File No: LTD/1818

May 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

2-Anthracenesulfonic acid, 1-amino-4-[(4-amino-2-sulfophenyl)amino]-9,10-dihydro-9,10-dioxo-, sodium salt (1:2), reaction products with 2-[[3-[(4, 6-dichloro-1,3,5-triazin-2-yl)ethylamino]phenyl]sulfonyl]ethyl hydrogen sulfate, sodium salts

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1818	Huntsman Advanced Materials Pty Ltd Chemiplas Australia Pty Ltd	2-Anthracenesulfonic acid, 1-amino-4-[(4-amino-2-sulfophenyl)amino]-9,10-dihydro-9,10-dioxo-, sodium salt (1:2), reaction products with 2-[[3-[(4,6-dichloro-1,3,5-triazin-2-yl)ethylamino]phenyl]sulfonyl]ethyl hydrogen sulfate, sodium salts	Yes	1 tonne per annum	Dye for textiles

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the table below.

Hazard classification	*Hazard statement*
Eye irritation (Category 1)	H318 – Causes serious eye damage
Skin Sensitisation (Category 1A)	H317 – May cause an allergic skin reaction

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

R41: Risk of serious damage to eyes
R43: May cause sensitisation by skin contact

The environmental hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute (Category 3)	H402 - Harmful to aquatic life
Chronic (Category 3)	H412 - Harmful to aquatic life with long lasting effects

Human health risk assessment
Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified chemical is not considered to pose an unreasonable risk to public health.

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemical should be classified as follows:
  - Eye irritation (Category 1): H318 – Causes serious eye damage
  - Skin Sensitisation (Category 1A): H317 – May cause an allergic skin reaction

The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present and the intended use/exposure scenario.

- Due to the sensitising and irritating properties of the notified chemical, the notifier should consider their obligations under the Australian Dangerous Goods Code.

Health Surveillance

- As the notified chemical is a skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced in the product Eriofast Blue 3G:
  - Enclosed and automated processes, where possible
  - Adequate general ventilation and local exhaust ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced in the product Eriofast Blue 3G:
  - Avoid contact with skin and eyes
  - Avoid breathing in any dust, mist or aerosol

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced in the product Eriofast Blue 3G:
  - Coveralls
  - Gloves
  - Goggles
  - Respiratory protection including organic vapour cartridges, if formation of dust, mist or aerosol is expected

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

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency procedures

- Spills and/or accidental release of the notified chemical should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS 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 importation volume exceeds one tonne per annum notified chemical;
- the notified chemical is intended to be introduced in a solid form other than non–dusting powder/granule that may generate inhalable or respirable particles;
- additional information has become available to the person as to potential for carcinogenicity of the notified chemical;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a dye for textiles, or is likely to change significantly;
- the amount of chemical being introduced has increased, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

(Material) Safety Data Sheet
The (M)SDS of the notified chemical and products containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Huntsman Advanced Materials Pty Ltd (ABN: 93 091627 879)
Gate 3, 765 Ballarat Rd
Deer Park VIC 3023

Chemiplas Australia Pty Ltd (ABN: 29 003 056 808)
Level 3, 112 Wellington Parade
East Melbourne VIC 3002

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer (1 tonne or less per year)

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: None.

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
South Korea (2004)
EU (2009)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Eriofast Blue 3G (Product containing the notified chemical at > 60%)

CAS NUMBER
500717-36-2

CHEMICAL NAME

2-Anthracenesulfonic acid, 1-amino-4-[(4-amino-2-sulfophenyl)amino]-9,10-dihydro-9,10-dioxo-, sodium salt (1:2), reaction products with 2-[[3-[(4,6-dichloro-1,3,5-triazin-2-yl)ethylamino]phenyl]sulfonyl]ethyl hydrogen sulfate, sodium salts

The notified chemical is a chemical substance of unknown or variable composition, complex reaction products and biological materials (UVCB).

OTHER NAME(S)
FAT 45412/A (or FAT 45’412/A)
Reactive Blue 273
Blue DAS 289

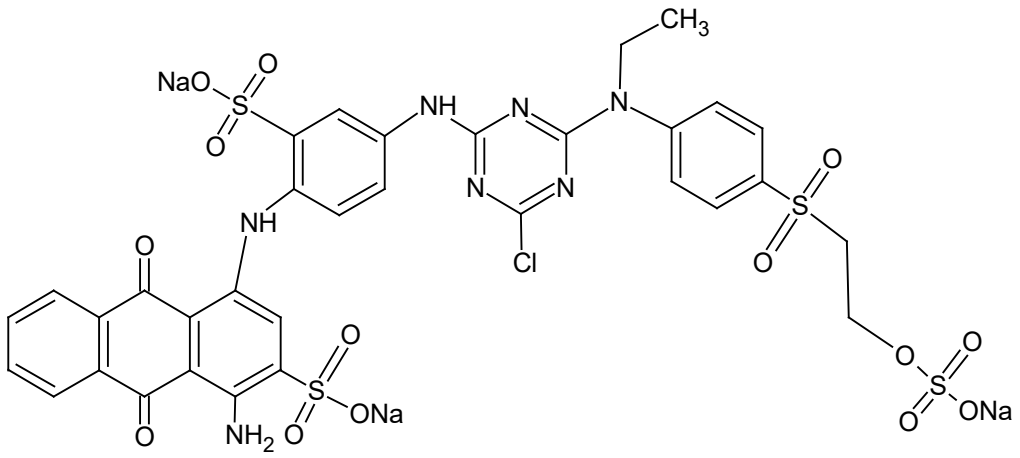
MOLECULAR FORMULA
Unspecified

Based on the analytical data provided, the main components of the notified chemical have the following molecular formulae:
Component A: $C_{33}H_{25}ClN_7Na_3O_{14}S_4$
Component B: $C_{33}H_{24}ClN_7Na_2O_{10}S_3$

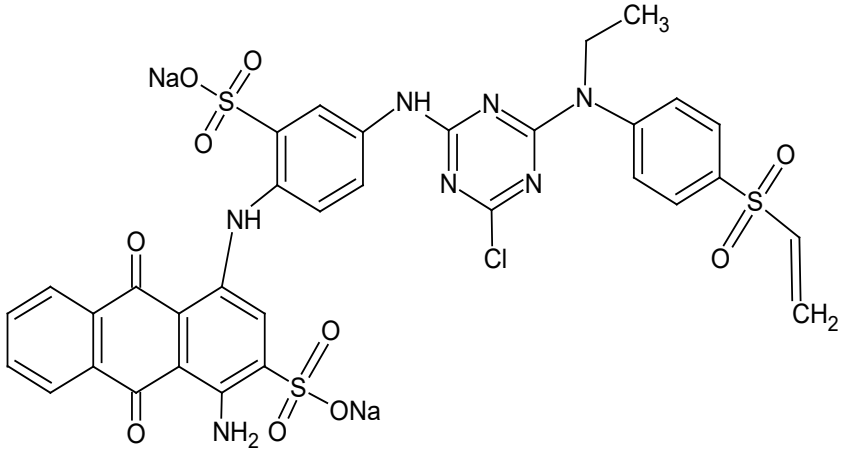
STRUCTURAL FORMULA
Unspecified

Based on the analytical data provided, the main components of the notified chemical have following structural formulae:

