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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Chemical in Acid Red HT 3728

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Chemical in Acid Red HT 3728

1. APPLICANT

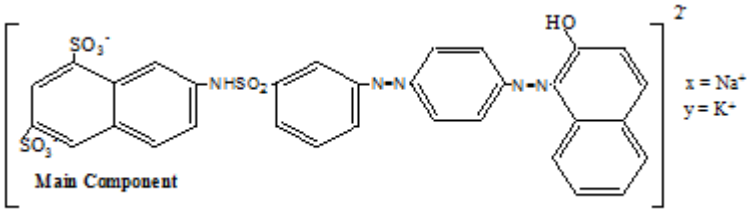
Ciba Specialty Chemicals Pty Ltd of 235 Settlement Road THOMASTOWN VIC 3074 has submitted a standard notification statement in support of their application for an assessment certificate for Chemical in Acid Red HT 3728.

There is no exempt information claimed by the notifier.

2. IDENTITY OF THE CHEMICAL

Chemical Name:	1,3-Naphthalenedisulfonic acid, 7-[[[3-[[4-[(2-hydroxy-1-naphthalenyl)azo]phenyl]azo]phenyl]sulfonyl]amino-, potassium sodium salt
Chemical Abstracts Service (CAS) Registry No.:	141880-36-6
Other Names:	Acid Red HT 3728 FAT 45155/B
Marketing Name:	Erionyl Red A-3G (containing 80% Acid Red HT 3728 or 43.4% notified chemical); or Neolan Red A-G (containing 27.8% Acid Red HT 3728 or 15.1% notified chemical)
Molecular Formula:	$C_{32}H_{23}N_5O_9S_3.xNa.yK$

Structural Formula:



Molecular Weight: 717.8 (main component)

The composition of Acid Red HT 3728 containing the notified chemical is as follows:

Chemical Name	*CAS No.*	*Weight %*
Acid Red HT 3728	141880-36-6	54.2
Known coloured by-products	Not known	6.1
Unknown coloured by-products	Not known	4.4
Known uncoloured by-products	Not known	0.9
Unknown uncoloured by-products	Not known	0.4
Sodium sulphate	7757-82-6	1.8
Sodium chloride	7647-14-5	25.5
Potassium sulphate	7778-80-5	0.1
Potassium chloride	7447-40-7	0.9
Water	7732-18-5	6.2
Unsulphonated primary aromatic amine	Not known	20mg/kg

Method of Detection and Determination: Ultra-violet (UV), Infra-Red (IR) and Nuclear Magnetic Resonance (NMR) ^{1}H and ^{13}C

Spectral Data:

Comments on Chemical Identity-

The notified chemical is a complex reaction product containing approximately 54% of the main chemical component identified using UV, IR and NMR. The remainder consists of unreacted starting materials, colored and uncolored by-products, and salts.

3. PHYSICAL AND CHEMICAL PROPERTIES

The properties below are that of Acid Red HT 3728 containing 54% notified chemical.

Appearance at 20°C and 101.3 kPa: Black green powder

Melting Point: >298.8°C

Specific Gravity: 1.74 at 23°C

Vapour Pressure: 1 x 10^{-5} kPa at 20°C

Water Solubility: >48 g/L at 20°C

Partition Co-efficient (n-octanol/water): log P_{ow} < -1.14

Hydrolysis as a Function of pH:	$T_{1/2}$ at pH 4.0: > 1 year at 25°C $T_{1/2}$ at pH 7.0: > 1 year at 25°C $T_{1/2}$ at pH 9.0: > 1 year at 25°C Hydrolysis at pH 4.0: <10% at 50°C Hydrolysis at pH 7.0: <10% at 50°C Hydrolysis at pH 9.0: <10% at 50°C
Adsorption/Desorption:	Not determined
Dissociation Constant:	Acidic 1: pK_a 8.02 Acidic 2: pK_a 11.97 Sulphonic 2 x SO_3^- pKa -2.5 to -3.0 (see comments below)
Particle Size:	>40µm = 98% >63µm = 96% >100µm = 94% >200µm = 81% >315µm = 58% >400µm = 51% >800µm = 12% >1 000µm = 1% Median mass diameter = 410µm
Flammability Limits:	Not highly flammable. The substance can be ignited, but the flame does not spread (European Economic Community, 1984)
Autoignition Temperature:	365°C (European Economic Community, 1984)
Explosive Properties:	Not explosive.
Reactivity/Stability:	Not reactive Thermally stable
Surface Tension:	61.5 – 61.7 mN/m at 10g/L and 20°C
Fat Solubility:	>0.1mg/100g fat at 37°C
Fixation Rate:	>95 % on wool 97% on nylon

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines at facilities complying with OECD Principles of Good Laboratory Practice.

