrophilic, Disazo Violet DK 2123 and its sulphonated metabolites can be expected to partition to sediment as other highly sulphonated *bis*(azo) dyes have been shown to sorb to sediment (5). Degradation of such dyes in sediment water systems proceeded with a half-life of 2-16 days. Accordingly, no significant increase in dissolved concentrations over time is predicted, while residues bound to sediment are expected to undergo reductive degradation.

The bulk of effluent from one of the sites will receive primary treatment at the mill site before secondary treatment at Latrobe Water and Sewerage Authority's Dutson Downs plant and ultimate discharge to Lake Cameron (3). Unfixed dye, discharged as effluent for sewage treatment, is likely to be removed through degradation (chemical or biological) or binding to sludge. A study of adsorption of dyes to biomass in an activated sludge plant found that similar direct dyes were highly adsorbed to sludge where anaerobic degradation is likely (6). Residues which survive sewage treatment will enter freshwater or marine environments in solution.

Disposal of unused dyestuff (contaminated or spillage) is by incineration or by secure landfill according to state and municipal regulations.

Environmental exposure from the extraction of the substance during the paper recycling processes is likely to be insignificant given the widespread use of the coloured paper and the current low levels of paper recycling in Australia.

. **Hydrolysis**

Hydrolytic degradation is unlikely given that tests indicate the lack of hydrolysis under any conditions.

. **Biodegradation**

Some biodegradation was observed when the dye was tested using effluent from a domestic sewage plant according to OECD Guideline 301A (51.4% loss of dissolved organic carbon in 28 d). While this does not pass the requirements for this screening test, the result appears to indicate potential for faster biodegradation than previous dyes notified by the company. Highly sulphonated dyes are known to degrade slowly under aerobic conditions (7). Further, testing of biological oxygen demand indicates a resistance to degradation (BOD_5 = 0 mg/g O_2) and, although the dye was susceptible to chemical oxidation (COD_5 = 1642 mg/g O_2), the BOD/COD ratio of 0 supports suggestions that the dye is relatively undegradable (8)

. **Bioaccumulation**

The bioaccumulation potential of Disazo Violet DK 2123 was not investigated because of the low partition coefficient. Hydrophilic dyes with log P_{ow} < 3 have been shown not to bioaccumulate (9).

8. EVALUATION OF TOXICOLOGICAL DATA

8.1 Acute Toxicity

Table 2: Summary of acute toxicity of Disazo Violet DK 2123

Test	Species	Max. Dose	Outcome	Reference
Oral	Rat	5000 mg/kg	LD50=2375 mg/kg(M) =1241 mg/kg(F) =1728 mg/kg(M&F)	10
Dermal	Rat	2000 mg/kg	LD50>2000 mg/kg	12
Skin Irritation	Rabbit	0.5 g	Non-irritating	14
Eye Irritation	Rabbit	0.1 g	Non-irritating	16
Skin Sensitisation	Guinea Pig	1% induction 25% challenge	Non-sensitising	18

8.1.1 Oral Toxicity (10)

This study was carried out in accordance with the OECD Guidelines for Testing of Chemicals No: 401 (11)

The acute oral toxicity of Disazo Violet DK 2123 was studied in Wistar Han. rats. The rats (5/sex/dose) were administered an aqueous solution of the test substance by gavage at doses of 500 (G1), 1000 (G2), 2000 (G3) or 5000 mg/kg (G4) and were observed for 15 days. Clinical signs noted were spasms, ruffled fur, sedation, hunched posture, weight loss, dyspnea and uncoordinated movements. These signs were more severe and were observed at lower doses in the females. Deaths were observed in G2 - G4 males and G1 - G4 females and generally occurred 2 days after dosing in the males and from 5 hours to 4 days post-dosing in the females. The calculated oral LD50s were 2375 and 1241 mg/kg for males and females, respectively, and 1728 mg/kg combined. At necropsy, macroscopic findings included a dark-red discolouration of the lungs which was dose-dependent in incidence.