Component A:



Component B:



MOLECULAR WEIGHT
Unspecified

Based on the analytical data provided, molecular weights of the main components of the notified chemical are shown below:
Component A: 976.28 Da
Component B: 856.22 Da

ANALYTICAL DATA

METHOD	HPLC – UV/Visible
Remarks	Reference spectra were provided. The two main reaction products were detected, covering retention areas of 14.6% for Component A and 56.9% for Component B.
TEST FACILITY	RCC Ltd

METHOD	^{1}H NMR
Remarks	Reference spectra were provided.
TEST FACILITY	RCC Ltd

METHOD IR
Remarks Reference spectra were provided.
TEST FACILITY RCC Ltd

METHOD UV/Visible
Remarks Reference spectra were provided. The notified chemical was detected at pH 6.2, pH 1.1 and pH 12.5 with maximum absorption peaks observed at 612, 616 and 612 nm respectively.
TEST FACILITY RCC Ltd

3. COMPOSITION

DEGREE OF PURITY
Over all 71.5%, including:
Component A 14.6%
Component B 56.9%

IDENTIFIED IMPURITIES

Chemical Name 1-Amino-9,10-dioxo-4-(4-propionylamino-2-sulpho-phenyl-amino)-9,10-dihydro-anthracene-2-sulphonic acid, disodium salt
CAS No. Unassigned *Weight %* 0.3

Chemical Name Bis-{4,6-[4-(4-Amino-9,10-dioxo-3-sulpho-9,10-dihydro-anthracen-1-ylamino)-3-sulpho-phenylamino]-6-hydroxy-[1,3,5]triazin, tetra-sodium salt
CAS No. Unassigned *Weight %* 0.5

Chemical Name 4,6-Dichloro-[1,3,5]triazin-2-yl)-(3-ethenesulfonyl-phenyl)-ethyl-amine
CAS No. Unassigned *Weight %* 1.2

Chemical Name Bis-{4,6-[4-(4-Amino-9,10-dioxo-3-sulpho-9,10-dihydro-anthracen-1-ylamino)-3-sulpho-phenylamino]-6-chloro-[1,3,5]triazin, tetra-sodium salt
CAS No. Unassigned *Weight %* 3.7

Chemical Name 1-Amino-4-{4-[6-N-ethyl-N-3-(2-sulfoxy-ethylsulphonyl)phenylamino]-4-[2-[3-N-ethyl-N-[4-chloro-6-[4-(4-amino-3-sulpho-anthraquinone-1-ylamino)-3-sulpho-phenylamino]-[1,3,5]triazine-2-ylamino]-phenyl-sulphonyl]-ethoxyl]-[1,3,5]triazine-2-ylamino]-2-sulphophenylamino}-anthraquinone-2-sulphonic acid sodium-salt
CAS No. Unassigned *Weight %* 3.7

Chemical Name 6-Chloro-N,N'-bis-(3-ethenesulphonyl-phenyl)-N,N'-diethyl-[1,3,5]triazine-2,4-diamine
CAS No. Unassigned *Weight %* 0.5

Chemical Name Unknown organic products
CAS No. Unassigned Weight % 0.3

Chemical Name Water
CAS No. 7732-18-5 *Weight %* 4.7

Chemical Name Sodium Sulphate
CAS No. Unassigned *Weight %* 10.5

Residue of unsulphonated aromatic amines in the notified chemical was examined to be < 10 ppm using thin-layer chromatography with diazotation reaction for visual detection. Compared to the calibration solutions which showed positive dark colour, violet spots, the notified chemical did not produce colour reaction.

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Solid blue powder

Property	Value	Data Source/Justification
Melting Point	> 400 °C	Measured
Boiling Point	> 400 °C at 101.3 kPa	Measured
Relative Density (D^{20}_4)	1.69 at 20 °C	Measured
Vapour Pressure		
Component A	5.0×10^{-27} kPa at 25 °C	Calculated
Component B	2.3×10^{-28} kPa at 25 °C	Calculated
Water Solubility	> 30 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	pH 4.0 $t_{1/2}$ > 1 year pH 7.0 $t_{1/2}$ > 1 year pH 9.0 $t_{1/2}$ > 23 days	Measured
Partition Coefficient (n-octanol/water)	log Pow = -2.6 at 20 °C	Measured
Surface Tension	66.4 mN/m at 20 °C ± 0.2 °C	Measured
Adsorption/Desorption	log K_{oc} < 1.32 at 25 °C	Measured
Dissociation Constant	-6.04 ± 0.20 to 0.57 ± 0.50	Calculated
Particle Size	MMD* < 214.7 µm Inhalable fraction (< 100 µm): 22.57% Respirable fraction (< 10 µm): 0.86%	Measured
Flash Point	Not determined	The melting point is > 400 °C.
Flammability	Not highly flammable	Measured
Autoignition Temperature	328 °C	Measured
Explosive Properties	Not determined	Theoretically assessed not to be classified as explosive material based on the expert statement provided by the notifier.
Oxidising Properties	Not determined	Theoretically assessed to be non-oxidising based on the expert statement provided by the notifier.

* MMD = Mass Median Diameter

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, refer to Appendix A.

The notifier provided a general process report about the dye dedusting/non-dusting process and the particle size distribution of the treated dyes. The dedusting process involves the dye being treated with dedusting oils (0.5-2%) and/or being dedusted mechanically during the production process in order to minimise and protect workers from inhalation exposure. The notifier states that such treated dye will contain less than 20% inhalable and less than 1% respirable particles.

Reactivity

The notified chemical is expected to be stable under normal conditions of use.

Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will not be manufactured in Australia. The notified chemical will be imported as a component of Eriofast Blue 3G at a concentration of 55% - 65%, in the form of non-dusting powder or as

granules. The imported finished product, Eriofast Blue 3G, will be used in the textile industry. No further reformulation and repackaging of the product containing the notified chemical will occur in Australia.

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

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

PORT OF ENTRY
Melbourne

IDENTITY OF RECIPIENTS
Chemiplas Australia Pty Ltd
Level 3, 112 Wellington Parade
East Melbourne VIC 3002

Huntsman Advanced Materials Pty Ltd
Gate 3, 765 Ballatat Road
Deer Park VIC 3023

TRANSPORTATION AND PACKAGING
Eriofast Blue 3G containing the notified chemical at a concentration of 55% - 65% will be imported in non-dusting powder/granule form in robust anti-static polyethylene lined 20-kg fibreboard container and transported from wharf to the contracted warehouse for storage and further distribution.

USE
The imported Eriofast Blue 3G containing the notified chemical is a reactive aromatic amine dye for colouration of cotton and manufactured fibres including polyesters and polyamides. It will be used to dye textiles, which include domestic textile products used for apparel, sheeting and other household uses. It will be used in industrial dye houses only. The concentration of the notified chemical in the final textile dye solution is < 1%.

