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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Levafix Navy CA

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Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

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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 names(s)
Other name(s)
CAS number
Molecular formulae
Structural formula
Molecular weight
Spectra data
Purity
Identity of toxic or hazardous impurities
% Weight of toxic or hazardous impurities
Non-hazardous impurities
Import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

Absorption/desorption
Dissociation constant
Flash point
Flammability limits
Explosive properties
Reactivity
Acute inhalation toxicity
Induction of germ cell damage
Bioaccumulation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
No

NOTIFICATION IN OTHER COUNTRIES
European Union (1998)
Canada (1998)
China (1998)
United States (1998)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Levafix Navy CA

METHODS OF DETECTION AND DETERMINATION

METHOD	UV-VIS, ^{1}H NMR, ^{13}C NMR, IR spectroscopy. High Performance Liquid Chromotography
Remarks	Reference UV-VIS, NMR and IR spectrum, and chromatograms of the reaction mixture were provided
TEST FACILITY	Aventis Research and Technologies GmbH and Co KG (1998d) and Aventis Research and Technologies GmbH and Co KG (1998e)

3. COMPOSITION

DEGREE OF PURITY
Medium

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported at up to 60% concentration as de-dusted granules and only formulation will be undertaken 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
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

TRANSPORTATION AND PACKAGING
25 kg cartons will be transported from the dock by road to a single plant

5.2. Operation description

Dyechem is the importer and distributor of the product and does not perform the textile dyeing processes. It is anticipated that up to seven dye houses in Australia will purchase the dye containing the notified chemical and carry out textile dyeing processes.

Transport, Warehouse and Storage
Following importation, Dyechem warehouse or stores personnel will receive and store the commercial product prior to consignment. The product will be handled in the warehouse by forklift handling of pallets or manual handling of individual packages. Dyechem will transport 25 kg cartons by road to customer dye houses.

Processing
At customer dye houses, the following procedures are typically undertaken:

Laboratory technicians will perform colour matching prior to the dyeing process. A small sample of powdered dye ranging between 1 g to 200 g will be formulated in warm water containing a final

concentration of no more than 6% of the notified chemical during colour matching.

For local production, workers will weigh and manually add required quantities of the notified chemical in 2 kg aliquots and other ingredients into a mixing tank of between 50 L to 300 L in capacity. This process will occur under adequate local mechanical ventilation to produce a dye solution containing no more than 6% of the notified chemical.

After dissolving the dye with warm water in the mixing tank, approximately 5 kg to 10 kg of the resulting dye solution will be manually transferred to an open feed tank of 50 L to 300 L in capacity. Dye will then be automatically sprayed (<1% notified chemical) onto textiles via an enclosed dyeing machine using a continuous roller system. The dyeing process is typically undertaken at 60°C and uses approximately 5 kg to 10 kg of dye solution per dyeing cycle and involves a rinsing stage allowing for excess dye solution to be washed from the fabric. The used dye solution will then go into the enclosed waste stream. The dyed cloth is fixed at low pH at a rate of 90% and then washed in warm soapy water to remove any free dye.

At the conclusion of the automated dyeing process, finishing chemicals such as softeners may be applied to the textile and the wet dyed cloth is manually transferred to trays for drying at room temperature. The dye solution is considered safe at this point and local exhaust ventilation is not required.

During the cleaning process, contents of the feeding tank are flushed into the main dye vessel. There is no release to the atmosphere because the notified chemical is in solution. The main mixing tank is then drained and refilled with clean water for after wash treatment and this process is fully enclosed.

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 h/day	10 d/year
Weighing and mixing	40-45	0.5 h/day	200 d/year
Laboratory technicians	5	0.5 h/day	100 d/year
Dyeing	160	1 h/day	200 d/year
Curing/rinsing/drying	100	0.5 h/day	200 d/year
Cleaning and waste disposal	40-45	0.5h/day	200 d/year

Exposure Details

Transport and storage:

When the notified chemical is imported, occupational exposure to the neat notified chemical during transport and storage will be limited as the dyestuff containing the notified chemical in a de-dusted powder contained within sealed packages. A limited number of workers in the transport and storage sector will handle the notified chemical for brief periods, with no exposure expected except in the case of an accident. Should a spill occur, it is expected to be contained and placed into properly labelled and sealed containers for disposal in accordance with the MSDS and official regulations, with measures taken to minimise exposure.

Processing:

Laboratory technicians:

Laboratory technicians at customer dye houses may be exposed to the neat notified chemical when performing colour matching prior to the dyeing process. There is potential for a small amount of dermal or ocular exposure to the powder and liquid formulation. However, laboratory technicians will wear appropriate personal protective equipment. The potential for inhalation exposure would be minimised by the de-dusted formula.

Weighing and mixing, Dyeing, Curing/rinsing/ drying, Cleaning:

At customer dye houses, dermal and ocular exposure due to splashes and spillages may occur during

weighing (neat 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 de-dusted formula, the use of local exhaust ventilation during the dissolution process and by the enclosed nature of the dying process.

Operators of the dye house typically wear splash proof goggles, chemically resistant gloves, safety shoes, aprons, or other protective clothing, and appropriate respirators when required. 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) if textile becomes tangled in the dyeing machine. In this case, the dyeing machine is required to be switched-off and opened to allow mechanical gleaning (via a hose) of loose fibres, realignment of the roller and to untangle the textile. 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.

Emergency Personnel:
Emergency personnel will be involved in clean up operations in the event of accidental spills. There is a potential risk of dermal, ocular and inhalation exposure to the notified chemical during clean up operations of the granules and dust, and dermal and ocular exposure to the dye solutions via accidental splashes.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The chemical is a dye, designed to fix to textiles. The dyeing of textiles is performed in a vessel in a batch wise manner with draining of the vessel after each batch. It is expected that approximately 90% of the notified chemical will be fixed to the textile, whilst 10% will be released to sewer. Australia wide this will mean up to 300 kg of chemical will be released per annum from several dye houses.

