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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Levafix Yellow CA

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
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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NICNAS

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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
Spectral data
Purity
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:

Adsorption
Reactivity
Acute inhalation toxicity
Induction of germ cell damage
Ready biodegradation
Bioaccumulation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Nil

NOTIFICATION IN OTHER COUNTRIES
European Union (1998)
Canada (1999)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Levafix Yellow 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 Hoechst AG CR&T Analytical Laboratories Frankfurt am Main Brüningstrasse 50 (1997)
Aventis Research and Technologies GmbH and Co KG (1998a)

3. COMPOSITION

DEGREE OF PURITY
Medium

4. INTRODUCTION AND USE INFORMATION

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

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 the Dyechem facility

5.2. Operation description

The notified chemical will be imported as a dye component in de-dusted powder form and only formulation will occur in Australia.

Dyechem is only an 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 textile dyeing processes.

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.

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 containing > 50% of the notified chemical will be formulated in warm water containing a final concentration of no more than 6% of the notified chemical.

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. The dye will then be automatically sprayed on textiles via an enclosed dyeing machine using a continuous roller system. The dyeing process is typically undertaken at 60ºC 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.

Contents of the feeding tank are flushed into the main dye vessel. There is no release of notified chemical because of the de-dusted powder formulation. 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 < 6% 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 notified chemical during transport and storage will be limited as the dyestuff containing the notified chemical is 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.

Laboratory technicians:

Laboratory technicians at customer dye houses may be exposed to the 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.

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, mixing, transferring and equipment cleaning procedures at the dye plant. Dye houses are expected to possess adequate mechanical ventilation to prevent workers from breathing vapour, mist or dust.

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 well-trained staff. There is potential for dermal and ocular exposure to the 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.

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 from 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, 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 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 Orange granules

Melting Point/Freezing Point > 400ºC

METHOD	EC Directive 92/69/EEC A.1 Melting Point /Melting Range Explosive Properties.
Remarks	No melting point was observed in the range 25ºC–400ºC. No protocol deviations were reported.
TEST FACILITY	Hoechst Research & Technology Deutschland GmbH & Co. KG (1998a)

Boiling Point Not relevant for a solid-state test material

Density 1510 kg/m^3 at 4ºC

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 Hoechst Research & Technology Deutschland GmbH & Co. KG (1998g)

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 21°C and 149°C. No protocol deviations were reported.
TEST FACILITY Hoechst Research & Technology Deutschland GmbH & Co. KG (1998c)

Water Solubility 375.4 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 6.2 with the exclusion of light, 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 (1998d),

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	10.0
7	25	15.6
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 showed greater than 50% decomposition after 2.4 hours at pH 9 at 50°C. The results for the half life at pH 4 and 7 at 25ºC were obtained by extrapolating from the test result temperatures (50, 55 and 70ºC; and 50, 55 and 65°C respectively).
TEST FACILITY Aventis Research and Technologies GmbH and Co KG (1998e)

Partition Coefficient (n-octanol/water) log Pow ≈ - 6.2

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks Estimate by measuring solubility in n-octanol and comparing with solubility in water. Duplicate analysis was performed by adding 15.268 mg and 12.876 mg of test substance to 50 mL n-octanol and stirred for 4 h at 20°C. 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 < 0.2 mg/L.
TEST FACILITY Aventis Research and Technologies GmbH and Co KG (1998f)

Adsorption/Desorption log K_{oc} = 1.1
– screening test

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.

Dissociation Constant pKa = 3.2

METHOD OECD TG 112 Dissociation Constants in Water.
Remarks The results are based on three independent tests in the acid range and investigated using UV/VIS spectrophotometry. The pKa value for the alkaline range was not determined due to decomposition of the test material.
TEST FACILITY Aventis Research and Technologies GmbH and Co KG (1998g)

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 combustible

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids)
Remarks The substance could not be ignited. Glowing of the test material without propagation was observed. The results show the test material not to be flammable.
TEST FACILITY Hoechst Research & Technology Deutschland GmbH & Co. KG (1998e).

