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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Dyestuff in Levacell Fast Blue

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 Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Health and Family Services.

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, Worksafe Australia, 92-94 Parramatta Road, Camperdown NSW 2050, between the hours of 10.00 a.m. and 12.00 noon and 2.00 p.m. and 4.00 p.m. each week day except on public holidays.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Dyestuff in Levacell Fast Blue

1. APPLICANT

Bayer Australia Limited, Speciality Products Group of 633-647 Springvale Road MULGRAVE NORTH VICTORIA 3170 has submitted a standard notification statement for an assessment certificate for Dyestuff in Levacell Fast Blue.

2. IDENTITY OF THE CHEMICAL

Dyestuff in Levacell Fast Blue has been classified as hazardous by Worksafe Australia due to its irritant potential. However for commercial reasons, the chemical identity, chemical composition and spectral data have been granted exemption from publication in the Full Public Report and 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 , Dyestuff in Levacell Fast Blue
- 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 an irritant 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.

Trade Name:	Levacell Fast Blue HS Liquid
Molecular Weight:	>1 000
Method of Detection	infrared (IR), ultraviolet (UV) and nuclear magnetic

and Determination:	resonance (^{1}H-NMR); separation by HPLC

Comments on Chemical Identity

The group of dyes to which this dye belongs fall into the acid, basic, reactive, azoic, vat, sulphur and direct dye classes dependent upon the substituents bound to the copper molecule (1). The notified substance has direct dye properties. Direct dyes are anionic compounds, soluble in water and able to dye cellulose fibres without the aid of mordants (2).

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	dark blue powder, imported formulation is a liquid which contains 17% (w/v) of dyestuff
Melting Point:	> 50°C (at 760 mm Hg), substance decomposes before melting
Relative Density:	1.440 at 20^{o}C
Vapour Pressure:	not measured, expected to be low
Water Solubility:	47.41 g/L was the highest concentration at which no precipitate could be observed, visual evaluation of precipitate on attempted dissolution, with dyestuff concentration determined by UV-absorption); however, much of the dye is more soluble; while a precipitate formed at higher concentrations, at the highest concentration of 400 g/L which could be successfully tested, 337 g/L dissolved
Partition Co-efficient (n-octanol/water):	P_{ow} < 2.4 X 10^{-3} (at 22^{o}C $^+/_-$ 1^{o}C), log P_{ow} < -2.6 by the(n-octanol/water) shaking flask method; (no clear interpretation was possible, as the absorption spectrum of the octanol phase differed from that of the standard solution, possibly because minor compounds were extracted into the organic phase; calculation of the maximum concentration P_{ow} assuming the organic phase did contain the main compound gave the above estimates)
Hydrolysis as a Function of pH:	not determined; hydrolytic degradation is unlikely
Adsorption/Desorption:	not determined; the low P_{ow} suggests that

	adsorption to soil is likely to be low, but the substance fixes strongly to cellulose
Dissociation Constant:	dissociation constant not determined; a 10% w/v solution of the substance gave a pH of 12.0 and a 1% solution a pH of 11.4; the pH of the solution at maximum total solubility (4.74%) was 11.2; the pH of the 17% liquid formulation (Levacell Fast Blue HS Liquid) is 12.5
Fat Solubility	< 4 X 10^{-5} % w/w at 37^{o}C (no clear interpretation was possible, as the absorption spectrum of the fat phase differed from that of the standard solution, possibly because minor compounds were extracted into the fat phase; calculation of maximum concentration assuming that the organic phase did contain the main compound gave the above estimate)
Flash Point:	not flammable
Flammability Limits:	not flammable
Autoignition Temperature:	does not autoignite
Explosive Properties:	not explosive
Reactivity/Stability:	not reactive, no oxidising properties

Comments on Physico-Chemical Properties

Melting point could not be determined as the substance decomposes before melting. The notifier indicates that the vapour pressure is likely to be low. A dissociation constant was not measured; however, a 10% solution of the notified substance gave a pH of 12.

