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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Orange ROE 13 in NOVACRON® BLACK LS-N-01

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Ageing, 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 and Water Resources.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

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Director
NICNAS

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FULL PUBLIC REPORT

Orange ROE 13 in NOVACRON® BLACK LS-N-01

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Huntsman Corporation Australia Pty Ltd (ABN: 67 083 984 187)
454-456 Somerville Road
West Footscray VIC 3012

AND

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

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.
Chemical Name; Other Names; CAS Number; Molecular Formula; Structural Formula; Molecular Weight; Spectral Data; Purity; Identity and % Weight of Toxic or Hazardous Impurities; Identity and % Weight of Non-Hazardous Impurities; Identity and % Weight of Additives/Adjuvants; Import Volume; Identity of Customer Sites

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Europe (2001); Switzerland (2001); South Korea (2001); USA (2001); China (2004); Canada (2006); Japan

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
NOVACRON® BLACK LS-N-01 (containing 10-20% notified chemical)

OTHER NAME(S)
ORANGE ROE 13
FAT 40577
FAT 40577/A
FAT 40’577/A

MOLECULAR WEIGHT
500 - 1000 Da

ANALYTICAL DATA
Reference NMR, IR, HPLC, LC, UV spectra were provided. Elemental analysis, water content and the content of hexane soluble unsulfonated primary aromatic amines were also determined.

3. COMPOSITION

DEGREE OF PURITY 40-50%
The impurities are mainly non hazardous by-products.

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Brown powder

Property	Value	Data Source/Justification
Melting Point	>400°C	Measured
Boiling Point	~790°C	Calculated
Density	1715 kg/m^3 at 20.7°C	Measured
Vapour Pressure	1.57 x 10^{-29} kPa at 25°C	Calculated
Water Solubility	≥409 g/L at 20°C	Measured (determined visually)
Hydrolysis as a Function of pH	$t_{½}$ = 321 d at pH 4, 25°C $t_{½}$ > 1 year at pH 7, 25°C $t_{½}$ = 96 d at pH 9, 25°C	Measured
Partition Coefficient (n-octanol/water)	log P_{OW} = -4.6 at 20°C	Estimated
Surface Tension	72.8 mN/m at 20.3±0.1°C	Measured
Adsorption/Desorption	K_{OC} ≥ 1495 mL/g at 20°C.	Measured
Dissociation Constant	pKa = -7.1 to 3.9	Calculated
Particle Size	Inhalable fraction (<100 μm): 98.19% Respirable fraction (<10 μm): 21.54% MMD* = 25.8 μm	Measured
Flash Point	Not determined	
Flammability	Not highly flammable	Measured
Autoignition Temperature	230°C	Measured
Explosive Properties	Not explosive	Measured
Oxidising Properties	Not oxidising	The notified substance has a negative oxygen balance.

* MMD = Mass Median Diameter

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

Reactivity
The notified chemical is considered to be non-oxidizing and is not capable of causing fire or enhancing the risk of fire when in contact with combustible material. No incompatible substances have been identified with the notified substance. The notified chemical is stable at room temperature and does not evolve any flammable gases in contact with water or humid air. The notified chemical is not considered to be an explosive as it is not thermally sensitive, not shock sensitive and not sensitive to friction. Conditions have not been identified which would contribute to the instability of the product; the product is considered to be stable under normal conditions of use. Typical decomposition products are oxides of carbon, oxides of nitrogen and oxides of sulfur. No other toxic gases/vapours have been identified.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported by sea as a 10 – 20% component of NOVACRON® BLACK LS-N-01 as granules or dedusted powder. NOVACRON® BLACK LS-N-01 is a mixture that contains azo dyes, including the azo dye notified as STD/1271, and one other.

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

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

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Chemiplas Australia Pty Ltd

TRANSPORTATION AND PACKAGING
NOVACRON® BLACK LS-N-01 will be transported into Australia by ship in 25 kg fibreboard cartons, with inner PE liner. The product is transported by road from the dockside to the Chemiplas warehouse in Laverton North (Victoria), where it is stored until required for despatch to customers.

USE
The notified chemical is a reactive azo dye, used for the colouration of cotton and cotton-blend fibres (blended with synthetic fibres such as polyester, polyamide, elastane, or possibly blended with wool or silk). The notified chemical reacts with hydroxyl groups in cellulosic fibres during fixation to form covalent bonds with the fibre, such that high levels of wash and colourfastness are generated. The notified chemical will be used to dye domestic textiles that are intended for apparel, sheeting and other uses.

OPERATION DESCRIPTION
At customer dyehouses, the product containing the notified chemical (10-20% concentration) will be manually weighed into a dispensary and subsequently manually transferred to the blending vessel, both of which are equipped with local exhaust ventilation. Mixing and blending of dye components takes place in closed mixing vessels. Following blending, the notified chemical is present at <1% in the final textile dye solution. The textile dye solution will be applied to fabric at elevated temperatures.

The dyeing process is mainly automated once the dye is in solution (<1% notified chemical), with the cloth driven by mechanical rollers through the dyeing and washing steps in a mainly enclosed system. At the completion of the rinsing phase the wet fabric will be removed from the dyeing equipment by mechanical means, assisted by operators. Wet fabric will be carried on trolleys covered with plastic to prevent contamination and transported to either a centrifuge or mangle to remove excess water. The damp fabric will then be fed onto a pin frame for drying.

Cleaning and maintenance operations involve flushing the holding and mixing tanks with water.

For cotton fabrics, exhaustion is achieved by adding electrolyte (NaCl or Na_2SO_4) and fixation will be achieved by the addition of alkali (normally NaOH or $NaCO_3$, or both) at temperatures of 60-70ºC. The concentrations used of these additives will be dependent on the amount of dye used and the water to fabric ratio. Exhaustion rates of ~85-95% are expected, of which ~70-90% will be bound to cellulosic fibres (fixed) and the remainder will react with water and alkali (allowing for variations between mills). The fabric will then be washed free of unfixed dye in a series of wash-off baths (five to eight) at temperatures ranging from 30ºC to 95ºC At completion of this process, there is expected to be <1% of the hydrolysed dye on the fabric.