8.1.2 Dermal Toxicity (12)

This study was carried out in accordance with the OECD Guidelines for Testing of Chemicals No: 402 (13)

The acute dermal toxicity of Disaso Violet DK2123 was investigated in Wistar Han. rats. The test substance at a dose of 2000 mg/kg was applied under semi-occlusive dressing to the shaved skin of rats (5/sex) and was left in contact with the skin for 24 hours. The animals were observed for a period of 15 days. There were no deaths during this period. The skin at the application site was purple in colour and was scaly. At necropsy, there was a dark-red discolouration of the lungs.

The dermal LD50 was found to be >2000 mg/kg.

8.1.4 Skin Irritation (14)

This study was carried out in accordance with the OECD Guidelines for Testing of Chemicals No: 404 (15)

Disazo Violet DK 2123 was tested for skin irritation potential in New Zealand white rabbits (2 males and 1 female). The test substance (0.5 g, undiluted) was applied to shaved skin under semi-occlusive bandage for 4 hours. The application site was examined at 1, 24, 48 and 72 hours after removal of the dressing. There was no erythema or oedema at any of the time intervals. The skin at the application site was stained violet, which nay have masked any erythema.

The test substance was found to have a low skin irritation potential.

8.1.5 Eye Irritation (16)

This study was carried out in accordance with the OECD Guidelines for Testing of Chemicals No: 405 (17)

The eye irritation potential of Disazo Violet DK 1213 was determined in New Zealand white rabbits (1 male and 2 females). The test substance (0.1 g) was placed in the conjunctival sac of the left eye of each rabbit. The right eye of each animal served as a control. The unwashed eye was examined after 1, 24, 48 and 72 hours. There was no signs of irritation or damage to the cornea, iris or the conjunctivae at any of the time intervals.

Violet staining of the conjunctivae, nictitating membrane, sclera and eyelashes was observed in the treated eye.

The test substance was shown to have a low ocular irritation potential.

8.1.6 Skin Sensitisation (18)

This study was carried out in accordance with the OECD Guidelines for Testing of Chemicals No: 406 (19)

Disazo Violet DK 2123 was assessed for potential skin sensitisation potential in albino guinea pigs using the maximisation test.

A preliminary study was carried out to determine the minimum irritant and maximum non-irritant concentrations of the test article. In this study, intradermal injections (0.1 mL) were given of the test substance at concentrations of 1, 3 or 5%, at separate sites on each of four guinea pigs. The test article at concentrations of 5, 10 or 15% was also applied under occlusive dressing to the shaved application site. The bandages were removed after 24 hours and the site was examined. There was no signs of irritation at any of these concentrations. Consequently, concentrations of 5% for intradermal application 25% for epidermal application were chosen for the main study.

In the induction phase of the main study, three intradermal injections were made to the clipped scapular region of each of ten male and ten female guinea pigs. These were:

1. Freund's complete adjuvant 50:50 with bi-distilled water,

2. the test substance at 5% concentration,

3. the test substance (5%) and Freund's complete adjuvant 50:50.

A separate control group consisting of 5 male and 5 female guinea pigs received identical treatment except that physiological saline was used in place of the test substance. One week after the intradermal injections, the scapular region was again clipped and then shaved. The application site was treated with 10% sodium laural sulfate 24 hours prior to the application of the

test article in order to enhance sensitisation by provoking a mild inflammatory response. The test article at 25% concentration was applied under occlusive dressing to this area. The dressing was removed after 48 hours and the application site was assessed for erythema and oedema immediately, 24 and 48 hours after the removal of the dressing. Staining of the skin in all the treated animals and slight oedema in half the treated animals were observed at application sites 2 and 3.

Two weeks after the application of the epidermal induction dose, the application site was shaved and the challenge dose of the test article (25%) was applied epidermally to this area under occlusive dressing for 24 hours. The application site was assessed for erythema and oedema immediately, 24 and 48 hours after the removal of the dressing. There was no erythema or oedema observed.

The test substance does not appear to cause allergic skin sensitisation.

8.2 Repeated Dose Toxicity

8.2.1 Five Day Oral Dose-Ranging Study in Rats (20)

Wistar KFM-Han. rats (3/sex/dose) were treated by oral gavage with Disazo Violet DK2123 at doses of 0, 200 or 1000 mg/kg/day for 5 days. One high dose male died on day 3 and two females in this group died on day 6, prior to scheduled necropsy. Clinical signs were observed only in the high dose group and included ruffled fur, spasms, slight to moderate sedation and hunched posture. Food consumption was decreased in the high dose animals and this was reflected in a decrease in body weight in these animals. Ophthalmoscopy showed one high dose female to have recession of the eyeballs which was consistent with a decrease in body weight. At necropsy, there was bluish discolouration of many of the internal organs of the high dose animals. A dark-red discolouration of the lungs was observed in one male and two females in the high dose group. The spleen size was reduced in two high dose females.