The release of the chemical to the environment from empty cartons is expected to be minimal as the cartons are rinsed. The rinseate may then be added to the process or released to sewer.

Minimal release of the chemical is expected form spills during transport and use if all safety measures are adhered to.

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
At the end of the useful life of the textile product 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 exposure of the consumer to the notified chemical will vary according to the end-use of the textile. Potential exposure would be higher for uses with close bodily contact such as clothes and bed linen and lower for direct exposure from fabric furnishings and more of another character like inhalation of volatile compounds or compounds adsorbed to dust fibres. Exposure occurs if children, for example,. place the textile in the mouth and suck or chew on the textile. Exhausted textile products will be disposed of to landfill. However release is expected to be minimal as 90% of the chemical is fixed in the dyed material.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Dark-blue granules

Melting Point/Freezing Point Decomposes over 140°C

METHOD EC Directive 92/69/EEC A.1 Melting Point /Melting Range Explosive Properties.
Remarks No melting point was observed in the range 25 ºC–450 ºC. No protocol deviations were reported.
TEST FACILITY Aventis Research & Technologies GmbH & Co KG Analytical Technologies (1988a)

Boiling Point Not relevant for a solid-state test material

Density 1570 kg/m^3 at 22.5ºC

METHOD EC Directive 92/69/EEC A.3 Relative Density
Remarks Pycnometer method (as relevant for a solid). No protocol deviations were reported
TEST FACILITY Aventis Research & Technologies GmbH & Co KG Analytical Technologies (1988b)

Vapour Pressure < 10^{-8} kPa at 25ºC

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure
Remarks Determined using a vapour pressure balance. Measurements were performed between 22°C and 120°C. No protocol deviations were reported.
TEST FACILITY Aventis Research & Technologies GmbH & Co KG Analytical Technologies (1988c)

Water Solubility 437 g/L at 20ºC

METHOD EC Directive 92/69/EEC A.6 Water Solubility..
Remarks Flask Method. Analytical technique: HPLC (corrected for the purity). Non-guideline conditions were reported: pH 6, stirring time 3 hours, amount of test substance less than 5 times higher than the pre-test determined water solubility, in which solution became too viscous.
TEST FACILITY Aventis Research and Technologies GmbH and Co KG (1998f)

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$ days*
4	25	> 365
7	25	2.46
9	25	< 1

Remarks The flask containing the hydrolysis mixture was placed in a waterbath at specific temperature and pH. The HPLC analysis of the unhydrolysed test substance was performed. Preliminary tests at 50°C for 5 days showed that the test substance was hydrolytically stable at pH 4 with less than 10% decomposition, but showed greater than 50% decomposition after 2.4 hours at pH 9. The results for the half life at pH 7 at 25ºC were obtained by extrapolating from the test result temperatures (50, 55 and 65ºC).
TEST FACILITY Aventis Research and Technologies GmbH and Co KG (1998i)

Partition Coefficient (n-octanol/water) log Pow = -6.6 at 20ºC

METHOD EC Directive 92/69/EEC A.8 n-octanol/water partition coefficient.

Remarks	Estimate by measuring solubility in n-octanol and comparing with solubility in water. Duplicate analysis was performed by adding 44.852 mg and 44.689 mg of test substance to 50 mL n-octanol and stirred for 4 h 20 min. 8 mL aliquots were centrifuged and filtered. The n-octanol phases were diluted with acetonitrile (50/50 (v/v)) and investigated by HPLC UV/VIS detector and the solubility determined as 0.1 mg/L.
TEST FACILITY	Aventis Research and Technologies GmbH and Co KG (1998j)

Adsorption/Desorption Log Koc = 1.1

METHOD	Used analogue (STD/1089), which is accepted to have similar properties to test substance. This had a log Koc of 1.1 indicating relative mobility in soils.
Remarks	
TEST FACILITY	

Dissociation Constant pKa = 2.9 to 6.9

METHOD	OECD TG 112 Dissociation Constants in Water.
Remarks	The results are based on three independent tests in the acid range. The pKa for the alkaline range were not determined, as testing indicates decomposition in that pH range.
TEST FACILITY	Aventis Research and Technologies GmbH and Co KG (2000a)

Fat (or n-octanol) Solubility < 0.003 mg/100 g Standard Fat HB 307 at 37°C

METHOD	OECD TG 116 Fat Solubility of Solid and Liquid Substances.
Remarks	Analytical Method: Tests were performed by mixing approximately 26 mg with approximately 45 g of fat and stirring at temperatures of 30°C or 50°C for 3 hours. The test samples were further stirred at 37°C for 3 or 27 hours. A portion of the fat 34 - 41 g was dissolved in 75 mL n-hexane, and then extracted with water 3 x 7 mL. The extractant was made up to volume of 25 mL and filtered and subjected to spectrophotometric analysis.
TEST FACILITY	Aventis Research & Technologies GmbH & Co KG Analytical Technologies (2000b)

Surface Tension 66.8 mN/m at 20ºC

METHOD	EC Directive 92/69/EEC A.5 Surface Tension.
Remarks	Concentration: 1.0 g/L. Determined using a tensiometer and the ring method. The notified chemical is not surface active.
TEST FACILITY	Aventis Research and Technologies GmbH and Co KG (1998h)

Particle Size > 115 μm and < 200 μm

Remarks	Report not provided. Personal communication received from the notifier.
TEST FACILITY	Dyechem Industries Pty Ltd (2004)

Flash Point Not highly flammable

METHOD	EC Directive 92/69/EEC A.10 Flammability (Solids)
Remarks	Temperature range tested: 22 ºC–416ºC. The test material could not be ignited in the preliminary test, therefore the main test was not performed.
TEST FACILITY	Aventis Research and Technologies GmbH and Co KG (1998g)

Flammability Limits Not determined

Remarks	Not expected to be flammable based on vapour pressure

Autoignition Temperature 367ºC

METHOD EC Directive 92/69/EEC A.16 Auto-flammability (Solids – Determination of Relative Self-Ignition Temperature).
Remarks Temperature range tested: 25 ºC – 481ºC. No protocol deviations were reported.
TEST FACILITY

Explosive Properties Not explosive

METHOD EC Directive 92/69/EEC A.1 Melting Point /Melting Range Explosive Properties.
Remarks The heat of decomposition was determined to be above 500 J/g, therefore the test was not performed.