4. PURITY OF THE CHEMICAL

Degree of Purity:	high
Toxic or Hazardous impurities:	not known
Non-hazardous Impurities (> 1% by weight):	> 10%

No information on the toxicity of one of the impurities was supplied by the notifier, it is not listed in Worksafe Australia's *List of Designated Hazardous Substances* (3), Toxline (4) or Sax and Lewis (5).

Additives/Adjuvants: no additives or adjuvants are used

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured locally but imported in 60 L drums as the finished sales product Levacell Fast Blue HS Liquid. The notified chemical will be used to dye paper substrates such as tissue and writing paper.

Dyestuff in Levacell Fast Blue will be used solely in the paper industry for the industrial colouration of paper and tissue and not for home dyeing and paper making. Approximately 5-10 tonnes/annum of the dye will be imported in the next five years.

6. OCCUPATIONAL EXPOSURE

Exposure during transport and warehousing will only occur in the event of accidental spillage. The notified chemical is imported in 60 L drums which are transported from the notifier's warehouse to the paper mill for use. The notified chemical is classified as a Class 8 dangerous good (corrosive substance) and Hazchem code 2R according to the *Australian Dangerous Goods Code* (6). The contents of the drum are pumped to the reservoir of the dyeing apparatus. The potential for occupational exposure to the notified chemical will be greatest during these transfer operations.

The dye is applied to the paper by a totally automated enclosed spray system. The dye is applied at a rate of 0.3 g dye/100 g of fibre. The paper is fed into the dye application system (16 tonnes/hour) by continuous conveyor and is then conveyed to a drying tunnel. Occupational exposure may occur during maintenance and repair of this equipment. The main exposure routes are likely to be through dermal contact, or if inadvertently splashed, then the eyes. The expected low vapour pressure should limit inhalational exposure.

Occupational exposure to the notified chemical when fixed to the dyed paper will be limited as the dye binds strongly to the paper fibre and is unlikely to migrate from the fibre surface.

Occupational exposure to residues within the shipping drums will be limited. Prior to recycling, the drums are washed out and the effluent discharged into the dyeworks' effluent treatment system as is the spent dye liquor.

7. PUBLIC EXPOSURE

There is negligible potential for public exposure to Dyestuff in Levacell Fast Blue arising from the end use process. The dyestuff suspension will be transported to a single warehouse and then supplied by road to several papermills. In the event of a transport accident, the spill is to be contained. Residual liquids can be neutralised,

absorbed in vermiculite, sand or soil prior to collection and disposal according to local regulations.

Dyestuff in Levacell Fast Blue is imported as a ready to use suspension and is pumped directly to a totally automated enclosed spray system. In this system, paper is supplied by continuous conveyor, spray-dyed and then fed into a drying tunnel.

Waste water containing drum residues and application losses is disposed of to the dyeworks effluent treatment system. Assuming there is a maximum of 1% of the spray liquor lost during spray application, then nationally, an estimated 100 kg/year of the notified substance would be lost to waste disposal.

Most of the notified dyestuff will enter the public domain as finished paper products. The dyestuff will not be sold to the public and will only be used for industrial applications. Although public contact with the notified substance will occur, the notifier states that the substance binds strongly to paper fibres and is unlikely to be released or migrate from the paper surface.

8. ENVIRONMENTAL EXPOSURE

Release

Dyestuff in Levacell Fast Blue contains groups, which impart high water solubility and have a high affinity for cellulosic fibre (7). The notified substance presumably acts as a direct dye. Direct dyes are applied to substrate from neutral or slightly alkaline baths containing additional electrolyte (8).

Dyestuff in Levacell Fast Blue will be used solely in the paper industry for the industrial colouration of paper and tissue and not for home dyeing and paper making.