The partition coefficient was determined using the shake flask method. A preliminary estimation of the partition coefficient, using the CLOGP computer program, indicated a log P_{ow} value of - 2.01.

Adsorption/desorption coefficient results were not determined. However, the low K_{ow}, high water solubility and the absence of positive binding sites on the notified chemical suggests that the ability of the notified chemical to bind to soil oxides, aluminosilicate minerals and organic matter would be low. Oxides and aluminosilicate minerals may possess pH dependent charge and whilst anion sorption is likely to increase as soil pH decreases, it will remain low (relative to cation sorption) over the environmentally relevant pH range.

The notified chemical has two acidic aromatic SO_3 groups and one phenolic OH group. The strongly acidic SO_3 groups will render the molecule negatively charged over the environmentally relevant pH range.

The notified chemical is not expected to be surface active. By definition, a chemical has surface activity when the surface tension is less than 60 mN/m (European Economic Community, 1992). It has a very low fat solubility.

4. PURITY OF THE CHEMICAL

Degree of Purity: 95% (90 - 100% range) of the notified chemical, comprising approximately 54% main component

Impurities (including isomers and by products):

Chemical Name	*CAS No.*	*Weight %*
Known coloured by-products	Not known	6.1
Unknown coloured by-products	Not known	4.4
Known uncoloured by-products	Not known	0.9
Unknown uncoloured by-products	Not known	0.4
Sodium sulphate	7757-82-6	1.8
Sodium chloride	7647-14-5	25.5
Potassium sulphate	7778-80-5	0.1
Potassium chloride	7447-40-7	0.9
Water	7732-18-5	6.2
Unsulphonated primary aromatic amine	Not known	20mg/kg

Additives/Adjuvants: None in the notified chemical. Additives and adjuvants such as stabilising agents, inhibitors and anti-dusting agents are included only in the commercial version of the dyestuff, not in the notified chemical itself.

5. USE, VOLUME AND FORMULATION

Acid Red HT 3728 containing 54% notified chemical will not be manufactured in Australia. It will be imported as a component of commercial dye products Neolan Red A-G and Erionyl Red A-3G containing 15% and 43% notified chemical, respectively. Both products will be sold for use in colouring textile fibres by exhaust dyeing methods. The dyes will be used in dyehouses only. The notifier has submitted evidence to show that the dye has a fixation performance of 98% to nylon.

The dyestuff will be imported in a ready-to-sell packages in 30 kg polylined cardboard. Most imported dye will be sold as received, although a small proportion may be repacked into smaller containers for use in mill trials. Repacking will take place at the notifier's facility.

Import volumes for the commercial dye containing the notified chemical are expected to be as follows:

Year	Tonnes
1	0.5 - 1
2	1 – 2
3	1 – 3
4	1 – 3
5	1 – 3

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported in a non-dusting formulation with particle size range approximately 200 - 800µm (mean 410µm). Approximately 20% of particles will be <200µm (inspirable) and 2% <40µm. The dyestuff will be dissolved in water to produce dye solutions containing 0.108% (max) notified chemical. The potential routes of exposure to the dyestuff will be skin contact (both in dry and wet form) and inhalation of fine particles. Workers who will handle the notified chemical include transport workers, dyehouse workers and storemen.

Transport and storage
No details of the numbers of workers exposed to the notified chemical during these activities were given. The notifier indicated that these workers could be exposed to the notified chemical in the case of an accident where the packaging was breached.

Repackaging
The notifier estimates that less than 100 kg of the notified chemical will be repackaged into smaller containers at the notifier's site per year. The notifier's site has facilities for safe handling of hazardous substances. Two workers will be exposed to the imported powder for

approximately 15 to 20 minutes per day, ten days per year. The worker exposure during this process will be by skin contact and possible inhalation of the fine powder. In the down-flow booth where dyes are repacked, the airflow is away from operators and the capture velocity for particulates is exceeded to minimise the exposure. The repack operators are trained in the handling of hazardous substances.