TEST FACILITY Aventis Research & Technologies GmbH & Co KG Analytical Technologies (1988a)

Dust Explosivity Not determined

Remarks Fine organic dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

Oxidizing Properties Not determined

Remarks The structural formula indicates low oxidising properties

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.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	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	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL 250-mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Mammalian Chromosome Aberration Test	genotoxic
Genotoxicity – in vivo Micronucleus Test	non genotoxic
Developmental and reproductive effects	not determined
Carcinogenicity	not determined

7.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 401 Acute Oral Toxicity – Limit Test.
EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.

Species/Strain: Rat/ Sprague Dawley
Vehicle: Water
Remarks - Method: Only one dose was tested 2000 mg/kg bw. The animals were dosed by gavage as a 20% solution in deionized water, the administration volume being 10 mL/kg bw. The test animals were observed for the following 14 days. Symptoms were recorded twice daily (once on weekends and public holidays) and weight was taken weekly. At the end of the observation period animals were killed by CO_2 asphyxiation, dissected and examined for macroscopically visible changes.

RESULTS

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

LD50: > 2000 mg/kg bw
Signs of Toxicity
Effects in Organs: No macroscopic changes
Remarks - Results: The animals showed blue collared faeces and diarrhoea. Two days after application the symptoms were reversible. The skin of the animals

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

TEST FACILITY: Hoechst (1998a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 402 Acute Dermal Toxicity – Limit Test.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test..

Species/Strain: Rat/ Sprague Dawley
Vehicle: Water
Type of dressing: Occlusive.

Remarks - Method	The test substance was moistened with water on aluminium foil and was administered together with the foil on a shaved area of the animal (30 cm^2) and was kept fixed to the body. After 24 hours the foil was removed and the area washed from the excess substance. Post-treatment observation period was 14 days. Symptoms were recorded twice daily (once on weekends and public holidays) and weight was taken weekly. At the end of the observation period animals were killed by CO_2 asphyxiation, dissected and examined for macroscopically visible changes

RESULTS

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

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	None
Signs of Toxicity - Systemic	None
Effects in Organs	The skin of the animals showed blue discolorations up to day 13 of the study.
Remarks - Results	No macroscopic changes observed after sacrificing the animals at the end of observation period.

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

TEST FACILITY Hoechst (1998b)

7.3. Irritation – skin

TEST SUBSTANCE Notified chemical

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 female
Vehicle	water
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks - Method	The test substance was mixed to a paste with water (0.5 g in 0.45 ml) and placed on a shaved dorsal area of 25 cm^2 under a semi-occlusive dressing for 4 hours. After 4 hours the remaining test substance was washed from the skin with warm tap water. Skin at the treated area was examined 0.5-1, 24, 48 and 72 hours after removal of patches.

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	0.7	0.7	**	3	1 day	0
Oedema	0	0	0	1	1 hour	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.
**Could not be scored because of dark blue discolouration.

Remarks - Results	For 2/3 animals, light blue discoloration was visible from 1 hour to 2 days. For 1/3 animal, dark blue discoloration was visible from 1 hour up

to the end of study and interfered with assessment of erythema irritations in that animal. Based on the comparable oedema reactions as well as the overall behaviour of this animal during palpation, persistent skin irritation can be excluded.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY Hoechst(1998c)

7.4. Irritation – eye

TEST SUBSTANCE Notified substance

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
and
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain Rabbit/New Zealand White
Number of Animals 3 females
Observation Period 72 hours
Remarks - Method 100 mg of notified chemical was administered once to the conjunctival sac of the left eye. 24 hour after treatment and any time discharge was observed or fluorescin sodium was used for examination of lesions (24 and 72 hours), eye was washed with isotonic saline 37°C. Eyes were examined 1, 24, 48 and 72 hours post –treatment.

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	0.33	0.66	0.33	1	2 days	0
Conjunctiva: chemosis	0	0	0	0	-	0
Conjunctiva: discharge	0	0	0	0	-	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results Clear coloured discharge was noted at the 1 h observation. The nictating membrane was discoloured blue from one hour up to the end of the study.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Hoechst (1998d)

7.5. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD OECD TG 406 Skin Sensitisation - Skin sensitisation
EC Directive 96/54/EC B.6 Skin Sensitisation – Acute toxicity Sensitisation of the skin.

Species/Strain Guinea pig/Pirbright - White
PRELIMINARY STUDY Maximum Non-irritating Concentration: 3 animals
intradermal: 1%
topical: 25 %
The intradermal injection with the 5% notified substance caused well-

defined oedema, however 5% concentration was chosen for induction phase in the main test. The treated skin was not assessable for erythema irritations as application sites with 5% notified substance were discoloured dark blue.

MAIN STUDY

Number of Animals: Test Group: 10 Control Group: 5

INDUCTION PHASE: Intradermal: 5% w/v in deionised water
Topical: 25% w/v in deionised water

Signs of Irritation: Intradermal treatment with 5% notified substance showed well-defined oedema. Similar treatment with notified substance in the presence of 50% adjuvant, as well as 50% adjuvant alone caused severe oedema, indurations and encrustations.
The skin of the treatment area of all animals treated with the test substance was not assessable for erythema as the sites were discoloured dark blue.
Due to the strong irritation reactions of the skin, 10% sodium dodecylsulfate was not administered at day 7.

