File No: NA/538

July 1999

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Component of Basazol Violet 46 L

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act* 1989 (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Aged Care.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, National Occupational Health and Safety Commission, 92-94 Parramatta Road, Camperdown NSW 2050, between the following hours:

Monday - Wednesday	8.30 am - 5.00 pm
Thursday	8.30 am - 8.00 pm
Friday	8.30 am - 5.00 pm

Copies of this full public report may also be requested, free of charge, by contacting the Administration Coordinator on the fax number below.

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) 9577-9514 FAX (61) (02) 9577-9465

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Component of Basazol Violet 46 L

1. APPLICANT

BASF Australia Ltd of 500 Princes Highway NOBLE PARK 3174 has submitted a standard notification statement in support of their application for an assessment certificate for Component of Basazol Violet 46 L.

2. IDENTITY OF THE CHEMICAL

The following requests for exempt information were accepted: chemical name, CAS No., molecular and structural formulae, concentration level in the imported product, spectral data and formulation details.

Molecular Weight:	515
Spectral Data:	spectral data were not provided as the notified chemical is synthesised as a component of a mixture; however, ultraviolet/visible spectra for chemically similar substances were provided
Method of Detection and Determination:	infrared spectroscopy

3. PHYSICAL AND CHEMICAL PROPERTIES

Little data exist for the notified chemical itself. Information was provided for the imported product or a similar substance, crystal violet chloride (CAS No. 548-62-9), which is chemically similar to the notified chemical.

Appearance at 20°C and 101.3 kPa:	the imported solution is a dark violet liquid
Melting Point:	the melting point of crystal violet chloride is 195 - 198°C

Density:	approximately 1 080 kg/m^3 at 20°C; the density of crystal violet chloride is 1 190 kg/m^3
Vapour Pressure:	not determined
Water Solubility:	miscible in all proportions at room temperature; the water solubility of crystal violet chloride is 10 g/L at 20°C
Partition Co-efficient (n-octanol/water):	log P_{ow} for crystal violet chloride is 1.39
Hydrolysis as a Function of pH:	not determined
Adsorption/Desorption:	not determined
Dissociation Constant:	not determined
Particle Size:	not applicable as the notified chemical is in liquid form
Flash Point:	> 100°C (imported product)
Flammability Limits:	not determined
Autoignition Temperature:	> 200°C (imported product)
Explosive Properties:	not explosive based on structure
Reactivity/Stability:	not considered reactive

Comments on Physico-Chemical Properties

The notifier did not submit any data regarding vapour pressure as the notified chemical is ionic in nature, and hence the vapour pressure is expected to be low.

The water solubility of the chemically similar substance Crystal Violet Chloride has been determined, and given as 10 g/L at 20°C in the Material Safety Data Sheet (MSDS).

The chemical doesn't contain any functionalities which would be expected to undergo hydrolysis under the usual environmental pH range between 4 and 9.

Since the substance is of high water solubility, the partition coefficient (value supplied also based on the substance Crystal Violet Chloride and taken from the literature (Tonogai *et al*., 1982)) and adsorption/desorption will be relatively low. However, the chemical contains a

charged centre which will be attracted to the colloidal material in the aquatic compartment which is usually negatively charged.

No dissociation data were provided. However, the compound contains aromatic amino groups, which are normally of low basicity, eg pK_a for N,N-diethylanaline is 6.61. However, in the present compound the potential for protonation of the amino groups will be further reduced due to the delocalised positive charge on the aromatic centres. Consequently, the new compound is likely to be protonated only in low pH environments.

4. PURITY OF THE CHEMICAL

Degree of Purity: > 99%

Toxic or Hazardous Impurities: none

Non-hazardous Impurities (> 1% by weight): none

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical is to be imported at a level of l0 -< 30% (see Material Safety Data Sheet (MSDS) – the product contains 2 dyes, accounting for the figure of 30 - < 60%) in a dye formulation containing acetic acid, solvent and water. The chemical is a dye used in the manufacturing industry as a colouring agent for moulded objects such as fruit trays. It is estimated that the fruit trays will contain 0.1% notified chemical. The notified chemical will be imported at a rate of approximately 2.5 tonnes per year for the first five years in 1 000 L Schuetz type containers.