The dye containing the notified chemical has low affinity for polyester and elastane. For polyamide fabrics, the hydrolysed notified chemical dyes the fibre, with the majority expected to remain fixed. When used with wool or silk, some of the dye is fixed, and some hydrolysed dye (30% of the original amount) will be removed by rinsing and soaping processes.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport drivers	1 – 5	20 – 30 min/day	50 – 100
Warehouse operators	3 – 6	20 min/day	100 – 150
Batch area operators	4 – 8	20 min/day	180 – 240
Dye machine operators	4 – 8	60 min/day	180 – 240

EXPOSURE DETAILS

Transport and warehouse workers are not expected to be directly exposed to the notified chemical, except in the event of a spill or leak.

Dye machine operators are likely to be exposed to the imported product (containing 10-20% notified chemical) by inhalation, ingestion, skin contact or eye contact while manually weighing out the dye and adding it to mixing vessels to form the dye solution. The imported product is supplied as granules or dedusted powder, reducing the potential for inhalation exposure that would otherwise be significant, given that 21.5% of the particles of the notified chemical are within the respirable range. Dye machine operators will wear personal protective equipment (PPE) that includes gloves, coveralls, goggles and a dust mask/breathing apparatus. Local and general exhaust ventilation will be present where the solid product containing the notified chemical is handled. EASE modelling of the weighing process was performed to estimate dermal/inhalation exposure of workers to the notified chemical. The following assumptions were used for these estimates: direct handling, non-dispersive use (only used by workers with knowledge of the processes and use of controls), and intermittent contact level (assumed to be 2-10 events per day). The predicted dermal exposure to the notified chemical is 0.02-0.2 mg/cm^2/day. This is equivalent to 0.46-4.6 mg/kg bw/day, based on assumptions outlined by the European Commission (EC, 2003).

The dyeing process is mainly automated once the dye is in solution (<1% notified chemical), with the cloth driven by mechanical rollers through the dyeing and washing steps. The system is mainly enclosed to prevent splashes and spills. Some manual handling of wet cloth will occur during some steps of the process. Therefore, dermal and possibly ocular exposure to the dye solution is possible.

Cleaning and maintenance of the machines will be performed by the machine operators. During this process, inhalation, dermal and ocular exposures are possible, but a significant proportion of the residue in the machines is expected to be hydrolysed dye. Workers involved with cleaning of machines will wear an organic vapour cartridge respirator, gloves, safety goggles and overalls.

6.1.2. Public exposure

The imported product containing the notified chemical will be available only to industrial end-users. Fabrics that are dyed with the notified chemical may be used for apparel and sheeting (and other uses), with which members of the public would be expected to make frequent dermal exposure. However, the notified chemical belongs to a class of dyes that reacts with fabrics, becoming covalently bound during the exhaustion and fixation steps of the dyeing process (Smith, 1993). Less than 1% of the free, hydrolysed dye is expected to remain in dyed fabrics, and this unfixed material is likely to be removed upon washing of fabrics by consumers. Therefore, public exposure to the notified chemical is not likely to be significant.

6.2. Human health effects assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	Low toxicity oral LD50 >2000 mg/kg bw
Rat, acute dermal toxicity	Low toxicity LD50 >2000 mg/kg bw
Rabbit, skin irritation	Non-irritating
Rabbit, eye irritation	Severely irritating
Guinea pig, skin sensitisation – adjuvant test	No evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL = 200 mg/kg bw/day NOEL = 50 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	Non mutagenic

Genotoxicity –in vitro mammalian chromosome aberration test	Genotoxic
Genotoxicity – in vivo mammalian erythrocyte micronucleus test	Non-genotoxic

Toxicokinetics, metabolism and distribution
Based on its molecular weight (>500) and $logP_{ow}$ (<0), the notified chemical is not expected to be readily absorbed transdermally or from the gastrointestinal tract. Nonetheless, the effects observed in the mouse micronucleus and 28-day repeat oral dose toxicity studies, suggest that it will at least be partly absorbed from the gastrointestinal tract. In addition, impurities and azo reduction species produced by intestinal bacteria may be more readily absorbed than the notified chemical (Chung, 1983).

The inhalation of respirable particles of the notified chemical is possible, given the particle size of the powder (MMD = 25.8 μm). The notified chemical would be likely to dissolve, as it is highly water soluble, be retained in the mucus lining the respiratory tract, and ultimately ingested. Significant absorption from the lung is not probable, but given the reactivity of the notified chemical, some reaction with and/or toxicity towards cells of the lung epithelium is possible.

Once absorbed, the notified chemical is likely to be metabolised to some extent, with one mechanism being reduction of the azo linkage to form aromatic amines (see below).

Ultimately, the metabolites of azo dyes are excreted in the urine and bile (Brown & DeVito 1993, referenced in Øllgaard *et al* 1998 and Fuji 2007). Sulfonation of azo dyes appears to decrease their toxicity by enhancing their urinary excretion, and that of their metabolites. Light brown coloured urine observed in the mouse micronucleus study is likely to be indicative of the urinary excretion of metabolites of the notified chemical.

Acute and repeat dose (sub-acute) toxicity
The notified chemical was found to be of low acute toxicity by the oral and dermal route (LD50 > 2000 mg/kg bw).

In the 28-day repeat dose oral toxicity study, abnormal clinical observations and laboratory findings as well as effects on the target organs (mainly cecum) were observed in animals treated with 1000 mg/kg/day. No treatment-related effects were found at 200 mg/kg/day and 50 mg/kg/day. Based on these results, the No Observed Adverse Effect Level (NOAEL) was established as 200 mg/kg bw/day.

The possible acute or chronic effects of inhalation of respirable particles of the notified chemical are not known. However, in the 28 day repeat dose oral study, lung lesions were observed in several animals. This may indicate that the notified chemical has the potential for adverse effects upon inhalation.

Irritation and sensitisation
The notified chemical was found to be non-irritating to the skin, based on a rabbit skin irritation study. The notified chemical caused mild irritant effects to the eyes, as well as irreversible staining to the conjunctivae of all animals treated in the eye irritation study.

Reactive dyes have been reported as the causative agents in sensitisation of the public to textiles (Estlander, 1988; Manzini et al, 1996). However, the notified chemical was not found to be sensitising to the skin of guinea pigs in a maximisation study. Also, relatively few sulfonated azo dyes have been demonstrated to be skin sensitisers (Øllgaard *et al* 1998). Therefore, the notified chemical is unlikely to cause skin sensitisation in exposed humans.