OPERATION DESCRIPTION

At dye houses, Eriofast Blue 3G containing 55 - 65% the notified chemical will be weighed in a dispensary equipped with local exhaust ventilation. The weighed dye containing the notified chemical will be dispensed through a hatch into the enclosed dyeing vat, where water will be added to prepare a dye solution. The notifier stated that the dye product will be imported in dried dedusted powder form which is expected to be treated with dedusting oils and/or to be mechanically dedusted during the production. When handling the dry powder of the dye, workers are expected to wear respiratory protection including dust masks or organic vapour cartridge respirators to minimise the possible inhalation of the dust. Appropriate use of additional PPE such as elbow-length PVC gloves, safety glasses/face shield and protective coveralls will reduce the potential for exposure further. Once the dye is dissolved in water, the notified chemical will be present at < 1% in the final textile dye solution. Following fixation, the textile will be washed free of unfixed dye in wash off baths, and dried by hydroextraction, followed by heating to 180 °C. Products which may be dyed include domestic textiles used for apparel, sheeting and other household uses.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport drivers	0.5 - 12	30 - 60
Warehouse operators	0.33	100 - 150
Batch area operators	0.33	~200
Dye machine operators	1	~200

EXPOSURE DETAILS

Transport and Storage
Transport and warehouse workers may experience dermal, ocular and inhalation exposure only in the event of an accidental packaging breakage.

Preparation of Dye Solution and End Use Application
There is a possibility of dermal, ocular and inhalation exposure to the notified chemical at concentrations up to 65% during weighing out and dissolving the dye. Dust formation of the notified chemical during the processes is possible; however, it will be reduced by the anti-dust nature of the dye product and use of local exhaust ventilation as proposed by the notifier. The notifier also states that the exposure of workers to the notified chemical will be minimised by the presence of appropriate engineering controls and the use of PPE such as dust mask, organic vapour cartridge respirator, gloves, coveralls and goggles when handling the dye containing the notified chemical. Exposure will also be minimised by the use of an automated enclosed system during the dyeing process to prevent splashes and spills where the cloth is driven by mechanical rollers.

When the dyed materials are transported to the wash off batch on a pin chain, dermal and ocular exposure to the notified chemical at < 1% concentration may occur during manual handling of dyed wet cloth. Inhalation exposure to the mist of the notified chemical (< 1% concentration) is also possible. However, the cloth will be wrapped in plastic film and thus exposure is expected to be minimal. During the subsequent washing and drying (hydroextraction) processes, dermal, ocular and inhalation exposure may occur to the diluted dye solution containing the notified chemical (< 1% concentration). Appropriate PPE will be used by workers during the processes to minimise the potential for exposure.

During cleaning and maintenance processes such as flushing the holding and mixing tanks with water, dermal, ocular and inhalation exposure (to mists or aerosols) to the notified chemical (< 1% concentration) may occur. Workers are expected to wear an organic vapour cartridge respirator, gloves, safety glasses and coveralls to minimise exposure, as proposed by the notifier.

6.1.2. Public Exposure

The dye product (Eriofast Blue 3G) containing the notified chemical will only be available to industrial users and will not be available to the general public. However, the general public may come into contact with the notified chemical through the use of dyed textiles such as apparel and sheeting.

The notifier stated that over 90% of the dye in the dye solution (containing < 1% of the notified chemical) will be strongly fixed to the fibre. Data on fixation/exhaustion curves of the notified chemical on fabric were provided by the notifier. The excess unfixed dye will be washed off, and the textile will be dried by hydroextraction followed by further heating. It is expected that there will be negligible unfixed residues of the notified chemical available for further exposure after the process. Although no leaching/bleeding study was provided by the notifier, considering covalent chemical bond fixation and low concentration (< 1%) of the notified chemical in the dye solution, a significant amount of the notified chemical is not expected to be released from the dyed textile, over time.

Therefore, considering the lack of commercial availability of dyes containing the notified chemical to the public and the fact that a significant amount of the notified chemical is not expected to be released from the dyed textile over time, public exposure to the notified chemical is not considered to be significant.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	Slightly irritating
Rabbit, eye irritation	Severely irritating
Mouse, skin sensitisation – Local lymph node assay	Evidence of sensitisation

Rat, repeat dose oral toxicity – 28 days.	NOAEL 1,000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation test	Non-mutagenic
Genotoxicity – *in vitro* mammalian chromosome aberration test	Genotoxic
Genotoxicity – *in vivo* mammalian erythrocyte micronucleus test	Non-genotoxic

Toxicokinetics, metabolism and distribution
The notified chemical is a blue powdery sodium salt, which serves as a reactive aromatic amine dye. The notified chemical is a hydrophilic and consists of a mixture of two components with molecular weights > 500 Da, ionisable and has a partition coefficient of -2.6; therefore, the dermal absorption and accumulation of the notified chemical in fatty tissues is expected to be limited. This is also supported by the lack of systemic effects in the acute dermal toxicity study provided. Based on the 28 day repeat dose oral toxicity study and the expert report provided by the notifier, the notified chemical and its metabolites may probably distribute from the portal vein blood into the liver and kidneys where the soluble metabolites including conjugated compounds are excreted via urine.

Acute toxicity
Acute oral and dermal toxicity studies showed that the lethal median dose (LD50) for the notified chemical was greater than 2,000 mg/kg bw/day. No mortality or any substance-related systemic effects or changes on organs were observed, indicating that the notified chemical exhibits low acute toxicity in rats.

Irritation and sensitisation
The notified chemical was slightly irritating to rabbit skin. Erythema was observed; however, the effect was reversible and was not observed at 72 hours. Blue staining of the treated skin was observed in treated animals throughout the study.

The notified chemical was found to be severely irritating to the eyes of rabbit in an eye irritation study. Reddening, discharge and chemosis of the conjunctivae were observed together with reddening of sclerae. Corneal opacity with a score of 2 was not fully reversible in one animal and was evident 21 days after the treatment. Blue staining from the notified chemical was observed and prevented sclerae observations for up to 48 hours in all animals and up to 72 hours in two animals.

A local lymph node assay (LLNA) for skin sensitisation on the notified chemical was provided. Stimulation indices (SI) of 12.5, 17.1 and 18.3 were reported for 5%, 10% and 25% of the notified chemical respectively, showing clear dose-response. The notified chemical was found to be a skin sensitiser; however, an exact EC3 value could not be calculated.

Repeated dose toxicity
A 28 day oral toxicity study was conducted on the notified chemical in rats at the dose levels of 0, 50, 200 and 1,000 mg/kg bw/day. Treatment related effects were elevated sodium levels in males treated with 50 mg/kg bw/day, and in both sexes treated with 200 and 1,000 mg/kg bw/day. An increased urinary output in both sexes at 1,000 mg/kg bw/day and an increased incidence of yellow-green discoloration of the urine, possibly related to a metabolite of the notified chemical, were noted. The No Observed Adverse Effect Level (NOAEL) was established by the study authors at 1,000 mg/kg bw/day, based on the highest dose tested.

Mutagenicity/Genotoxicity
The notified chemical showed no evidence of mutagenicity in a bacterial reverse mutation assay. In the *in vitro* mammalian chromosome aberration test in Chinese hamster V29 cells, the notified chemical was found to be clastogenic. An *in vivo* mammalian erythrocyte micronucleus test showed that the notified chemical was not clastogenic under the conditions of the test. However, although some clinical toxic effects of the notified chemical on the test animals were noted, it was unclear whether significant amount of the notified chemical was able to reach the bone marrow during the test. The potential for clastogenicity of the notified chemical cannot be ruled out.