6. OCCUPATIONAL EXPOSURE

The dye formulation containing the notified chemical will be imported in 1 000 L Schuetz containers approximately 12 times per year. It is estimated that approximately 7 workers will handle the containers for a maximum 3 hours per year. Transport and storage should not result in exposure except in the event of accidental spillage. The notifier states that the imported product may be sampled by the laboratory with 3 analysts handling 200 mL samples for approximately 6 hours per year.

Following transport to a single customer site, 4 plant operators will be involved in the paper dyeing process for approximately 3 hours per year. The dyeing process takes place in a closed system and the notifier states that the product is only handled when the end of the dye line to the outlet valve of a new Schuetz tank is connected once per month. The notifier estimates that a maximum of 20 mL of the product may be spilt during each connection and

may potentially lead to dermal exposure. The notifier states that personal protective equipment (overalls, gloves, chemical face shields and goggles) are made available to operators although the actual protection to be worn during each operation was not stated. Local exhaust ventilation is installed in areas of the workplace where natural ventilation is inadequate.

The paper dyeing process does not involve workers with any direct contact with the dye solution. The dye solution is pumped directly from the Schuetz tank into a suspension of newsprint/magazine fibre suspension (1% solids) in water. The dye is exhausted on to the fibre by the time it reaches the headbox of the machine, after which forming occurs. From the headbox, the dyed stock is introduced onto a porous rotating drum fashioned with fruit tray moulds on its outer surface. On the drum, a fibre mat forms which is transferred to a continuous tray. From the drum the formed trays pass through a drying section where they emerge as finished trays . Once the trays are dried, the dye is fixed to the fibre and the notified chemical is not bioavailable.

7. PUBLIC EXPOSURE

The notified chemical is for industrial use only as a colouring agent. The potential for public exposure during transport, production of food packaging products or from disposal is assessed as negligible. Members of the public will make dermal contact with food packaging products (such as fruit trays), however exposure will be low because of the low concentration of the notified chemical in these products (0.1%) and its low leachability from the dyed products.

8. ENVIRONMENTAL EXPOSURE

Release

During production of the moulded paper products the newsprint/magazine is “slushed” with water in a pulper to form a thickstock. The thickstock is diluted to a 1% solids fibre suspension with recycled process water and the dyeing process takes place simultaneously. The dyed stock is introduced onto a porous rotating drum fashioned with fruit tray moulds on its outer surface. The water drained from the dyed pulp is recycled again and reused to dilute incoming thickstock. A fibre mat is formed and transferred to a continuous tray. The finished trays pass through a drying section with an estimated moisture content of 8-12 %.

The dyeing process takes place in a closed system with continuous water recycle. The connection of the dye line to a new Schuetz tank occurs once a month and a maximum of 20 mL of product may be spilt during each connection.

Release from the dyehouse into the wastewater system is estimated by the notifier to be 20 kg of the notified chemical per annum. This will be predominantly sorbed to the high content of solids in the effluent (see below). This figure presumably also includes the spillage amount that occurs in changing dye lines to a new tank.

Residual dyestuff may remain in the packaging after use. It is estimated that less than 10 L of the product (*ie.* 2 L of the notified chemical) will be retained. Given a maximum import of 10 tonnes in 10 packages, a total of less than 100 kg of the dyestuff (*ie.* 20 kg of the new chemical) will be retained in the packaging. The packaging and residue will be disposed to an incinerator or landfill.

Fate

The bulk of the dye will become chemically fixed to the paper fibres and a low percentage of the chemical will be discharged to the sewer, where it may remain in colloidal suspension or be removed with sludge during treatment. The fate of the majority of the notified substance is linked with the fate of the particular item and in this state is not expected to impact on the environment. Paper based products containing the new dye would be disposed of into landfill, incinerated or possibly recycled. During recycling activities the dye would become associated with the fibrous material in the waste sludge which is likely to be either placed into landfill or incinerated. In a landfill the paper and dye are expected to be slowly degraded through biological processes, and the dye would decompose to water, and oxides of carbon and nitrogen. Incineration would also destroy the dye, with evolution of water vapour and oxides of carbon and nitrogen.