The notifier indicates that respiratory protection with P2 filters would normally be used during this process. The Material Safety Data Sheet (MSDS) indicates that a dust mask should be used in conjunction with local exhaust ventilation and a half facemask in the absence of local exhaust ventilation.

Use in Dyehouses
The commercial products containing the notified chemical are distributed from the notifier's warehouse to four dyehouses. The notifier states that the notified chemical will be handled 125 days per year. The notifier estimates that 144 workers throughout Australia will be exposed to the notified chemical during the following activities:

Weighing and mixing
At each dyehouse, 12 workers will be involved in weighing (2/shift, 2 shifts/day) and mixing (6/shift) the dyes. The dyestuff (2-5 kg lots) is manually scooped from the 30 kg containers into a sealable weighing vessel, and charged to a mixing vessel. The dye is dissolved in 2 000 L of water with slow mechanical stirring at 90 – 99ºC.

Workers may be exposed to the notified chemical during weighing and mixing of the powdered dyestuff and during disposal of empty used liner bags. Skin contact, eye contact and inhalation are the main routes of exposure to the product.

Dust formation is minimised through the use of local exhaust ventilation over weighing and blending vessels. Also, batch weigh-men and operators receive induction training and refresher courses on the handling of the notified chemical.

The notifier stated that as part of existing practices, operators are required to wear overalls, protective gloves, glasses and respiratory protection (Class P2 particulate filter) when weighing and handling the products.

Once the dye product is dissolved, it is metered from the mixing vessel using a metering pump, to the enclosed dyeing machine. Potential for skin contact with the product at <0.25% (w/v) in solution (<0.038 – 0.108% notified chemical) may occur during mixing, while the operators connect/disconnect metering pump hoses from the mixing vessel to the dyeing machine, during clean up operations and maintenance of equipment. Inhalation exposure to the dissolved dye is considered negligible because the chemical is not volatile, and any aerosol formation during mixing would be controlled through the use of enclosed systems.

The notifier provided a worker exposure estimate to the notified chemical during weighing. There are two shifts per day. The first shift worker weighs twice in his/her shift period. The first weighing is consumed during the first shift and the remaining amount will be used in the duration of the next shift. Assuming a total quantity of 8 kg of product is weighed each day, the notifier calculated that the airborne concentration of the notified chemical would be 2.36 mg/m^3. This value was used to estimate a daily exposure level of 0.30 mg by incorporating the percent concentration of the notified chemical in the weighed product, volume or air

inhaled and exposure duration during weighing. Assuming 125 days weighing/year, 40 years work and 70 years life expectancy, the average daily lifetime exposure would be 0.00084 mg/kg/day for a 70 kg worker and the average daily inhalation exposure is 0.0043 mg/kg/day. This represents inhalation exposure only and does not account for any skin contamination and absorption. The values used in the estimation are taken from a US monitoring study and using US-EPA methodology (reference not provided). The rationale for the calculation of the airborne concentration of the notified chemical is not provided.

Dyeing
It is estimated that four workers will operate the dyeing machine each shift (2 shifts/day). These workers may be exposed to the notified chemical at 0.038 – 0.108% during dyeing, mainly via the dermal route when handling wet dyed textiles or by eye contact through contaminated hands. Inhalation exposure is negligible since aerosols are contained within the enclosed dyeing system.

The cloth to be dyed is manually loaded and cycled through the machine via a winch and roller system. Any unfixed dye is removed from the textile by a cold rinse bath.

Manual handling of the wet dyed textiles may be required if the cloth becomes tangled, which presents potential for short-term exposure to the notified chemical mainly by skin contact. Given the anticipated low concentration of the notified chemical, the high fixation rate and the use of personal protective equipment, worker exposure is expected be low.

Dermal exposure to low concentrations of notified chemical may also occur if the dyeing machine has to be opened in case of malfunction and clean up activities.

Drying /Curing
It is estimated that 4 workers/site/shift will be exposed to the notified chemical during drying/curing activities. Minimal handling of the wet textile is expected, since mechanically operated winches are used to remove the textiles from the dyeing machine. Moisture is removed from the wet textile by hydroextraction and the textiles are dried through a stenter at 120-140°C. This operation is conducted in a partly enclosed system and operators will be briefly exposed to low concentrations of notified chemical, mainly by skin contact, as they transfer the textiles from the hydro-extractor to the stenter. However, gloves and safety goggles are worn during this operation.