Reactive dyes that are formulated as respirable particles have also caused respiratory sensitisation in workers handling them for a period of years, for example during weighing procedures (Alanko K *et al,* 1978; Docker *et al,* 1987; Topping *et al*, 1989). As such, the notified chemical may induce respiratory sensitisation, however, further testing is required to confirm this possibility.

Mutagenicity/carcinogenicity
The notified chemical was not mutagenic to bacteria *in vitro*, under the conditions of the Ames test used. The Ames test performed was a standard test, according to OECD Test Guideline 471. However, the test guideline strongly recommends the use of alternative procedures for the detection of mutagenicity of azo dyes, as it is recognised that the standard procedure may not be sufficiently sensitive for these chemicals. Modified tests, such

as that of Prival and Mitchell, utilise a reductive pre-incubation step (during which the azo dye is reduced to amine species) before the test is carried out (Prival and Mitchell, 1982). This modified test is thought to yield a greater detection of mutagenic azo dyes. As such, mutagenicity of the notified chemical cannot be ruled out on the basis of the studies performed.

The notified chemical was clastogenic to cultured mammalian cells, in the presence and absence of metabolic activation. It was not found to be clastogenic in an *in vivo* mouse bone marrow micronucleus assay. As there was no effect on the PCE/NCE ratio in this assay, some doubt exists as to whether the notified chemical reached the bone marrow. However, it should be noted that there were some significant haematological changes in the 28 day repeat dose study. The available results are not sufficiently conclusive to allay all concern for mutagenicity and/or carcinogenicity in exposed humans.

Azo dyes as a class are a concern for their potential induction of mutagenicity and carcinogenicity (Combes and Haveland-Smith, 1982). In general, the degree of correlation between mutagenicity study results and the carcinogenicity of azo dyes as a class is poor, likely due to their complex metabolism *in vivo* (Brown and DeVito, 1993, referenced in Øllgaard *et al* 1998). Mutagenicity from azo dyes may result from the intact chemical or from amines formed by reductive metabolism or degradation. Reductive cleavage or degradation into component aromatic amines is a major mechanism leading to the genotoxicity of azo dyes (SCCNFP, 2002). The aromatic amines that arise from the azo reduction and cleavage of azo dyes are thought to be activated as mutagens through their *N*-oxidation by cytochrome P450 isozymes. This mechanism is thought to contribute to the carcinogenicity of many azo dyes, and as a result, azo dyes should be assessed for toxicity and classified similarly to their component amines (DFG, 1988, quoted in Golka *et al*, 2004). The notified chemical is not expected to be reductively cleaved to release any of the restricted aromatic amines specified in either the Appendix to EC Directive 76/769/EEC (EC 2004) or the annexes of EU SCCNFP/0495/01 (SCCNFP 2002). However, the notified chemical can be broken by azo reduction into a number of arylamine species, some of which may be mutagenic/carcinogenic.

In addition to these concerns, azo dyes in general are renowned for their content of impurities, particularly for the presence of component arylamines (SCCNFP, 2002; Øllgaard *et al*, 1998). The identity of some of these species is known for the notified chemical, but their mutagenic potential is unknown. The identified impurities are in general likely to display similar or lower genotoxic properties to the notified chemical, but in some cases might display greater genotoxicity.

The notified chemical also fits into the US EPA category of concern for vinyl sulfones (US EPA, 2002), due to the presence of vinyl sulfone groups. Such groups are considered to be of concern for their potential oncogenicity and mutagenicity. During its use in dyeing textiles, the reactive vinyl sulfone groups of any of the notified chemical that does not react with the fabric will be hydrolysed to form hydroxyl species (Smith, 1993). These hydrolysis products are expected to be of lower concern for mutagenicity than the notified chemical, due to the loss of the reactive functional groups.

Overall, these results do not rule out the notified chemical as a possible mutagen or carcinogen. However, the weight of evidence does not meet the criteria for classification of the notified chemical as genotoxic. Carcinogenicity would need to be determined by further testing.

Based on the irreversible conjunctival staining seen in the eye irritation study, the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).
R41 - Risk of serious damage to eyes

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Transport and warehouse workers would only be exposed to the notified chemical in the event of a spill or leak. The risk arising from occupational exposure to the notified chemical can be divided into exposure to the powdered solid, the dye solution, and to the dyed cloth.

Powdered solid notified chemical
Batch area operators may be exposed to solid product containing 10-20% notified chemical while weighing out the dye and during addition of the dye powder to solution. Dermal/inhalation/ocular exposure of workers is estimated to be 0.46-4.6 mg/kg bw/day. A dermal NOEL/NOAEL was not determined, however, a NOAEL of

200 mg/kg bw/day and NOEL of 50 mg/kg bw/day were established in a 28 day oral study in the rat. Use of this NOAEL results in a margin of exposure (MOE) of 435, and use of the NOEL results in a MOE of 109. The MOE suggests that the risk to workers from use of the notified chemical is acceptable. However, the health risk of the notified chemical may be significant upon inhalation, given its potential for mutagenicity and/or respiratory sensitisation (in the absence of sufficient negative test data). In addition, the health risk arising from ocular exposure is also significant, given the irreversible staining of the eye observed during the eye irritation study.

It should be noted that the current practice is for workers to manually weigh the powdered notified chemical and add it to dye solution under conditions where engineering and other measures are in place to limit occupational exposure to the notified chemical, including the use of dedusted powder formulations, local exhaust ventilation, and appropriate PPE such as dust masks, goggles, gloves and overalls. However, it is recommended that these procedures be modified such that automated processes to exclude manual handling of the notified chemical be used.

Dye solution
Exposure of dye machine operators to the notified chemical in solution is unlikely during the majority of the dyeing process as the machinery is largely enclosed and mostly automated. These workers may experience predominantly dermal and ocular exposure to dye solution (<1%) – both during the manual handling stages of the dyeing process (notified chemical and hydrolysed dye in solution) and during the cleaning of the dye equipment (expected to be mostly hydrolysed dye). The health risk from ocular exposure is expected to be significant, but dermal exposure is expected to present a lower risk (as described above). The wet fabric will be wrapped in plastic during handling, and workers will wear gloves, overalls and goggles to prevent incidental exposure. These measures are expected to significantly reduce worker exposure to the notified chemical in dye solutions. During dyeing processes, dye machine workers will require eye and skin protection to avoid exposure to splashes and accidental exposure.