In the event of accidental spillage of the dyestuff into waterways, the chemical is not expected to disperse into the water, but settle out onto sediments after adsorbing to the organic fraction. If the dyestuff is spilt on land, either during usage or transport, it is expected that the chemical would become immobilised in the soil layer. Contaminated soil can then be collected and disposed to landfill.

Biodegradation/Bioaccumulation
The notifier provided no direct evidence to indicate that the new chemical is biodegradable. However, data on similar products that contain the dyestuffs Basic Violet 1 and Basic Violet 3 indicate that the biodegradability of such products is 50-100 %. This percentage range is based on MSDS information only and the notifier did not provide any units or time length with these figures.

The high claimed level of biodegradability and the low log Pow of 1.39 would suggest little potential for bioaccumulation. Furthermore, low exposure and adsorption to sediment in the sewage treatment of waste from the dyehouse would reduce the quantity of notified substance eventually released to the aquatic environment and limit the bioaccumulation potential.

9. EVALUATION OF TOXICOLOGICAL DATA

No toxicological data were provided for the notified chemical. The acute oral toxicity, skin and eye irritation studies were performed using the product to be imported, Basazol Violet 46 L. The bacterial mutagenicity and chromosome damage studies were conducted using ethyl

violet chloride, an analogue of the notified chemical. In the absence of specific data, the toxic endpoints obtained are assumed to be applicable to the notified chemical.

9.1 Acute Toxicity

Summary of the acute toxicity of Basazol Violet 46 L (21% notified chemical)

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} = 620 mg/kg (males), 420 mg/kg (females), 510 mg/kg (combined)	(Kirsch & Kersebohm, 1988)
skin irritation	rabbit	not irritant	(Kirsch & Gamer, 1988a)
eye irritation	rabbit	severe irritant	(Kirsch & Gamer, 1988b)

9.1.1 Oral Toxicity (Kirsch & Kersebohm, 1988)

Species/strain: rat/Wistar

Number/sex of animals: 5/sex/dose group

Dose groups: 100, 215, 464, 825 or 2 000 mg/kg

Observation period: 21 days

Method of administration: oral gavage, chemical in distilled water

Clinical observations: none at 100 mg/kg; clinical observations were noted at the other doses as follows:

Males

Dose (mg/kg):	2 000	825	464	215
Symptom				
Dyspnea	3-6D*	1-9D	1-6D	1H-1D
Apathy	"	1-9D	1-6D	
Staggering	"	2-9D		1H-1D
Spastic Gait	"	2-9D		
Faeces – Blue-Violet	"	4H-7D	4H-5D	4H-1D
Urine – Blue-Violet	4H-6D	1-7D	4H-5D	
Piloerection				
Diarrhea	4H-6D	8-16D		4H-4D
Exsiccosis	4H-5D	7D		
Poor General State	3-6D	1-9D	1-6D	1H-6D
	3-6D			
				1H-1D

- H = hour, D = day

Females

Dose (mg/kg):	2 000	825	464	215
Symptom				
Dyspnea	3-7D*	1-16D	1-16D	4H-1D
Apathy	3-7D	1-15D	1-8D	
Abnormal Posn	3D			4H-1D
Staggering	3-7D	2-15D	2-8D	
Paresis	3D			
Spastic Gait	3-7D	2-15D	2-8D	
Faeces – Blue-Violet	4H-7D	1H-7D	1H-7D	
Urine – Blue-Violet	4H-7D	4H-7D	4H-7D	4H-4D
Piloerection				
Diarrhea		8-21D	8-16D	
Exsiccosis	4H-5D	1-5H	1H-5H	1H-5D
Impaired General State	3D	7D	7D	
Poor General State		16D	16D	
	3-7D	1-15D	1-8D	
				4H-1D

* H = hour, D = day

Mortality:	2 000 mg/kg: all animals; 825 mg/kg: 3/sex; 464 mg/kg: 2 males, 4 females; 215 mg/kg: 0 males, 1 female; 100 mg/kg: no animals
Morphological findings:	in animals that died: general congestion; mucosa of the stomach/intestines discoloured by the test substance; liver/musculature/skin: discoloured by the test substance
Test method:	similar to OECD guidelines
LD_{50}:	620 mg/kg (males); 420 mg/kg (females); 510 mg/kg (combined)
Result:	the notified chemical was of low acute oral toxicity in rats

9.1.2 Dermal Toxicity

Data not provided.