Although not detailed by the notifier, operators may also be exposed to low concentrations of notified chemical when handling dry textiles, for example during reeling and packaging. If the chemical is effectively fixed and dried, this source of exposure should not be significant.

Laboratory
It is estimated that two laboratory technicians at each dyehouse will be involved in the preparation of colour matches, which entail the weighing and mixing of small samples of dye. Exposure to the particulate or dissolved notified chemical during these operations may occur via the dermal, ocular or inhalation routes, but is expected to be low given the small quantities handled, the engineering control measures in place and the use of personal protective equipment.

7. PUBLIC EXPOSURE

Exposure of the general public to the notified chemical is expected to be minimal since the chemical is not available for retail use. The public will only come into contact with the notified chemical in finished articles made from dyed wool and nylon fibres. At this stage the chemical is fixed to the fibres. Once fixed, the notified chemical would not be available for separate exposure. In addition, the fastness to washing and dry cleaning is high hence there would be negligible residues on the dyed textiles.

In case of accidental spill, releases should be damped down to prevent dust, and spills should be scooped into chemical waste containers for disposal by incineration.

8. ENVIRONMENTAL EXPOSURE

Release

The commercial dyestuff containing the notified chemical will be used in four dyehouses in both city and country locations. The notifier claims that the commercial dyestuff has an estimated fixation rate of 95% on wool and 97% on nylon. This fixation rate was determined through an inhouse fixation and fastness test of the commercial dye product containing the notified chemical. The majority of the dye will become chemically fixed to the fibres of the fabric. Approximately 5% of dye will remain unfixed and will be released to the aquatic environment.

Generation of waste is also expected to result from spillage during repackaging, transfer, and as residues in containers. This is estimated to be up to 2%. Empty transport containers will be disposed of to landfill. All spilled, dry dye products will be disposed of to the sewer. Fibres collected from the in-house water treatment plant will be disposed of to secure landfill or by incineration. Expected products of incineration include carbon, nitrogen and sulfur oxides. There may also be acidic sulfur combustion products.

There is also potential for accidental release during transport. Such spills involving small pack sizes and chemicals in powdered form are usually readily contained and cleaned up. Dyed products, ex-factory, may also release dyes during regular washing by consumers. The amount of dye which may be released via this route has not been addressed but would be expected to be low and diffuse.

Fate

The majority of the unfixed dye is expected to enter the aquatic compartment through

discharge of dye mill effluents. The ability of the notified chemical to adsorb to charged surfaces is not known. However, given the absence of positive binding sites on the chemical, the high water solubility and the low K_{ow}, the chemical is unlikely to strongly sorb to soils or effluent sludge. This is confirmed by the modified Zahn-Wellens test described below. The majority of the dye is expected to remain in solution as the notifier expects bioelimination to be close to zero. Dye effluent will ultimately enter the aquatic compartment. The notified chemical is unlikely to bioaccumulate due to its high molecular weight, high water solubility, low K_{ow} and low fat solubility. Once in the aquatic environment, the chemical is expected to swiftly dilute to low concentrations, and ultimately undergo biotic and abiotic degradation.

Ready Biodegradability of the notified chemical was tested according to the modified AFNOR test (OECD TG 301A). Two deviations occurred, (1) determination of bacterial concentration was determined by plating and (2) the inoculum, consisting of a mixture of polyvalent bacteria, was sourced from effluent of a domestic sewage treatment plant. The biodegradation of the notified chemical after 28 days was measured as 0% indicating that the notified chemical is not readily biodegradable. There appeared to be no inhibition of the bacteria in this test.

Inherent biodegradability was determined using the modified Zahn-Wellens test (OECD TG 302B). Bioelimination of both the test and a reference substance (diethyleneglycol) were determined. Test concentrations for both substances were 150 mg/L DOC (dissolved organic carbon) nominal. The bioelimination of the test substance, after 28 days, corrected by a blank control, was 12.2%. Adsorption after 3 hours was 9.2%. Bioelimination of the reference substance was 100% at day 13.

9. EVALUATION OF TOXICOLOGICAL DATA

Tests were performed according to OECD test guidelines (Organisation for Economic Co-operation and Development, 1995-1996) at facilities complying with OECD Principles of Good Laboratory Practice.