Carcinogenicity
No data were provided to assess the carcinogenicity of the notified chemical.

The notified chemical contains aromatic amines and amino anthraquinones. A small number of the aromatic amines are classified as being carcinogenic or potentially carcinogenic to humans (SCCNFP, 2002). Based on the structural formula provided for the main components of the notified chemical, the notified chemical may be metabolised *in vivo* to release aromatic amines. However, release of carcinogenic amines listed in the SCCNFP

report is not expected. The presence of sulfonate groups in the notified chemical is likely to slow systemic uptake and enhance excretion of the chemical and its potential metabolites; however, the extent of these mitigating effects is unclear. There are also studies on anthraquinone dyes exhibiting carcinogenicity in workers (IARC Monograph, 2012). In the absence of a carcinogenicity study on the notified chemical, the potential for carcinogenicity cannot be completely ruled out.

It is also noted that, based on the analysis report provided by the notifier, residues of primary unsulfonated aromatic amines in the notified chemical that may be of carcinogenic concern were determined to be < 10 ppm.

Toxicity for reproduction
No data were provided to assess the potential for reproductive and/or developmental toxicity of the notified chemical.

Health hazard classification
Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Eye irritation (Category 1)	H318 – Causes serious eye damage
Skin Sensitisation (Category 1A)	H317 – May cause an allergic skin reaction

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):

R41: Risk of serious damage to eyes
R43: May cause sensitisation by skin contact

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The primary risk to workers from exposure to the notified chemical is eye irritation and skin sensitisation. In addition, its potential for carcinogenicity cannot be completely ruled out. Workers may be possibly exposed (via dermal, ocular and inhalation) to the notified chemical during various processes involving the notified chemical such as importation, transport, storage and textile processing.

Transport and storage
During importation, transport and storage, occupational exposure is minimal as workers would only be exposed to the notified chemical in the case of an accident involving damage to the packaging. Use of PPE would further reduce the potential for exposure.

Textile process
The notified chemical is a solid blue powder, with the percentages of respirable and inhalable particles at 0.86 % and 22.6% respectively. Eriofast Blue 3G containing the notified chemical at 55% - 65% that will be imported into Australia will contain anti-dusting agent and the notifier states that such treated dye will normally contain less than 20% inhalable and less than 1% respirable particles. The health risk caused by inhalation exposure during weighing out and pouring the dye containing the notified chemical into the enclosed dyeing vat is expected to be low, since apart from the anti-dust treatment, engineering controls including local exhaust ventilation and enclosed dyeing vat and PPE such as gloves, safety goggles, organic vapour cartridge and protective coveralls are expected to be used during these procedures.

The health risk associated with occupational exposure during preparation of dye solution and end use application of dye solution containing < 1% notified chemical is also expected to be low, as enclosed and mainly automated systems will be used to transfer prepared dye solution and to process the textiles with the cloth driven by mechanical rollers. Workers are expected to wear eye protection, gloves and coveralls. When manual handling of wet cloth occurs, plastic films will be used to wrap up the wet cloth to minimise the potential for exposure.

The risk associated with occupational exposure during transfer of the wet cloth to the wash off batch on a pin chain and during further washing and drying processes is also expected to be low. Due to the covalent linkage of the dye to the substrate, it is not expected that, following the wash and fixation steps, there will be significant residual of free chemical available for further exposure.

Maintenance
During cleaning and maintenance, as workers will wear PPE such as a respirator with an organic vapour cartridge, gloves, safety goggles and coveralls, the risk associated with occupational exposure is expected to be low.

Overall, provided that the recommended controls are being adhered to, the risk to workers is not considered to be unreasonable.

6.3.2. Public Health

The dye product (Eriofast Blue 3G) containing the notified chemical will only be available to industrial users. Therefore, the general public is not expected to come into contact with the notified chemical at significantly high concentrations. However, the general public will come into contact with dyed textiles such as apparel and sheeting. The concentration of the notified chemical in the final dye solution for textiles is < 1%.

The notifier states that over 90% of the notified chemical in the dyed textile will be bound covalently to the substrate (cloth). The dyed textile will be washed, dried by hydroextraction followed by further heating. It is expected that unfixed dye will be eliminated during the washing and heating cycles. Significant amount of the notified chemical is not expected to be released from the treated textiles over time.

Therefore, based on the available information, the risk to the public is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
Since the notified chemical will not be manufactured or repacked locally, there will be no environmental exposure associated with these processes in Australia.

RELEASE OF CHEMICAL FROM USE
The dye containing the notified chemical will be supplied to customers in a non-dusting powder or granules for direct use in dye houses in Victoria and New South Wales. The notified chemical will be used in a batch dyeing process in closed automated systems in the textile industry. The polyamide dyeing operations are expected to take place in closed equipment from aqueous media at temperatures of about 90 °C. The notified chemical will be fixed permanently (chemical covalent bound) to the fabric material with a high degree of fixation (99%). Consequently, a release value of 1% to waste water is expected. After the dyeing process, the dyed fibres are washed with water and dried. Process waters will be pre-treated before discharge to the wastewater treatment plant. Purification steps such as membrane filtration, flocculation with appropriate agents or treatment with ozone are expected to further lower the concentration of dye in the resulting wastewater. A reduction in the dye concentration in wastewater of at least 50% will be achieved with these additional treatments prior to the treatment in an industrial waste water treatment plant. Empty packaging is expected to contain approximately 0.1% of the imported product.

RELEASE OF CHEMICAL FROM DISPOSAL
The majority of notified chemical will share the fate of articles in which it is incorporated. These articles are expected to be disposed of to landfill at the end of their useful life. Empty packaging is expected to contain approximately 0.1% of the imported product (0.06% of notified chemical). Therefore, the annual maximum of 0.6 kg (1,000 kg × 0.06%) is likely to be disposed of to landfill. The treated effluent containing the notified chemical will be disposed of to the sewer.

7.1.2. Environmental Fate

A hydrolysis study on the notified chemical indicated that it is hydrolytically stable in water at pH 4.0 and 7.0 and not stable at pH 9.0. The notified chemical is not readily biodegradable (0% in 28 days) nor inherently biodegradable. Therefore the notified chemical has the potential to be persistent in the environment. The potential for bioaccumulation of the notified chemical is low due to its very high water solubility, large molecular weight and low log P_{OW}. Notified chemical released to sewer is not likely to be removed from the water column during sewage treatment plant (STP) processes as it has a low soil adsorption coefficient (Koc) and is not expected to degrade rapidly. The notified chemical released to STPs is therefore expected to reach surface waters. The notified chemical is not expected to bioaccumulate based on its high water solubility, high molecular weight and charge.

The majority of the notified chemical incorporated into dyed textiles is expected to share the fate of the articles in which it will be incorporated and is likely to ultimately be sent to landfill. The notified chemical fixed into dyed goods is not expected to be mobile nor bioavailable. In landfill or water, the notified chemical is expected to eventually degrade abiotically and biotically to form water, oxides of carbon, nitrogen, sulphur and metal salts.

For details of the fate studies refer to Appendix C.

