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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Levafix Blue CA

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Director
NICNAS

TABLE OF CONTENTS

FULL PUBLIC REPORT

Levafix Blue CA

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Dyechem Industries Pty Ltd (ABN 76 055 025 879)
60-62 Kylta Road
West Heidelberg, Victoria 3081

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical name, other names, CAS number, molecular formula, molecular weight, spectral data, impurities, additives, import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Vapour pressure, adsorption/desorption, particle size, flash point, flammability, autoignition temperature, acute inhalation toxicity, *in vitro* chromosomal aberration.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US (1998)
EU (1995)
Canada (1999)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Levafix Blue CA

ANALYTICAL DATA
Reference IR, UV-Vis, and elemental analysis were provided. HPLC and ion chromatography were used to determine purity.

3. COMPOSITION

DEGREE OF PURITY
55%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical is imported as a 60-65% preparation in the form of a low dust granulate. No manufacturing will occur in Australia.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1-3	1-3	1-3	1-3	1-3

USE
The notified chemical is used for the colouration of cellulose textile mixtures.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Dyechem Industries Pty Ltd: Dyechem is the importer and distributor of the product and does not perform the textile dyeing processes. It is expected that the notified chemical will be used at dye houses in Victoria, with the bulk of the product being used at a dyehouse in country Victoria.

TRANSPORTATION AND PACKAGING
The notified chemical is imported in cardboard boxes, 15 kg to 25 kg in size. The shipment is transported from the dock to the notifier's warehouse, and then to the dyehouse sites by road.

5.2. Operation description

The typical procedures undertaken at the dyehouse sites are detailed below.

Laboratory technicians perform colour matching in which they weigh and mix small samples of the imported product (60-65% notified chemical) and then dilute it in water to give a final concentration of < 6%.

The imported product (60-65% notified chemical) will be weighed and then manually added into the dilution tank in 2 kg aliquots. The notified chemical is diluted to give a dye solution containing < 6% notified chemical. The weighing area has local mechanical ventilation to remove any build up of dye mist.

The dye solution (< 6% notified chemical) is manually transferred to an open feed tank, and then automatically sprayed onto cloth on a continuous roller inside the enclosed dyeing machine. The machine is opened on a regular basis to glean loose fibres out of the filter with a hose. It may also be opened if the cloth becomes tangled and has to be realigned on the rollers. The used dye solution will go into the waste stream. The dyed cloth is fixed at low pH and then washed in warm soapy water to remove any free dye.

The wet dyed cloth is manually transferred into dryers. The concentration of free dye is expected to be low at this time, as the dye is fixed to the cloth and the excess has been washed out during the dyeing process.

The finished dyed textile containing < 1% notified chemical will then be stored or delivered to customer facilities and used to produce a variety of consumer textile products.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and storage	4-6	2 hours/day	10 days/year
Laboratory - colour matching	5	0.5 hours/day	100 days/year
Weighing and mixing	60	1 hour/day	200 days/year
Dyeing	160	1 hour/day	200 days/year
Curing/rinsing/drying	100	0.75 hours/day	200 days/year

Exposure Details

Transport and storage

Transport and storage workers will handle closed containers of the imported product containing 60-65% notified chemical. Exposure to the notified chemical is not expected except in the case of an accident where the packaging is breached.

Dyehouse Laboratory technicians

Laboratory technicians may be exposed to the imported product (60-65% notified chemical) granules, or to dyes solutions containing < 6% notified chemical. Dermal and ocular exposure is possible due to spills of the product granules, or drips, spills and splashes of the dye solution. Inhalation would be minimised by the low dust formulation of the granules. Personal protective equipment, including protective clothing and safety glasses, is expected to be worn.

Dyehouse weighing/mixing, dyeing and drying

At customer dye houses, dermal and ocular exposure due to splashes and spillages may occur during weighing (60-65% notified chemical), and mixing, transferring and equipment cleaning procedures (up to 6% notified chemical) at the dye plant. Any potential inhalation of the notified chemical would be minimised by the low dust formulation, the use of local exhaust ventilation during the dissolution process and by the enclosed nature of the dyeing process.

While some manual handling of the notified chemical and of textiles treated with the notified chemical occurs, the dyeing process is automated, enclosed and performed by trained staff. There is potential for dermal and ocular exposure to the notified chemical (<1% notified chemical) when the dyeing machine is opened to untangle the textile or to glean loose fibres. Operators of the dyeing machines typically wear safety glasses, chemically resistant gloves, safety shoes, and aprons or other protective clothing. In addition, appropriate respiratory protection is worn during weighing and mixing, as well as cleaning and maintenance procedures. Copies of the MSDS will be readily accessible in all work areas.

After the dyeing, fixation, rinsing, and drying process, exposure to the notified chemical by means of contact with the treated textile is not expected as the notified chemical is covalently bound to the textile.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Since the notified chemical will not be manufactured locally, there will be no environmental exposure associated with this process in Australia.

Nearly all of the dye containing the notified chemical will be removed from the import container liners by shaking and less than 1% of the chemical per annum will remain as residue. Given the potential for recovery and reuse and the high unit cost of the dyestuff the waste due to spills is expected by the notifier to be less than 1% per annum. Dissolution of the dye takes place in an enclosed vat and the dye is pumped through a closed system to the dyeing machine, therefore, release of the chemical is not expected at this stage.

The dye will be used to colour cellulosic textiles using a jet dyeing method. Once the dye has been sprayed onto the fabric it is adsorbed and diffused into the fibre matrix where it reacts with active sites on the substrate during the fixing process at low pH producing strong covalent bonds. The fabric is then washed to remove the unreacted dye. Fixation data provided by the notifier indicates that the fixation rate of the notified chemical to be 90%. The notified chemical adsorbed to the fabric with the

dye will not be released to the environment. The rinsate generated via fabric rinsing should contain up to 10% of the notified chemical imported. This will represent the major route of environmental exposure (up to 300 kg of notified chemical per annum based on the maximum import volume).

The dye washed off the fabric will be discharged to the dyehouse effluent system. The notifier indicates that the majority of the notified chemical will be used at a country dye house in Victoria. The effluent from this dye house is sent directly to a trade waste centre where the effluent is treated with activated sludge before discharge to the local waterway system.

RELEASE OF CHEMICAL FROM USE
The dye is expected to remain bound to the textile. Minimal amounts of the chemical may be released during the life of the textile product through washing, where the chemical is expected to be released to sewer.