All toxicity studies were conducted on Acid Red HT 3728 (FAT 45' 155/B) containing 50 – 60% notified chemical.

9.1 Acute Toxicity

Summary of the acute toxicity of Acid Red HT 3728 (FAT 45' 155/B).

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	Rat	LD50 > 2000 mg/kg	(Hartmann HR, 1992b)
acute dermal toxicity	Rat	LD50 > 2000 mg/kg	(Hartmann HR, 1992a)
skin irritation	Rabbit	non-irritant	(Hagemann C, 1992a)
eye irritation	Rabbit	non-irritant	(Hagemann C, 1992b)
skin sensitisation	Guinea pig	extreme sensitiser	(Hagemann C, 1993)

9.1.1 Oral Toxicity (Hartmann HR, 1992b)

Species/strain:	rat/albino Tif:RAI f
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	single oral dose (gavage); 2000 mg/kg in distilled water
Test method:	OECD TG 401
Mortality:	No mortalities occurred.
Clinical observations:	Piloerection, hunched posture and dyspnoea were seen but considered normal symptoms in acute studies; reduced locomotor activity was observed in all animals; all animals recovered within 6 days.
Morphological findings:	At autopsy, a spotted thymus was found in 4 males, in one animal the thymus was involuted and there was a spotted liver.
LD_{50}:	> 2000 mg/kg
Result:	The test substance was of very low acute oral toxicity in rats.

9.1.2 Dermal Toxicity (Hartmann HR, 1992a)

Species/strain:	rat/albino Tif:RAI f
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	semi-occlusive dressing; test material removed after 24 hours
Test method:	OECD TG 402
Mortality:	No mortalities occurred in the study.
Clinical observations:	Piloerection, hunched posture and dyspnoea were seen but considered normal symptoms in acute studies; at the application site, erythema was observed until day 7 in the males and day 9 in the females; females developed necrosis; all animals recovered within 10 days.
Morphological findings:	No abnormalities were noted at necropsy.
LD_{50}:	> 2000 mg/kg
Result:	The test substance was of low dermal toxicity in rats.

9.1.3 Inhalation Toxicity

The notifier stated inhalation exposure may be excluded based on the particle size distribution of final sales form. The notified substance is a powder with a small respirable and inspirable fraction and the incorporation of an antidusting compound will reduce occurrence of workplace air contamination.

9.1.4 Skin Irritation (Hagemann C, 1992a)

Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	3 females
Observation period:	7 days

Method of administration:	0.5 g of test material was applied on moistened patches to an area of 36 cm^2 on the right flank of animals and a control gauze patch was applied to the contralateral flank; patches were held in place by adhesive tape for 4 hours
Test method:	OECD TG 404
Comment:	The application area was red-stained because of the test material but this disappeared by 48 hours; no oedema formation was noted over the 7 day observation period.
Result:	The test substance was non-irritating to the skin of rabbits.

9.1.5 Eye Irritation (Hagemann C, 1992b)

Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	2 males, 1 female
Observation period:	7 days
Method of administration:	0.1 mL (91 mg) of test material was placed into the conjunctival sac of the left eye of each animal and lids were held together for about 1 second; the left eye served as control
Test method:	OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation											
Animal	***1 hour***			***1 days***			***2 days***			***3 days***		
Cornea	***o***		***a***	***o***		***a***	***o***		***a***	***o***		***a***
1	[1]0			0			0			0		
2	0			0			0			0		
3	0			0			0			0		
Iris												
1	1			0			0			0		
2	0			0			0			0		
3	0			0			0			0		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	2	2		1	0		1	0		1	0	
2	2	2		1	1		1	0		1	0	
3	2	2		2	1		1	0		1	0	

[1] see Attachment 1 for Draize scales
o = opacity a = area r = redness c = chemosis d = discharge

Comment: Because reactions were observed at 72 hours, the observation period was extended to 7 days, by which time all reactions had reversed.