7.1.3. Predicted Environmental Concentration (PEC)

A Predicted Environmental Concentration (PEC) has been determined based on the notifier's information for the operational procedures at the dyehouse. It was assumed that a maximum of 10 kg of the notified chemical (i.e. 10 kg of the imported dye/day × 60%) would be used at the dyehouse per day with a total of 10% released to sewer based on a conservative 90% fixation rate. The notified chemical concentration entering the STP was calculated as the mass of unfixed notified chemical released to sewer per day divided by the volume of rinsate per day (given by the notifier as 40,000 L). Additional dilution of the wastewater was indicated by the notifier to occur within the total dyehouse effluent (dilution factor ≥ 5), release to country sewer (dilution factor 3), and at receiving waters (dilution factor 10). It has been estimated by the notifier that 50% of the notified chemical will be removed during secondary STP processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Maximum daily use of notified chemical	6	kg/day
Chemical in dyehouse wastewater released to STP per day	0.6	kg/day
Rinsate usage in dyehouse	40,000	L/day
Amount in the rinsate	15	mg/L
Dilution in to total Mill effluent (at least 5 times)	3	mg/L
Dilution to sewer (3:1)	1	mg/L
Removal of notified chemical within STP	50%	
Dilution Factor – River	1	
Dilution Factor – Ocean	10	
PEC – River:	50.00	µg/L
PEC – Ocean:	5.00	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1,500 kg/m^3). Using these assumptions, irrigation with a concentration of 50.00 µg/L may potentially result in a soil concentration of approximately 0.33 mg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 1.670 mg/kg and 3.340 mg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity (96 h)	LC50 = 14.0 mg/L	Harmful to fish
Daphnia Toxicity (48 h)	EC50 = 51.2 mg/L	Harmful to aquatic invertebrates
Algal Toxicity (72 h)	E_rC50 = 25.0 mg/L	Harmful to algae
Inhibition of Bacterial Respiration	IC50 > 1,000.0 mg/L	Not inhibitory to microbial activity

The notified chemical is considered to be harmful to fish, aquatic invertebrates and algae. On the basis of the acute toxicity data, the notified chemical is harmful to aquatic organisms. Therefore, Under the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS; United Nations, 2009), the notified chemical is formally classified as Acute Category 3: Harmful to aquatic life. Based on its acute toxicity and potential to persist in the environment, the notified chemical has been formally classified under GHS as Chronic Category 3: Harmful to aquatic life with long lasting effects.

As the notified chemical is a dye which results in coloured media, the modified algal test has demonstrated that the observed growth inhibition effect on algae was caused in part due to the indirect effect of light absorption in the coloured test solutions. However, the experimental data does not suggest that the algal growth is inhibited solely as a result of a reduction in light intensity.

7.2.1. Predicted No-Effect Concentration

The endpoint range of the most sensitive species, 96 h fish LC50, determined from ecotoxicological studies submitted for the notified chemical was used to calculate the Predicted No-Effect Concentration range ($PNEC_{fish}$). An assessment factor of 100 was used as acute toxicity endpoints are available for the effects of the notified chemical on aquatic species from three trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish).	14.0	mg/L
Assessment Factor	100	
PNEC:	140.0	µg/L

7.3. Environmental Risk Assessment

Based on the above PEC and PNEC values, the following Risk Quotient (Q = PEC/PNEC) has been calculated:

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	50.00	140	0.358
Q - Ocean:	5.00	140	0.036

The Q for the worst case discharge scenario has been calculated to be < 1 for the river and ocean compartments. Furthermore, flocculation is expected to efficiently remove the notified chemical from the dyehouse waste stream. If released to surface waters, the notified chemical is expected to disperse and degrade. It is not expected to bioaccumulate nor have significant effect on aquatic biota. Therefore, the notified chemical is not expected to pose an unacceptable risk to the aquatic environment based on its reported use pattern.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point > 400 °C

Method OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks The test substance did not melt at temperature of up to 400 °C under the conditions of the test. After the test, the sample was unchanged in its appearance but had lost up to 19% of its mass.
Test Facility RCC Ltd (2003a)

Boiling Point > 400 °C at 101.3 kPa

Method OECD TG 103 Boiling Point.
EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks The test substance did not boil at temperature of up to 400 °C under the conditions of the test. Broad endothermic (90 – 200 °C) and exothermic (200 – 330 °C) peaks were observed. At the end of the experiment, the test substance was lost up to 25% of its mass without change of appearance.
Test Facility RCC Ltd (2003b)

Relative Density 1.69 at 20 °C

Method OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks Determined using the gas comparison pycnometer method.
Test Facility RCC Ltd (2003c)

Vapour Pressure 5.0×10^{-27} kPa at 25 °C (Component 1)
2.3×10^{-28} kPa at 25 °C (Component 2)

Method OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Determined using Modified Watson Correlation
Test Facility RCC Ltd (2003d)

Water Solubility < 30 g/L at 20 °C

Method OECD TG 105 Water Solubility.
Remarks Flask Method. The individual results from each sample did not differ by more than 15%. Therefore, the study is considered to be valid. The water solubility was not corrected for the purity of the notified chemical.
Test Facility RCC Ltd (2003e)

Hydrolysis as a Function of pH

Method OECD TG 111 Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$ <hours >*
4	25	> 1 year
7	25	> 1 year
9	25	23 days

Remarks The emerging peak of the notified chemical at pH 9.0 was not stable, further testing was performed at elevated temperatures in order to calculate the rate constant and the half-life time of the hydrolysis at pH 9.0 and 25 °C.
Test Facility RCC Ltd (2003f)

Partition Coefficient (n-octanol/water) log Pow = -2.6 at 20 °C

Method OECD TG 107/117 Partition Coefficient (n-octanol/water).
Remarks HPLC Method and Flask Method. In the preliminary test, a very good solubility in water and a very poor solubility in n-octanol were found indicating a partition coefficient below -2. Hence, a main test according to OECD Guidelines 107/117 (either HPLC or flask shaking method) could not be applied. Therefore, the partition coefficient of the notified chemical was estimated using the solubility data in n-octanol (as obtained in the preliminary test) and in water. The water solubility of the notified chemical was stated to be at least 30 g/L (or above). The result was used for the calculation of the partition coefficient. The tabulated values represent rounded results, which were obtained by calculation using the exact raw data.
Test Facility RCC Ltd (2003g)

Surface Tension 66.4 mN/m at 20.0 °C ± 0.2 °C

Method OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.
Remarks Concentration: Surface tension of the notified chemical was determined at a concentration of about 0.1% in water. Based on the criteria outlined in the EEC Guidelines, the notified chemical is not a surface active substance.
Test Facility RCC Ltd (2003h)

Adsorption/Desorption log K_{oc} < 1.32 at 25 °C

Method OECD TG 121 Adsorption Coefficient - High Performance Liquid Chromatography (HPLC) Method.
Remarks The test item solution was injected three times and the combined reference solution was injected six times. The log Koc was calculated using a regression curve (log k' vs. log Koc) and was found to be < 1.32 which is equal to a Koc value of < 21. This value indicates that the notified chemical is mobile and will not be adsorbed by organic carbon in soil.
Test Facility RCC Ltd (2003i)

Dissociation Constant pK_a -6.04 ± 0.20 to pK_a 0.57 ± 0.50

Method Calculated with ACD Inc. LogD Solubility Suite v.7.0
Remarks The notified chemical is a salt and has acid and base groups that are expected to dissociate.
Test Facility RCC Ltd (2003j)

Particle Size MMD* < 214.7 µm
Inhalable fraction (< 100 µm): 22.57%
Respirable fraction (< 10 µm): 0.86%

Method European Commission, Directorate General XII- JRC, Science Research and Development-Joint Research Centre. "Particle Size Distribution, Fibre Length and Diameter Distribution" Guidance Document, ECB/TM/February 1996.