9.1.3 Inhalation Toxicity

Data not provided.

9.1.4 Skin Irritation (Kirsch & Gamer, 1988a)

Species/strain:	Rabbit/White Vienna
Number/sex of animals:	2 males, 1 female
Observation period:	8 days; readings at 4 hours, 1, 2, 3 and 8 days
Method of administration:	0.5 mL of the test substance under a semi-occlusive dressing
Test method:	OECD TG404
Result:	the notified chemical was not a skin irritant in rabbits under the conditions of the test; however, due to staining readings of erythema could not be made up to 48 hours after dressing removal and in 2 of 3 animals at 72 hours and 8 days; the remaining animal at 72 hours and 8 days did not exhibit erythema; no oedema was observed at any time point

9.1.5 Eye Irritation (Kirsch & Gamer, 1988b)

Species/strain:	rabbit/White Vienna
Number/sex of animals:	1 male
Observation period:	72 hours
Method of administration:	0.1 mL of the test substance to the conjunctival sac of the right eye
Test method:	OECD TG405
Result:	the notified chemical was a severe eye irritant in rabbits; although corneal and iridal effects and conjunctival redness could not be scored at either 1, 24, 48 or 72 hours post-instillation due to discolouration, chemosis was well-defined at 1 hour and very severe at the other time points; discharge was clearly increased up to 24 hours and distinctly increased thereafter; the study was terminated at 72 hours because of severe irritation

9.1.6 Skin Sensitisation

Data not provided.

9.2 Repeated Dose Toxicity

Data not provided.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay with ethyl violet chloride (Hoffmann & Engelhardt, 1995b)

Strains:	TA 1535, TA 1537, TA 98 and TA 100
Concentration range:	5 µg/plate – 1 000 µg/plate (plate test) 5 µg/plate – 80 µg/plate (preincubation test)
Test method:	OECD TG471; metabolic activation was provided by the liver S9 fraction from Aroclor 1254-induced rats
Result:	the background mutation frequency was within the historical limits for the strains used and the

positive control substances demonstrated the sensitivity of the test

no chemical-induced increase in mutation frequency was observed in any strain in the absence or presence of metabolic activation provided by rat liver S9 fraction; however, toxicity was observed from approximately 5 µg/plate in the preincubation test and 80 µg/plate in the standard plate test; therefore, a mutagenic potency of less than approximately 1 mutant/µg may not have been detected

9.3.2 Chromosomal Aberration Assay in Chinese Hamster V79 Cells (Hoffmann & Engelhardt, 1995a)

Cell line:	Chinese Hamster V79 cells
Treatment time, Harvest time and Doses:	cells were treated for 4 hours and chromosomes were prepared after either 18 hours (low, mid and high doses) or 28 hours (high dose only) of incubation; metabolic activation was provided by the liver S9 fraction from Aroclor 1254-induced rats on the basis of preliminary cytotoxicity experiments, the low, mid and high doses, respectively, were 0.4, 0.6 or 0.8 µg/mL without S9 and 2, 4 or 6 µg/mL with S9
Test method:	OECD TG473
Result:	the negative controls gave background chromosomal aberration frequencies with the range expected for V79 cells and the positive control chemicals gave the expected increases in the first of 2 experiments a statistically significant increase in the percentage of cells withstructural chromosomal aberrations was observed with the test chemical at 0.4 µg/mL ($P \leq 0.05$, excluding gaps, without S9); however, as no other positive results were obtained, this result appears to be due to chance; on balance ethyl violet chloride is not clastogenic in either the absence or presence of metabolic activation provided by rat liver S9 fraction

9.4 Overall Assessment of Toxicological Data

The imported solution containing the notified chemical (Basazol Violet 46L) was of moderate to low acute oral toxicity in rats (LD_{50} = 420 mg/kg, females). The skin irritancy study in rabbits was inconclusive due to staining of the skin. However, the imported product is likely to be a skin irritant, based on the concentration of acetic acid. Similar staining of the eye in rabbits did not obscure eye damage and Basazol Violet 46L was a severe eye irritant. On the basis of results with an analogue, ethyl violet chloride, the notified chemical is probably not genotoxic. The notified chemical is classified as a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a) in terms of acute lethal effects and severe eye effects and the risk phrases R 22: harmful if swallowed and R 41: risk of serious damage to eyes should be included on the Material Safety Data Sheet (MSDS) and label for Basazol Violet 46L.