8.2.2 Twenty Eight Day Oral Toxicity Study in Rats (21)

This study was carried out in accordance with the OECD Guidelines for Testing of Chemicals No: 407 (22)

Wistar KFM-Han. rats (5/sex/group) were given Disazo Violet DK 2123 by oral gavage at 0, 20, 100 and 500 mg/kg/day (vehicle was distiled water); following the deaths of all HD animals within the first 11 days, a 200 mg/kg group was added. An extra 5/sex were added to this group and to the control group; as the first 5 females in the 200 mg/kg group died prematurely (or were killed in extremis) within 2 weeks of commencement of dosing. The treatment period was followed by a 14 day recovery period.

There were no clinical signs at doses up to 100 mg/kg. At the higher dose levels, clinical signs were dose-related in incidence and severity. The females were affected more than males. In the 200 mg/kg group 5/10 males had slightly emaciated appearance which lasted until day 2 of recovery. In decreasing order of incidence the following signs were noted in 200 mg/kg females; ruffled fur, hunched posture, slight/moderate emaciation, slight spasms, slight sedation, and slight uncoordination. Recovery was complete within 13 days of abstinence from the test article. At 500 mg/kg, in addition to the above, dyspnoea and black discoloured faeces were noted.

Food consumption was reduced in 200 mg/kg females and all 500 mg/kg animals. There was a decrease in body weight in the 500 mg/kg animals, while there was only a slight and reversible decrease in the rate of body weight gain in the 200 mg/kg males. Ophthalmoscopy did not reveal any treatment-related changes.

No noteworthy haematological changes were reported.

Biochemical changes included:-

- slightly decreased glucose (200 mg/kg F)
- dose-dependent increase in AST, up to 14-fold (100 and 200 mg/kg M&F)
- dose-dependent increase in ALT, up to 3-fold (100, 200 mg/kg M&F)
- slight increase in LDH (200 mg/kg M&F)
- increased gamma-glutamyltransferase, up to 2-fold (200 mg/kg M&F)
- at the 200 mg/kg dose, slightly increased phosphorus (F) and slightly decreased potassium (M)
- slightly decreased total protein concentration (200 mg/kg)

Apart from glucose, phosphorus and protein, all changes were reversible over the recovery period. The findings suggest some liver toxicity (and possibly kidney, with the GGT increase, although urinalyses were normal).

In males, slightly increased relative weights were seen for liver (200 mg/kg only, reversible) and kidneys (all treated males, reversible), while there was a significant reduction (50%) in testes weights (not reversible over 14 days) in the 200 mg/kg group. For females, there were no significant differences between relative organ weights for control and 200 mg/kg recovery animals (note that there were no necropsies of 200 mg/kg females at the end of dosing).

At gross necropsy, GI discolouration was seen in 200 and 500 mg/kg animals. Microscopic examination revealed an increase in incidence and severity of myocarditis at 200 and 500 mg/kg. Two 500 mg/kg animals had moderate adrenal cortical necrosis (possibly due to poor condition rather than a direct effect). The cause of death of animals dying or killed in extremis was not established.

These results suggest the liver, kidney, heart and testes as target organs for toxicity.

8.3 Genotoxicity

8.3.1 Reverse Mutation Assay in *Salmonella typhimurium* (23)

This study was carried out in accordance with the OECD Guidelines for Testing of Chemicals No: 471 (24)

Disazo Violet DK 2123 was tested in *Salmonella typhimurium* strains TA 1535, TA 1537, TA 98 and TA 100 for its ability to cause gene mutations. Concentrations of 10, 100, 333, 1000 and 5000 ug/plate were used, both in the presence and absence of S9 prepared from Aroclor-induced rat liver. The experiment was independently replicated on different days (triplicate plates/assay).