Size (µm)	*Mass percentage (%)*
< 0.5	0
< 1	0.01
< 5	0.3
< 10	0.86
< 100	22.57
< 2,000	99.08

Remarks The test substance was dispersed in 2-propanol at room temperature and the particle size was measured by laser scattering/diffraction. The particle size was found to range from approximately 0.5 to 2,000 µm. The mass median diameter (MMD) was determined to be < 214.7 µm.
Test Facility RCC Ltd (2003k)

Flammability Not highly flammable

Method	EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks	The test substance could not be ignited with flame during the preliminary test (contact time of about 2 minutes). In contact with the ignition source, the surface of the test substance started to glow and the colour of the gas flame changed to orange. The surface of the test substance was carbonized but underneath the test item was found to be powdery.
Test Facility	RCC Ltd (2003l)

Autoignition Temperature 328 °C

Method	EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks	Applying a linear increase in temperature of about 0.5 °C/min, the test substance showed an exothermic reaction starting at about 320 °C. At the end of the measurement, the test item was reduced to ashes. The test substance is auto-flammable under the conditions of the test.
Test Facility	RCC Ltd (2003m)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified Chemical (approximately 92% in purity)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 96/54/EEC B.1 tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/HanBrl:WIST (SPF)
Vehicle	Purified water
Remarks - Method	No significant protocol deviations were noted. The application volume of the notified chemical was 10 mL/kg body weight at a concentration of 0.2 g/mL.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 (female)	2000	0/3
2	3 (female)	2000	0/3

LD50	> 2,000 mg/kg bw
Signs of Toxicity	No unscheduled death was recorded. No clinical signs were evident in any animal during the course of the study.
Effects in Organs	No macroscopic findings were recorded at necropsy.
Remarks - Results	The body weight of the test animals were within the range of the strain and age.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	RCC Ltd (2003n)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical (approximately 92% in purity)
METHOD	OECD TG 402 Acute Dermal Toxicity. EC Directive 92/69/EEC B.3. Acute Toxicity – Dermal.
Species/Strain	Rat/ HanBrl:WIST (SPF)
Vehicle	Purified water
Type of dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations were noted. The application volume of the notified chemical was 8 mL/kg bw at a concentration of 0.25 g/mL.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 M + 5 F	2,000	0/10

LD50	> 2,000 mg/kg bw
Signs of Toxicity - Local	Slight blue staining of the treated skin area was observed after the removal of the dressing at 24 hour and persisted up to test day 6. Slight erythema was evident in all animals after removal of the dressing, and persisted in all female animals and four male animals up to test day 4 and in the remaining male up to day 5.
Signs of Toxicity - Systemic	There were no unscheduled deaths or systemic effects observed during the study period.
Effects in Organs	No macroscopic findings were observed at necropsy.

Remarks - Results	The body weight of the animals was within the range of the strain and age.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	RCC Ltd (2003o)

B.3. Irritation – skin

TEST SUBSTANCE	Notified chemical (approximately 92% in purity)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4. Acute Toxicity – Skin Irritation.
Species/Strain	Rabbit/New Zealand White, SPF
Number of Animals	3 (2 F + 1 M)
Vehicle	None. The test substance was moistened with approximately 0.1 mL of purified water before application.
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No protocol deviations. The dose of the chemical was 0.5g/ animal.

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	0.67	0.67	0.33	1	< 72 hours	0
Oedema	0	0	0	0	0	0

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

Remarks - Results	No clinical signs of systemic toxicity and mortality were observed. Light blue staining of the test item was observed from the 1 hour reading up to 7 days in all animals and up to 14 days in two animals.
CONCLUSION	The notified chemical is slightly irritating to the skin.
TEST FACILITY	RCC Ltd (2003p)

B.4. Irritation – eye

TEST SUBSTANCE	Notified chemical (approximately 92% in purity)
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White, SPF
Number of Animals	3 (2 F + 1 M)
Observation Period	21 days
Remarks - Method	No significant protocol deviations observed.

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	2	1.67	2	2	< 17 days	0
Conjunctiva: chemosis	2.67	2.67	2.33	3	< 10 days	0
Corneal opacity	1	1.5	1	2	> 21 days	1
Iridial inflammation	1	1	0.5	1	< 17 days	0

* Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal. Assessment of corneal opacity and iris was not possible at 24 hours due to the blue staining produced by the test substance; therefore mean scores for these two lesions were calculated based on the observations at 48 and 72 hours.

Remarks - Results	One animal screamed immediately after the application of the test substance. Ocular discharge with moistening of the lids and hair, and considerable area around the eye was observed in all animals 1 hour after treatment. Slight ocular discharge was observed in two animals up to 72 hours. Mucus in eyes were observed at 24 hours and persisted up to 72 hours. Assessment of the corneal opacity and iris was impossible at 1 and 24 hours due the blue staining of the test substance. Assessment of the corneal opacity was also affected by the blue staining at 48 and 72 hours. The severity of the corneal opacity in one animal increased 72 hours after treatment. Slight blue staining was evident in all animals at the end of the study (day 21). Delayed/reduced light reflex of iris was noted in all animals at 48 hours and persistent in two animals up to 72 hours and in one animal up to 14 days. As corneal opacity score of one was observed in one animal at the end observation period (21 days), the notified chemical is considered to cause irreversible eye effects.
CONCLUSION	The notified chemical is severely irritating to the eye.
TEST FACILITY	RCC Ltd (2003q)

B.5. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Notified chemical (approximately 92% in purity)
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain	Mouse/CBA/CaOlaHsd
Vehicle	Acetone : olive oil, 4:1 (v/v)
Remarks - Method	No significant protocol deviation was noted. A non –GLP conform pre-test was carried out on two mice to identify the dosing concentrations. The notified chemical was tested at 1%, 5%, 10% and 25 % (w/v). No irritation effects were observed at these concentrations applied. It was concluded that 25% (w/v) was the highest technically achievable concentration to avoid systemic toxicity and excessive local irritation in the study. However, no irritation score or test results were provided. Pooled treatment group approach was used for the assay Positive control: Alpha- hexyl cinnamic aldehyde

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	387	-
5	4,830	12.5
10	6,614	17.1
25	7,066	18.3
Positive Control		
0 (vehicle control)	523	-
5	1,316	2.5
10	1,948	3.7

25	5,082	9.7

Remarks - Results	No deaths and treatment related clinical signs were observed in control and in groups 2 (5%) and 3 (10%). On day 3, a slight swelling was observed at both dosing sites in all mice belonging to group 4 (25%) which also persisted for three days. The positive controls gave satisfactory responses confirming the validity of the test system. An EC3 value was not calculated for the notified chemical since the stimulation index (S.I) values were all above three.
CONCLUSION	There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	RCC Ltd (2003r)

B.6. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical (approximately 92%)
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/HanBrl:WIST (SPF)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7/7 days per week Post-exposure observation period: 14 days
Vehicle	PEG 300
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5M + 5F	0	0/10
low dose	5M + 5F	50	0/10
mid dose	5M + 5F	200	0/10
high dose	5M + 5F	1,000	0/10
control recovery	5M + 5F	0	0/10
high dose recovery	5M + 5F	1,000	0/10

Mortality and Time to Death

There were no unscheduled deaths during the study.