The dermal induction treatment of the test material alone showed well defined oedema. Severe oedema to necrosis was caused where 50% adjuvant was used. Due to the dark blue discoloration of the skin treated with the notified substance, the animals could not be assessed for erythema.

CHALLENGE PHASE

1st challenge: topical: 25 % notified substance

Remarks - Method: No protocol deviations reported. A second challenge was not conducted.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	25%	0/10	0/10
Control Group	25%	0/5	0/5

Remarks - Results

CONCLUSION: Based on the absence of irritation in the treatment group similar to that in the control group, 24 and 48 hours after removal of the occlusive bandage after the challenge treatment, it may be concluded that there was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY: Hoechst (1998e)

7.6. Repeat dose toxicity

TEST SUBSTANCE: Notified substance

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/Sprague Dawley
Route of Administration: Oral – gavage
Exposure Information: Total exposure days: 28 days , 7 days/week
Post-exposure observation period: 14 days
Vehicle: water

Physical Form	liquid
Remarks - Method	Statement of GLP compliance. No protocol deviations reported.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0
II (low dose)	5/sex	62.5	0
III (mid dose)	5/sex	250	0
IV (high dose)	5/sex	1000	0
V (control recovery)	5/sex	-	0
VI (high dose recovery)	5/sex	1000	0

Mortality and Time to Death

No deaths occurred through out the study.

Clinical Observations

No test substance related adverse clinical findings were observed in all dose groups. Neurotoxicological parameters remained unaffected by the administration of the test substance in all treatment groups.
A compound dependent effect on body weight development was not evident in any of the dosed groups. Food and water consumption remained unaffected by the administration of the test substance in all treatment groups.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Haematological examination showed a slight increase in thrombocyte counts of the high dose group. This was considered to be treatment-related although the deviation from the control was statistically significant only in the males. The increased thrombocyte number was reversible by the end of the observation period in both, males and females.
Urine showed a treatment related reversible brownish-yellow (3 males, 2 females) to blue violet (2 males) discoloration in the high dose group however this was reversible and not considered to be of toxicological relevance.

Effects in Organs

Organ weight showed no treatment related changes in any of the treatment groups. At necropsy, treatment related brown or olive discolouration of the kidneys were observed in 2 intermediate dose females and in 4 high dose group males and 5 high dose females at the end of the treatment period and in 1 male and 4 females of the high dose group at the end of the recovery period. There were no other histopathological findings which could be related to the discoloration of the kidneys.

Histopathologically, the test substance caused acute inflammatory cell infiltration with slight secretory disorder of the stomach mucous membrane (fundus) in high dose group males and females. This change was not associated with destructive processes and was reversible.

There were no other histological changes which could be related to the administration of the test substance.

Remarks – Results

The dose level of 250-mg/kg bw/day led to olive discoloration of the kidneys in 2 females. No test substance-related effect was observed at dose level of 65 mg/kg bw/day. The discolouration of the kidneys at 250-mg/kg bw/day was not accompanied by other microscopic changes, and is considered a treatment related effect without toxicological significance.

CONCLUSION

The No Observed (Adverse) Effect Level (NO(A)EL) was established as 250 mg/kg bw/day in this study, based on stomach/fundic inflammation at 1000 mg/kg bw/day.

TEST FACILITY Hoechst, Germany (1998)

7.7. Genotoxicity – bacteria

TEST SUBSTANCE	Notified substance
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 92/69, L383 A, Annex B14 And US EPA: 798.5265 _ Salmonella typhimurium reverse mutation assay Plate incorporation procedure/Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100
Metabolic Activation System	Rat liver S9 microsomal fraction from Aroclor 1254 treated rats.
Concentration Range in Main Test	a) With metabolic activation: 4 to 5000 µg/plate b) Without metabolic activation: 4 to 5000 µg/plate
Vehicle	Double-distilled water (notified chemical) Double-distilled water and Dimethylsulfoxide (reference compounds)
Remarks - Method	Statement of GLP compliance. No protocol deviations reported. Positive control without activation: sodium-azide for TA100 and TA1535; 9-aminoacridine for TA 1537; 2-nitrofluorene for TA98 Positive control with activation: 9-aminoacridine for all strains.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1		> 5000	> 5000	Absent for all strains & all dose levels
Test 2		> 5000	> 5000	As above
Test 3		> 5000	> 5000	Absent for all dose levels only TA 100 tested
Present				
Test 1		> 5000	> 5000	Absent for all strains & all dose levels
Test 2		> 5000	> 5000	As above
Test 3		> 5000	> 5000	Absent for all dose levels only TA 100 tested

Remarks - Results	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 was 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	Hoechst, Germany (1998)

7.8. Genotoxicity – in vitro

TEST SUBSTANCE	Notified substance
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test. EC Directive 92/69/, L383 A, Annex B. 10 p. 148-150 US EPA: 798.5375 In vitro mammalian cytogenetics (1985)
Cell Type/Cell Line	V79 Chinese Hamster Cells
Metabolic Activation System	Rat liver S9 microsomal fraction from Aroclor 1254 treated rats
Vehicle	Mammalian Cell Culture Media -MEM
Remarks - Method	Statement of GLP compliance. No protocol deviations reported

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period* [+]	*Harvest Time*
Absent			
Test 1	500*, 1581.1* and 5000*	3	20
Test 2	125*, 250*, 500*, 750*	20	20
Test 3	500.0* and 750.0*	20	20
Present			
Test 1	500.0*, 1581.1* and 5000.0*	3	