5.5. Disposal

Any solid waste generated at the dyehouse including the residue in empty import containers will be disposed of as chemical waste according to the MSDS instructions. Incineration is recommended due to the high water solubility of the notified chemical.

At the end of the useful life of the textile product, it will be disposed to landfill. Although some recycling of textiles occurs, this is expected to merely extend the useful life of the textile or yarn.

5.6. Public exposure

The public will come into contact with treated textiles containing < 1% of the notified chemical. However at this stage the notified chemical is covalently bound to the fabric and the public exposure to the notified chemical is therefore expected to be minimal.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Dark blue granules

Melting Point/Freezing Point > 300ºC

METHOD	EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Determined using Tottoli/capillary method. No melting point observed up to 300°C.
TEST FACILITY	Bayer AG (1995a)

Density 1512 kg/m^3

METHOD	EC Directive 92/69/EEC A.3 Relative Density.
Remarks	The displacement method was used to determine density. The temperature at which the density was determined was not recorded.
TEST FACILITY	Bayer AG (1995a)

Vapour Pressure Not determined

Remarks	The notified polymer is a salt and is therefore expected to have a very low vapour pressure.

Water Solubility 220 g/L at 20ºC

METHOD	Bayer AG SOP F 0036902 DZA
Remarks	Different amounts of dye were dissolved in water and the concentration of the saturated solution was determined graphically from the solubility curve and the regression straight line. The test was conducted at room temperature. Test material concentrations were determined using HPLC.
TEST FACILITY	Bayer AG (1995b)

Fat (or n-octanol) Solubility ≤ 0.003 mg/100 g fat at 37°C

METHOD OECD TG 116 Fat Solubility of Solid and Liquid Substances.
Remarks Mixtures containing test substance and fat were stirred at 30ºC or 50ºC for 3 h and at 37ºC for 3 or 27 h. The saturated liquid phase was separated from the undissolved substance by filtration. The extracts from the filtrate were subject to spectrophotometric analysis.
TEST FACILITY Aventis Research and Technologies GmbH and Co KG (2000a)

Hydrolysis as a Function of pH

METHOD EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$ (hours)*
4	25°C	65.5
7	25°C	9097
9	25°C	812.5

Remarks The concentrations of the test material were monitored using HPLC. The hydrolysis of the test material was examined at three temperatures (50°C, 65°C and 75°C) at the pH values of 7 and 9, while at a pH 4 the hydrolysis was studied at 39°C and 50°C. The test material contains two main compounds. The sum of both compounds was determined.
TEST FACILITY Bayer AG (1997)

Partition Coefficient (n-octanol/water) log Pow < -2.7 at 20°C

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks Flask Method. An n-octanol saturated water solution of the test material (1.294 g/L) was added to water saturated n-octanol. The resultant mixture was shaken for 1 h, then the two phases were separated and the concentration of the test substance in each phase determined. The concentration in the aqueous phase was determined to be 1.33 g/L and the concentration in the organic phase was $<3 \times 10^{-3}$ g/L. The ratio of the concentrations was used to estimate the partition coefficient. This was considered a pre study and was not conducted according to GLP.
TEST FACILITY Bayer AG (1995c)

Adsorption/Desorption Not Determined

Remarks The high water solubility and the low partition coefficient of the notified chemical would indicate that it is not likely to bind strongly to soils or sediments.

Dissociation Constant pKa = 1.8 -5.8 at ~22ºC

METHOD OECD TG 112 Dissociation Constants in Water.
Remarks The pKa determination was performed in triplicate in the acid and alkaline range. The pKa for the alkaline range was not determined as the notified chemical decomposed in alkaline solutions as demonstrated in the hydrolysis study. The pH and the UV-Visible spectra of each solution were measured. It is noted that the chemical has a purity of about 65% and the possible effects of impurities were not examined. The notified chemical is a salt of a strong acid and is expected to remain completely ionised in the environmental pH range of 4-9.
TEST FACILITY Aventis Research and Technologies GmbH and Co KG (2000b)

Particle Size Not determined

Remarks The notified chemical is imported and used as low dust granules. The notifier has indicated the average diameter of the granules is 165 μm. No testing report was available.

Flash Point Not determined

Remarks Based on the expected low volatility of the salt, the notified chemical is not expected to form a flammable air/vapour mixture.

Flammability Not highly flammable

Remarks Although no study was provided, the combustion behaviour at ambient temperature is characterised by the combustion number BZ.2 (catches fire briefly and extinguishes rapidly). The combustion behaviour at elevated temperature (100°C) is characterised by the combustion number BZ.3 (local burning or glowing without spreading). Based on this information the notified chemical is not classified as flammable according to the Australian Dangerous Goods classification (FORS, 1998).

Autoignition Temperature Not determined

Remarks The notified chemical is not expected to autoignite under normal conditions of use.

Explosive Properties Minimally explosive (non dedusted formula)

Remarks No test report was provided. The dust explosibility of the non dedusted product (not the form imported) was investigated and found to be minimally explosive. The screening test in the Hartmann Apparatus enabled the derivation of the minimum ignition energy (MIE) as >> 10 J. This high MIE indicates that ignition risk by normal ignition sources (especially by electrostatic discharges) can be excluded. The risk of dust explosion is limited to strong ignition sources, e.g. flames and smouldering nests. The low dust formulation, which is imported into Australia, is expected to be even less explosive.

Reactivity

Remarks The test material is fibre-reactive; otherwise the reactivity of the test material is expected to be low under ordinary conditions of use and storage. The notified chemical was determined to be stable in water for 8 days at room temperature (Bayer AG, 1995d). The notified chemical is stated to decompose in a closed system in a two stage process starting at 150°C. Combustion products may contain carbon, nitrogen, and sulphur oxides.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral	LD50 > 2000 mg/kg bw; low toxicity
Rat, acute dermal	LD50 > 2000 mg/kg bw; low toxicity
Rat, acute inhalation	not determined

Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test.	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL = 40 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro	not determined
Genotoxicity – in vivo mouse micronucleus test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical (60-65% purity)
METHOD	EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.
Species/Strain	Rat/ SPF-bred Wistar
Vehicle	Demineralised water
Remarks - Method	No significant protocol deviations. The calculation of the amount of test substance to be administered was done taking into account a content of 65% notified chemical.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 male; 5 female	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity	Blue discolouration of the faeces was observed from four hours until the third day following treatment. No other clinical signs from the fourth day until the end of the observation period.
Effects in Organs	No noticeable gross pathological findings.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Bayer AG (1995e)

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical (60-65% purity)
METHOD	EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/ SPF-bred Wistar
Vehicle	Cremophor EL (PEG-35 Castor oil) used to form a paste with the notified chemical.
Type of dressing	Occlusive
Remarks - Method	No significant protocol deviations. The calculation of the amount of test substance to be administered was done taking into account a content of 65% notified chemical.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 male; 5 female	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	No signs of local toxicity. Blue discolouration of the skin at the

	application site was observed in all animals, which persisted until the 9th day of observation.
Signs of Toxicity - Systemic	No signs of systemic toxicity were observed. Body weight development of all animals was not affected.
Effects in Organs	No visible change in macroscopic examinations.
Remarks - Results	No animals died during the 14 day observation period.