Skin sensitisation data were not provided but it is unlikely that a positive response could be detected due to staining of skin by the dye. Acute dermal toxicity and repeated dose toxicity data were not provided. Therefore, on the basis that Basazol Violet 46L exhibited acute oral toxic effects (low/moderate toxicity) and that the dye discoloured the liver, musculature and skin following oral administration (i.e. was absorbed from the gut), it is possible that the notified chemical could be hazardous in terms of acute dermal effects and severe effects after repeated or prolonged exposure.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies on the imported product have been supplied by the notifier. The tests were performed in compliance with OECD/EEC Test Methods and according to OECD Principles of Good Laboratory Practices.

Species	*Test*	*Test concs (nominal) mg/L*	*Result*
Rainbow trout (*Salmo Gairdneri* Rich.)	Acute Toxicity (static) (OECD TG 203)	> 0.1	0.1< 96 h LC_{50} < 0.215 mg/L
Activated sludge bacteria	Robra test		0.5 h LC_{50} = 61 mg/L

The tests on rainbow trout were performed using a static test methodology. A stock solution of the test material was made up at a nominal concentration of 1 000 mg/L, and this was then used to prepare five solutions of the chemical in water (which had been dechlorinated by filtering through charcoal), with nominal concentrations of 0.0464, 0.100, 0.215, 0.464 and 1.0 mg/L. The tests were conducted over a 96-hour period at a controlled temperature of 12 ± 1°C.

Ten fish were tested at each concentration, and during these tests the pH of the test solutions was always between 7.0 and 7.9, while dissolved oxygen levels were always between 7.1 and 9.8 mg/L. The test results were apparently analysed using probit analysis (Finney, 1971), and indicate that the new dye is highly toxic to the rainbow trout, with a 96 hour LC_{50} between 0.1 and 0.215 mg/L (99% confidence). In fact, after 96 hours exposure to a nominal concentration of 0.1 mg/L no fish mortality had occurred, but after exposure to a nominal 0.215 mg/L, all had died. The only sub-lethal effect indicated in the report was general apathy within the fish population.

No other reports on ecotoxicity were submitted, although the MSDS indicated that a test on the inhibition of respiration of activated sludge bacteria had been conducted (the Robra test), which indicated the chemical to be mildly toxic to these bacteria.

The notifier has not provided any ecotoxicological data for daphnia species or algae, largely on the basis of the anticipated low environmental exposure.

It is noted that the new chemical is highly toxic to fish, and is assumed to be also toxic to daphnia and algae (Nabholz *et al*. 1993). This lack of data is only acceptable because of the expected strong binding to suspended solids of the charged species predominating in the aquatic environment and to the low expected exposure to the water compartment.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Based on a maximum annual import of 10 tonnes of the product (ie. 2 tonnes of notified chemical) the notifier estimates that up to 1 % (20 kg) of the chemical will be required to be processed through the wastewater treatment plant per annum. The notifier notes that the discharge rate by the dyehouse to the sewer is 2 L/s and estimates this would have a maximum of 0.15% of the dye fixed to the suspended solid fraction. Though the notifier has not provided any information to enable the fixation percentage to be determined, it is accepted that the majority of the released dye will be associated with the suspended solids of the paper fibre.

The environmental hazard from the dye, when fixed to paper products such as newsprint and magazines is rated as negligible, with the dye sharing the fate of the paper products. The most significant environmental exposure would be from the release of the dye in the wastestream from dyehouse to the aquatic compartment. The Predicted Environmental Concentration (PEC) in the dye house effluent is estimated below.