Clinical Observations

No test item-related findings of toxicological relevance were noted across all levels of dosing. Dark or blue faeces were noted in test item-treated rats. Soft faeces were noted in both control and treated animals mainly due to the use of PEG 300 as vehicle. Blue bedding was noted in male and female rats treated with 1,000 mg/kg bw/day and were considered to be possibly related to the excretion/elimination of the test item via the kidneys. Localized alopecia was noted in one male treated with 1,000 mg/kg bw/day.

A significant reduction in locomotor activity was observed within first hour of treatment in both males and females treated with 50 mg/kg bw/day. In females treated with 200 mg/kg bw/day there was an increase in activity for 15 minutes after the treatment. However, none of these were observed in females treated with 1,000 mg/kg bw/day and hence was considered these events to be fortuitous.

Food consumption and body weights were similar to that of the respective control samples during the treatment and recovery phases.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Significantly elevated sodium levels were noted in males treated with 50 mg/kg bw/day and in both sexes

treated with 200 and 1,000 mg/kg bw/day. These changes were considered to be related to the treatment and were found to be reversible during recovery. Elevated blood glucose levels were noted in males treated with 200 and 1,000 mg/kg bw/day. Elevated glucose levels remained after the recovery period in males treated with 1,000 mg/kg bw/day. However, the glucose levels remained within the range of the historical control values and no clear dose response relationship was identified. Other changes in treated males, including reduction of total bilirubin, lower aspartate aminotransferase activity and lower creatine kinase level, were also noted during the study but not considered to be adverse by the study authors.

After the treatment period, absolute and relative reticulocyte counts in treated males were significantly increased ($p < 0.01$). The changes were not dose-related. Similar changes were not observed in treated females. A few other haematology parameter changes including methaemoglobin level and red or white blood cell counts were also noted. However, in the absence of systemic effects or dose-response, these changes were not considered by the study authors to be adverse.

The post-treatment mean urine volume was significantly elevated for males treated with 1,000 mg/kg bw/day and in females treated with 200 and 1,000 mg/kg bw/day when compared with the controls. Yellow-green discoloration of the urine was observed in six males and all females treated with the test item at 1,000 mg/kg bw/day possibly due to metabolite of the notified chemical.

Effects in Organs

Blue discolouration of the intestinal mucosa in a proportion of animals treated with 200 or 1,000 mg/kg bw/day and was considered to be related to the presence of the blue test compound without histopathological correlations to the test substance and hence no toxicological significance. The absolute and relative organ weights of the treated rats were similar to those of the respective controls after both the treatment and recovery phases of the study.

Remarks – Results

There was no toxicologically significant necropsy or histopathological finding in the study.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 1,000 mg/kg bw/day in this study, based on the highest dose tested.

TEST FACILITY RCC Ltd (2003s)

B.7. Genotoxicity – bacteria reverse mutation test

TEST SUBSTANCE	Notified chemical (approximately 92% in purity)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
	Test 1: plate incorporation Test 2: pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9 fraction Phenobarbital/β-naphthoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 33-5,000 µg/plate b) Without metabolic activation: 33-5,000 µg/plate.
Vehicle	Deionised water
Remarks - Method	No significant protocol deviations.
	In the pre-experiment, the concentration range of the test item was 3-5,000 µg/plate. The pre-experiment is reported as Test 1. Since no toxic effects were observed at up to 5,000 µg/plate, this concentration was chosen as maximal concentration. In Test 2, concentration used were 33, 100, 333, 1000, 2500 & 5000 µg/plate.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5,000	-	-	Negative
Test 2	-	> 5,000	-	Negative
Present				
Test 1	> 5,000	-	-	Negative
Test 2	-	> 5,000	-	Negative

Remarks - Results

No toxic effects or no substantial increase in revertant colony numbers of any of the five tester strains was observed following treatment with the notified chemical at any dose level, neither in the presence nor absence of metabolic activation. In test 2, slight toxic effects were observed at 5,000 µg/plate in strains TA 1535 and TA 1537 with metabolic activation. The study authors concluded that there was no tendency of higher mutation rates with increasing concentrations of the notified chemical in the range below the generally acknowledged border of biological significance.

The positive controls (sodium azide, 2-aminoanthracene, 4-nitro-o-phenylene-diamine, methyl methane sulfonate) showed a distinct increase in induced revertant colonies, confirming the efficacy of the test system.

CONCLUSION

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

TEST FACILITY

RCC Ltd (2003t)

B.8. Genotoxicity – *in vitro* mammalian chromosome aberration test

TEST SUBSTANCE

Notified chemical (approximately 92% in purity)

METHOD

OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test.
EC Directive 2000/32/EC B.10 Mutagenicity - *In vitro* Mammalian Chromosome Aberration Test.

Species/Strain: Chinese Hamster
Cell Type/Cell Line: V79
Metabolic Activation System: S9 fraction Phenobarbital/β-naphthoflavone induced rat liver
Vehicle: Deionised water
Remarks - Method: No significant protocol deviations.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period (hrs)*	*Harvest Time (hrs)*
Absent			
Test 1	10, 20*, 40*, 60*, 80, 100	4	18
Test 2	5, 10*, 20*, 40*, 60, 80	18	18
Test 3	20*, 40, 60, 80	28	28
Present			
Test 1	10, 20, 40*, 60*, 80*, 100	4	18
Test 2	10*, 20*, 40*, 60, 80, 100	4	28

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 71.9	≥ 100	> 100	Positive
Test 2		≥ 40	> 80	Positive
Test 3			> 80	Equivocal
Present				
Test 1	≥ 71.9	≥ 80	≥ 80	Positive
Test 2		≥ 40	> 100	Positive

Remarks - Results

In the test 1, an aberration rate of up to 5.3% (40 µg/mL) and 5% (60 and 80 µg/mL) was observed without and with metabolic activation respectively. In test 2, an aberration rate of up to 6.5% (20 µg/mL) and 7.5% (40 µg/mL) was observed without and with metabolic activation respectively.

No increase in the frequencies of polyploidy metaphases was noted in the study.

Ethylmethane sulfonate (EMS) and cyclophosphamide (CPA) were used as positive controls and showed distinct increases in cells with chromosomal aberrations

CONCLUSION

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

TEST FACILITY

RCC Ltd (2003u)

B.9. Genotoxicity – *in vivo* mammalian erythrocyte micronucleus test

TEST SUBSTANCE

Notified chemical (approximately 92% in purity)

METHOD

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

Species/Strain: Mouse/NMRI
Route of Administration: Oral – gavage
Vehicle: 30% DMSO/70% PEG
Remarks - Method: A pre-test study estimated that 2,000 mg/kg bw as the maximum guideline-recommended dose and hence chosen for the study.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	6M + 6F	0	24
II (low dose)	6M + 6F	500	24
III (mid dose)	6M + 6F	1,000	24
IV (high dose)	6M + 6F	2,000	24
	6M + 6F	2,000	48
V (positive control, CP)	6M + 6F	40	24

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity

Pre-experimental test on 4 mice (2 M/2 F) at the dose level of 2,000 mg/kg bw showed toxic reactions such as reduction of spontaneous activity, eyelid closure and ruffled fur.