Flammability Limits Not determined

Remarks Not expected to be flammable based on vapour pressure

Autoignition Temperature 330°C

METHOD EC Directive 92/69/EEC A.16 Auto-flammability (Solids – Determination of Relative Self-Ignition Temperature).
Remarks Temperature range tested: 25 °C – 481°C. No protocol deviations were reported.
TEST FACILITY Hoechst Research & Technology Deutschland GmbH & Co. KG (1998f).

Explosive Properties Not explosive

METHOD EC Directive 92/69/EEC A.14 Melting/Melting Range Explosive Properties
Remarks No protocol deviations were reported.
TEST FACILITY Hoechst Research & Technology Deutschland GmbH & Co. KG (1998a)

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.

Surface Tension 66.8 mN/m at 20°C

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 Hoechst Research & Technology Deutschland GmbH & Co. KG (1998)

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

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	moderately irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL =62.5 mg/kg bw day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosome aberration	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE: Reaktivgelb FD 08064 (Containing notified chemical as major component)

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

Species/Strain: Rat/ Sprague Dawley
Vehicle: Deionized water
Remarks - Method: On the bases of a previous dose range study (500, 100 and 2000 mg/kg/bw), only one dose was tested 2000 mg/kg bw in the main study. The animals received the test material as a 20% solution in deionized water, the administration volume being 10 ml/kg bw. The prepared test substance was administered by gavage to fasted animals and they were observed for the following 14 days. Symptoms were recorded twice daily (once on weekends and public holidays) and weight was measured 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: None
Effects in Organs: No symptoms were observed
Remarks - Results: Development of body weight was not impaired.
No macroscopic changes observed after sacrificing the animals at the end of observation period.

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

TEST FACILITY: Hoechst (1998c)

7.2. Acute toxicity – dermal

TEST SUBSTANCE: Reaktivgelb FD 08064 (Containing notified chemical as major component)

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	Deionized water
Type of dressing	Occlusive
Remarks - Method	The test substance (0.5 g) was moistened with (0.4mL) deionized 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 measured 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 treated skin areas of the animals were sporadically discoloured orange up to the end of the study, day 15, in two of the male and 4 of the female animals.
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 (1998d)

7.3. Irritation – skin

TEST SUBSTANCE Reaktivgelb FD 08064 (Containing notified chemical as major component)

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand albino / Charles River
Number of Animals	3 female
Vehicle	Deionized water
Observation Period	72 days.
Type of Dressing	Occlusive
Remarks - Method	The test substance was pasted with water (0.5 g in 0.4 mL) and placed on cellulose patch (2.5x2.5 cm) and over surgical plaster. The plaster was fixed to a shaved dorsal area (25 cm^2) with bandage. After 4 hours the dressing was removed and the area carefully washed from the excess substance with warm tap water. Skin at the treated area was examined 0.5, 1, 24, 48 and 72 hours after removal of patches. Because of persistent irritations 72 hours after removal of patches, additional recordings were performed after 7 days. Erythema, eschar formation or oedema were evaluated according to the score of Draize. All other changes of the skin were also recorded.

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	1.3	2.0	1.7	3	< 7 days	0
Oedema	0.3	0.3	0.3	1	1 day	0

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

Remarks - Results: No effects were noted at 7 days.

CONCLUSION: The notified chemical is moderately irritating to the skin.

TEST FACILITY: Hoechst (1998e)

7.4. Irritation – eye

TEST SUBSTANCE: Reaktivgelb FD 08064 (Containing notified chemical as major component)

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

Species/Strain: Rabbit/New Zealand albino.
Number of Animals: 3
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 at any time discharge was observed or fluorescein sodium was used for examination of lesions (24 and 72 hours), eye was washed with isotonic saline 37^{o}C. Eyes were examined 1, 24, 48 and 72 hours post –treatment. The study was carried out to GLP.

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	0.3	0.3	1	2	48 h	0
Conjunctiva: chemosis	0	0	0.3	2	24 h	0
Conjunctiva: discharge	0	0	0	1	1 h	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: Irritating effects were confined to the conjunctivae and resolved within 72 hours.

CONCLUSION: The notified chemical is slightly irritating to the eye.