Dyed cloth
After fixation of the dye to the textile and washing off of unfixed dye, the remainder of the notified chemical will be covalently linked to the fabric and thus expected to be unavailable to cause significant exposure.

6.3.2. Public health
The product containing the notified chemical will be available only to industrial end users. The dyed cloth may be used for apparel, sheeting and other uses. The notified chemical is covalently linked to the cloth after the dyeing process. Colourfastness test results indicate a high degree of fastness of the notified chemical to dyed textiles. Therefore, there will be significant exposure to the dyed product, but exposure to the notified chemical is not likely to be significant.

If any residual, unfixed dye remains on the dyed fabric (after industrial fixation and washing), it is likely to be a hydrolysed species of lower concern for mutagenicity (see above). Residual dye is likely to be removed from fabrics during domestic washing.

Should any azo reduction occur on the fabric (for example through the action of bacterial skin flora or photolysis), this would not be expected to liberate arylamine species that are of concern for mutagenicity.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE
No manufacture or reprocessing of the notified chemical will take place. Therefore, there will be no environmental exposure associated with this process in Australia.

Release to the environment may occur in the unlikely event of an accident during transport or storage.

RELEASE OF CHEMICAL FROM USE

Nearly all of the dye containing the notified chemical will be removed from the import container liners by shaking. Less than 0.5% of the chemical per annum will remain as residue. Given the potential for recovery and reuse and the high unit cost of the dyestuff the waste due to spills is expected to be less than 0.5% per annum. Dissolution of the dye takes place in an enclosed vat and the dye is pumped through a closed system to the dyeing machine, therefore, release of the chemical is not expected at this stage.

The dye will be used to colour cotton and cotton blend textiles by exhaust dyeing. Fixation is performed at 60-70°C with the fixation rate expected to be ~75%. The notified chemical adsorbed to the fabric will not be released to the environment. The rinsate, generated via fabric rinsing, contains ~25% of the import volume of the notified chemical. This will represent a major route of environmental exposure. The rinsate will be discharged to the dyehouse effluent system, where flocculation will be used to remove the dyestuff. The treated effluent containing minor traces of the notified chemical will be disposed of to the sewer, where the sludge/solids will be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Any solid wastes generated in the dyehouses, including container residues, will either go to landfill or be incinerated. Incineration of the notified chemical will produce water, oxides of carbon, nitrogen and sulphur. Incineration is the preferred method of disposal due to the ready water solubility of the notified chemical.

Once bound to the fabric the notified chemical is expected to remain fixed throughout the useful life of the fabric. Hence it will share the fate of fabric and be either disposed of in landfill or incinerated.

7.1.2 Environmental fate

Two tests relating to biodegradability were presented. The results indicate that the notified chemical is poorly biodegradable. For the details of the environmental fate studies please refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

The dye will be used in a small number of dyehouses. The environmental hazard has been determined for dyehouses located in two general locations, one metropolitan based and the other country based. The Predicted Environmental Concentration (PEC) is estimated below:

Calculation Factor	Country Dyehouse (Low volume STP discharge)	City Dyehouse (High volume STP discharge)
Typical use of product expected per day	50.000 kg	50.000 kg
Amount of notified chemical	9.750 kg	9.750 kg
Concentration in wastewater (fixation rate 75%)	2.438 kg	2.438 kg
Typical daily volume of dye wash-water effluent	0.400 ML	0.400 ML
Concentration in dye wash water	6.094 mg/L	6.094 mg/L
Typical daily volume of dye house wash-water effluent	2.900 ML	2.900 ML
Concentration in dyehouse effluent	840.517 µg/L	840.517 µg/L
Dilution factor in sewage treatment plant	1:10	1:100
Concentration in effluent from sewage treatment plant	84.052 µg/L	8.405 µg/L
Predicted environmental concentrations (PECs) in receiving waters		
PEC Ocean (Dilution Factor 1:10)	8.405 µg/L	0.841 µg/L
PEC River (Dilution Factor 1:1)	84.052 µg/L	8.405 µg/L

These calculations assume that no dye is removed in treatment of the different waste effluents and represent the worst case scenario for dyehouses.

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	LC50 >100 mg/L	Not harmful
Daphnia Toxicity	E_iC50 >100 mg/L	Not harmful
Algal Toxicity	E_rC50 >100 mg/L	Not harmful
Inhibition of Bacterial Respiration	E_iC50 >1000 mg/L	No toxic effect

7.2.1 Predicted No-Effect Concentration

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
E_iC50 (Alga)	>100	mg/L
Assessment Factor	100	
PNEC:	>1000	µg/L

7.3. Environmental risk assessment

Using the PEC and PNEC values derived above, the following Risk Quotients have been calculated.

Risk Assessment (Country Dyehouse)	PEC µg/L	PNEC µg/L	Q
Q - River:	84.052	>1000	<0.084
Q - Ocean:	8.405	>1000	<0.008

Risk Assessment (City Dyehouse)	PEC µg/L	PNEC µg/L	Q
Q - River:	8.405	>1000	<0.008
Q - Ocean:	0.841	>1000	<0.001

These calculations show that the exposure to fish, daphnia, algae and waste water treatment bacteria is at levels unlikely to cause any significant effect. At higher release rates, there is still unlikely to be any significant effect on these species. Once in the aquatic environment, the chemical is expected to swiftly dilute to undetectable concentrations, and undergo biotic and abiotic degradation and adequate safety factor exists for use in country locations.

With a fixation rate of ~75%, ~25% of the imported volume of the notified chemical will enter the sewer in the rinsate from fabric rinsing following dyeing. The high water solubility and low P_{OW} value indicate that the notified substance is not likely to adsorb to sludge. However, effluent flocculation is expected to effectively precipitate the notified chemical. The solids containing the notified chemical would be disposed of through incineration or as chemical waste along with other solid waste (due to spills, leaks and container residues) from the dyehouse. Incineration is the preferred option because of the high water solubility and potential mobility of the material. Incineration of the sludge or waste containing the notified chemical will produce oxides of carbon, oxides of nitrogen, oxides of sulphur, and other main elements in the ash.