In the main experiment, animals treated with the test substance showed

	toxic reactions starting at 500 mg/kg bw. The effects included reduction of spontaneous activity, abdominal position and ruffled fur. One female died at the highest dose level of 2,000 mg/kg bw.
Genotoxic Effects	There was no substantial decrease in the number of polychromatic erythrocytes when treated with the notified chemical compared to the vehicle control, indicating no cytotoxic effects of the test substance in the bone marrow. There was no statistically significant or biologically relevant enhancement in the frequency of the detected micronuclei from the treatments. The mean values of micronuclei observed from the treatments with the notified chemical were below or near to the value of the vehicle control group.
Remarks - Results	Cyclophosphamide (40 mg/kg bw) was used as positive control and exhibited substantial increase of induced micronucleus frequency. As no toxic effects were observed in the bone marrow of the treated animals, there was no adequate evidence to indicate that the test substance was able to reach the target organ bone marrow.
CONCLUSION	The notified chemical was not clastogenic under the conditions of this *in vivo* mammalian erythrocyte micronucleus test.
TEST FACILITY	RCC Ltd (2003v)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 301 A Ready Biodegradability: DOC Die-Away Test.
Inoculum	Activated Sludge
Exposure Period	28 Days
Auxiliary Solvent	None Reported
Analytical Monitoring	Dissolved organic carbon (DOC)
Remarks - Method	The test was conducted in accordance with the test guideline above with no significant deviation from the protocol reported.

RESULTS

Test substance		*D (+) - Glucose*	
Day	*% Degradation*	*Day*	*% Degradation*
1	0	1	42
7	0	7	94
10	0	10	93
21	0	21	95
28	0	28	96

Remarks - Results	All validity criteria were met. The difference of extremes values of the removal of the notified chemical at the plateau, at the end of the test or at the end of the 10-day window was less than 20%; the degradation of the reference item at day 14 reached the pass level of 70%; the degradation of the inhibitory action at day 14 was ~ 35%; the abiotic degradation of the sterile control at day 28 was not > 10%.
CONCLUSION	The notified chemical is not readily biodegradable
TEST FACILITY	Solvias AG (2003a)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static.
Species	Zebra fish (*Danio rerio*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	160 mg $CaCO_3$/L
Analytical Monitoring	Liquid Chromatography
Remarks – Method	Tested in accordance with the test guideline without significant deviation from the protocol. Good Laboratory Practices (GLP) was followed.

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality*				
Nominal		*2-4h*	*24 h*	*48 h*	*72 h*	*96 h*
10	7	0	0	0	0	0
19	7	0	5	7	7	7
33	7	0	7	7	7	7
57	7	0	7	7	7	7

100	7	0	7	7	7	7

LC50 14 mg/L at 96 hours.

Remarks – Results All validity criteria for the test were satisfied.

The highest concentration with no sublethal or lethal effects corresponded to 10 mg/L. The results were based on nominal concentration as the actual concentrations for the test substance were not determined. At the test concentration of 10 mg/L as well as in the control, no lethal and sublethal effects (e.g. changes in swimming behaviour, respiratory function, and loss of equilibrium) were observed during the 96h exposure period.

CONCLUSION The notified chemical is harmful to fish

TEST FACILITY Solvias AG (2003b)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified Chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None Reported
Water Hardness	231 mg $CaCO_3$/L
Analytical Monitoring	Liquid Chromatography
Remarks - Method	The test was carried out according to the test guideline above without significant deviation from the protocol. Good Laboratory Practices (GLP) was followed.

RESULTS

Concentration mg/L	*Number of D. magna*	*Number Immobilised*	
Nominal		*24 h [acute]*	*48 h [acute]*
4.3	10	0	0
9.4	10	0	0
21	10	0	0
45	10	1	4
100	10	6	10

LC50 51.2 mg/L at 48 hours *[acute]*

Remarks - Results All validity criteria for the test were satisfied. No immobilisation of Daphnia was observed in the control and at test concentrations of 4.3, 9.4 and 21 mg/L after 24 and 48 hours of the test. At 24 hours, 5% immobility was recorded at a test concentration of 45 mg/L and 60% immobility of Daphnia at the highest concentration of 100 mg/L. At the end of the test, immobility of Daphnia had increased to 25% and 100% at test concentrations of 45 and 100 mg/L, respectively.

CONCLUSION The notified chemical is harmful to aquatic invertebrates

TEST FACILITY Solvias AG (2003c)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified Chemical

METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 4.6, 10, 22, 46 and 100 mg/L
Auxiliary Solvent	None Reported
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	
Remarks - Method	The test was carried out according to the test guideline above without significant deviation from the protocol. Good Laboratory Practices (GLP) was followed. As the test substance is a dye which results in coloured media, the test method was modified to differentiate between a reduced growth of algae due to real toxic effects of the test substance and the algal cells or due to an indirect effect, a reduced algal growth by light absorption in coloured test solutions. Two experiment parts were used: Part A used the usual algal toxicity test protocol. Erlenmeyer flasks containing test substance and algae were covered with glass dishes containing untreated test water. Algal growth inhibition in these vessels would be due to any toxic effects in addition to reduced light intensity. Part B used the same procedure but replaced the contents of the glass dishes with the coloured test substance. The Erlenmeyer flasks contained algae but no test substance. Thus Part B results show the algal growth inhibition due to light absorption only.

RESULTS

	Biomass		*Growth*	
	E_bC50 (95% CI) mg/L at 72 h	*NOEC mg/L*	*E_bC50 (95% CI) mg/L at 72 h*	*NOEC mg/L*
Part A-Test solutions (coloured)	25 (20-32)	4.6	76 (54-130)	4.6
Part B-No test substance	78 (35->>100)	10.0	>>100 (n.d)	10.0

Remarks - Results	This modified algal test has demonstrated that the observed growth inhibition effect on *Scenedesmus subspicatus* was caused in part due to the indirect effect of light absorption in the coloured test solutions. However, the differences between experimental parts A and B were too high to state that the algal growth is inhibited solely as a result of a reduction in light intensity. Therefore, the results of experimental part A, where the algae grew in the test media with dissolved test item as in a usual algal growth inhibition test should be taken into consideration for the determination of the toxic effect of the test item on the growth of *Scenedesmus subspicatus*.
CONCLUSION	The notified chemical is harmful to algae.
TEST FACILITY	RCC Ltd (2003w)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: 3.2, 10, and 32 mg/L of mg/L Actual: 26, 64, 160, 400 and 1,000 mg/L
Remarks – Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported.

RESULTS	
IC50	> 1000 mg/L
Remarks – Results	All validity criteria for the test were satisfied. The EC50 was out of the tested concentration range (> 1,000 mg/L).
CONCLUSION	The notified chemical is not expected to inhibit microbial respiration.
TEST FACILITY	Solvias AG (2003d)

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