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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Levafix Red 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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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
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:

Particle Size
Flash Point
Flammability Limits
Reactivity
Acute Inhalation Toxicity
Genotoxicity - Induction of Germ Cell Damage
Bioaccumulation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
No

NOTIFICATION IN OTHER COUNTRIES
European Union (1998)
Canada (1999)
China (1998)
United States (1998)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Levafix Red CA

METHODS OF DETECTION AND DETERMINATION

METHOD	Ultraviolet-visible (UV-VIS), Nuclear Magnetic Resonance (^{1}H NMR, ^{13}C NMR), Infrared (IR) Spectroscopy and High Performance Liquid Chromatography (HPLC).
Remarks	Summary report of UV-VIS, NMR and IR analysis only. HPLC chromatograms of the reaction mixture provided.
TEST FACILITY	Aventis Research and Technologies GmbH and Co KG (1998). Aventis Research and Technologies GmbH and Co KG (1998b).

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 in a neat (i.e., 100% medium purity notified chemical) form as a 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 the Dyechem facility.

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. The 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 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.

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 well-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
Since the notified chemical will not be manufactured locally, there will be no environmental exposure associated with this process in Australia. The notified chemical will be imported into Australia in 25 kg cartons.

RELEASE OF CHEMICAL FROM USE
The notifier indicates that no notified chemical will remain in empty cartons as all dyes are water soluble and cartons will be cleaned before disposal. The dye solution will be manually transferred to a feed tank, then automatically sprayed onto cloth on a continuous roller in an enclosed dyeing machine. After each dye bath, the vessel will be emptied and refilled, and the spent dye and water directed towards waste water treatment. Typically dyehouses have their own waste water treatment facilities with the treated waste water then released to communal waste water system.

The notifier indicates that the dye fixation rate is 90% and approximately 10% (maximum of 300 kg per annum) will go to the dye house waste water. The dyed cloth will be fixed at low pH, then washed in warm soapy water to remove any free dye at the end of the dyeing cycle. Except in the case of accidental release during transport, the primary source of release will be via the industrial waste water discharged to sewer. The majority of the notified chemical will ultimately be released to landfill or incinerated as part of the textile when this has finally reached the end of its useful life.

The notified chemicals will be used in textile dyehouses and mills in Australia.

5.5. Disposal

The wastewater after dyeing process will be discharged to sewer. The majority of the notified chemical will ultimately be released to landfill as part of the discarded textiles or be incinerated.

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 Red granules

Melting Point/Freezing Point Melting Point > 400 ºC

METHOD EC Directive 92/69/EEC A.1 Melting Point /Melting Range Explosive Properties
Remarks Differential Scanning Calorimetry (DSC) method used. No melting point was observed in the range 25 – 400 ºC. No protocol deviations were reported.
TEST FACILITY Aventis Research and Technologies GmbH and Co KG (1998c)

Density 1640 kg/m^3 at 22.8 C

METHOD EC Directive 92/69/EEC A.3 Relative Density
Remarks Gas comparison pycnometer. No protocol deviations were reported.
TEST FACILITY Aventis Research and Technologies GmbH and Co KG (1998d)

Vapour Pressure 1.3 x 10^{-7} kPa at 25ºC

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure
Remarks Vapour pressure balance system using a Differential Scanning Calorimetry. No protocol deviations were reported.
TEST FACILITY Aventis Research and Technologies GmbH and Co KG (1998e)

Water Solubility 389.3 g/L at 20ºC

METHOD EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Based on the preliminary visual experiments, the water solubility was determined by the Flask Method. The concentration of the test substance was determined by HPLC after stirring for 24, 48 and 72 h at 30ºC and equilibrated for a 24 h at 20ºC No protocol deviations were reported.
TEST FACILITY Aventis Research and Technologies GmbH and Co KG (1998f)

Hydrolysis as a Function of pH

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

PH	*T (°C)*	*$t_{½}$ (days)*
4	25	3.2
7	25	406
9	25	14.4

Remarks The flask containing the hydrolysis mixture was placed in a water bath at specific temperature and pH. The HPLC analysis of the unhydrolysed test substance was performed. The results for the half life at pH 4 (incubated at 50, 55 and 65ºC), 7 (at 50, 70 and 80ºC) and 9 (at 50, 55 and 65ºC) were obtained by extrapolating to a temperature at 25ºC.
TEST FACILITY Aventis Research and Technologies GmbH and Co KG (1998g)

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

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks The solubility in *n*-octanol was determined where two weighed portions were added to *n*-octanol and stirred for 4 h at 20°C. Aliquots were taken and analysed by HPLC. The n-octanol/water partition coefficient was estimated from the ratio of its solubility in n-octanol and water.