*Cultures selected for metaphase analysis. [+] Period treated with test subtance. [Δ] Period after the start of treatment.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1 (3h)	> 5000.0 (78.7% RS[+])	> 5000 (73.1% RS[+]) (71.8% RMI*)	Not Observed	Not statistically significant increase observed
Test 2 (20 h)	500.0 (73.2% RS[+])	1000 (36.5% RS[+]) 500 (56.6% RMI*)	Not Observed	Observed
Test 3(20 h)		750.0 (59.3% RMI*)	Not Observed	Observed
Present				
Test 1 (3h)	> 5000.0 (84.1% RS[+])	> 5000 (81.5% RS[+]) (100.0% RMI*)	Not Observed	Not observed

[+] Relative survival; * Relative Mitotic Index; nd-not determined

Remarks - Results

The solvent control data were within the laboratory's normal control range for the spontaneous mutant frequency. The positive control substances used without S9 mix EMS (ethyl methane sulfonate) and with S9 mix CPA (cyclophosphamide) induced significant increase in chromosome mutation frequency within the laboratory's normal range, demonstrating the sensitivity of the assay and the efficacy of the S9-mix. However, no historical control data was provided. The biometry of the results for chromosomal aberrations was performed with one-sided Fisher –Exact test.

In the first and second experiment cytotoxicity of the notified substance

was evaluated through the SR and RMI of cells treated for 3 or 20 hours. The results demonstrated that survival was not reduced in the 3 hours treatment group with or without S9 activating mix. Treatment for 20 hours in the absence of activating mix reduced survival in a dose dependent manner beyond 500 μg/ml . SR at this dose level was 73.2 % and reached 5.7% for cells treated with 5000 μg/ml of notified substance.

In all experiments the mitotic index was reduced (indicating toxicity) after treatment with the highest dose levels in the absence of metabolic system (for 3 hours treatment) and for all doses tested at 20 hours treatment.

There was no significant increase in number of polyploid cells as compared to the solvent control. However, there was a statistically significant enhancement of aberrations including gaps at he 20 h treatment time with 500 and 750 μg/ml without S9 mix. Although not always statistically significant, chromosome aberration excluding gaps showed tendency to increase at and beyond 500 μg/ml of the test substance. There was also increase in aberration in the highest dose group treated for 3 h without S9 mix, however this was not statistically significant.

CONCLUSION

The notified chemical was mutagenic to V79 Chinese Hamster Cells treated in vitro in the absence of metabolic activation, under the conditions of the test.

TEST FACILITY

Hoechst, Germany (1998)

7.9. Genotoxicity – in vivo

TEST SUBSTANCE

Notified substance

METHOD

OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
OECD guideline for testing of chemicals, Proposal for updating Guideline 474US EPA: 798.5395
EEC Directive 92/69 L383 A, Annex B

Species/Strain: Mouse/HsdWin:NMRI
Route of Administration: Oral – gavage
Vehicle: Deionized water
Remarks - Method: Statement of GLP compliance. No protocol deviations reported.
A preliminary study demonstrated that 2000 mg/kg bw was not toxic to 3 males and 3 female mice. Thus for this test the notified substance was administered once at doses 200, 600 and 2000 mg/kg bw.
CPA (cyclophosphamide) or Endoxan was also administered once orally as positive control substance at dose of 50 mg/kg bw.
Folowing dosing the animals were examined regularly for mortality and clinical signs of toxicity. The surviving animals were sacrificed by CO_2 asphyxiation, 24 or 48 hours after dosing. Bone marrow cells were anialized by standard protocol. One-sided-Wilcoxon Test was used to evaluate the statistical validity of the study. Biological significance was also considered in the evaluation.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5/sex	0	24
II (low dose)	5/sex	200	24
III (mid dose)	5/sex	600	24
IV (high dose)	5/sex	2000	24
V (positive control, CP)	5/sex	50	24

I (vehicle control)	5/sex	0	48
II (low dose)	5/sex	2000	48

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity	All animals survived after treatment No signs of toxicity were observed only faeces were blue coloured. The dissection of the animals revealed no macroscopic findings.
Genotoxic Effects	The incidence of micronucleated polychromatic erythrocytes as well as the ratio of to total erythrocytes in all of the dose groups was within normal range and similar to that of the negative control group.
Remarks - Results	CPA induced a marked and statistically significant increase in the number of polychromatic erythrocytes with micronuclei.

CONCLUSION The notified chemical was not clastogenic under the conditions of this in vivo mouse erythrocyte micronucleus assay under the conditions of the test.

TEST FACILITY Hoechst, Germany (1998)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE Reaktiv-Marineblau FC 63805 (70% 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 micro-organisms 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 14.8 mg/L and 19.6 mg/L DOC, respectively.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
0	*0*	*0*	*0*
7	*0*	*7*	*100*
14	*0*	*14*	*97*
21	*0*	*21*	*99*
28	*0*	*28*	*99*

Remarks - Results No degradation was observed for the notified chemical over the 28 days exposure. The reference substance aniline achieved a 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 (1998a)

8.1.2 Bioaccumulation

Not Determined. Due to its water solubility and log Kow of -6.6 the chemical is unlikely to bioaccumulate.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Reaktiv-Marineblau FC 63805 (70% Notified Chemical)
METHOD	OECD TG 203 Fish, Acute Toxicity Test. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish.
Species	Zebra Fish (*Danio rerio*)
Exposure Period	96 Hours
Auxiliary Solvent	Nil
Water Hardness	2.1 mmol Ca & Mg ≡ 210 mg $CaCO_3$/L.
Analytical Monitoring	
Remarks – Method	Based on the range-finding test, seven 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 3, 6, 24, 48 72 and 96 h.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1h*	*24h*	*48h*	*72h*	*96h*
Control		7	0	0	0	0	0
100	97	7	0	0	0	0	0