TEST FACILITY: Hoechst (1998f)

7.5. Skin sensitisation

TEST SUBSTANCE: Reaktivgelb FD 08064 (Containing notified chemical as major component)

METHOD: OECD TG 406 Skin Sensitisation – Magnusson and Kligman
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: topical: 5% intradermal: 5% After topical treatment, the 25% solution caused discrete or moderate erythema, with no signs of irritation after treatment with the 5% and 1% solutions. The intradermal injection with the 5% notified substance caused well-defined erythema and oedema as well as encrustations.
MAIN STUDY	
Number of Animals	Test Group: 10 female Control Group: 5 female
INDUCTION PHASE	Induction Concentration: intradermal: 5% w/v in deionized water 5% w/v in 50% Freund adjuvant topical: 25% w/v in deionized water
Signs of Irritation	Intradermal injection with adjuvant (with and without test substance) caused severe erythema and oedema as well as indurations and encrustations. Sites treated with adjuvant plus notified substance showed open wounds and necrosis while sites injected with test substance in deionized water showed well-defined erythema and oedema as well as encrustations. The dermal induction treatment with adjuvant or the test material alone showed severe erythema and oedema, indurated and encrusted skin as well as necrosis and open wounds.
CHALLENGE PHASE	
1st challenge	topical: 5% w/v in deionised water
Remarks - Method	No protocol deviations reported. Sodium dodecyl sulfate was not used, as there was significant skin irritation. 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	5%	0/10	0/10
Control Group	5%	0/5	0/5

Remarks - Results	Evidence of dermal irritation was seen in this study
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Hoechst (1998g)

7.6. Repeat dose toxicity

TEST SUBSTANCE	Reaktivgelb FD 08064 (Containing notified chemical as major component)
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 SD
Route of Administration	Oral – gavage/
Exposure Information	Total exposure days: 28 days;

	Dose regimen: 7 days per week; Post-exposure observation period: 1 day
Vehicle	Deionized 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

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
No test substance related changes in haematological, clinical chemistry or urinalysis parameters were observed.

Effects in Organs
No test substance related macroscopic changes or effects on organs were observed.
Histopathologically, the test substance caused inflammatory reaction in the submucosal layer and beyond the muscular mucosal layer of the glandular stomach in animals of the intermediate and high dose group. This reaction consisted of round cells interspersed with neutrophilic granulocytes. While some similar effects were seen in the low dose groups, they were of lesser severity and similar to those found in the control animals. No other significant microscopic changes were noted.

Remarks – Results
The adverse effects observed in the study were limited to microscopic changes in the glandular stomach.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 62.5 mg/kg bw/day in this study, based on increased severity of acute submucosal inflammation in the glandular stomach, in the dose groups of 250mg/kg bw day and above.

TEST FACILITY Hoechst (1998h)

7.7. Genotoxicity – bacteria

TEST SUBSTANCE	Reaktivgelb FD 08064 (Containing notified chemical as major component)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 92/69, L383 A, Annex B 14 Plate incorporation and modified pre-incubation (prival) methods
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100
Metabolic Activation System	Rat liver S9 microsomal fraction from Aroclor 1254 treated rats and from non pretreated Syrian hamsters.
Concentration Range in	a) With metabolic activation: 4 to 5000 µg/plate

Main Test	b) Without metabolic activation: 4 to 5000 µg/plate
Vehicle	Double-distilled water (notified chemical) Double-distilled water or 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 (10% ret liver): 2-aminoanthracene for all strains. Positive control with activation 30% Syrian hamster: 2-aminoanthracene for TA100, TA1535, TA1537; Congo red TA98. The description of the method did not make it clear which parts of the test used the Prival (modified pre-incubation) method.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1		> 5000	> 5000	Negative for all strains & all dose levels
Test 2		> 5000	> 5000	As above
Test 3		> 5000	> 5000	Negative for all dose levels, only TA 100 tested
Present				
Test 1		> 5000	> 5000	Negative for all strains & all dose levels
Test 2		> 5000	> 5000	An apparent increase was seen in the level of revertants, only in TA 1537 at the highest dose.
Test 3 (rat S9 and hamster +S9 tested)		> 5000	> 5000	No 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. A twofold increase in revertants in TA 1537 in the presence of S9 activation was less than the threefold increase needed to indicate mutagenicity in this strain and may have been due to a statistical aberration, as the level of revertants was very low (10 or below). Apart from this result, 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 mouse S-9 nor mouse and hamster mix.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Hoechst (1998i)