TEST FACILITY Aventis Research and Technologies GmbH and Co KG (1998h)

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

METHOD OECD TG 121 Estimation of the Adsorption Coefficient (Koc) on soil and sewage sludge using HPLC.
Remarks The adsorption coefficient was determined using the HPLC method where the retention time is compared with that of the calibration substances (urea, phenol, acetanilide, monuron, triapenthenol, linuron, fenthion and trifluralin). The mean of two log Koc values were determined.
TEST FACILITY Infracor GmbH (2001)

Dissociation Constant pKa = 0.6-5.3 at 22ºC

Remarks The notified chemical is a salt of a strong acid and is expected to remain completely ionised in the environmental pH range of 4-9.
METHOD OECD guideline No. 112
Remarks The pKa determination was performed in triplicate in the acid and alkaline range. The pKa for the alkaline range was not determined as the notified chemical decomposed in alkaline solutions. The pH and the UV-Visible spectra of each solution were measured. It is noted that the chemical has a purity > 50% and the possible effects of impurities were not examined.
TEST FACILITY Aventis Research and Technologies GmbH and Co KG (1998i)

Particle Size > 115 μm and < 200 μm

Remarks Report not provided. Typical values were quoted. The notified chemical is imported in granulated de-dusted form.

Flash Point Not combustible
METHOD EC Directive 92/69/EEC A.10 Flammability (Solids)
Remarks The substance could not be ignited with a flame.
TEST FACILITY Aventis Research and Technologies GmbH and Co KG (1998g)

Autoignition Temperature > 400 ºC

METHOD 92/69/EEC A.16 Auto-flammability (Solids: Determination of Relative Self-Ignition Temperature).
Remarks No self ignition registered, tested up to 400 ºC
TEST FACILITY Aventis Research and Technologies GmbH and Co KG (1998h)

Explosive Properties Not determined

METHOD EC Directive 92/69/EEC A.14 Melting/Melting Range Explosive Properties
Remarks Not expected to be explosive as the measured decomposition energy using DSC was below 500 J/g and as such the main test of explosive properties was not undertaken.
TEST FACILITY Aventis Research and Technologies GmbH and Co KG (1998c)

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.

Reactivity

Remarks The test material is fibre-reactive otherwise the reactivity of the test material is

expected to be low under ordinary conditions of use and storage. The structural formula indicates low oxidising properties.

ADDITIONAL TESTS

Fat (or n-octanol) Solubility ≤0.004 mg/100 g fat at 37°C

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

Surface Tension 63.8 mN/m at 20ºC

METHOD EC Directive 92/69/EEC A.5 Surface Tension.
Remarks Surface tension was determined for the test substance with a concentration of 1 g/L using a ring tensiometer at 20ºC. The notified chemical is not a surface active substance as the surface tension is >60 mN/m.
TEST FACILITY Aventis Research and Technologies GmbH and Co KG (1998j)

7. TOXICOLOGICAL INVESTIGATIONS

The toxicological investigations were undertaken on the notified chemical.

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	test not conducted
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, repeat dose <oral> toxicity – 28 days.	NO(A)EL 250 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro <V79 Chinese Hamster Lung Cells>	genotoxic
Genotoxicity – in vivo <mammalian erythrocyte micronucleus>	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD OECD TG 401 Acute Oral Toxicity (adopted Feb 24 1987).
EC Directive 92/69/EEC B.1 Acute Toxicity (Oral).
Species/Strain Rat/Sprague Dawley
Vehicle Deionised water
Remarks - Method Dosed as a 20% solution.