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

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

Therefore, based on the proposed use pattern and volume, the notified chemical is not expected to pose an unacceptable risk to the aquatic environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. The classification and labelling details are:

- 5 ≤ conc < 10%: Xi: R36 Irritating to eyes.
- ≥10%: Xi: R41 Risk of serious damage to eyes.

and

As a comparison only, the classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	*Hazard statement*
Irreversible effects	1	Causes serious eye damage

Human health risk assessment
The risk to workers from handling of the notified chemical is considered to be acceptable. However, further measures should be taken to automate the processes for weighing and transferring of the notified chemical so as to exclude manual handling. Respiratory protection and eye protection are required during handling of the powdered notified chemical. Skin and eye protection are required during dyeing operations.

When used in the proposed manner the risk to the public is considered to be acceptable, as the notified chemical will be covalently bound to dyed fabrics.

Environmental risk assessment
The notified chemical is not considered to pose a risk to the environment based on its reported use pattern.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classification for the notified chemical:
  - R41 Risk of serious damage to eyes.

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - 5 ≤ conc < 10%: Xi: R36 Irritating to eyes.
  - ≥10%: Xi: R41 Risk of serious damage to eyes.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following isolation and engineering controls to minimise occupational exposure to the notified chemical as introduced:
  - Local exhaust ventilation where there is potential exposure to the solid product
  - Isolation controls during weighing and transfer operations of the solid product

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - Avoid dust formation
  - Avoid inhalation of dust
  - Avoid exposure to eyes and skin
  - Clean spills immediately, taking care to avoid dust formation

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical in dye solutions:
  - Avoid exposure to eyes and skin
  - Clean spills immediately

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Dust mask or respirators capable of removing all product particles
  - Gloves, overalls and goggles or face-shield

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in dye solutions:
  - Gloves, coveralls and goggles or face-shield

  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 *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of by incineration or to sealed landfill.

Emergency procedures

- Spills 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
  - additional data becomes available on the genotoxicity or 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 reactive textile dye, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 5 tonnes, or is likely to increase, significantly;
  - if 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 MSDS of the products containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point >400°C

Method OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Differential thermal calorimetry.
An endothermic effect was observed, however, further investigation concluded that the endothermic heat effect was not due to melting of the test substance.
Test Facility RCC (2000b)

Boiling Point ~790°C

Method OECD TG 103 Boiling Point.
EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Calculated using Meissner's method (Lyman 1990).
Test Facility RCC (2000c)

Density 1715 kg/m^3 at 20.7 ± 0.2°C

Method OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Gas comparison pycnometer
Test Facility RCC (2000d)

Vapour Pressure 1.57 x 10^{-29} kPa at 25°C

Method OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Calculated using the Modified Watson Correlation (Lyman 1990).
Test Facility RCC (2000c)

Water Solubility ≥409 g/L at 20°C

Method OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Simplified Flask Method with HPLC Analysis. A dark red-brown, viscous solution was obtained. The solution was centrifuged and analysed and the water solubility judged to be higher than determined in the present study.
Test Facility RCC (2000e)

Hydrolysis as a Function of pH

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

pH	*T (°C)*	$t_{½}$
4	25	321 d
4	50	527 h
4	60	183 h
4	70	80 h
7	25	>365 d
9	25	96 d
9	50	63 h
9	60	14.5 h
9	70	5 h

Remarks As the test substance was found to be unstable at pH 4 and pH 9, further testing was performed. The test substance was found to be stable at pH 7 at 50°C and no further

testing was performed at these pH-values. Analysis was by HPLC.
Test Facility RCC (2000f)

Partition Coefficient (n-octanol/water) log P_{OW} = -4.6 at 20°C

Method OECD 107 Partition Coefficient (n-octanol/water): Shake Flask Method
OECD TG 117 Partition Coefficient (n-octanol/water), HPLC Method.
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks Based on the results of the preliminary test, neither the flask method nor the HPLC-method were applicable for the determination of the Log P_{OW}. Therefore, the value was estimated from the solubility of test substance in water and n-octanol, being 375.5 g/L (as determined in the preliminary test) and 8.46 mg/L, respectively.
Test Facility RCC (2000g)

Surface Tension 72.80 mN/m at 20.3±0.1°C

Method OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.
Remarks The determination was accomplished by means of a tensiometer, using the ring method. The notified chemical should not be regarded as a surface active substance.
Test Facility RCC Ltd (2000h)

Adsorption/Desorption – screening test K_{OC} > 1495 mL/g at 20°C.

Method OECD TG 106 Adsorption - Desorption Using a Batch Equilibrium Method with HPLC analysis.
EC Directive 2001/59/EC C.18 Adsorption - Desorption Using a Batch Equilibrium Method with HPLC analysis.

Soil	*Soil Type USDA*	*Organic Carbon Content g/100 g dry soil*	*K' mL/g*	*K'_{OC} mL/g*	*K'_{OM} mL/g*
Speyer	Loamy Sand	2.19	>54.4	>2484	>1441
Sisseln	Sandy Clay Loam	1.71	39.8	2329	1351
Les Barges	Silt Loam	3.64	>54.4	>1495	>867

Remarks The screening test revealed a strong adsorption of notified chemical on all three soils tested. At a concentration of 4.80 mg/L and soil samples of 5 g, the amount of notified chemical adsorbed was at least 91.6% for soil Speyer 88.8% for soil Sisseln and at least 91.6% for soil Les Barges.

The notified chemical can therefore, be regarded as having slight mobility in all three soils.
Test Facility RCC Ltd (2000i)

Dissociation Constant pKa = -7.1 to 3.9

Method OECD TG 112 Dissociation Constants in Water.
Remarks The behaviour of the notified chemical in aqueous solutions is dominated by the strongly acidic groups. Therefore, the molecule is negatively charged and is present in anionic form over the whole environmentally relevant pH range.
Test Facility RCC Ltd (2000j)

Particle Size

Method European Commission, Document ECB/TM/February 1996: "Particle Size Distribution Fibre Length and Diameter Distributions", Guidance Document
Laser diffraction method.
The notified chemical was dispersed in ethyl acetate and the below values are the mean of

four values.