CONCLUSION The notified chemical is of low toxicity via the dermal route.

TEST FACILITY Bayer AG (1995f)

7.3. Acute toxicity – inhalation

REMARKS Not determined

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical (60-65% purity)

METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Moistened with deionised water
Observation Period	7 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0**	0**	0**	0	-	-
Oedema	0	0	0	0	-	-

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.
**No eschar formation observed; erythema could not be evaluated due to skin colouration by the test substance.

Remarks - Results	Due to the intense colouration of the skin by the notified chemical the evaluation of erythema was not possible. However, no other inflammatory signs (eschar or oedema) were observed during the observation period.

CONCLUSION The notified chemical is non-irritating to the skin.

TEST FACILITY Bayer AG (1995g)

7.5. Irritation – eye

TEST SUBSTANCE Notified chemical (60-65% purity)

METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3

Observation Period	7 days
Remarks - Method	No significant protocol deviations. Fluorescein application to the eye 24 hours after instillation was used to define the epithelial damage. In addition to the observations required in OECD TG 405, the aqueous humour (opacity) was also examined.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	-[a]	0.7[b]	0.7[b]	1	< 72 h	0
Conjunctiva: chemosis	0	0	0	1	< 24 h	0
Conjunctiva: discharge	0	0	0	2	< 24 h	0
Corneal opacity	0	0	0	0	-	-
Iridial inflammation	0	0	0	0	-	-

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.
[a] evaluation not possible at 24 h due to colouration by the test substance. Draize grades were 1 and 0 at 48 and 72 hours respectively.
[b] colouration by the test substance was observed at all time points, but evaluation was possible.

Remarks - Results	Slight discharge was observed in all three animals 1 hour after instillation. Slight chemosis of the conjunctivae was also observed in one animal 1 hour after instillation. Both the discharge and the chemosis had resolved by 24 hours. The slight conjunctival redness observed in all three animals had resolved by 72 hours. No other signs of toxicity were observed.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	Bayer AG (1995g)

7.6. Skin sensitisation

TEST SUBSTANCE	Notified chemical (60-65% purity)
METHOD	OECD TG 406 Skin Sensitisation – Maximisation Test EC Directive 96/54/EC B.6 Skin Sensitisation – Maximisation Test
Species/Strain	Guinea pig/SPF-bred of strain Hsd/Win:DH
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 5% topical: 50%
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 10
INDUCTION PHASE	Induction Concentration: intradermal: 5% topical: 50%
Signs of Irritation	After the second induction four control animals and four test group animals showed sporadic incrustations on the treated area.
CHALLENGE PHASE	
1st challenge	topical: 25% and 50%
Remarks - Method	No significant protocol deviations. Test sites were pre-treated with sodium lauryl sulphate prior to topical induction.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*

Test Group	25%	1	2	-	-
	50%	0	1	-	-
Control Group	25%	1	0	-	-
	50%	2	1	-	-

Remarks - Results: The skin reaction observed in both test group animals and control animals was very slight erythema, with no oedema observed. Therefore the severity and frequency of skin reaction at challenge was not greater in the test group than the control group.

CONCLUSION: There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY: Bayer AG (1994b)

7.7. Repeat dose toxicity

TEST SUBSTANCE: Notified Chemical (60-65% purity)

METHOD: OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).

Species/Strain: Rat/ SPF-bred Wistar
Route of Administration: Oral – gavage
Exposure Information: Total exposure days: 28days
Dose regimen: 7 days per week
Post-exposure observation period: 14 days
Vehicle: Demineralised water
Remarks - Method: Calculation of dosages was based on a notified chemical content of 65%. Deviations from protocol: functional observations not conducted; epididymis and thymus organ weights not measured.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0
II (low dose)	5/sex	40	0
III (mid dose)	5/sex	200	0
IV (high dose)	5/sex	1000	0
V (control recovery)	5/sex	0	0
VI (high dose recovery)	5/sex	1000	0

Mortality and Time to Death
No treatment related deaths were recorded.

Clinical Observations
There was no effect on appearance, clinical findings, and general behaviour up to and including 1000 mg/kg bw. Blue discolouration of the faeces (200 and 1000 mg/kg bw) and urine (1000 mg/kg bw) was observed. Feed intake and growth were not affected in males up to and including 200 mg/kg bw, and in all female groups. At 1000 mg/kg bw significant reduced body weight (up to about 15%) and slightly reduced feed intake (approximately 10% less) was observed in males. Water intake of males and females was increased at 1000 mg/ kg bw (31% to 36% relative increase), but not altered in the remaining groups.

Laboratory Findings
Haematology
Haematological investigations gave no indication of toxicologically relevant damage to blood and haematopoietic organs up to and including 200 mg/kg bw. At 1000 mg/kg bw most of the parameters of the red blood count were markedly and significantly decreased in male rats. In females of this dose group haemoglobin and haematocrit values were significantly reduced and there was also a tendency to reduced

values with regard to MCV, MCH and MCHC but the effects were less pronounced than in males. As a compensation the percentage of reticulocytes was increased in these groups. Some of these effects were still to be seen at the end of the recovery period but were less distinct.

The number of thrombocytes was significantly higher in 1000 mg/kg bw males and females at the end of the treatment, in females also at the end of the recovery period.

Clinical Chemistry
Increased urea and potassium as well as decreased total protein and sodium concentrations were observed for males at 1000 mg/kg bw. Increased alkaline phosphatase activity was seen for females at 1000 mg/kg bw.

Urinalysis
There were considered to be no toxicologically significant findings. A bluish-green discolouration of the urine was observed in 1000 mg/kg bw animals.