RESULTS Statement of GLP compliance. No protocol deviations reported.
A range finding study was undertaken of 2/sex dosed by oral gavage (20% notified chemical) in water at 100 and 2000 mg/kg bw/day.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	None

LD50	> 2000 mg/kg bw
Signs of Toxicity	Diarrhoea, red discoloured faeces and red urine were observed.
Effects in Organs	No macroscopic visible changes were observed.
Remarks - Results	No deaths occurred during the range finding or study period. Development of body weight was not impaired.

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

TEST FACILITY Hoechst (1998b)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Notified chemical

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

Species/Strain	Rat/Sprague Dawley
Vehicle	Deionised water
Type of dressing	Occlusive.
Remarks - Method	Statement of GLP compliance. No protocol deviations reported.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	None

LD50	> 2000 mg/kg bw in both male and female rats
Signs of Toxicity - Local	The skin surface of the animals was discoloured red. The discoloration had not disappeared up to the end of the study.
Signs of Toxicity - Systemic	No signs of systemic toxicity were noted during the study. Body weight was above the initial weight during the whole observation period.
Effects in Organs	No visible changes in macroscopic examination.
Remarks - Results	None

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

TEST FACILITY Hoechst Marion Roussel (1988c)

7.3. Acute toxicity – inhalation

The test was not conducted. A variation of the Schedule Data requirement with respect to acute toxicity – inhalation was granted on the basis that inhalation exposure would be unlikely to occur due to the nature of the notified chemical in the granulated de-dusted formulation (particle size >115 μm and < 200 μm) as introduced.

7.4. 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
Vehicle	Deionised water (paste thereof)
Observation Period	14 days

Type of Dressing	The notified chemical (0.5 g) in water (0.6 mL) was applied under a semi-occlusive dressing for 4 hours
Remarks - Method	Statement of GLP compliance. No protocol deviations reported.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0.3	0	1	24 h	0
Oedema	0	0	0	0	–	0

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

Remarks - Results	For one hour up to one day after removal of the patch, the treated skin of the animals showed very slight erythema. Two days after patch removal, the irritations were reversible.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY Hoechst Marion Roussel (1988d)

7.5. Irritation – eye

TEST SUBSTANCE Notified chemical

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

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 females
Observation Period	21 days
Remarks - Method	Statement of GLP compliance. No protocol deviations reported.

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	1.33	1	1	2	24 h	0
Conjunctiva: chemosis	0.33	0	0	2	24 h	0
Conjunctiva: discharge	0	0	0	2	24 h	0
Corneal opacity	0	0	0	0	–	0
Iridial inflammation	0.33	0	0	1	24	0

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

Remarks - Results	From one hour up to 3 days after instillation, the conjunctiva of the animals showed blood vessels above normal up to diffuse deeper crimson red colours and swelling with partial eversion of the lids. The irritations were attended by clear substance coloured eye discharge. Seven days after instillation, the irritations were reversed. The nictitating membrane and the iris were discoloured violet from one hour up to the end of the study (day 21).

CONCLUSION The notified chemical is severely irritating to the eye on the basis of violet discolouration of the iris and nictitating membrane.

TEST FACILITY Hoechst Marion Roussel (1988e)

7.6. Skin sensitisation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 406 Skin Sensitisation - < maximisation test >. EC Directive 96/54/EC B.6 Skin Sensitisation - < maximisation test >.
Species/Strain	Guinea pig/Pirbright-White
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 1% (w/v) in deionised water topical: 25% (w/v) in deionised water. Due to skin discoloration, the topically treated skin could not be assessed for erythema. No oedema, however, was detected.
MAIN STUDY	
Number of Animals	Test Group: 10 females Control Group: 5 females
INDUCTION PHASE	Induction Concentration: intradermal: 5% (w/v) in deionised water topical: 25% ((w/v) in deionised water
Signs of Irritation	The administration sites treated with 5% (w/v) intradermally, showed well-defined oedema. Due to the red colour of the test substance, the treated skin could not be assessed for erythema. 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 slight oedema. Due to the red colour of the treated skin, the animals could not be assessed for erythema.
CHALLENGE PHASE	
1st challenge	topical: 25% (w/v) in deionised water
Remarks - Method	Statement of GLP compliance. No protocol deviations reported.

RESULTS

Animal	*Challenge Concentration(w/v)*	*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

* Based on the measurement of fold thickness of treated skin.