Range (μm)	*Mass (%)*
< 5.0	11.75
< 10.0	21.54
< 50.0	82.30
< 100.0	98.19
< 250.0	99.92

Remarks Mass median diameter (MMD) = 25.8 μm
Test Facility RCC (2000k)

Flammability Not highly flammable

Method EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks In contact with the ignition source, the surface of the notified chemical started to glow and a black encrustation resulted. No flame was observed and the glowing zone did not spread.
Test Facility RCC (2000l)

Autoignition Temperature 230ºC

Method EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks The maximum temperature of the sample during the exothermic reaction was 604 ºC. After measurement, the test substance was carbonised with a white centre.
Test Facility RCC (2000m)

Explosive Properties Not explosive

Method EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks The notified chemical is not considered to be an explosive as it is not thermally sensitive, not shock sensitive and not sensitive to friction.
Test Facility Institute of Safety & Security (2000)

Oxidizing Properties Not oxidising

Method Expert statement
Remarks The oxygen balance of the notified chemical is negative, meaning that there is a surplus of carbon atoms. Therefore, it is expected that the notified chemical is incapable of causing fire or enhance the risk of fire when in contact with combustible material.
Test Facility RCC (2000n)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical (~50% purity)

METHOD: OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain: Rat/HanIbm: WIST (SPF)
Vehicle: Bi-distilled water
Remarks - Method: No significant protocol deviations

RESULTS

Number and Sex of Animals	*Dose mg/kg bw*	*Mortality*
3 F	2000	0
3 M	2000	1

LD50: > 2000 mg/kg bw
Signs of Toxicity: One male animal died spontaneously approximately 5 hours after administration. Hunched posture and dyspnea were observed in this animal at the 2 and 3 hour observation of day 1
Effects in Organs: Distended stomach was observed in one male animal at the unscheduled necropsy.

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

TEST FACILITY: RCC Ltd (2000o)

B.2. Acute toxicity – dermal

TEST SUBSTANCE: Notified chemical (~50% purity)

METHOD: OECD TG 402 Acute Dermal Toxicity.
Species/Strain: Rat/HanIbm: WIST (SPF)
Vehicle: Bi-distilled water
Type of dressing: Semi-occlusive.
Remarks - Method: No significant protocol deviations

RESULTS

Number and Sex of Animals	*Dose mg/kg bw*	*Mortality*
5 M	2000	0
5 F	2000	0

LD50: >2000 mg/kg bw
Signs of Toxicity – Local/Systemic: None
Effects in Organs: None
Remarks - Results: Orange staining on the skin produced by the test item was observed in all animals on days 2 and 3.
Two female animals displayed a marginal loss of body weight on the first week after administration, and recovered by the end of the study.

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

TEST FACILITY RCC Ltd (2000p)

B.3. Irritation – skin

TEST SUBSTANCE Notified chemical (~50% purity)

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3 (1 M, 2 F)
Vehicle Bi-distilled water
Observation Period 72 h
Type of Dressing Semi-occlusive.
Remarks - Method No significant protocol deviations

RESULTS

Remarks - Results Slight red staining by the test substance of the treated skin was observed during the whole observation time. The staining did not have an influence on the skin reaction reading.

No irritation effects were observed throughout the duration of the study.

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

TEST FACILITY RCC Ltd (2000q)

B.4. Irritation – eye

TEST SUBSTANCE Notified chemical (~50% purity)

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3 (1 M, 2 F)
Observation Period 24 days
Remarks - Method No significant protocol deviations

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	N/A	N/A	N/A	1	17 days	0
Conjunctiva: chemosis	0.7	0.7	0.3	2	72 hr	0
Conjunctiva: discharge	0	0.3	0.3	1	48 hr	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.
N/A = not assessable due to staining produced by test material.

Remarks - Results Test item staining prevented examination of the redness of the conjunctivae and nictitating membrane in all animals, and persisting for time periods of 21 days. Moderate swelling of the conjunctivae and/or nictitating membrane was seen in all animals at the 1 hour examination. By 24 hours the swelling was slight in all animals, disappearing in one animal at 48 hours, and in the other two by 72 hours.

Marked red-orange staining of the treated eye by the test item was

observed in all animals from the 1-hour reading until day 10 before decreasing on day 14 (1 animal) and day 17 (2 animals). Orange-red remnants of the test item in the eye or conjuctival sac were noted in all animals at the 1 and 24 hour observation. At the end of the study all animals showed a slight red-orange staining of the treated eye (wholly orange eye).

CONCLUSION The notified chemical is severely damaging to the eye on the basis of the observed irreversible colouration.

TEST FACILITY RCC Ltd (2000r)

B.5. Skin sensitisation

TEST SUBSTANCE Notified chemical (~50% purity)

METHOD OECD TG 406 Skin Sensitisation – adjuvant test
EC Directive 96/54/EC B.6 Skin Sensitisation – adjuvant test

Species/Strain Guinea pig/Ibm: GOHI; SPF-quality

PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: 30%
topical: 25%

MAIN STUDY

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

INDUCTION PHASE Induction Concentration:
intradermal: 30%
topical: 50%

Signs of Irritation It was not possible to determine whether erythema were present due to red-brown staining of the skin by the test item. No oedema were observed.

CHALLENGE PHASE

1st challenge topical: 25%

Remarks - Method No significant protocol deviations.

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

TEST FACILITY RCC Ltd (2000s)

B.6. Repeat dose toxicity

TEST SUBSTANCE FAT 40577/A

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.

Species/Strain Rat/HanIbm:WIST (SPF)

Route of Administration Oral – gavage

Exposure Information Total exposure days: 28 days
Dose regimen: 7 days per week
Post-exposure observation period: 14 days

Vehicle Bi-distilled water

Remarks – Method No significant protocol deviations

RESULTS

Dose mg/kg bw/day	*Number and Sex of Animals*	*Mortality*
0	5/sex	0 %
50	5/sex	0 %
200	5/sex	0 %

1000	5/sex	0 %
0 (recovery)	5/sex	0 %
1000 (recovery)	5/sex	0 %

Mortality and Time to Death
All animals survived until scheduled necropsy.

Clinical Observations
No test item-related toxic signs were noted during daily or weekly observations, or during functional observational battery. Dark and/or red faeces were noted in animals treated with 200 mg/kg/day and 1000 mg/kg/day. These findings were considered to be common passive effects noted after oral administration of dyestuffs, rather than an indication of toxicity. Fire- and hindlimb grip strength was unaffected at all dose levels. When compared with the controls, statistically significant reductions in mean locomotor activity were noted in males and females treated with 1000 mg/kg/day, particularly during the first measurement interval (0-15 minutes). A possible relationship with treatment could not be excluded.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Clinical Chemistry
Statistically significant increased glucose levels and decreased total bilirubin levels were found in males treated with 1000 mg/kg/day. Other changes in clinical chemistry were either within the ranges of 95% tolerance limit of the historical control data or considered to be incidental changes.