Effects in Organs
Macroscopic findings
Blue staining of the kidneys was observed in males and females at 200 mg/kg bw and above, as well as in the recovery group. Blue staining of the stomach, intestines and tail skin was also observed in the 1000 mg/kg bw group and the recovery group.

Organ weights
Increased relative liver weight was observed for females at 1000 mg/kg bw. Increased relative kidney weight was observed for both males and females at 1000 mg/kg bw.

Histopathology
Effects on kidney morphology were not observed in males up to 200 mg/kg bw and in females of all groups. Males at 1000 mg/kg bw had degenerative changes of cortical tubules. At 200 mg/kg bw and above males and females showed gastritis with increased mucous production between forestomach and glandular stomach, which was almost fully reversible. There were no treatment-related effects at 40 mg/kg bw.

Remarks – Results
Blue discolouration of the faeces and urine is due to the excretion of the notified chemical, which is a blue dye.

At 1000 mg/kg bw treatment-related effects included hypochromic anaemia, increased haematopoiesis, thrombocytosis, decreased body weight and degenerative changes in the kidney.

The dose level of 200 mg/kg bw led to blue staining of the kidneys, as well as gastritis in both males and females. No test substance related effects were observed at a dosage of 40 mg/kg bw. There were no histopathological findings which were related to the discolouration of the kidneys at 200 mg/kg bw, and therefore this is considered to be a treatment related effect without toxicological significance. The finding of gastritis, however, is considered to be toxicologically significant.

CONCLUSION
The No Observed Effect Level (NOEL) was established as 40 mg/kg bw/day in this study, based on the observation of gastritis in males and females at dosages of 200 mg/ kg bw and above, and effects on the blood and kidneys at 1000 mg/kg bw.

TEST FACILITY Bayer AG (1995h)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical (60-65% purity)

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure (Test 1) and Pre-incubation procedure (Test

2)

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100
Metabolic Activation System	Ames test (Test 1): Rat liver S9 microsomal fraction from Arochlor 1254 treated rats. Prival Assay (Test 2): Hamster liver S9 microsomal fraction from male Syrian Hamsters, no enzyme induction.
Concentration Range in Main Test	a) With metabolic activation: 16-5000 µg/plate b) Without metabolic activation: 16-5000 µg/plate
Vehicle	Deionised water
Remarks - Method	Due to the structure of the notified chemical, and the fact that the first Ames test showed no mutagenic effects of the tests substance, the repeat test was performed according to the method of Prival and Mitchell (1982). This pre-incubation method uses a different S9 mix to the standard Ames test. The test did not include *E.coli* WP2 strains or *S. typhimurium* TA102. Therefore certain oxidizing mutagens, cross-linking agents and hydrazines may not have been detected. No other significant protocol deviations reported. The positive controls used were sodium azide, nitrofurantoin, 4-nitro-1,2-phenylene diamine, benzidine, Congo red and 2-amino-anthracene.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1 (Ames)	-	> 5000	> 5000	Absent for all strains and dose levels
Test 2 (Prival)	-	5000	> 5000	As above
Present				
Test 1 (Ames)	-	> 5000	> 5000	Absent for all strains and dose levels
Test 2 (Prival)	-	5000	> 5000	As above

Remarks - Results	The cytotoxicity observed in the Prival assay at 5000 µg/plate was weak and strain specific (TA 1535 only). Control plates without mutagen showed that the number of spontaneous revertant colonies was within the laboratory's control range. All the positive control compounds showed the expected increase in the number of revertant colonies. Thus the sensitivity of the assay and the efficacy of the exogenous metabolic activation system were demonstrated. The test substance did not cause a significant increase in the number of revertant colonies at any dose level in all test strains either in the absence or in the presence of S-9 mix in either mutation test.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Bayer AG (1994c)

7.9. Genotoxicity – in vitro

REMARKS Not determined

7.10. Genotoxicity – in vivo

TEST SUBSTANCE	Notified chemical (60-65% purity)
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test. EC Directive 2000/32/EC B.12 Mutagenicity - Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Mice / Hsd/Win: NMRI bred
Route of Administration	Intraperitoneal
Vehicle	Physiological saline
Remarks - Method	Only one treatment dose (300 mg/kg bw) was used. This was shown in a pilot test to be the maximum tolerated dose. Test substance was administered once.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5 male; 5 female	0	24
II	5 male; 5 female	300	16
III	5 male; 5 female	300	24
IV	5 male; 5 female	300	48
V (positive control, CP)	5 male; 5 female	20	24

CP=cyclophosphamide.

RESULTS	
Doses Producing Toxicity	In the pilot test groups of five animals were treated with 250 mg/kg bw, 300 mg/kg bw, 500 mg/kg bw and 1000 mg/ kg bw. Symptoms of toxicity were observed at all dose levels. In addition, 1, 3 and 5 of 5 animals died in the 250, 500 and 1000 mg/kg bw groups. 300 mg/kg bw was therefore chosen as the maximum tolerated dose for the main test. In the main study treated animals showed the following compound-related symptoms until sacrifice: apathy, roughened fur, blue discolouration of hairless parts of skin, spasm, shivering, difficulty in breathing, red tears, diarrhoea, and blue discoloured urine. One animal died during the test period. The ratio of polychromatic to normochromatic erythrocytes (PCE/NCE) was not altered by the treatment with the notified chemical for the 16 and 24 hours groups. An altered PCE/NCE ratio was observed for the 48 hours group.
Genotoxic Effects	Treatment with the notified chemical did not result in any significant increase in the incidence of micronucleated polychromatic erythrocytes when compared with the results from the control animals.
Remarks - Results	The decrease in PCE/NCE ratio and systemic effects observed indicate that the notified chemical reached the target organ. The sensitivity of the test was demonstrated as the positive control, cyclophosphamide caused a clear increase in the number of polychromatic erythrocytes with micronuclei.
CONCLUSION	The notified chemical was not clastogenic under the conditions of this in vivo micronucleus test in the mouse.
TEST FACILITY	Bayer AG (1994d)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified Chemical