Dyestuff in Levacell Fast Blue will be imported as the finished sales product Levacell Fast Blue HS Liquid in 60 L drums and transported from the point of entry (dockside) to the Bayer site at Mulgrave North, Victoria. It will be stored there in a chemical warehouse prior to being transported to the user's site, Australian Paper, Burnie, Tasmania. The dye will be pumped from the 60 L drums into the reservoir of an automated dyeing apparatus, where it will be mixed with additives to form the dye liquor. Thus it will not be reformulated or repackaged in Australia. Barring the unlikely event of a major transport accident, spillage during product distribution is not expected.

The residue remaining in drums after unfilling is estimated to be 0.5 L of product, corresponding to 0.085 kg of the notified substance (~ 1%). The drums will be recycled (presumably to the dye manufacturer) after washing with water, and the washings will be discharged into the dyeworks effluent treatment plant.

The dye liquor prepared in the dyeing apparatus reservoir is applied to paper products in an enclosed pump/spray system. Hence in the absence of equipment failure, the only likely means of environmental release during the dyeing process are in spent dye liquor as excess dye not picked up by the paper (claimed to be < 2%

remaining in the aqueous phase - see below) and as a result of washing of the dyeing apparatus. The notifier states that unused liquor material and washings will be discharged into effluent, and estimates that losses by this means will be < 0.5%.

Effluent from the pulp and paper mill containing dye residues passes through primary treatment only before being discharged by ocean outfall into Burnie Bay. Dye residues may be present in effluent re-used in a section of the pulp mill before passing to primary treatment. The notifier states that the fixation rate has not yet been determined and will depend on exact conditions during use (concentration of additives, flow rate of materials etc.). However, the dye will not be used if a high fixation rate to paper (> 98%) is not achieved, as residues in effluent would exceed requirements for bleaching and recycling.

Advice on the Material Safety Data Sheet (MSDS) for control and disposal of spills is to absorb spills with materials such as vermiculite, earth or sawdust and dispose of this material in accordance with Local and State regulations.

Fate

A standard of 98% dye fixation will be required by Australian Paper at Burnie.

The notifier claims that the dye binds strongly with cellulose fibres and is unlikely to migrate from the fibre surface, though it should be noted that conditions (pH and electrolyte concentration) during exposure in effluent may be greatly different from those in the dye bath. A study of adsorption of dyes to biomass in an activated sludge plant found that sulphonated and other cationic substituted basic and direct dyes are highly adsorbed to sludge, where anaerobic degradation of the dye's substituted derivatives may occur (9). Thus although hydrophilic, Dyestuff in Levacell Fast Blue present in effluent can be expected to bind strongly to cellulose material, either during any re-use of water in the pulp mill, or to cellulose particles in sludge (a significant component of sludge in this case, from the pulp and paper mill). It is presumed that this dye will be resistant to chemical change as a result of any contact with bleaching agents.

Thus the concentration of the notified substance in effluent due to rinsing of drums, washing of equipment, unused dye liquor and spent dye liquor is likely to be reduced greatly by adsorption to cellulose fibres during water re-use and primary effluent treatment. Only a small proportion of residues are likely to enter freshwater or marine environments (Burnie Bay) in solution, and the concentration in discharged treated effluent will be greatly diluted to insignificant levels. As indicated below, Dyestuff in Levacell Fast Blue is not readily biodegradable during sewage treatment, but slow biodegradation of residues in sediment is likely. It is presumed that release of the substance to solution from degradation of cellulose would be gradual and limited. Residues adsorbed to sludge at the Burnie mill are disposed of to landfill (10), where slow break down may occur.

Another possible source of environmental exposure to the free substance is during paper recycling, which is a growing industry in Australia. Waste paper is repulped using a variety of alkalis, dispersing agents, wetting agents, water emulsifiable organic solvents and bleaching agents. These chemicals enhance fibre separation,

ink detachment from the fibres, pulp brightness and the whiteness of the paper. After pulping, the contaminants and the ink are separated from the fibres by pumping the stock through various heat washing, screening, cleaning, flotation and dispersion stages. It is uncertain to what extent the notified substance would be altered or removed during such processes, but any of the notified substance which was removed would be disposed of in landfill in sludge from the recycling plant, where it would be likely to degrade slowly.