7.8. Genotoxicity – in vitro

TEST SUBSTANCE	Reaktivgelb FD 08064 (Containing notified chemical as major component)
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test. EC Directive 92/69/, L383 A, Annex B. 10 p. 148-150
Cell Type/Cell Line	V79 Chinese Hamster lung 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 were reported. The biometry of the results for chromosomal aberrations was performed with one-sided Fisher –Exact test.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period* [+]	*Harvest Time*
Absent			
Test 1	312.5, 625 and 1250	20	20
Test 1	1250	20	28
Test 2	312.5, 625 and 1250	20	20
Test 2	1250	20	28
Present			
Test 1	1250 and 2500and 5000.0	3	20
Test 1	5000	3	28
Test 2	1250 and 2500and 5000.0	3	20
Test 2	5000	3	28

[+] Period treated with test substance. [Δ] Period after the start of treatment. 50-100 metaphases per experimental group and cell culture were examined.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1 (20h)	2000.0 (42.7% RS[+]) 3000.0 (4.3% RS[+])	1250.0 (76.9% RS[+]) 2000.0 (13.5% RS[+]) 1250.0 (86.4-62.8% RMI*)	> 5000.0	not observed
Test 2 (28h)		1250.0 (52.9-64.4% RMI*)	> 5000.0	not observed
Present				
Test 1 (20h)	4000.0 (66.1% RS[+])	5000.0 (87.4% RS[+]) 1259.0 (52.9-64.4% RMI*)	> 5000.0	not observed
Test 2 (28h)		5000.0 (84.6-106.9% RMI*)	> 5000.0	not observed

[+] Relative survival; * Relative Mitotic Index

Remarks - Results	There was no relevant reproducible enhancement of metaphases with or without S9 mix. The sensitivity of the test system was demonstrated by enhanced mutation frequency in the cell cultures treated with positive control compounds CPA (cyclophosphamide) and EMS (ethyl methane sulfonate).
CONCLUSION	The notified chemical was not clastogenic to Chinese Hamster lung cells

treated in vitro under the conditions of the test.

TEST FACILITY Hoechst (1998j)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

Not Determined.
Used analogue (Reaktiv Blau FC 05717), which is accepted to have similar properties to test substance. Dyes of this type are unlikely to be readily biodegradable.

8.1.2. Bioaccumulation

Not Determined.
Due to its water solubility and log Kow of -6.2 the chemical is unlikely to bioaccumulate.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE Reaktivgelb FD 08064 (Containing notified chemical as major component)

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 Hours
Auxiliary Solvent	Nil
Water Hardness	2.1- 2.3 mmol (Ca^{2+} & Mg^{2+}) ≡ 210 - 230 mg $CaCO_3$/L
Analytical Monitoring	Photospectrometry
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*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control		7	0	0	0	0	0
100	92.5	7	0	0	0	0	0

LC50	> 100 mg/L at 96 hours
NOEC	100 mg/L at 96 hours
Remarks – Results	All concentrations measured were in the range of ± 10% of the nominal concentrations. No particulate matter was observed. Although some changes occurred to behaviour and respiration rate, which were reversible after 96 hours after exposure, 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 (1998a)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Reaktivgelb FD 08064 (Containing notified chemical as major component)
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static conditions EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – Static conditions.
Species	*Daphnia magna*
Exposure Period	48 hours *[acute study]*
Auxiliary Solvent	Nil
Water Hardness	2.1- 2.3 mmol (Ca^{2+} & Mg^{2+}) ≡ 210 - 230 mg $CaCO_3$/L
Analytical Monitoring	Photospectrometry
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	99.2	20	0	0