Result: Mean scores:
corneal opacity: 0, 0, 0
iris lesions: 0, 0, 0
conjunctival redness: 1, 1, 1.33
conjunctival chemosis: 0, 0.33, 0.33

the mean scores are below the threshold for classification as an eye irritant and all conjunctival lesions resolved by day 7; therefore, the notified chemical can be considered as a slight irritant to the eyes of rabbits

9.1.6 Skin Sensitisation (Hagemann C, 1993)

Species/strain: Guinea pig/albino Pirbright White Strain

Number of animals: 10/sex in test group; 5/sex in control group

Induction procedure:	Intradermal induction: injection of 1% test material in saline (injection of 3% and 5% in the pretest induced necrosis at the injection site) Epidermal induction: application of 30% test material in vaseline (highest applicable concentration) – no skin initiation observed although evaluation was hindered by colour of test substance
Challenge procedure:	Epidermal challenge: application of 30% test material in vaseline
Test method:	OECD TG 406; Magnusson and Kligman Maximization test
Observations and findings:	The evaluation of erythema was hindered by the colour of the red test material. Therefore microscopic examination of the skin of all test and control animals was conducted. When compared to the tissues of control animals and to the remote site in treated animals, the application site of all treated animals showed prominent changes indicative of an allergic skin reaction. Histologically, the following features were noted: • a minimal to moderate spongiosis (without prominent presence of blister-formation; • a minimal to moderate congestion in the upper dermis; • a minimal to moderate acanthosis with minimal to moderate hyper- and parakeratosis and a minimal to marked lymphohistiocytic infiltration predominantly to the upper dermis, in some animals with invasion to the dermis; • two animals showed additional pustules with cell debris in the epidermis; • in some animals there was a minimal lymphohistiocytic infiltration also in the subcutaneous tissue, mostly located around blood vessels. One test animal showed similar, minimal focal changes at the remote site, localised at the margin of the sample; thus, the test material was assumed to have spread beyond the testing site during the application. There were no signs of irritation at either the application or remote site.
Comment:	Although the Draize scores were zero, due to the difficulty in assessing erythema with a red test material, the

	microscopic examinations demonstrated that strong skin reactions occurred in all test animals at challenge.
Result:	The test substance was extremely sensitising to the skin of guinea pigs.

9.2 28-Day Repeated Dose Oral Toxicity (Gerspach R, 1993)

Species/strain:	rat/albino (Sprague-Dawley derived)
Number/sex of animals:	5/sex/group plus additional 5/sex/group for controls and 1 000 mg/kg/d (recovery groups)
Method of administration:	Oral (gavage) in distilled water (vehicle)
Dose/Study duration:	0, 50, 200 and 1 000 mg/kg/d, 7 days/week for 4 weeks
Test method:	OECD TG 407
Clinical observations:	No mortality occurred during the study. Reddish discolouration of faeces was noted in animals treated at 200 and 1 000 mg/kg/d. No other treatment-related findings were reported. Overall food consumption in males was considered normal but it was slightly decreased in females.

Clinical chemistry/Haematology:

Biochemistry

All 1000 mg/kg/d animals had a marked bilirubin increase with females at 200 mg/kg/d also showing a moderate increase. At 1 000 mg/kg/d, males had elevated glucose and cholesterol concentrations, and potassium levels were slightly elevated in both sexes. These were the only findings considered to be treatment-related and all parameters returned to normal during the 4-week recovery period.

Hematology

Both sexes revealed signs of normochromic anaemia, consisting of reduced red blood cell indices, haemoglobin, and haematocrit for the 200 and 1 000 mg/kg/d groups. In the latter group, this was associated with an increased number of reticulocytes which is a sign of effective erythropoietic activity in response to anaemia. Additionally, females of these two groups had macrocytosis (elevated mean cell volume). High-dose animals had increased platelet counts. All hematological effects returned to normal within the 4-week recovery period.

Urinalysis:

Animals in the 200 and 1000 mg/kg/d groups excreted discoloured urine during the treatment period. This effect was reversible within the recovery period.

Pathology

Organ weights:

In 1000 mg/kg/d males, absolute/relative mean weights of liver and kidneys were significantly increased by 20%/13% and 23%/16%, respectively, compared with controls. Even after 4 weeks recovery, values were still elevated at 5%/7% and 8%/10%, respectively. Slight increases in absolute adrenal and testes weights were noted in males at 1 000 mg/kg/d; however, the relative weights were similar to control values.

Macroscopic examination:

There were no treatment-related macroscopic findings.

Histopathology:

Microscopically, treatment-related findings were restricted to the spleen where an increased incidence and severity of congestion, and an increased severity of haemosiderosis was found in both sexes at 200 and 1 000 mg/kg/d. After the treatment-free recovery period, splenic haemosiderosis remained in the 1 000 mg/kg/d group (both sexes).