Remarks - Results	Due to red colour of the test substance, the treated skin of the animals could not be assessed for erythema 24 and 48 hours after removal of the occlusive bandage. No significant differences in the fold thickness of the treated skin were detected between the animals of the control and the treatment group. In addition, no significant difference was found between the animals of the control and the treatment group with respect to the histopathological evaluation of the treated skin area. The findings in both the control and the treatment group reveal a slight reaction of the skin tissue indicating an irritant response to the occlusion of the skin. Based on both measurement of fold thickness and histopathological examination of the treated skin, the notified chemical showed no evidence for sensitising properties.
CONCLUSION	Based on measurement of the fold thickness and histopathological examination of the treated skin, there was no evidence of reactions indicative of skin sensitisation to the notified chemical under the

conditions of the test.

TEST FACILITY Hoechst Marion Roussel (1988f)

7.7. Repeat dose toxicity

TEST SUBSTANCE Notified chemical

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: 29 days; Dose regimen: 7 days per week; Post-exposure observation period:
Vehicle	Deionised water
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		
II (low dose)	5/sex	62.5	
III (mid dose)	5/sex	250	
IV (high dose)	5/sex	1000	
V (control recovery)	5/sex	0	
VI (high dose recovery)	5/sex	1000	

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. Food and water consumption remained unaffected by the administration of the test substance in all treatment groups. Body weight development of males in all treatment groups did not deviate from that of the control groups. Body weight development in the intermediate and high dose group females appeared to be dose-dependently accelerated which however was not considered to be of toxicological relevance.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Haematological examination showed a slight increase in thrombocyte counts which was considered to be treatment-related while clinical chemistry revealed no treatment related changes in any dose groups. Urine showed a treatment related reversible salmon pink discoloration in one intermediate dose female and in all high dose males and females which, however, was 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 red discoloured kidneys were observed in all high dose group males and in tow intermediate and all high dose females at the end of the treatment period and in all high dose group males and females at the end of the recovery period. There were no histopathological findings which could be related tot eh red 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

At the dose level of 250-mg/kg bw/day there was still a salmon pink discoloration of the urine (1 female) and a red discoloration of the kidney (2 females).

CONCLUSION

The No Observed (Adverse) Effect Level (NO(A)EL) was established as 250 mg/kg bw/day in this study, based on no compound related effects observed at the dose level of 62.5 mg/kg bw day.

TEST FACILITY Hoechst Marion Roussel (1988j)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure for Test 1
Pre-incubation for Test 2.

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, *E. coli*: WP2uvrA
Metabolic Activation System	Rat liver S9 microsomal fraction from Aroclor 1254 treated rats.
Concentration Range in Main Test	a) With metabolic activation: 50 to 5000 µg/plate. b) Without metabolic activation: 50 to 5000 µg/plate.
Vehicle	Double-distilled water (notified chemical) 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; MNNG for WP2urA Positive control with activation: 9-aminoacridine for all strains.

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 (all strains)	>5000 (all strains)	Not observed (all strains)
Test 2		>5000 (all strains)	>5000 (all strains)	Not observed (TA1535, TA1537, TA98, TA100, WP2uvrA)*
Present				
Test 1	–	>5000 (all strains)	>5000 (all strains)	Not observed (all strains)
Test 2		>5000 (all strains)	>5000 (all strains)	Not observed (TA1535, TA1537, TA98, TA100, WP2uvrA)*

* With the test strain TA1535 only in the second experiment an increased number of revertants was obtained in the absence and presence of S-9 mix. However, this effect was not dose dependent and not reproducible and therefore considered to be without biological relevance.

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 the test strains TA100, TA1535, TA98 and WP2 either in the absence or in the presence of S-9 mix in either mutation test. No dose-dependent effect was observed.

CONCLUSION The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Hoechst Marion Roussel (1988g)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
EC Directive 92/69, L383, 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 reported.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*[+]	*Harvest Time*
Absent			
Test 1	158.1, 500.0*, 1581.0* and 5000.0*	3	20
Test 2	125.0, 250.0*, 500.0*, 1000.0*, 1750.0, and 2500.0	20	20
Present			
Test 1	158.1, 500.0*, 1581.0* and 5000.0*	3	20

* Cultures selected for metaphase analysis. + Period treated with and without activation. 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	>5000	>5000 (78.2% RMI+))	1000	Not Observed*
Test 2		1000 (26.3% RMI+)	1000	Observed
Present				
Test 1	>5000	>5000 (98.7% RMI+)	1000	Not observed*

∗ A slight enhancement of the aberration rates after treatment for 3 hours with 5000 (µg/mL) with and without S9-mix. + RMI = Relative Mitotic Index.