LC50	> 100 mg/L at 48 hours
NOEC	100 mg/L at 48 hours
Remarks - Results	All concentrations measured were in the range of ± 10% of the nominal concentrations. No particulate matter was observed. No immobility 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 daphnia.
TEST FACILITY	Hoechst Marion Roussel (1998b)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Reaktivgelb FD 08064 (Containing notified chemical as major component)
METHOD	EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	Scenedesmus subspicatus CHODAT
Exposure Period	2 hours
Concentration Range	Nominal: 25 - 100 mg/L Actual: 24 - 90 mg/L
Auxiliary Solvent	Nil
Water Hardness	Not Specified, de-ionised water used for dilution.
Analytical Monitoring	TOC

Remarks - Method	Test concentrations of 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	*Nominal LOEC*	*Nominal NOEC*	*ErC50 (Growth Rate)*
mg/L at 72 h	*mg/L at 72 h*	*mg/L at 72 h*	*mg/L*
43.5 – 87.0	43.5	22.5	> 87.0

Remarks - Results	The concentration of the test substance was calculated from TOC values (1 mg/L TOC = 3.0 mg/L of the test substance). The value 1 mg/L TOC = 3.0 mg/L of the test substance is based on the assumption of 100% purity of the chemical. As the test substance only contains the notified chemical as its main component, the TOC values merely represent exposure conditions of all carbon containing components.
CONCLUSION	The test substance is considered harmful to algae (United Nations, 2003)
TEST FACILITY	Bayer AG (1998)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Reaktivgelb FD 08064 (Containing notified chemical as major component)
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: 250 - 1000 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 250, 500 and 1,000 mg/L. 3,5-dichlorophenol was used as the reference substance at test concentrations of 5 and 30 mg/L. The incubation time of 3 h with permanent aeration, instead of the 30 minutes incubation time, was used.
RESULTS	
EC50	> 1000 mg/L (nominal)
Remarks – Results	No inhibitions were observed at the highest test concentration of 1,000 mg/L after 3 h of incubation. The 3 h EC50 could not be calculated but was determined to be >1,000 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	Infraserv GmbH & Co Höchst KG (1998)

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 kg	Amount released per day assuming 90% fixation kg	Concentration in Sewer effluent assuming 10 ML per day discharge
1500	5.77	0.577	57.7 µg/L

Therefore the worst case PEC is calculated to be 57.7 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 another scenario would be 50% use in a single metropolitan location.

Amount of Chemical kg	Amount used per day assuming 260 days kg	Amount released per day assuming 90% fixation kg	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, EbC50 at 43.5 mg/L for algae 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	>100
Algae	72 h	E_bC50	43.5 – 87.0
Sludge micro-organisms	3 h	IC50	>1,000

A predicted no effect concentration (PNEC - aquatic ecosystems) of 435 µg/L has been derived by dividing the end point of 43.5 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 57.7 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 435 µg/L means that a risk quotient may be calculated as 0.13 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 low level of toxicity to aquatic organisms, 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 notifier has stated that the 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 (in vitro only).

No toxicokinetic studies were submitted. Based on the hydrophilicity of the chemical (log Kow is estimated to be approximately 6.2 and measured water solubility is high) and absence of indicators of absorption in the dermal toxicity study, dermal absorption of the notified chemical is expected to be low.

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. Testing in the rabbit showed the notified chemical is moderately irritating to skin and slightly irritating to the eye. More significant dermal irritation was noted in the sensitisation study, where contact time was longer.

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 inflammatory reaction in the submucosal layer and beyond the muscular mucosal layer of the glandular stomach at 250 mg/kg bw/day and above. The effects manifested as a dose-related grading of the effect in these tissues, but did not extend to the glandular cells themselves. Body weight development, haematological and clinical chemistry parameters and organ weights were unaffected.

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 not clastogenic.

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 chemical, 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 62.5 mg/kg bw/day, derived from a 28-day rat oral study the margin of exposure (MOE) is calculated as 367. 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:

1. Addition of the text "NON-HAZARDOUS SUBSTANCE. NON-DANGEROUS GOOD" to Section 2
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 and skin.
  - 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

- Accidental spills or release of the notified chemical should be handled by physical collection without raising dust such as 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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