METHOD	OECD TG 301 E Ready Biodegradability: Modified OECD Screening Test (SOP 2030-6600202-96 D). Commission Directive 92/69/EEC, Official Journal of the EC L 383 A, Part C, Method C.4B: Modified OECD Screening Test
Inoculum	Secondary effluent of a domestic sewage treatment plant
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	DOC
Remarks - Method	The test substance was suspended in a mineral medium, inoculated with a mixed population of aquatic microorganisms for 28 days under aerobic conditions in the dark at 22ºC. The biodegradation of the test substance was determined on the basis of the reduction in DOC. The initial concentration of the test substance and the reference substance were 20.0 mg/L and 18.1 mg/L DOC, respectively.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
0	0	0	0
7	3	7	92
14	0	14	94
21	3	21	95
28	0	28	97

Remarks - Results	No degradation was observed for the notified chemical over the 28 days exposure. The reference substance aniline achieved 97% degradation within 14 days thus the validity of the test was met. At the concentration used in the test, no toxic effects to bacteria were observed.
CONCLUSION	The test substance is considered to be not readily biodegradable.
TEST FACILITY	Bayer AG (1995i)

8.1.2. Inherent biodegradability

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 302 B Ready Biodegradability: Zahn-Wellens/EMPA Test
Inoculum	Activated Sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	DOC
Remarks – Method	The test substance was suspended in a mineral medium, inoculated with a mixed population of aquatic microorganisms for 28 days under aerobic conditions in the dark at 22ºC. The biodegradation of the test substance was determined on the basis of the reduction in DOC. The initial concentration of the test substance and the reference substance were 100 mg/L and 100 mg/L DOC, respectively.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
0	0	0	0
7	1	7	95
14	0	14	98
21	0	21	99

28	0	28	100

Remarks – Results: No degradation was observed for the notified chemical over the 28 days exposure. The reference substance aniline achieved 98% degradation within 14 days thus the validity of the test was met. At the concentration used in the test, no toxic effects to bacteria were observed.

CONCLUSION: The test substance is considered to be not inherently biodegradable.

TEST FACILITY: Bayer AG (1995i)

8.1.3. Bioaccumulation

REMARKS: Based on the log Ko/w value of <-2.3, the notified chemical is unlikely to bioaccumulate.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 203 Fish, Acute Toxicity Test-Static conditions
EC Directive 92/69/EWG C.1 Acute Toxicity for Fish–Static conditions

Species	Zebra fish (*Danio rerio*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	13.2 º dH (236 mg/L $CaCO_3$)
Analytical Monitoring	TOC
Remarks – Method	Based on the range-finding test, ten fish were used for treatment at a nominal concentration of 100 mg/L and as a control. Observations for mortality and visible abnormalities were performed at 2, 6, 24, 48, 72 and 96 h. Oxygen content (8.6-9.6 mg/L in control and 8.7-9.5 mg/L in the test substance solutions), pH (7.8 to 8.3 in both control and test solutions) and temperature (21.3 to 21.5°C in both control and test solutions) were all satisfactorily maintained.

RESULTS

Concentration (mg/L)	*Number of Fish*	*Mortality*				
Nominal		*2 h*	24 h	48 h	*72 h*	96 h
Control	10	0	0	0	0	0
100	10	0	0	0	0	0

LC50	>100 mg/L at 96 hours.
NOEC	100 mg/L at 96 hours (only concentration tested).
Remarks – Results	No precipitation was observed in the test solution throughout the study period. No mortalities were observed in the control or test media. Observation of the sub-lethal effects was not possible due to the intensity of the colour of the test media.

CONCLUSION	The test substance is considered to be practically non-toxic to fish.
TEST FACILITY	Bayer AG (1995i)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	Council Directive 67/548/EEC C.2 Acute Toxicity for Daphnia – Static conditions.
Species	*Daphnia magna*
Exposure Period	48 h
Auxiliary Solvent	None
Water Hardness	12.9 º dH (231 mg/L $CaCO_3$)
Analytical Monitoring	TOC
Remarks - Method	Duplicates of 10 daphnia each were used for the single test concentration and control. The nominal concentration in the test media samples was 100 mg/L. The immobility of the daphnia was determined visually after 24 and 48 h of exposure.

RESULTS

Concentration mg/L Nominal	*Number of D. magna*	*% Immobilised*	
		24 h	*48 h*
Control	20	0	5
100	20	0	0

EC50	>100 mg/L at 48 hours.
NOEC (or LOEC)	100 mg/L at 48 hours (only concentration tested).
Remarks - Results	Oxygen content (8.6 mg/L in control and 8.7 mg/L in the test substance solutions at 48 h), pH (8.0 in both control and test solutions at 48 h) and temperature (21.0°C in control and 20.8°C test solutions at 48 h) were satisfactorily maintained. The concentration of the test substance was calculated from TOC values (1 mg/L TOC equals to 2.5 mg/L of the test substance). The test concentrations remained constant over the period of 48 h.
CONCLUSION	The notified chemical is practically non-toxic to aquatic invertebrates.
TEST FACILITY	Bayer AG (1995i)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	Council Directive 67/548/EEC C.3 Algal Inhibition Test.
Species	Green alga (*Scenedesmus subspicatus*)
Exposure Period	72 hours
Concentration Range	Nominal: 12.5, 25, 50 and 100 mg/L
Auxiliary Solvent	None
Water Hardness	Not stated
Analytical Monitoring	TOC
Remarks - Method	Nominal test concentrations of 12.5, 25, 50 and 100 mg/L and a control were incubated for a period of 72 h during which the cell density in each was measured at every 24 h. The inhibition of growth and growth rate in relation to a control was determined after 72 h of incubation. Analysis of

the test concentration at 100 mg/L without algal inoculum and the pH of the solution at the start and after 72 h of exposure were also performed.

RESULTS

Biomass		*Growth*	
EbC50	*ErC50*	*NOEC*	*LOEC*
mg/L (0-72 h)	*mg/L (0-72 h)*	*mg/L*	*mg/L*
48	>71	18	33

Remarks - Results: The concentration of the test substance was calculated from TOC values (1 mg/L TOC = 2.53 mg/L of the test substance) and remained constant throughout the duration of the study. The pH of the test solutions increased from an initial value of ~8.1 to ~10.5 in all test solutions except the highest test concentration where it increased to a pH value of 9.0 at the completion of the study.

CONCLUSION: The notified chemical is slightly toxic to algae.