Haematology
Males and females which received 1000 mg/kg/day showed changes commensurate with methaemoglobinemia reticulocytosis and compensated anemia when compared with the control values. These differences were considered to be test item-related. All other haematology parameters were unaffected by the treatment with the test item. No differences from the control values were noted after two weeks' recovery.

Urinalysis
The urine pH of both sex animals treated with 1000 mg/kg/day was significantly higher than the controls. However, they were within the ranges of 95% tolerance limit of the historical control data. No other test item-related changes were noted in the urinalysis parameters after four weeks' treatment and two weeks' recovery.

Effects in Organs
The absolute heart weight was significantly low in females of all doses as well as the adrenal weight in females of 50 mg/kg/day and 1000 mg/kg/day. However, the significance of these changes were questioned by lack of dose-response relationship and absence of associated morphological changes. Other organ weights did not show test item-related changes when compared with those of the controls after the treatment and recovery periods.

Black-brown contents of the ileum and cecum were noted at necropsy in a few rats treated with 50 mg/kg/day or 1000 mg/kg/day and were considered to be passive effects resulting form oral ingestion of a dyestuff rather than a sign of toxicity.

Attenuation of the surface mucosal epithelium of the cecum was noted in all rats treated with 1000 mg/kg/day, and was considered to be test item-related. This change was consistent with augmented regeneration, considered to represent reparative responses to areas of previous and probable ongoing mucosal injury (e.g. small erosions, rapidly desquamating surface mucosal epithelium). The cecal mucosa of rats sacrificed after the 14-day recovery period was considered to be histologically normal, indicating full recovery of normal morphologic features.

The lesions diagnosed in the lungs (such as increased incidence / severity of alveolar macrophages, interstitial fibrosis, dark yellow-brown pigmented macrophage aggregates, dark yellow-brown pigmented granulomas, bronchiolization and / or reactive bronchiolar hyperplasia) in one male treated with 200 mg/kg/day and a number of rats treated with 1000 mg/kg/day after the 28-day treatment period and, in rats treated with 1000 mg/kg/day after the 14-day recovery period were considered to be indirectly related to the dosing procedure (gavage). These histopathologic lesions may be considered consistent with findings noted in the lungs following the aspiration of minute amounts of foreign solutions that are not readily absorbed, and were not considered by the testing laboratory to be reflective of toxic effects of the test item. These lesions persisted during the recovery period at 1000mg/kg/day, especially in females.

No other histopathologic findings were observed in rats following the 28-day treatment period or the 14-day recovery period that were considered to be related to treatment with the notified chemical. All other histopathologic changes observed in rats of this study were considered to be incidental findings commonly diagnosed in rats of this strain and age.

Remarks – Results
A number of effects including abnormal clinical observations and laboratory findings as well as effects on the target organs (mainly cecum) were found in animals treated with 1000 mg/kg/day. No treatment-related effects were found at 50 mg/kg/day.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 200 mg/kg bw/day based on the microscopic effects seen in the lungs at this dose level. The No Observed Effect Level (NOEL) was established as 50 mg/kg bw/day.

TEST FACILITY RCC Ltd (2000t)

B.6. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical (~50% purity)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure/Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9 mix derived from Phenobarbital induced Wistar rat liver.
Concentration Range in Main Test	a) With metabolic activation: 33, 100, 333, 1000, 2500, 5000 µg/plate b) Without metabolic activation: 33, 100, 333, 1000, 2500, 5000 µg/plate
Vehicle	Deionised water
Remarks - Method	The positive controls used in the TA98, TA1537 and WP2 uvrA strains (without metabolic activation) were not those specifically recommended by the test guideline. In addition, 2-Aminoanthracene was used as the only positive control for assays with metabolic activation. The test guideline advises against this.
RESULTS	
Remarks - Results	In strain WP2 uvrA a minor increase in revertant colony numbers was observed at the higher concentrations tested both with and without metabolic activation. This was not considered to be of biological relevance.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	RCC Ltd (2000u)

B.7. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical (~50% purity)
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Species/Strain	Chinese hamster
Cell Type/Cell Line	V79 cells
Metabolic Activation System	S9 mix derived from Phenobarbital induced Wistar rat liver.
Vehicle	Deionised water
Remarks - Method	No significant protocol deviations

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	37.5, 75, 150*, 300*, 600*, 1200	4 hr	18 hr
Test 2a	37.5, 75, 150*, 300*, 450, 600*	18 hr	18 hr
Test 2b	150, 300*, 450*, 600*	28 hr	28 hr
Present			
Test 1	20*, 40*, 80*, 120, 160, 200	4 hr	18 hr
Test 2	10, 20, 40*, 80*, 120*, 160*	4 hr	28 hr

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:* *Cytotoxicity in Main Test*	*Genotoxic Effect*
Absent		
Test 1	600-1200	Negative
Test 2a	>600	Positive
Test 2b	600	Positive
Present		
Test 1	~160	Negative
Test 2	80	Positive

Remarks - Results

In Test 1 and 2 there was a reduction in the mitotic index indicating toxic effects in the presence and absence of metabolic activation.

In Test 2, statistically significant increases in the incidence of chromosomal aberrations were observed both with (3% and 21% aberrant cells excluding gaps) and without (9% aberrant cells, excluding gaps) metabolic activation at the 28 hr preparation interval, and without metabolic activation at the 18 hr preparation interval (2.5% aberrant cells excluding gaps).

CONCLUSION

The notified chemical was clastogenic to V79 Chinese hamster cells treated in vitro under the conditions of the test.

TEST FACILITY

RCC Ltd (2000v)

B.8. Genotoxicity – in vivo

TEST SUBSTANCE

Notified chemical (~50% 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: Deionised water
Remarks – Method: No significant protocol deviations.