After use, paper containing the dye may also be disposed of to landfill, to sewer, or by incineration. Incineration should destroy the notified substance, while residues reaching landfill or the sewer are likely to remain attached to cellulose or sludge particles and are likely to degrade slowly.

Biodegradation

The substance was determined to be not readily biodegradable in a Manometric Respirometry Test (according to EEC Directive 79/831, Annex V, Part C, Method C.4-D, July 1990). The test substance was suspended in a mineral medium, inoculated with activated sewage sludge and incubated for 28 days in the dark at 20^0C. No degradation of Dyestuff in Levacell Fast Blue occurred in this period.

Bioaccumulation

The bioaccumulation potential of Dyestuff in Levacell Fast Blue was not investigated. The substance has a high molecular weight (> 1 000), low partition coefficient (log P_{ow} <-2.6), high water solubility (> 47.4 g/L) and low fat solubility (< 0.4 mg/kg), hence significant bioaccumulation is not likely (11).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Dyestuff in Levacell Fast Blue

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 000 mg/kg	12
acute dermal toxicity	rat	LD_{50} > 2 000 mg/kg	14
skin irritation	rabbit	not undertaken	refer to 14
eye irritation	rabbit	not undertaken	refer to 14
skin sensitisation	guinea pig	not a skin sensitiser	15

9.1.1 Oral Toxicity (12)

Species/strain:	Wistar rats
Number/sex of animals M/F:	5/5
Observation period:	14 days
Method of administration:	gavage in 0.9% physiological saline, 2 000 mg/kg
Clinical observations:	none, discolouration of faeces
Mortality:	nil
Morphological findings:	nil
Test method:	based on OECD Guidelines for Testing Chemicals (13)
LD_{50}:	> 2 000 mg/kg
Result:	low oral toxicity

9.1.2 Dermal Toxicity (14)

Species/strain:	Wistar rats
Number/sex of animals M/F:	5/5
Observation period:	14 days
Method of administration:	dermal application for 24 hours under

	occluded dressing of 2 000 mg/kg pasted in 0.9% physiological saline solution
Clinical observations:	no signs of systemic toxicity
Mortality:	nil
Morphological findings:	blue discolouration, 4/3 test animals had inflammation; until day 13 in 0/2 test animals; in one female a wound was apparent at application site
Draize scores (15):	not available
Test method:	based on OECD Guidelines for Testing Chemicals (13)
Result:	low dermal toxicity, potential for skin irritancy with prolonged exposure; no skin or eye irritation studies were undertaken as a 10% solution of the notified chemical was found to have a pH of 12; the caustic nature indicates that the test material would be damaging and tests were not considered necessary.

9.1.6 Skin Sensitisation (16)

Species/strain:	Bor: DHPW guinea pigs
Number of animals:	20 test animals, 2 groups of 10 controls; all test animals were females
Induction procedure:	three pairs of injections of 0.1 ml: FCA in physiological saline (1:1); 0.5% notified chemical in physiological saline; 5% notified chemical formulated in physiological saline and Freund's Complete Adjuvant (FCA); topical induction: at day 6, 10% sodium lauryl sulphate in paraffin oil followed by hypoallergenic patches treated with either 0.5 ml of test substance or 0.5 ml of sterile physiological saline.
Challenge procedure:	3 weeks after induction. 0.5 ml of 12% or 25% test solution on patches for 24 hours.
Challenge outcome:	no reaction
Test method:	based on OECD Guidelines for Testing Chemicals (13)