TEST FACILITY: Bayer AG (1995i)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 209 Activated Sludge, Respiration Inhibition Test.
EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test

Inoculum: Activated sludge
Exposure Period: 3 hours
Concentration Range: Nominal: 100, 1000 and 10,000 mg/L
Remarks – Method: The activated sludge was mixed with synthetic medium and the respiratory rate was measured. The rate was compared with those of the nominal test concentrations of 100, 1000 and 10,000 mg/L. 3,5-dichlorophenol was used as the reference substance at test concentrations of 5, 10 and 20 mg/L. An incubation time of 30 minutes with permanent aeration was used.

RESULTS

Test Concentration (mg/L; Nominal)	**Inhibition (%)**
Control	-
100	0.0
1000	11.8
10000	18.2

EC50: >10,000 mg/L

Remarks – Results: Some inhibition of the respiration of the bacteria was observed in the two higher test concentrations. In neither case did this exceed 50% inhibition. Hence, the 30 minute EC50 could not be calculated but was determined to be >10,000 mg/L.
The 30 minute EC50 for the reference was within the recommended range of 5-20 mg/L confirming the suitability of the activated sludge.

CONCLUSION	The notified chemical is considered not inhibitory to sewage micro-organisms.
TEST FACILITY	Bayer AG (1995i)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The low Kow value and the inherent biodegradability test results indicate that the test substance is not likely to adsorb to sludge. If any of the notified chemical does partition to sludge the solids containing the chemical would be disposed of through incineration or as chemical waste along with other solid waste (due to spills, leaks and container residues) from the dye house. Incineration is the preferred option because of the high water solubility and potential mobility of the material. Incineration of the sludge or waste containing the notified chemical will produce oxides of carbon and other main elements and metal salts in the ash.

If the dye containing the notified chemical is disposed of to landfill the residues may be mobile. Although the notified chemical cannot be considered as readily biodegradable it would degrade very slowly via biotic and abiotic processes. Disposal to landfill if any, will be as chemical waste, therefore, the risk of leaching to the water table is significantly reduced. The fate of the dye and the notified chemical bound to the fabrics would be the same as that of the fabrics. The fabrics may be disposed of to landfill, where the notified chemical would remain inert.

The notified chemical released to the communal sewer via the dye house effluent discharge will be its major environmental exposure. The majority of the dye containing the notified chemical will be used in a small country dye house. However, based on the typical use of the dye expected per day, worst-case predicted environmental concentration (PEC) values are estimated for one city (discharging into a large sewage treatment works) and one country dye house (discharging into a small sewage treatment works) assuming no partitioning to sludge within the sewage treatment works.

Process or Dilution Factor	City Dye House (High volume STP discharge)	Country Dye House (Low volume STP discharge)
Typical notified chemical use expected per day*	12 kg	12 kg
Quantity in wash water (at a fixation rate of 90%)	1.2 kg	1.2 kg
STP daily volume	100 ML	4 ML
Concentration in effluent from sewage treatment plant	12 µg/L	300 µg/L
Predicted environmental concentrations (PECs) in receiving waters		
Ocean (Dilution Factor 1:10)		
PEC	1.2 µg/L	30 µg/L
River (Dilution Factor 1:1)		
PEC	12 µg/L	300 µg/L

*Calculated based on the maximum import volume and assuming dyeing occurs on 250 days per year.

The potential for bioaccumulation is low due to the very high water solubility, large molecular weight and the low lipid solubility and log Kow of the notified chemical.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests are listed below. The most sensitive species were algae with 72 hour E_bC50 value of 33 mg/L and E_rC50 value of >71 mg/L.

Organism	*Duration*	*End Point*	*mg/L*
Fish	96 h	LC50	>100
Daphnia	48 h	EC50	>100
Algae	0-72 h	E_bC50	33
		E_rC50	>71
Bacteria	3h	IC50	>10000

A predicted no effect concentration (PNEC - aquatic ecosystems) of 0.71 mg/L has been derived by dividing the end point of 71 mg/L (E_rC50 considered most reliable) by a worst-case scenario uncertainty (safety) factor of 100 (as toxicity data are available for three trophic levels).

9.1.3. Environment – risk characterisation

	Location	PEC* µg/L	PNEC µg/L	Risk Quotient (RQ)*
City Dye house	Ocean outfall	1.2	>710	<0.002
	Inland River	12	>710	<0.017
Country Dye house	Ocean outfall	30	710	<0.042
	Inland River	300	710	<0.42

* The worst-case PEC and the RQ values calculated assuming the notified chemical is not removed during the wastewater treatment at the dyehouses or the STP process.

The resulting risk quotient (RQ = PEC/PNEC) values for the aquatic environment, assuming that the chemical is not removed in the dye house treatment facility or at communal STP, are all below 1 for both freshwater and marine water, indicating no immediate concern to the aquatic compartment.

Based on the proposed use pattern the notified chemical is not expected to pose an unacceptable risk to the health of aquatic life.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport and storage

Exposure to the notified chemical during transport and storage is expected to be negligible, except in the case of an accident.

Dyehouse personnel

While the textile treatment process is largely automated, dyehouse personnel may be exposed to the imported granules (60-65% notified chemical) or to dye solutions containing up to 6% notified chemical during colour matching, weighing, mixing, transferring and equipment cleaning procedures. Inhalation exposure is not expected to be significant based on the low vapour pressure of the notified chemical, the low dust formulation used and the presence of local exhaust ventilation during the dissolution process. In addition, respiratory protection is expected to be worn during weighing and mixing, as well as during equipment cleaning. However, dermal and accidental ocular exposure may occur due to spills, splashes and leaks. Exposure will be minimised by the use of PPE including protective clothing, safety glasses and gloves.

The greatest potential for exposure across the skin is expected to be during the weighing and manual addition of the imported product to the dilution tank. The estimated dermal exposure during these operations is 0.065-0.65 mg/cm^2/day, based on the EASE model and assuming a non-dispersive use pattern, with intermittent direct handling and that the notified chemical is present at a concentration of 65%. Therefore, for a 70 kg worker with surface area of hands 820 cm^2 and forearms 1140 cm^2, and assuming a 10% dermal absorption factor ((based on the high molecular weight and low log P_{ow}), systemic exposure is estimated to be 0.18-1.8 mg/kg bw/day. This estimate does not take into account the expected low frequency of exposure, the low dusting form of the notified chemical and the use of PPE. Taking these factors into consideration the lower limit of the modelled exposure range (0.18 mg/kg bw/day) should be used as the exposure value for the risk assessment.