Dose mg/kg bw	*Number and Sex of Animals*	*Sacrifice Time hours*
0	6/sex	24
500	6/sex	24
1000	6/sex	24
2000	6/sex	24
2000	6/sex	48
40 (positive control, CP)	6/sex	24

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity	>2000
Genotoxic Effects	>2000
Remarks - Results	The mean number of normochromatic erythrocytes was not increased after treatment with the test material as compared to the mean value of NCEs of the vehicle control indicating that the test material has no cytotoxic properties in the bone marrow. The mean values of micronuclei observed after treatment with the test material were below or near to the value of the vehicle control group.
CONCLUSION	The notified chemical was not clastogenic under the conditions of this in vivo Mammalian Erythrocyte Micronucleus Test.
TEST FACILITY	RCC (2000w)

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. EC Directive 92/69/EEC C.4-A Biodegradation: Determination of the " Ready" Biodegradability: Dissolved Organic Carbon (DOC) Die-Away Test
Inoculum	Activated sludge from a wastewater treatment plant
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	HPLC
Remarks - Method	No significant protocol deviations

RESULTS

Test substance		*Sodium benzoate*	
Day	*% degradation*	*Day*	*% degradation*
4	1	4	102
7	1	7	102
11	0	11	101
14	-6	14	98
21	-2	21	99
27	2	27	100
28	-1	28	98

Remarks - Results	All test validity criteria were satisfied. The test substance was found to be not biodegradable under the test conditions.
CONCLUSION	The notified chemical cannot be classed as ready biodegradable.
TEST FACILITY	RCC (2000x)

C.1.2. Inherent biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD 302B Inherent Biodegradability: Zahn-Wellens/EMPA Test EC Directive 88/302/EEC C.9 Biodegradation: Zahn – Wellens Test
Inoculum	Aerobic activated sludge from a wastewater treatment plant
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	HPLC
Remarks – Method	No significant protocol deviations

RESULTS

Test substance		*Sodium benzoate*	
Day	*% degradation*	*Day*	*% degradation*
3	3	3	100
7	0	7	98
10	-2	10	98
14	2	14	99
21	3	21	99
27	8	27	99
28	2	28	98

Remarks – Results: No DOC-Removal was observed during the first three hours of exposure indicating that the test item did not adsorb on activated sludge. All test validity criteria were satisfied. The test substance was found to be not biodegradable under the test conditions.

CONCLUSION: The notified chemical cannot be classed as ready biodegradable.

TEST FACILITY: RCC (2000y)

C.1.3. Potential for Bioaccumulation

The notified substance has low potential to bioaccumulate. This is based on the water solubility of the test substance (≥409 g/L) and the partition coefficient (log P_{OW} = -4.6).

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 203 Fish, Acute Toxicity Test – 96-hour static test.
EC Directive 92/69/EEC C.1 Acute Toxicity for Fish- 96-hour static test.

Species	Zebra fish (Brachydanio rerio)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	No significant protocol deviations

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control		7	0	0	0	0	0
100	111 - 119	7	0	0	0	0	0

LC50: >100 mg/L at 96 hours.
NOEC: 100 mg/L at 96 hours.
Remarks – Results: The analytically determined mean test item concentration in the test medium at the start and the end of the test was 111 and 119% of the nominal value, respectively. Under the test conditions, the test substance was stable during the test period of 96 h. Therefore, all reported results are related to the nominal concentration.

No remarkable observations were made concerning the appearance of the test medium. The test medium was a coloured solution throughout the whole test duration. All test validity criteria were satisfied.

CONCLUSION	The notified chemical is not harmful to zebra fish (*Brachydanio rerio*)
TEST FACILITY	RCC (2000z)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – 48-hour static test. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – 48-Hour Immobilisation test – 48-hour static test.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks - Method	No significant protocol deviations

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	0	20	0	0
100	102 - 104	20	0	0

E_iC50	>100 mg/L at 48 hours
NOE_iC	100 mg/L at 48 hours
Remarks - Results	During the test period, the test substance concentration in the duplicate samples from the start and the end of the test was measured to be 102 and 104% of the nominal value. Under the test conditions, the test substance was stable during the test period of 48 h. Therefore, all reported results are related to the nominal concentration of the test substance. No remarkable observations were made concerning the appearance of the test medium. The test medium was a coloured solution throughout the whole test duration. All test validity criteria were satisfied.
CONCLUSION	The notified chemical is not harmful to *Daphnia magna*.
TEST FACILITY	RCC (2000aa)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Scenedesmus subspicatus* CHODAT
Exposure Period	72 hours
Concentration Range Nominal	1.0, 3.2, 10, 32 and 100 mg/L
Auxiliary Solvent	None
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks - Method	The test method was modified to quantify the algicidal effect of the test item (Experiment A) and the growth inhibition effect caused by reduced

light intensities in the coloured test solutions (Experiment B). The test was performed in buffered test medium to keep the pH of the test media constant during the test period. No significant protocol deviations.

RESULTS

Experiment	*Biomass*		*Growth*	
	E_bC_{50} *mg/L at 72 h*	NOE_bC *mg/L*	E_rC_{50} *mg/L at 72 h*	NOE_rC *mg/L*
A	38 (95% CI: 23 - 77)	3.2	>100	3.2
B	28 (95% CI: 14 - 70)	3.2	>100	3.2

Remarks - Results

The analytically determined test item concentrations in the analysed test media varied in the range from 97 to 105% of the nominal value. The test substance was stable in the test media under the test conditions during the test period of 72 h. Therefore, the reported biological results are based on the nominal concentration.

This modified algal test has demonstrated that the observed growth inhibition effect of the test item on *Scenedesmus subspicatus* was caused only by an indirect effect, the light filter effect in the coloured test solutions. Thus a toxic effect of the test item on the algal cells can be excluded up to the highest test concentration of 100 mg/L.

CONCLUSION The notified substance had no toxic effect on the algae up to 100 mg/L.

TEST FACILITY RCC (2000ab)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE Notified chemical

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

Inoculum Aerobic activated sludge from wastewater treatment plant
Exposure Period 3 hours
Concentration Range Nominal 10 – 1000 mg/L
Remarks – Method No significant protocol deviations

RESULTS

IC50 > 1000 mg/L
NOEC 1000 mg/L
Remarks – Results All test validity criteria were satisfied.

CONCLUSION The notified substance had no toxic effect on the bacteria up to 1000 mg/L.

TEST FACILITY RCC (2000ac)

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