Result:	test substance has no sensitising potential under conditions of test

9.2 Repeated Dose Toxicity (17)

Species/strain:	Wistar rats
Number/sex of animals M/F:	5/5 per dose group and 5/5 additional test animals at high dose for recovery studies
Method of administration:	gavage test material in physiological saline solution
Dose/Study duration::	0, 40, 200 and 1 000 mg/kg for 29 days, additional 21 days for recovery studies for 1 000 mg/kg/days animals
Clinical observations:	all treatment groups showed discolouration of the faeces and the skin in the caudal region; high dose group also showed discolouration of the urine;
Clinical chemistry/Haematology	high dose females had a significant increase in total protein and albumin, in males there was a decrease of these parameters in all dose groups; all levels were within physiological range
Histopathology/necropsy:	no toxicologically relevant effect on organ weight; discolouration of gastrointestinal tract; this was found to be reversible in the high dose recovery group; one high dose female showed a bilateral necrosis in the adrenal cortex
Test method:	based on OECD Guidelines for Testing Chemicals (13)
Result:	doses up to and including 1 000 mg/kg were tolerated without adverse effects for the duration of the study

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (18)

Strains:	*Salmonella typhimurium* TA98, TA100, TA1535, TA1537
Concentration range:	8 - 5 000 μg/plate with or without rat liver S9
Test method:	in accordance with OECD Guidelines for Testing Chemicals (13)
Result:	non-mutagenic in bacteria, controls gave appropriate responses

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (19)

Species/strain:	Bor: NMRI mice
Number and sex of animals:	study 1 5/5, study 2 5/5
Dose:	350 mg/kg
Method of administration:	intraperitoneal injection, test article in physiological saline
Test method:	in accordance with OECD Guidelines for Testing Chemicals (13)
Result:	in study 1, 5% mortality in study 2, 25% mortality and all animals showed symptoms of toxicity; no evidence of clastogenesis (no significant increase in micronuclei formation); controls gave appropriate response

9.4 Overall Assessment of Toxicological Data

The notified chemical, Dyestuff in Levacell Fast Blue, in a rat oral toxicity study had low toxicity with an LD_{50} > 2 000 mg/kg. A dermal toxicity study in rats also indicated low toxicity with an LD_{50} > 2 000 mg/kg. There were signs of skin irritation in this study and due to the caustic nature of a solution of the notified chemical (pH12), eye and skin irritation studies were considered unnecessary. In a skin sensitisation study using guinea pigs the notified chemical was not a skin sensitiser.

A 28 day repeat dose study using rats showed no toxicologically significant dose related effects at a dose rate of 1000 mg/kg/day. There was staining of the gastrointestinal tract but this was found to be reversible following

necropsy of mice allowed to recover for fourteen days. The only other observations of significance were that females dosed at 1 000 mg/kg/day had a significant increase in total protein and albumin. In males it was decreased in all dose groups. The levels of protein and albumin in all test animals were within the physiological range.

In studies to assess the clastogenic potential of the notified chemical all results were negative. A *S. typhimurium* reverse mutation assay with, and without S9 activation at concentrations up to and including 5 000 μg/plate did not indicate that the notified chemical was a bacterial mutagen. An *in vivo* micronucleus assay in the bone marrow cells of the mouse gave negative results.

The notified chemical would not be classified as hazardous according to the Worksafe Australia *Approved Criteria for Classifying Hazardous Substances* (20) on the basis of its oral or dermal toxicity to rats or the results of the genotoxicity studies. On the basis of the pH of the notified chemical, it would be considered corrosive and therefore classified as hazardous due to its irritant potential.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following test results were obtained according to Council Directive 67/548/EEC (Draft 1992 - SOP 4.002, "Acute Toxicity for Fish" and SOP 4.004, "Acute Toxicity for Daphnia") and ISO 8192-1986 (E) (corresponding to OECD Guideline 209) SOP 3.005 (toxicity to bacteria). The notifier requested that permission be given to omit algal growth inhibition data, considering the minimal claimed release of the substance to the environment, but did provide a bacterial respiration inhibition study (Table 1). Algal toxicity could arise directly and also indirectly, through absorption of photosynthetically active wavelengths of light.