Once the dye solution has been transferred to the dye machine exposure to the notified chemical during the dyeing, rinsing, curing and washing operations is expected to be minimal due to the automated processes. Dermal and accidental ocular exposure may occur if workers are required to manually intervene in the processes, and when transferring wet dyed textile. However this will be limited due to the low concentration of notified chemical at this stage (<1%) and by the use of PPE such as safety glasses, gloves and protective clothing.

Exposure to the notified chemical when handling the dry treated textile is expected to be negligible as the dye is covalently bound to the textile at this point.

9.2.2. Public health – exposure assessment

The notified chemical will not be sold to the public, except in the form of treated textiles containing < 1% of the notified chemical. However at this stage the notified chemical is covalently bound to the fabric and is therefore not expected to be bioavailable. Public exposure to the notified chemical is therefore expected to be minimal.

9.2.3. Human health – effects assessment

Toxicokinetics

No toxicokinetic studies were submitted. The water solubility (220 g/L) and partition coefficient (Log Pow < -2.7) of the notified chemical suggest a good bioavailability after oral exposure. Based on the low partition coefficient and high molecular weight, as well as the absence of indicators of absorption in the dermal toxicity study, dermal absorption of the notified chemical is expected to be low. The colouration of faeces and urine in the sub-acute study indicates excretion of the unchanged notified chemical or a coloured metabolite.

Toxicological data for the notified chemical for the following health end points were submitted:

- acute oral and dermal toxicity
- primary dermal irritation
- eye irritation
- skin sensitisation
- 28-day subacute oral toxicity (gavage)
- *in vitro* mutagenicity
- *in vivo* clastogenicity

The notified chemical was found to be of low acute toxicity via both the oral and dermal exposure routes in tests on the rat. A primary dermal irritation study in the rabbit showed that the notified chemical is non-irritating to the skin, although the evaluation of erythema was hampered by the intense colour of the notified chemical. In an eye irritation study in the rabbit the notified chemical was shown to cause only mild irritation of the conjunctivae. A skin sensitisation test in guinea pigs showed no evidence of reactions indicative of sensitisation. The notified chemical is a reactive dye, and so respiratory sensitisation effects can not be ruled out.

In a 28 day subacute oral toxicity study in rats evidence of toxicity was observed at 1000 mg/kg bw/day, including increased water intake, reduced body weight gain (males only), hypochromic

anaemia, thrombocytosis, cortical tubule degeneration (males only) and gastritis. Gastritis was also observed at 200 mg/kg bw, but not at a dosage level of 40 mg/kg bw. The NOEL in male and female rats of 40 mg/kg bw is therefore based on the observation of gastritis at higher dosage levels.

The notified chemical was not mutagenic to *S. Typhimurium* in a Bacterial Reverse Mutation Test with (Arochlor-induced rat liver S9-mix and Prival non-induced hamster liver S9-mix) or without metabolic activation. With the Prival S-9 mix bacteriotoxicity was observed at the highest dose, indicating some biotransformatory activation of the notified chemical. In an *in vivo* micronucleus test in the mouse the notified chemical was found to be non-clastogenic.

The notified chemical contains a vinyl sulfone group and a β-sulfatoethyl-sulfonyl group (which can generate a vinyl sulfone group under certain conditions). Based on the mutagenicity of vinyl sulfone and methylvinyl sulfone, chemicals containing vinyl sulfone groups and their precursors are considered to carry a risk of mutagenicity and carcinogenicity when inhaled or ingested. The negative *in vivo* micronucleus assay is not considered sufficient to remove concern for new chemicals containing vinyl sulfone as potential mutagens and carcinogens (USEPA, 2002).

Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

Based on the toxicity data provided for the notified chemical it is a slight eye irritant. The chemical is not acutely toxic, but treatment-related effects were seen during chronic exposure. While the notified chemical was found to be non-genotoxic *in vivo* in the mouse, the presence of the vinyl sulfone group is still of concern for the mutagenicity/carcinogenicity risk of the notified chemical after ingestion or inhalation. The dermal absorption of the notified chemical is expected to be low based on the hydrophilicity and high molecular weight of the chemical.

The risk to transport and storage workers is considered to be low, based on the negligible exposure expected for this group of workers when used in the proposed manner.

During the textile dyeing process the workers expected to have the highest potential for dermal exposure to the notified chemical are predicted to be those involved in weighing and manual addition of the imported product to the dilution tank. A reasonable worst case dermal exposure for these workers is estimated to be 0.18 mg/kg bw/day. A dermal NOEL was not determined, however a NOEL of 40 mg/kg bw/day was established in a 28-day oral study in the rat. The use of this NOEL results in a margin of exposure (MOE) of 222. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. The MOE is based on conservative assumptions and may overestimate the risk. Therefore, the risk of systemic effects to workers during the textile-dyeing process is considered acceptable.

Although the notified chemical is slightly irritating to the eye the risk of eye irritancy in workers is expected to be low due to the PPE used (safety glasses), the low dusting formulation of the granules and the low concentration of the notified chemical in the dye solution.

The risk of mutagenic/carcinogenic effects in workers is considered to be low based on the negligible inhalation and ingestion exposure expected during use of the notified chemical in the proposed manner.

It is noted that the notified chemical is a reactive dye, and although skin sensitisation effects were not observed in guinea pigs, respiratory sensitisation cannot be ruled out. Employers may therefore wish to consider health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of skin and respiratory sensitisation. Individuals who become sensitised should not continue to handle the notified chemical.

The risk to workers handling dry treated textile is considered to be negligible based on the negligible expected exposure during this process. In addition, the treated textile is not expected

to contain any unreacted vinyl sulfone groups and therefore the mutagenic/carcinogenic risk to these workers is expected to be negligible.

9.2.5. Public health – risk characterisation

The risk to public health is considered to be low based on the minimal public exposure to the notified chemical. In addition, the treated textile is not expected to contain any unreacted vinyl sulfone groups and therefore the mutagenic/carcinogenic risk to the public is expected to be negligible.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

As a comparison only, the classification of notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes. For the environment the classifications are based on the reported E_rC50 for algae and the lack of biodegradation for the notified chemical.

	Hazard category	***Hazard statement***
Aquatic environment	Acute 3	Harmful to aquatic life
Aquatic environment	Chronic 3	Harmful to aquatic life with long lasting effects

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio the chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is low concern to occupational health and safety under the conditions of the occupational settings described, due to the negligible inhalation and ingestion exposure expected during use.