Calculation Factor	Dyehouse (per annum)
Amount of notified chemical used	2 tonnes
Release per annum	20 kg (1 % total usage)
Effluent Flow	200,000 L/day x 365 days = 63,072,000 L/yr
PEC in sewer (Mean concentration in effluent)	20 x 10^6 mg/63,072,000 L/yr ≅ 0.32 mg/L

These calculations assume the worst case scenario for the dyehouse *ie.* that all the chemical released is in the dissolved state. The calculations show that the exposure to fish and presumably daphnia, algae and wastewater treatment bacteria is at levels likely to cause a significant effect. However, the new chemical will carry a positive charge distributed over a system of aromatic rings, and consequently is likely to have a strong affinity for particulate and colloidal matter, which are usually negatively charged in the environment. Therefore, little of the chemical is likely to remain in a truly dissolved state, and association with particulate material would mitigate potential toxic effects.

The fate of the majority of the notified substance is linked with the fate of the particular item.

In this particular case, most of the dye will become attached to paper fibres that will ultimately go to landfill or incineration.

In the event of accidental spillage of the dyestuff into waterways, the chemical is expected to eventually become associated with the sediments. If the dyestuff is spilt on land, either during usage or transport, it is expected that the chemical would become immobilised in the soil layer. Contaminated soil would then be collected and disposed of to landfill.

Solid waste consigned to landfill, either from spillage or residues in packaging, would be expected to be retained at the landfill sites and not be mobile. Movement of the chemical by leaching from landfill sites is not expected because of its high binding affinity to soil.

Given the above, environmental exposure and the overall environmental hazard is expected to be acceptable.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

On the basis of the toxicological data submitted for the imported product, the notified chemical is likely to exhibit moderate to low acute oral toxicity. Skin irritation potential is uncertain given the staining of rabbit skin during the skin irritancy study. For this reason it is likely that a test for skin sensitisation potential would also be inconclusive. The product is a severe eye irritant in rabbits. Although it is likely the irritancy is due, at least in part, to acetic acid contained in the formulation, in the absence of a test using the notified chemical alone, it must be assumed that the chemical is hazardous according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a) on the basis of severe eye damage and acute oral effects. The risk phrases R 22: harmful if swallowed and R 41: risk of serious damage to eyes should be included on the Material Safety Data Sheet (MSDS) and label for Basazol Violet 46L. It is also reasonable to assume the chemical is a skin irritant.

An analogue of the notified chemical, ethyl violet chloride is not genotoxic as judged by tests for bacterial mutagenicity and chromosomal damage in Chinese Hamster V79 cells. Therefore, the notified chemical also may not exhibit genotoxic effects *in vitro*.

As the notified chemical exhibits acute toxic effects via the oral route and appears to be readily absorbed from the gut, it is possible that the notified chemical is a hazardous substance in terms of acute dermal effects and severe effects after repeated or prolonged exposure.

Occupational Health and Safety

The risk of adverse health effects resulting from exposure to the notified chemical during transport and storage of the 1 000 L Schuetz tanks in which it is imported is low as exposure is unlikely except in the event of accidental spillage.

Exposure of plant operators and quality control personnel is limited to 12 times per year when a new Schuetz tank containing the notified chemical is connected to a closed system in which the notified dye is exhausted on to paper fibre. The notifier estimates that approximately 20 mL of dye solution may be spilt on each of the 12 occasions and states that overalls, gloves, chemical face shields and goggles are made available for workers to wear during connection and disconnection operations.

The most likely adverse health effect from use or disposal of the notified chemical is skin or eye irritation (severe) in plant operators or quality control personnel. Infrequent exposure is likely to limit severe effects following repeated or prolonged use or acute dermal effects.

Once the dye is fixed to the fibre, the risk of adverse health effects is negligible as the notified chemical is bound to the matrix. It is likely to be no longer bioavailable, however fixation data were not provided by the notifier.

Acetic acid is present in the imported formulation at a concentration above the cut-off for irritancy and corrosivity according to NOHSC *List of Designated Hazardous Substances* (National Occupational Health and Safety Commission, 1997) endorsed by the National Commission. Therefore, the risk phrase R 34: causes burns should be included on MSDS and labels. Employers are responsible for ensuring that the NOHSC exposure standard of 25 mg/m^3 (TWA) and 37 mg/m^3 (STEL) is not exceeded in the workplace.