These results indicate that Dyestuff in Levacell Fast Blue is at most slightly toxic to fish and daphnids. While a reproduction toxicity test for daphnids was not conducted, the slight acute toxicity to these organisms, the low predicted environmental concentration and the probability that the dye will not undergo cellular absorption indicate that reproductive effects are unlikely to be observed.

The test evaluating respiratory inhibition of microorganisms in activated sewage sludge indicated that the dye is practically nontoxic to microbes, as expected for a sulphonated compound which is unlikely to be absorbed by microbial cells.

Table 1: Environmental toxicology tests of Dyestuff in Levacell Fast Blue.

Test	*Species*	*Results*
acute toxicity (mortality; static system; measured concentration)	zebrafish (*Brachydanio rerio*)	96 h LC_0, LC_{50} > 90.1 mg/L (no significant effect on fish length or weight, and all fish in each treatment showed normal swimming behaviour throughout the experiment)*
acute toxicity (immobilisation; static system; measured concentration)	*Daphnia magna*	48 h EC_0, EC_{50} > 92.1 mg/L (measured concentration)
bacterial respiration inhibition	activated sewage sludge	EC_{50} > 10 000 mg/L (14.5% inhibition at 10 000 mg/L)

* All fish died at a nominal concentration of 100 mg/L in an earlier test which was dismissed because of low water hardness caused by a pump malfunction

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The main hazard arising from use of Dyestuff in Levacell Fast Blue will be associated with direct discharge from paper mills or release from sewage treatment works of unfixed residues into the aquatic environment. Due to its chemical stability and poor biodegradability, Dyestuff in Levacell Fast Blue is likely to retain its copper phthalocyanine structure upon release to the 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 may undergo slow biodegradation.

The notifier has advised of only one site (Burnie) where the substance will be used and has advised that the dye is added at a rate of 0.3 g/100 g fibre, with a fibre flow rate of 16 t/hr. Thus the dye usage rate is 48 kg/hr. Assuming that 2% of this quantity remains in the used dye liquor, 1% remains in drums after they are emptied and 0.5% is lost in unused dye liquor and through washing of equipment, the rate of discharge of waste dye is 1.68 kg/hr. Flow rates of the paper mill wastewater and total mill site wastewater average 120 and 800 L/sec respectively (10). Thus an approximate estimate of the concentration of the notified compound in wastewater leaving the paper mill is 3.9 mg/L ((1.68 X 10^6)/(120 X 60 X 60)). If this concentration is taken as a worst case estimated environmental concentration (EEC), and the LC_{50} and EC_{50} values for fish and *Daphnia* taken to be ~ 90 mg/L, the Environmental Hazard Quotient (Q=EEC/LC_{50} - (21)) for residues of Dyestuff in Levacell Fast Blue in mill wastewater is 0.043, which falls into the "no environmental risk" category (Q < 0.1).

However, this quantity is further diluted (6-7 X) by wastewater from the rest of the mill site and passes through a primary treatment facility before discharge into Burnie Bay (10). The residence time during approximately 1 300 m of channel or pipe between the paper mill and treatment plant should be sufficient for a high proportion of the dye present in solution to fix to cellulose fibre also present in effluent. The

cellulose residues are then removed as sludge during primary treatment, dewatered and disposed of to landfill. Thus the quantity of dye likely to remain in effluent after primary treatment is small and the dilution in other wastewater and ocean water is large. If 85% of the dye is adsorbed to cellulose, the concentration of the dye remaining in the discharged water would be approximately 0.6 mg/L, producing a Q value of 0.007, and this concentration would be likely to be greatly diluted by other water from the site and from bay water subsequent to discharge.

Thus the predicted environmental concentration in bay water is expected to be at least 2 orders of magnitude lower than concentrations shown not to cause acute effects to fish or *Daphnia*, and far below concentrations causing significant inhibition of bacterial respiration. Toxicity data for algae and prolonged toxicity data to Daphnids are unavailable, but dilution is such that adverse environmental effects should not occur with release of effluent into the large volumes present in coastal waters. However, such data may be required if the product is to be used more widely.