Remarks – Results	All concentrations measured were in the range of ± 10% of the nominal concentrations. No particulate matter was observed. No mortality was observed throughout the whole exposure period. Water quality measurements (pH, dissolved oxygen and temperature) were within acceptable limits throughout the test.
CONCLUSION	The test substance is considered to be practically non-toxic to fish.
TEST FACILITY	Hoechst Marion Roussel (1998)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Reaktiv-Marineblau FC 63805 (70% Notified Chemical)
METHOD	EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	
Water Hardness	15.0°dH ≡ 267 mg $CaCO_3$/L
Analytical Monitoring	TOC
Remarks - Method	Duplicate of 10 daphnia each were used for each test concentration and control. The nominal concentration in the test media samples was at 100 mg/L. The immobility of the daphnia was determined visually after 24 and 48 h of exposure.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control		20	0	0
100	77.0	20	Not Determined*	0

* The intensity of the colouration did not permit a determination of immobilisation at 24 hours

Remarks - Results: NOEC ≥ 77.0 mg/L The concentration of the test substance was calculated from TOC values (1 mg/L TOC equals to 2.7 mg/L of the test substance). The test concentrations remained constant over the period of 48 h. Water quality measurements (pH, dissolved oxygen and temperature) were within acceptable limits throughout the test.

CONCLUSION: The test substance is practically non-toxic to daphnia, based on nominal concentration.

TEST FACILITY: Bayer AG (1998b)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE: Reaktiv-Marineblau FC 63805 (70% Notified Chemical)

METHOD: EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species: Scenedesmus subspicatus CHODAT
Exposure Period: …72 hours
Concentration Range: Nominal: 6.2 - 100 mg/L
Actual: < 5 - 76 mg/L
Auxiliary Solvent:
Water Hardness: Not Stated De-ionised water used for dilution
Analytical Monitoring: TOC
Remarks - Method: Test concentrations of 6.2, 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.

RESULTS

Biomass			*Growth*
EbC50 mg/L at 72 h	*Nominal LOEC mg/L at 72 h*	*Nominal NOEC mg/L at 72 h*	*ErC50 (Growth Rate) mg/L*
29.7	20.3	12.2	39.2 - 75.6

Remarks - Results: The concentration of the test substance was calculated from TOC values (1 mg/L TOC = 2.7 mg/L of the test substance).

CONCLUSION: The acute toxicity EbC50 was 29.7 mg/L

TEST FACILITY: Bayer AG (1998c)

8.2.3a. Modified Algal growth inhibition test

TEST SUBSTANCE	Reaktiv-Marineblau FC 63805 (70% Notified Chemical)
METHOD	EC Directive 92/69/EEC C.3 Modified Algal Inhibition Test.
Species	Scenedesmus subspicatus CHODAT
Exposure Period	…72 hours
Concentration Range	Nominal: 12.5 - 100 mg/L Actual: < 8 - 76 mg/L
Auxiliary Solvent	
Water Hardness	Not Stated De-ionised water used for dilution
Analytical Monitoring	TOC
Remarks - Method	Test concentrations of 12.5, 25, 50 and 100 mg/L with direct contact (Test I) with algae and through which light is allowed to pass with no contact with algae (Test II) and a control (Test III) 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.

RESULTS

Biomass		*Growth*	
Test I *EbC50* *mg/L at 72 h*	*Test II* *EbC50* *mg/L at 72 h*	*Test I* *ErC50 (Growth rate)* *mg/L at 72 h*	*Test II* *Er50 (Growth rate)* *mg/L at 72 h*
9. 5 - 20.3	9.5 - 20.3	27.0	20.3 – 37.8
EbC10 *mg/L at 72 h*	*EbC10* *mg/L at 72 h*	*ErC10(Growth rate)* *mg/L at 72 h*	*ErC10(Growth rate)* *mg/L at 72 h*
< 9.5	< 9.5	8.1	9.5 – 20.3

Remarks - Results	The concentration of the test substance was calculated from TOC values (1 mg/L TOC = 2.7 mg/L of the test substance).
CONCLUSION	EC10 is approximately 12.5 mg/L. No conclusion on EC50 could be made as all test concentrations with effects ≥ 50% may be solely due to light attenuation.
TEST FACILITY	Bayer AG (1998c)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Reaktiv-Marineblau FC 63805 (70% 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. The incubation time of 3 h with permanent aeration instead of the 30 minutes incubation time was used.
RESULTS	
EC50	> 10 000 mg/L
Remarks – Results	No inhibitions were observed at the highest test concentration of 10,000 mg/L after 3 h of incubation. The 3 h EC50 could not be calculated but was determined to be >10,000 mg/L. The 3 h EC50 for the reference was within the recommended range of 4-28 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 (1998d)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

After treatment of the fabrics, the notified chemical is assumed to have 90% fixation on the fabric and the remaining 10% will be removed from the fabric during the rinse phases. The low Koc and the high water solubility indicate that the notified chemical is unlikely to be adsorbed to sludge after waste water treatment. As a result the notified chemical is expected to remain in waste liquids after treatment and washing processes. Discharged waste water is released to the local waste treatment plant to undergo biological treatment before release to waterways.

The notified chemical released to the communal sewer via the dyehouse effluent discharge will be its major environmental exposure. Approximately 10% of the notified chemical (up to 300 kg per year) may be released to the environment from dyehouse waste. A worst-case PEC assuming 50% use in a single country dye-house with river outfall has been calculated based on water-use information available.

Amount of Chemical kg	Amount used per day assuming 260 days	Amount released per day assuming 90% fixation	Concentration in Sewer effluent assuming 10 ML per day discharge
1500	5.77	0.577	58.7 µg/L

Therefore the worst case PEC is calculated to be 58.7 µg/L. It is assumed that there will be no degradation or removal of the notified chemical within the STP and no further dilution at discharge.

A PEC based on a more likely scenario would be 50% use in a single metropolitan location.