Remarks - Results In the first experiment, no relevant indication of toxicity (reduction of mitotic index) was observed after treatment for 3 hours with and without S9-mix, however, there was a slight enhancement of the aberration rates after treatment for 3 hours with 5000 µg/mL with and without S9-mix. Consequently, a second experiment with a permanent treatment time of 20 hours without S9-mix was performed. Because of high cytotoxicity, only dose levels up to 1000 µg/mL were evaluated. In this experiment, the aberration rates were dose dependently enhanced. At a concentration of 500 µg/mL inclusive gaps (6% compared to controls of 1.5%) and at a

dose of 1000 µg/mL inclusive gaps (21.0% compared to controls of 1.5%) and exclusive gaps) 16.0% compared to controls of 1.5%), the data were found significantly increased (unspecified). In addition, an increased number of cells with exchanges (5.0% compared to controls of 0.0%) was found after treatment with the highest dose level (1000µg/mL). This was an indication of heavy chromosomal damage. In conclusion, in the second experiment, the mitotic index was dose-dependent reduced (indication of toxicity) after treatment for 20 hours in the absence of S-9-mix. In addition, the test substance induced a significant increase in the number of chromosome aberrations 20 hours after start of treatment with a concentration of 1000 (µg/mL) in the absence of S9-mix.

Appropriate reference mutagens used as positive controls showed a significant increase in chromosome aberrations indicating the sensitivity of the assay and the efficacy of the S9-mix.

No historical control data was provided. No statistical data was provided.

CONCLUSION The notified chemical was clastogenic to V79 Chinese Hamster Cells treated in vitro under the conditions of the test.

TEST FACILITY Hoechst Marion Roussel (1988h)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE Notified chemical

METHOD OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
EC Directive 2000/32/EC B.12 Mutagenicity - Mammalian Erythrocyte Micronucleus Test.

Species/Strain	Mouse/HsdWin:NMRI
Route of Administration	Oral – gavage
Vehicle	Deionised water
Remarks - Method	Statement of GLP compliance. No protocol deviations reported.

Based on a preliminary study, the test substance was given twice at an interval of 24 hours. In the preliminary dose range finding study, twice oral administration of 2000 mg/kg bw of test substance at an interval of 24 hours, with sacrifice 24 hours after administration of the second dose, did not cause any toxic effects in male and female mice (3/sex) over a 7 day observation period.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	15/sex	0	24
II (low dose)	15/sex	2000	24
V (positive control, CP)	15/sex	50	24

CP=cyclophosphamide (single administration by oral gavage).

RESULTS

Doses Producing Toxicity	No signs of toxicity were observed. Red coloured faeces and reddish urine were noted. All animals survived after treatment. All animals were free of clinical signs of toxicity 24 hours after the second administration. No test substance related macroscopic findings were observed at necropsy.
Genotoxic Effects	The number of polychromatic erythrocytes containing micronuclei was not increased by the administration of the test substance and was within

	the normal range of the negative control groups. The ratio of polychromatic erythrocytes to total erythrocytes in both male and female animals remained unaffected by the treatment with the test substance and was less than 20% of the control value.
Remarks - Results	Cylcophosphamide (positive control) induced marked statistically significant increase in the number of polychromatic cells with micronuclei indication the sensitivity of the test system.
CONCLUSION	The notified chemical was not clastogenic in this *in vivo* mouse erythrocyte micronucleus assay under the conditions of the test.
TEST FACILITY	Hoechst Marion Roussel (1988i)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 E Ready Biodegradability: Modified OECD Screening Test (SOP 2030-6600202-96 D). Commission Directive 92/69/EEC, Official Journal of the EC L 383 A, Part C, Method C.4B: Modified OECD Screening Test
Inoculum	Secondary effluent of a domestic sewage treatment plant
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	DOC
Remarks - Method	The test substance was suspended in a mineral medium, inoculated with a mixed population of aquatic microorganisms for 28 days under aerobic conditions in the dark at 22ºC. The biodegradation of the test substance was determined on the basis of the reduction in DOC. The initial concentration of the test substance and the reference substance were 15.6 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	98
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