There was no evidence of an increase in the number of revertants. Positive controls (sodium azide and 4-nitro-o-phenylene-diamine, without S9, 2-aminoanthracene with S9) gave the expected increase in the number of revertant colonies.

Under the conditions of this experiment Disazo Violet DK 2123 does not appear to have mutagenic activity in *Salmonella typhimurium*.

8.3.2 Chromosome Aberration Assay in Chinese Hamster V79 Cells (25)

This study was carried out in accordance with the OECD Guidelines for Testing of Chemicals No: 473 (26)

Disazo Violet DK 2123 (batch DK 2123/TV 1/89) was assessed for its potential to induce structural chromosome aberrations in Chinese hamster V79 cells in culture, both in the presence and absence of S9 mix prepared from Aroclor-induced rat liver. Treatment was for 4h, and preparation of chromosomes was done at 7, 18 and 28h after start of treatment. Concentrations of the teat article used (both + and -S9) were 1000 ug/ml (all times) and 100 and 600 ug/ml (18h time only). Higher concentrations than 1000 ug/mL were insoluble in the culture medium.

The compound did not induce structural chromosomal aberrations in V79 cells under the conditions of the assay. Positive controls (ethylmethanesulfonate, -S9, cyclophosphamide, +S9) gave the expected increase in the number of revertant colonies.

Under the experimental conditions described Disazo Violet DK 2123 did not appear to have any clastogenic activity.

8.4 Overall Assessment of Toxicological Data

In animal studies, Disazo Violet DK 2123 had low acute oral and dermal toxicity and did not cause skin irritation or skin sensitisation. It did not cause eye irritation.

Repeated oral administration in rats for 28 days resulted in deaths (or moribund sacrifices) of all animals at 500 mg/kg/day and deaths (or moribund sacrifices) of 5/10 females at 200 mg/kg/day. Biochemical parameters indicated reversible liver and kidney toxicity at 100 mg/kg/day and above. There was microscopic evidence of some myocarditis at 200 mg/kg/day and above. Testes weights were reduced at 200 mg/kg/day. There were no effects at 20 mg/kg.

There was no evidence from the studies provided (*Salmonella typhimurium* histidine reversion test, and a cytogenetics test in Chinese hamster cells V79 in culture) that Disazo Violet DK 2123 caused gene mutations or chromosomal aberrations.

9. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following test results, obtained according to OECD Guidelines 203 (27) and 202 (28), were provided for aquatic species.

Test	Species	Result
96 h toxicity	Zebrafish	LC_{50} >1000 $mg.L^{-1}$
Acute immobilization	*Daphnia magna*	48 h EC_{50} > 427 $mg.L^{-1}$

The above results indicate that Disazo Violet DK 2123 is practically nontoxic to aquatic fauna. While reproduction tests for daphnids were not conducted, the lack of acute toxicity and the probability that the dye, given its high molecular weight, will not undergo cellular absorption indicate that reproductive effects are unlikely to be observed.

Respiratory inhibition of microorganisms in activated sewage sludge was tested according to OECD Guideline 209 (29). The IC_{50} exceeded the highest concentration tested (100 $mg.L^{-1}$), indicating that the dye is practically nontoxic to microbes, and should not affect sewerage micro-organisms.

No data were provided for algal growth inhibition on the grounds that "the substance will colour alga strongly, and any growth changes will be masked by this effect and render the test unreliable". Algal growth inhibition tests on 56 dyestuffs showed close parallels with fish toxicity, apart from some acid dyes highly toxic to fish which did not affect algae (5). Accordingly, it appears unlikely that the notified substance will be toxic to algae and a test will not be required.

10. ASSESSMENT OF ENVIRONMENTAL HAZARDS

The main hazard associated with use of Disazo Violet DK 2123 will be associated with direct discharge from paper mill sites or release from sewage treatment works of unfixed residues into the aquatic environment. If released to the ocean or to a river (unless low flow conditions prevail), dilution would be expected to swiftly reduce the environmental concentration to undetectable levels. In the longer term, residues would be expected to bind to sediment and undergo reductive degradation, with amine metabolites being released to the water column where they can undergo further degradation through aerobic processes.

The notifier has provided two scenarios, light and medium paper colouration, which require closer scrutiny. In addition, consideration should be given to the mode of discharge of

effluent from the paper mill sites, whether it is directly to a lake, or release to sewage treatment works.