Amount of Chemical kg	Amount used per day assuming 260 days	Amount released per day assuming 90% fixation	Concentration in Sewer effluent assuming 250 ML per day discharge
1500	5.77	0.577	2.31 µg/L

In this case the PEC would be 2.31 µg/ L and 0.23 µg/ L for river and ocean release respectively.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests for the notified chemical are listed below. As algae showed the highest toxic effects for the three trophic levels, concentration at 29.7 mg/L for algae (although this may have been solely caused by light attenuation) based on the notified chemical will be used as the toxicological end point.

Organism	***Duration***	***End Point***	***mg/L***
Zebra fish	96 h	LC50	>100
Daphnia	48 h	EC0	>77.0
Algae	72 h	E_bC50	29.7
Sludge micro-organisms	3 h	IC50	>10,000

A predicted no effect concentration (PNEC - aquatic ecosystems) of 297 µg/L has been derived by dividing the end point of 29.7 mg/L for algae 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

A worst case scenario (country dyehouse) has a PEC of 58.7 µg/L.
Another scenario for a metropolitan dyehouse has a sewage outfall concentration of 2.31 µg/L resulting in a PEC for river outfall of 2.31 µg/L and 0.23 µg/L for ocean outfall.
The calculated PNEC of 297 µg/L means that a risk quotient may be calculated as 0.20 for a worst case scenario; and 0.01 and <0.01 for the scenarios of a metropolitan dyehouse with river or ocean sewer releases respectively.

The risk quotient indicates an acceptable risk for the aquatic environment.

The majority of the notified chemical will ultimately be released to landfill or incinerated as part of the textile at the end of its useful life. Incineration of the treated textiles will destroy the notified chemical producing water, oxides of carbon and nitrogen, sulphur and fluorinated compounds. The fabrics where the notified chemical would remain bound in an inert matrix will be disposed of to landfill. As the notified chemical is not readily biodegradable, it will eventually degrade slowly through abiotic and biotic processes under landfill.

Based on the expected use pattern and its toxicity to aquatic organisms, which is at most moderate the overall risk to the environment is considered low.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Due to the largely automated nature of the fabric treatment process and use of appropriate PPE including respiratory protection, as required, minimal occupational exposure to the notified chemical is expected. However, dermal and accidental ocular exposure to the neat notified chemical and diluted chemical (up to 6% notified chemical) could occur from inadvertent spills, drips, and splashes during weighing, colour matching and or addition of the imported product to the fabric treatment machine or via incidental leaks from the machine transfer hoses, fittings, and/or pumps and during quality control operations. Given the molecular weight of the notified chemical, absorption of the solubilized form of the notified chemical through intact skin cannot be excluded.

High dust concentrations may result in irritation of the mucous membranes (eye or respiratory tract). The de-dusted granulated nature of the notified chemical as introduced is expected to limit such exposure to eyes and the respiratory tract. Repeated exposure to high dust concentrations of some reactive dyestuffs may or occasionally cause respiratory hyper-sensitisation. The notifier states a sensitisation by the notified chemical has not been observed. Employers are responsible for maintaining nuisance dust levels below the NOHSC exposure standard of 10 mg/m^3 (NOHSC 1995).

Transport, Warehouse and Storage
Exposure to the neat form of the notified chemical is not expected during transport, warehousing and storage provided the 25 kg cartons containing the commercial product remains intact.

Processing
While minimal occupational exposure is expected, such exposure, albeit of short duration of approximately up to 1 hour per day, will result in frequent exposure to neat notified chemical during the weighing and colour matching and up to 6% notified chemical during transfer operations of the diluted solutions of the notified chemical into the dye machine.

While neat chemical exposure occurs during colour matching, the greater potential for exposure across biological membranes is predicted to be by means of the diluted solution, i.e., solubilized form of up to 6% notified chemical). This would could occur during the colour mixing and transfer of the diluted solution to the dye machine. The estimated dermal exposure during such operation is 0.006 - 0.06 mg/cm^2/day, based on EASE model (EASE) and assuming the notified polymer is present at concentration of 6%. Therefore, for a 70 kg worker with surface area for hands at 820 cm^2 and forearms at 1140 cm^2 and a 100% dermal absorption factor, systemic exposure is estimated to be 0.17 -1.7 mg/kg bw/day. This estimate assumes that all of the

notified chemical is transferred with the dye solution and it does not take into account the expected low frequency of exposure and use of PPE. Taking these factors into account, the lower limit (0.17 mg/kg bw/day) should be used as the exposure value.

Exposure to the notified chemical during the dyeing, rinsing, curing and washing operations is expected to be limited by the automated processes typically used in dye-houses in Australia. However, dermal and accidental ocular exposure cannot be discounted if workers are required to manually intervene in the processes or are required to manually handle and or transfer wet dyed textile. However, exposure is expected to be limited by the use of PPE such as safety glasses, impervious gloves and protective clothing and the low concentration (<1% notified chemical) in the dye solution. Inhalation exposure is expected to be low given the notified chemical's low vapour pressure and the de-dusted granulated nature of the neat chemical.

Exposure to the notified chemical is expected to be negligible when handling the finished dry fabric as the notified chemical is expected to be bound to the fabric and be at a low level in the finished textile (<1% notified chemical) with negligible residues.

Maintenance, Cleaning and Disposal
Maintenance, cleaning and disposal workers will have limited exposure to the notified chemical by skin contact as they are required to maintain and repair equipment and dispose of spent items, respectively. Any dermal exposure as a result of contaminated equipment will be mediated by the use of personal protective equipment (PPE) such as safety glasses, impervious gloves and protective clothing.

Any exposure in general to the notified chemical would be limited by the use of PPE. All workers handling the notified chemical are expected to wear PPE such as safety glasses, impervious gloves, protective clothing and respiratory protection if necessary and have access to the Material Safety Data Sheet.