Based on the log Ko/w value of -6.6, the notified chemical is unlikely to bioaccumulate.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test-Static conditions EC Directive 92/69/EWG C.1 Acute Toxicity for Fish–Static conditions
Species	Zebra fish (*Danio rerio*)
Exposure Period	96
Auxiliary Solvent	None
Water Hardness	250 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) Nominal	*Number of Fish*	*Mortality*					
		3 h	*6 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	7	0	0	0	0	0	0
100	7	0	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. Some fish showed changes in swimming behaviour but no mortality were 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	Notified chemical
METHOD	Council Directive 67/548/EEC C.2 Acute Toxicity for Daphnia – Static conditions.
Species	*Daphnia magna*
Exposure Period	48 h
Auxiliary Solvent	None
Water Hardness	14.8 [º dH] (M4-medium)
Analytical Monitoring	TOC
Remarks - Method	Duplicate of 10 daphnia each were used for each test concentration and control. The nominal concentrations in the test media samples were at 25.0, 50.0 and 100 mg/L. The immobility of the daphnia was determined visually after 24 and 48 h of exposure.

RESULTS

Concentration mg/L Nominal Actual	*Number of D. magna*	*% Immobilised*	
		24 h	*48 h*

Control	20	0	0
25.0	20	0	0
50.0	20	0	20
100	20	0	70

LC50	>27.0 <95.9 mg/L at 48 hours
NOEC	27 mg/L at 48 hours
Remarks - Results	At the highest test concentration (100 mg/L) a 70% immobilisation rate was observed. 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 notified chemical is considered to be harmful to Daphnia.
TEST FACILITY	Bayer AG (1998b)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	Council Directive 67/548/EEC C.3 Algal Inhibition Test.
Species	Green alga (*Scenedesmus subspicatus*)
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L
Auxiliary Solvent	None
Water Hardness	Not stated
Analytical Monitoring	TOC
Remarks - Method	A nominal test concentration of 100 mg/L and a control were incubated for a period of 72 h during which the cell density in each was measured at every 24 h. The inhibition of growth and growth rate in relation to a control was determined after 72 h of incubation. Analysis of the test concentration at 100 mg/L without algal inoculum and the pH of the solution at the start and after 72 h of exposure was also performed.

RESULTS

Biomass		*Growth*	
Control	*Test substance*	*Control*	*Test Substance*
% inhibition at 72 h	*% inhibition at 72 mg/L*	*% inhibition at 72 h*	*% inhibition at 72 h*
0	-21.6	0	0

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). No toxic effects were observed for alga at the estimated concentration of 75.6 mg/L. The pHs and concentrations measured during the course of the test were within acceptable limits and at 100% recovery rate, respectively. The NOEC was determined to be 72 h 75.6 mg/L and the 72 h EC50 >75.6 mg/L.
CONCLUSION	The notified chemical is considered to be not toxic to alga.
TEST FACILITY	Bayer AG (1998c)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE

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 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 has been calculated, based on water-use information available to the DEH.

Quantity of new chemical used per day [1500 kg/y ÷ (260 day/y)] = 5.75 kg/day
Quantity of substance NOT fixed (10%) [5.75 kg/day × 0.10] = 0.575 kg/day
Concentration of chemical in wash-off water [575 g/day ÷ 400,000 L] = 1.43 mg/L/day
Dilution in total Mill effluent [1.43 mg/L/day × 0.4 ML ÷ 2.9 ML] = 197 µg/L/day
Dilution to sewer [197 µg/L/day ÷ 10] = 19.7 µg/L/day

Therefore the worst case PEC is calculated to be 19.7 µg/L. It is assumed that there will be no degradation or removal of the notified chemical within the STP.