The worst case envisaged by the notifier would occur at the one unidentified site producing medium coloured paper on 10 days of the year. Given the daily quantity of Direct Violet DK 2123 used at each site, 2% average unfixed dye from the process and 50 % recovery in the "save all" and clarification procedures, the daily discharge to water bodies or release to sewage treatment works would be 0.04 kg of the technical mixture.

If mill effluent release is to sewage treatment works, an assumed daily flow rate of 2 ML would result in a Direct Violet DK 2123 concentration of 20 ppb to receiving waters, which compares to 4 ppb for light colouration (paper whitening). This daily flow estimation is very conservative considering that all sites are located in metropolitan or major coastal town regions. In addition a paper mill is likely to have other different processes running simultaneously, resulting in a greater dilution of substance before sewage treatment works. It is more likely that the predicted environmental concentration of substance to receiving waters after sewage treatment will be below 3 ppb.

If mill effluent is pumped directly to a lake (estimated volume 96,000 ML), the predicted environmental concentration, assuming even distribution throughout the lake and 0.4 kg release of unfixed dye per annum, will be approximately 4 ppt. The concentration will not exceed 1 ppb, in the event that mill effluent is concentrated in a 1% section of the lake.

In both scenarios, this is more than 4 orders of magnitude lower than concentrations causing acute effects in aquatic fauna, indicating that adverse environmental effects should not occur.

No processes involving the dark colouration (violet) of paper are envisaged.

11. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY

Under normal use conditions, the potential for public and occupational exposure is minimal. The most likely route of exposure is dermal, but some inhalational exposure of an aerosol form of the chemical, or dust from paper dyed with the chemical is possible.

Considering the small amount of dye used to colour paper and the higher affinity for paper than the existing dye it is intended to replace, the chance of significant human intake resulting from dye transfer from coloured paper (eg. serviettes) to foodstuffs would be minimal. There would be insignificant transfer to humans from other forms of dyed paper.

Significant risk from accidental spillage during transport is not anticipated since the quality of the container should ensure that spillage would not occur except in the case of a major traffic accident. Any uncontrolled release of large amounts would be detected by its intense violet colour.

The toxicity profile of Disazo Violet DK 2123 is not of major concern. It has low acute oral and dermal toxicity. It does not cause skin and irritation, or skin sensitisation. The 28-day repeat-dose oral toxicity study in rats revealed changes in the liver, kidney, heart and testes. However, there were no significant effects at 20 mg/kg/day. This dye was negative in two genotoxicity assays.

Overall, Disazo Violet DK 2123 is not expected to pose a significant hazard to the public and workers.

12. RECOMMENDATIONS FOR THE CONTROL OF PUBLIC AND WORKER EXPOSURE

To minimise public and worker exposure to Disazo Violet DK 2123 the following guidelines and precautions should be observed:

- Engineering control measures such as local exhaust ventilation, should be employed in areas where an aerosol of the dye solution may form and in areas where paper dust may form.
- Workers who are likely to be exposed to the dye should wear impervious gloves, face shield, and appropriate protective clothing, complying with the appropriate Australian Standards (30, 31).
- The generation of an aerosol of the dyestuff or dust from paper dyed with the chemical should be avoided.
- A copy of the MSDS should be easily accessible to all employees.

To minimise public exposure to Disazo Violet DK 2123 it is recommended that paper products coloured with the dye should not be allowed to come into contact with food.

13. MATERIAL SAFETY DATA SHEET(S)

The Material Safety Data Sheet (MSDS) for Disazo Violet DK 2123 (Attachment 1) was provided in Worksafe format (32). This MSDS was provided by CIBA GEIGY Ltd 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 Ltd.

14. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of Disazo Violet DK 2123 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise.

A secondary notification will be required if the use pattern for this dye indicates that there may be significant contact with food.

15. REFERENCES

1. White M., "The Dye Spectrum", *New Scientist*, Number 22, May 20, 1989.

2. McGraw-Hill Encyclopedia of Science and Technology, 6th Edition, Volume 5, pp. 436-450.

3. Industry Commission, *Paper and Pulp: Bleaching and the Environment*, Report No.1, May 21, 1990.

4. Yen C-P., Perenich and Baughman G. L., *Environmental Toxicology and Chemistry*, Volume 10, 1991, pp. 1009-1017.

5. Weber E. J., *Environmental Toxicology and Chemistry*, Volume 10, 1991 pp. 609-618.

6. Reference 25 in Hobbs S., *Industry Category Document: UK Dye Production and Use in the Textile Industry*, UK Department of the Environment, (CR36/38), July 1988.