9.2.2. Public health – exposure assessment

The notified chemical will not be sold to the public except in the form of finished textiles (<1% notified chemical). There is potential for extensive public exposure to such treated fabrics. While members of the public are expected to make dermal contact with fabrics treated with the notified chemical, such contact is not expected to be by means of a bioavailable form. This is because the notified chemical is covalently bound to the fabric and hence not bioavailable and as such unlikely to penetrate biological membranes. Exposure to the notified chemical is, therefore, assessed as low due to the inert nature of the notified chemical and negligible residues in the final fabric form.

9.2.3. Human health – effects assessment

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); and
genotoxicity

No toxicokinetic studies were submitted. Based on the hydrophilicity of the chemical (log Kow is – 6.6) and absence of indicators of absorption in the dermal toxicity study, dermal absorption of the notified chemical is expected to be low. A proportion of the notified chemical is probably excreted unchanged, as indicated by colouration of faeces and urine in the sub-acute study.

An acute oral and dermal toxicity study in the rat and rabbit, respectively, indicated the notified chemical is of low toxicity via the oral and dermal routes. A primary dermal irritation test in the rabbit showed the notified chemical is slightly irritating to skin. An eye irritation study in the rabbit showed some irritation of the conjunctivae with initial clear discharge. The swelling with partial eversion of the lids resolved by the third day after instillation. Discoloration of the nictitating membrane was observed to the study cessation at 3 days.

A skin sensitisation (adjuvant) test in guinea pigs showed no evidence of reactions indicative of sensitisation. Based on a 28-day subacute oral toxicity study in rats, a NOAEL in male and female rats of 250 mg/kg bw/day was indicated based on stomach/fundic inflammation at 1000 mg/kg bw/day. Discolouration of the kidneys observed at 250 mg/kg bw/day was considered as a treatment related effect without toxicological significance.

The notified chemical was not mutagenic in a bacterial reverse mutation test with and without metabolic activation.. A chromosomal aberration tests in V79 Chinese Hamster Lung Cells (in vitro) showed the notified chemical was clastogenic to CHL cells treated in vitro in the absence of metabolic activation. The notified chemical was not clastogenic, however, in an in vivo mouse micronucleus assay under the conditions of the test.

However the notified chemical contains a structural alert for mutagenicity and carcinogenicity and the possibility of these effects cannot be ruled out.

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 2002).

9.2.4. Occupational health and safety – risk characterisation

Based on the toxicity data provided for the notified polymer, it is a slight skin and eye irritant. The notified chemical contains a functional group that is a structural alert for mutagenicity or carcinogenicity. However based on available genotoxicity data it would not be classified for these endpoints. Dermal absorption is likely to be low because of the hydrophilicity of the notified chemical.

Import, storage and handling
Exposure to the notified chemical during transport and storage is not expected unless the packaging is accidentally breached. Therefore, on the basis of good work practices and safety-handling measures and the nature of the de-dusted granulated formulation to limit dust formation, the notified chemical as introduced is unlikely to pose a significant occupational health and safety risk when used in the proposed manner.

Processing
Workers who have the highest potential for dermal exposure to the notified chemical (in the solubilized form) during routine operations are predicted to be those involved in colour matching and mixing. The notified chemical is present at a concentration of up to 6% in the dye solution. A reasonable worst-case dermal exposure for workers involved in dye solution formulation is estimated to be 0.17 mg/kg bw/day. Based on a NOAEL of 250 mg/kg bw/day, derived from a 28-day rat oral study the margin of exposure (MOE) is calculated as 1471. 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 using estimated exposure data is considered acceptable for dye formulation workers.

The MSDS recommends that workers should wear safety glasses and impervious gloves. Consequently, at the concentration used in the dye solution formulation (up to 6%), the risk of irritation to the eyes and skin is expected to be low. Due to the low vapour pressure of the notified chemical, an inhalation exposure to the notified chemical by means of the dye solution is not expected, and hence as the risk of respiratory irritant effects under such circumstances is considered to be low.

It is noted that the notified chemical is a reactive dye, and as such employers may 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.

In conclusion, due to the automated nature of the dye formulation process and use of a non-

dusting formulation, the risk to process workers is expected to be low. However, due to the nature of the notified chemical, in the event of manual weighing, mixing and addition, and in the event of spill or machine malfunction where exposure is likely to be significant, workers should wear protective eyewear, chemical resistant industrial clothing (coveralls), impermeable gloves and respiratory protection, as required.

Following drying of the textile product, the risk to workers handling the fabric treated with the notified polymer is expected to be negligible.

9.2.5. Public health – risk characterisation

The notified chemical is not available to the general public and negligible residue of the notified chemical is expected in and from the finished textile.

There will be significant public exposure by dermal exposure to fabric treated with the notified chemical. However, the concentration of the notified chemical used is at low concentrations in treated textile (<1% by weight fabric) and is bound to the fabric, not bioavailable and as such not available for skin contact nor skin penetration. Therefore, the notified chemical is unlikely to pose a significant public health risk when used in the proposed manner.

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/polymer 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.

	Hazard category	*Hazard statement*
Chronic hazards to the aquatic environment	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.

10.3.2. Public health

There is No Significant Concern to public health when used in the manner proposed.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

NICNAS has recommended some amendments to the MSDS of the notified chemical provided by the notifier, so that it will be 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.

The changes recommended are:
Addition of the text "NON-HAZARDOUS SUBSTANCE. NON-DANGEROUS GOOD" to Section 2
Further information on the environmental hazard of the notified chemical to be added to the MSDS.

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 the event of contamination, change protective gloves immediately.
  - 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.

Environment

Disposal

- The notified chemical should be disposed of by authorised incineration.

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. Residues may be diluted without allowing entry to waterways and then collected using inert absorbent material (eg sand, earth, vermiculite, diatomaceous earth) and shovelled into suitable container for disposal.

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 formulation process for and or purity of the notified chemical is changed
- adverse reporting related to skin or respiratory sensitisation

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.

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