Based on this, the PECs in river and ocean are 19.7 and 1.97 µg/L/day, respectively.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests for the notified chemical are listed below. As Daphnia showed the highest toxic effects for the three trophic levels, concentration at >27 mg/L for

Daphnia 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	EC50	>27, <95.9
Algae	72 h	E_bC50	>75.6
Sludge micro-organisms	3 h	IC50	>10,000

A predicted no effect concentration (PNEC - aquatic ecosystems) of >270 µg/L has been derived by dividing the end point of >27 mg/L for Daphnia by a worst case scenario uncertainty (safety) factor of 100 (as toxicity data are available for three trophic levels).

9.1.3. Environment – risk characterisation

	Location	PEC µg/L	PNEC µg/L	Risk Quotient (RQ)
Dyehouse	Ocean outfall	1.79	>270	<0.0073
	Inland River	17.9	>270	<0.073

The risk quotients indicate an acceptable risk for both marine and freshwater release.

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.

Overall, the environmental risk from the proposed use of the notified chemical is expected to be low due to its low toxicity to aquatic organisms and its inert state in a bound matrix fabrics.

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 manualy 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
- acute inhalation
- primary dermal irritation
- eye irritation
- skin sensitisation
- 28-day subacute oral toxicity (gavage); and
- genotoxicity

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 blood vessels above normal up to diffuse deeper crimson red colours and swelling with partial eversion of the lids up to 3 days after instillation accompanied by clear substance coloured eye discharge up to three days after instillation with discoloration of the nictitating membrane and the iris to the end of the study.

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/day was indicated based on stomach/fundic inflammation at 1000 mg/kg bw/day.

A reverse mutation test in *Salmonella typhimurium* and *Escheria coli* indicated the notified chemical was not mutagenic to bacteria. A chromosomal aberration tests in V79 Chinese Hamster Lung Cells (*in vitro*) showed the notified chemical was clastogenic to CHL cells treated *in vitro* under the conditions of the test. In the first experiment, there was a slight enhancement of the aberration rates after treatment for 3 hours with 5000 µg/mL with and without S9-mix. In the second experiment (up to 1000 µg/mL without S9-mix), there was a dose-dependent increase in aberration rates and indications of heavy chromosomal damage at 1000 µg/mL. The notified chemical was not clastogenic, however, in an *in vivo* mouse micronucleus assay under the conditions of the test.

Based on the available data, the notified chemical is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2002). The classification and labelling details are:

Xi Irritant
R41 Risk of serious damage to eyes

9.2.4. Occupational health and safety – risk characterisation

Based on the toxicity data provided for the notified polymer, the notified chemical is a slight skin irritant and a severe eye irritant with the potential for adverse eye effects such as swelling and discoloration of the eye up to 3 days post exposure.

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 is predicted to be workers 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 and subchronic to chronic exposure. 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 workers 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, the risk to process workers is expected to be low. However, due to the nature of the notified chemical and its eye irritant properties at 6% in the colour matching dye solution, 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 classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

Xi Irritant
R41 Risk of serious damage to eyes

The notified chemical is assigned R41 on the basis of discoloration till day 21 of the study.
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	*Hazard category*	*Hazard statement*
Chronic hazards to the aquatic environment	3	Harmful to aquatic life with long lasting effects.
Serious eye damage / eye irritation	1*	Causes serious eye damage

*The notified chemical was reported to cause persistent discolouration in the iris and nictitating membrane, rather than the cornea. It therefore may not meet the criteria of Class 1.

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

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

11.2. Label

The label for the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS

Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - Xi Irritant
  - R41 Risk of serious eye damage

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥10%:
    - Xi Irritant
    - R41 Risk of serious eye damage
  - 10%> conc ≥5%
    - Xi Irritant

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 incineration and landfill

Storage and Handling

- The following precautions should be taken by the Notifier and end-users regarding storage and handling of the notified chemical:
  - Avoid formation and deposition of dust
  - Observe the usual precautionary measures required for chemicals with dust-explosive properties and take precautionary measures against static discharge
  - Observe the usual precautionary measures for organic dust and observe the NOHSC exposure standard for nuisance dust of 10mg/m^3

Emergency procedures

- Soap up spills with inert absorbent material (eg sand, earth, vermiculite, diatomaceous earth) and shovel into suitable container for disposal according to local authorities. Rinse away residues with water preventing washings from entering waterways.

12.1. Secondary notification

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

(1) Under Section 64(1) of the Act; if
  - the formulation process for and or purity of the notified chemical is changed

– adverse reporting regarding skin 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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