10.3.2. Public health

There is no significant concern to public health when used as a textile dye in the manner proposed.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified chemical provided by the notifier was in accordance with the NOHSC

National Code of Practice for the Labelling of Workplace Substances (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS
Health Surveillance

- As the notified chemical is a reactive dye, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of skin and respiratory sensitisation. Individuals who become sensitised should not continue to handle the notified chemical.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical during colour matching, and weighing and mixing operations:
  - Local exhaust ventilation to control dust

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced and during dyeing operations:
  - Do not breathe dust
  - Avoid contact with eyes
  - In case of contact with eye, rinse immediately with plenty of water and seek medical advice.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced and during manual operations:
  - Eye/face protection, e.g. safety glasses with side protection
  - Respiratory protection with particle filter when there is a chance of dust formation
  - Gloves
  - Industrial clothing and footwear

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of by incineration and landfill.

Storage and Handling

- The following precautions should be taken by the Notifier and end-users regarding storage and handling of the notified chemical:
  - Avoid formation and deposition of dust
  - Observe the usual precautionary measures required for chemicals with dust-

explosive properties and take precautionary measures against static discharge
- Observe the usual precautionary measures for organic dust and observe the NOHSC exposure standard for nuisance dust of 10mg/m^3

Emergency procedures

- Spills/release of the notified chemical should be handled by physical collection using suitable vacuum cleaner or dust binding material followed by disposal. Soak up spills of diluted solution with inert absorbent material (eg sand, earth, vermiculite, diatomaceous earth) and shovel into suitable container for disposal according to local authorities. Rinse away residues with water preventing washings from entering waterways.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
- the notified chemical is imported as a powder with inhalable (MMAD < 100 μm) and/or respirable (MMAD < 10 μm) particle sizes; or
- the notified chemical is used in a spray application which is no longer enclosed;

or

(2) Under Section 64(2) of the Act:
- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

13. BIBLIOGRAPHY

Aventis Research and Technologies GmbH and Co KG (2000a), Fat Solubility, Report No. PI 675, Analytical Technologies, Industriepark Hochst, G 865 D-65926 Frankfurt am Main. (Unpublished report provided by notifier)

Aventis Research and Technologies GmbH and Co KG (2000b), Dissociation Constant, Report No. PI 675, Analytical Technologies, Industriepark Hochst, G 865 D-65926 Frankfurt am Main. (Unpublished report provided by notifier)

Bayer AG (1994a) Notified Chemical: Identity Test (Study number N94/0064/00 LEV, November 2006) Bayer AG ZF-D Central Analytic Department, Leverkusen, Germany. (Unpublished report provided by notifier).

Bayer AG (1994b) Notified chemical: Study for Skin Sensitisation Effect on Guinea Pigs. (Study number T7055601, 12 July 1994) Bayer AG Institute of Toxicology, Wuppertal, Germany. (Unpublished report provided by notifier).

Bayer AG (1994c) Notified chemical: Salmonella/Microsome Test Plate Incorporation and Prival Modification. (Study number T8049393, 17 June 1994) Bayer AG Institute of Toxicology, Wuppertal, Germany. (Unpublished report provided by notifier).

Bayer AG (1994d) Notified chemical: Micronucleus Test on the Mouse. (Study numbers T5055645 and T3055643, 29 August 1994) Bayer AG Institute of Toxicology, Wuppertal, Germany. (Unpublished report provided by notifier).

Bayer AG (1995a) Notified chemical: Analytic Material Accountability, Physico-Chemical Properties. (Study number TN94/0064/01 LEV, 23 March 1995) Bayer AG ZF-D Central Analytic Department, Leverkusen, Germany. (Unpublished report provided by notifier).

Bayer AG (1995b) Notified chemical: Water Solubility. (Study number N94/0064/02 LEV, 17 March 1995) Bayer AG ZF-D Central Analytic Department, Leverkusen, Germany. (Unpublished report provided by notifier).

Bayer AG (1995c) Notified chemical: Distribution Coefficient, Prestudy. (Study number N94/0064/03 LEV, 17 March 1995) Bayer AG ZF-D Central Analytic Department, Leverkusen, Germany. (Unpublished report provided by notifier).

Bayer AG (1995d) Notified chemical: Stability/Homogeneity for Toxicological Studies. (Study number N94/0064/06 LEV, 8 February 1995) Bayer AG ZF-D Central Analytic Department, Leverkusen, Germany. (Unpublished report provided by notifier).

Bayer AG (1995e) Notified chemical: Acute Oral Toxicity Study in Male and Female Wistar Rats. (Study number T7059120, 12 July 1995) Bayer AG Institute of Toxicology, Wuppertal, Germany. (Unpublished report provided by notifier).

Bayer AG (1995f) Notified chemical: Acute Dermal Toxicity Study in Male and Female Wistar Rats. (Study number T8059121, 7 July 1995) Bayer AG Institute of Toxicology, Wuppertal, Germany. (Unpublished report provided by notifier).

Bayer AG (1995g) Notified chemical: Study for Skin and Eye Irritation/Corrosion in Rabbits. (Study number T0059042, 17 March 1995) Bayer AG Institute of Toxicology, Wuppertal, Germany. (Unpublished report provided by notifier).

Bayer AG (1995h) Notified chemical: Subacute Toxicity Study in Wistar Rats. (Study number T4058344, 17 August 1995) Bayer AG Institute of Toxicology, Wuppertal, Germany. (Unpublished report provided by notifier).

Bayer AG (1995i) Investigation of the ecological properties of Reactive Blue FC 75311. (Study number 514 N/94, 23 February 1995) Bayer AG Institute of Toxicology, Wuppertal, Germany. (Unpublished report provided by notifier).

Bayer AG (1997) Notified Chemical: Abiotic Degradation (Study number N94/0064/00 LEV, 23 March 1997) Bayer AG ZF-D Central Analytic Department, Leverkusen, Germany. (Unpublished report provided by notifier).

FORS (Federal Office of Road Safety) (1998) Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 6th Edition, Canberra, Australian Government Publishing Service.

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edn [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

Prival, MJ and Mitchell, VD (1982) Analysis of a method for testing azo dyes for mutagenic activity in Salmonella typhimurium in the presence of flavin mononucleotide and hamster liver. Mutation Res, **97**:103-116.

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.

USEPA (2002) TSCA New Chemicals Program (NCP) Chemical Categories. Revised October 2002. Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Washington, USA http://www.epa.gov/oppt/newchems/pubs/cat02.pdf Accessed 16/11/06