Public Health

The risk of adverse public health effects resulting from transport, storage, use or disposal of the notified chemical is minimal. Although the public will come into contact with food packaging products containing the notified chemical the public health risk is minimal given its low level (0.1%) in these products and low leachability from the products.

13. MATERIAL SAFETY DATA SHEET

The MSDS for the imported formulation containing the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994b).

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.

14. RECOMMENDATIONS

To minimise occupational exposure to the notified chemical the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992);
- Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987);
- Impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia /Standards New Zealand, 1998);
- All occupational footwear should conform to AS/NZS 2210 (Standards Australia/ Standards New Zealand, 1994);
- Spillage of the notified chemical should be avoided. Spillage should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Secondary notification of the notified chemical will be required under subsection 64(1) of the Act should the import volume be greater than 2.5 tonnes per annum or the concentration of the notified chemical in an imported formulation exceed 25% (w/v).

Secondary notification under subsection 64(2) shall be required if any of the circumstances stipulated in this subsection arise.

16. REFERENCES

1. Finney DJ (1991) *Probit Analysis*. Cambridge University Press.

2. Hoffmann HD & Engelhardt G (1995a) In vitro Chromosome Aberration Assay with Ethylviolett Chlorid in V79 Cells, Project No. 32M0284/944327, BASF Department of Toxicology, Ludwigshafen, Germany.

3. Hoffmann HD & Engelhardt G (1995b) *Report on the Study of Ethylviolett-Chlorid in the Ames Test, Project No. 40M0284/944330*, BASF Department of Toxicology, Ludwigshafen, Germany.

4. Kirsch P & Gamer AO (1988a) *Report on the Acute Dermal Irritation/Corrosivity to the Intact Dorsal Skin of the White Rabbit based on OECD Guideline 404; Test Substance: Basazol Violet 46L, Project No. 18H0217/882151*, BASF Aktiengesellschaft, Ludwigshafen/Rhein, Germany.

5. Kirsch P & Gamer AO (1988b) *Report on the Acute Irritation to the Eye of the White Rabbit; Test Substance: Basazol Violet 46L, Project No. 1H0217/882152*, BASF Aktiengesellschaft, Ludwigshafen/Rhein, Germany.

6. Kirsch P & Kersebohm B (1988) *Report on the Study of Acute Oral Toxicity; Test Substance: Basazol Violet 46L, Project No. 10A0217/881104*, BASF Aktiengesellschaft, Ludwigshafen/Rhein, Germany.

7. Nabholz JV, Miller P & Zeeman M (1993) *Environmental Risk Assessment of New Substances under the Toxic Substances Control Act Section Five*. In: W. G. Landis, J. S. Hughes and M. A. Lewis ed. Environmental Toxicology and Risk Assessment, American Society for Testing and Materials. ASTM STP 1179, Philadelphia, **:** 40-55.

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

9. National Occupational Health and Safety Commission (1997) *Draft List of Designated Hazardous Substances [NOHSC:10005(1997)]*.

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

11. Organisation for Economic Co-operation and Development (1995-1996) *OECD Guidelinesfor the Testing of Chemicals on CD-Rom.* OECD, Paris.

12. Standards Australia (1987) *Australian Standard 2919-1987*, Industrial Clothing. Standards Association of Australia, Sydney.

13. Standards Australia (1994) *Australian Standard 1336-1994, Eye protection in the Industrial Environment*. Standards Association of Australia, Sydney.

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

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

16. Standards Australia/Standards New Zealand (1998) *Australian/New Zealand Standard 2161.2- 1998, Occupational protective gloves, Part 2: General requirements*. Standards Association of Australia, Sydney.

17. Tonogai Y (1982*) Actual Survey On Tlm (Median Tolerance Limit) Values of Environmental Pollutants, Especially on Amines, Nitriles, Aromatic Nitrogen Compounds and Artificial Dyes*. The Journal of Toxicological Sciences, 7 : 193.