7. Wuhrmann K., Mechsner K. and Kappeler T., *European Journal of Applied Microbiology and Biotechnology*, Volume 9, 1980, pp. 325-338

8. Lyman W. J. *et al.*, "Handbook of Chemical Property, Estimation methods - Environmental Behaviour of Organic Compounds", 1982, pp. 7-15.

9. Anliker R., Clarke E. A. and Moser P., Chemosphere, Volume 2, American Dye Manufacturer's Institute, New York, 1974

10. Acute oral toxicity study with FAT 11'011/D in rats. Research & Consulting Company AG, Itingen, Switzerland. RCC project 262102, 1990.

11. *OECD Guidelines for Testing of Chemicals*, "Acute Oral Toxicity" No: 401, 1981.

12. Acute dermal toxicity study with FAT 11'011/D in rats. Research & Consulting Company AG, Itingen, Switzerland. RCC project 262113, 1990.

13. *OECD Guidelines for Testing of Chemicals*, "Acute Dermal Toxicity" No: 402, 1987.

14. Primary skin irritation study with FAT 11'011/D in rabbits. Research & Consulting Company AG, Itingen, Switzerland. RCC project 262135, 1990.

15. *OECD Guidelines for Testing of Chemicals*, "Acute Dermal Irritation/Corrosion" No: 404, 1981.

16. Primary eye irritation study with FAT 11'011/D in rabbits. Research & Consulting Company AG, Itingen, Switzerland. RCC project 262124, 1990.

17. *OECD Guidelines for Testing of Chemicals*, "Acute Eye Irritation/Corrosion" No: 405, 1987.

18. Contact hypersensitivity to FAT 11'011/D in albino guinea-pigs, maximisation test. Research & Consulting Company AG, Itingen, Switzerland. RCC project 262146, 1990.

19. *OECD Guidelines for Testing of Chemicals*, "Skin Sensitisation" No: 406, 1981.

20. 5-Day oral toxicity (range-finding) study with FAT 11'011/D in rats. Research & Consulting Company AG, Itingen, Switzerland. RCC project 262170, 1990.

21. Subacute 28-day oral toxicity (gavage) study with FAT 11'011/D in the rat. Research & Consulting Company AG, Itingen, Switzerland. RCC project 262168, 1990.

22. *OECD Guidelines for Testing of Chemicals*, "Repeated Dose Oral Toxicity - Rodent: 28-day or 14-day Study" No: 407, 1981.

23. Salmonella typhimurium reverse mutation assay with FAT 11'011/D. Research & Consulting Company AG, Itingen, Switzerland. RCC project 178018, 1990.

24. *OECD Guidelines for Testing of Chemicals*, "Genetic Toxicology: *Salmonella typhimurium*, Reverse Mutation Assay" No: 471, 1983.

25. Chromosome aberration assay in Chinese hamster V79 cells *in vitro* with FAT 11'011/D. Research & Consulting Company AG, Itingen, Switzerland. RCC project 178020, 1990.

26. *OECD Guidelines for Testing of Chemicals*, "Genetic Toxicology: *in vitro* mammalian cytogenetic test" No: 473, 1983.

27. *OECD Guidelines for Testing of Chemicals*, "Fish, Acute Toxicity Test" No: 203, 1981.

28. *OECD Guidelines for Testing of Chemicals* "*Daphnia sp.*, 14-day Reproduction Test (including an Acute Immobilisation Test)" No: 202, 1981.

29. *OECD Guidelines for Testing of Chemicals*, "Activated Sludge, Respiration Inhibition Test" No: 209, 1984.

30. Australian Standard 1337-1984, "Eye Protectors for Industrial Applications", Standards Association of Australia Publ., Sydney, 1984.

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

32. National Occupational Health and Safety Commission, *Guidance Note for the Completion of a Material Safety Data Sheet*, 2nd. edition, AGPS, Canberra, 1990.