Residues of Dyestuff in Levacell Fast Blue in sludge from the pulp and paper mill or paper recycling plants, or on waste paper, should remain attached to cellulose fibres and may degrade slowly if buried in landfill (most likely fate), or break down during incineration.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical has a low oral and dermal toxicity to rats of LD_{50} > 2 000 mg/kg in both cases. A 28 day repeat dose study using rats did not result in any toxicologically significant dose related responses at doses up to 1 000 mg/kg/day. It was not genotoxic in a *S. typhimurium* reverse mutation assay with and without S9 activation at concentrations up to and including 5 000 μg/plate. An *in vivo* micronucleus assay in the bone marrow cells of the mouse also gave negative results. On the basis of its corrosive nature (pH 12) the notified chemical would be classified as hazardous according to the Worksafe Australia *Approved Criteria for the Classifying Hazardous Substances* (20) due to its potential to irritate skin and eyes. There is significant risk during occupational exposure and appropriate personnel protective equipment to minimise eye and skin contact is required.

It should be noted that for one of the impurities, no information was supplied by the notifier on its toxicology; it was not listed on various databases (3,4,5). Additionally there is no indication that it will be firmly bound to the end use paper products. However the toxicity tests described above were performed with 73% pure notified substance in aqueous suspension, and presumably the toxicity of the impurities would have been evident under these conditions. Additionally the low level of the impurity (calculated at 5 mg/piece of A4 paper (weighing 5 g) would mean that a child or sensitive individual could be exposed orally to toxicologically insignificant concentrations of the impurity.

Occupational exposure during transport and warehousing will only occur in the event of accidental spillage. It is classified as a dangerous good Class 8 and Hazchem

code 2R under the Australian Dangerous Goods Code (6). The notified chemical is imported in 60 L drums. The contents are pumped into the reservoir of the dyeing apparatus at the paper mills. Occupational exposure to the notified chemical will be greatest during these transfer operations.

The dye is applied to the paper by a totally automated enclosed spray system. The paper is fed into the dye application system by continuous conveyor and is then conveyed to a drying tunnel. Occupational exposure may occur during maintenance and repair of this equipment. The main exposure routes are likely to be through dermal contact, or if inadvertently splashed, then the eyes. The expected low vapour pressure should limit inhalational exposure.

Occupational exposure to the notified chemical when fixed to the dyed paper will be limited as the dye binds strongly to the paper fibre and is unlikely to migrate from the fibre surface. There is a degree of risk associated with occupational exposure to the notified chemical when in the liquid form due to its caustic and corrosive characteristics.

There is negligible potential for public exposure to Dyestuff in Levacell Fast Blue from paper dyeing processes. There may be widespread public contact with the notified substance on the surface of treated papergoods, but its firm adhesion to the substrate will be sufficient to preclude absorption across the skin or other biological membranes. Oral intake is possible but unlikely.

13. RECOMMENDATIONS

To minimise occupational exposure to Dyestuff in Levacell Fast Blue the following guidelines and precautions should be observed:

- If engineering controls and work practices are insufficient to reduce exposure to Dyestuff in Levacell Fast Blue to a safe level, then the following personal protective equipment which conforms to Australian Standard (AS) or Australian/New Zealand Standard (AS/NZS) should be worn;

  Safety goggles should be selected and fitted in accordance with AS 1336 (22) to comply with AS/NZS 1337 (23),

  Industrial clothing should conform to the specifications detailed in AS 2919 (24) and AS 3765.1 (25),

  Impermeable gloves or mittens should conform to AS 2161 (26) and AS 3765.1 (27),

  All occupational footwear should conform to AS/NZS 2210 (28);

- Spillage of the notified chemical should be avoided, spillages 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 Material Safety Data Sheet should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the formulation containing the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (29).

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. Secondary notification will also be required if the notifier supplies the notified chemical to other paper mills. In that event, the notifier should provide information supporting 98% fastness, plus algal toxicity data.

16. REFERENCES

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