All other microscopic changes found in this study were considered to be incidental and unrelated to treatment. No effects on the liver and kidney were observed.

Comment:

Under the conditions of the study, treatment with the notified chemical did not produce mortality, and clinical observations were confined to discoloured faeces in both sexes at 200 and 1 000 mg/kg/d.

The principal effect observed was the dose-related incidence of congestion and haemosiderosis of the spleen, observed in both sexes. Together with the significantly increased plasma bilirubin levels, these effects were consistent with the anaemia observed in the haematological tests, viz. decreased red cell, haemoglobin and haematocrit values. The changes in bilirubin level and haematological parameters were reversible.

Increases in relative liver weight, kidney weight and elevated blood cholesterol are suggestive of generalised toxicity; however, no corresponding microscopic changes were observed. The increase in cholesterol concentration was reversible; however, the relative liver and kidney weight increases were only partially reversed in the 4-week recovery period.

Result: Based on the increased incidence of splenic effects at 200 and 1 000 mg/kg/d, the no observed effect level (NOEL) is 50 mg/kg/d in this study.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay (Deparade E, 1992)

Strains:	*Salmonella typhimurium*: TA98, TA100, TA1535, TA1537, TA1538 *Escherichia coli*: WP2*uvr*A$^-$
Concentration range:	0, 61, 185, 555,1666 and 5000 μg/plate each concentration was tested in triplicate, with or without metabolic activation, in two independent experiments; appropriate strain specific positive control reference substances were used
Metabolic activation:	liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Test method:	OECD TG 471, 472
Comment:	Test material was dissolved in double-distilled water. There were no signs of toxicity of the test material to the bacterial strains up to the highest test concentration of 5 000 μg/plate. No significant increases in revertant colony numbers at any concentration, in the presence or absence of metabolic activation were noted. Concurrent positive controls used in the test induced marked increases in the frequency of revertant colonies and the activity of the S9 fraction was found to be satisfactory.
Result:	The test substance was non mutagenic in the bacterial strains tested under the conditions of the study.

9.3.2 Chromosomal Aberration Assay in Chinese hamster ovary cells *in vitro* (Hertner T, 1992)

Cells: Chinese hamster ovary cells

Metabolic activation system: Liver fraction (S9 mix) from rats pretreated with Aroclor 1254

Dosing schedule: The test substance was dissolved in double distilled water and tested in duplicate cultures in three independent experiments with or without metabolic activation.

The experimental design and concentrations tested are represented in the table below.

Metabolic Activation	• Experiment/ Study	Test concentration (µg/mL)	Controls
-S9	Experiment 1 Confirmatory Study1 Confirmatory Study 2	treatment time = 18 hours 39.06, 78.13 and 156 µg/mL treatment time = 18 hours 39.06, 78.13 and 156.25 µg/mL treatment time = 42 hours 78.13, 156.25 and 312.5 µg/mL	Positive: Mytomycin C (MMC) – 0.2 µg/mL Negative: Bidistilled water
+S9	Experiment 1 Confirmatory Study 1 Confirmatory Study 2	treatment/harvest time = 3/18 hours 78.13, 156.25 and 312.5 µg/mL treatment/harvest time = 3/18 hours 78.13, 156.25 and 312.5 µg/mL treatment/harvest time = 3/42 hours 156.25, 312.5 and 625 µg/mL	Positive: cyclophosphamide - 20 µg/mL Negative: Bidistilled water

Test method: OECD TG 473

Comment: In both original experiments there were slight, but statistically significant increases at the two highest concentrations because negative controls had 0% aberrant cells. However, this effect was considered to have no biological significance as the frequency of aberrations was well below the level required for a positive response. In the confirmatory tests, no significant increases in the number of cells with chromosomal aberrations were observed.

Positive controls used in the test caused marked increases in

	the incidence of aberrant cells and the activity of the S9 fraction was found to be satisfactory.
Result:	The test substance was non-clastogenic under the conditions of the study.

9.4 Overall Assessment of Toxicological Data

In acute studies in rats the test substance Acid Red HT 3728 (containing 54% notified chemical) was of very low oral toxicity and low dermal toxicity (LD_{50}>2000 mg/kg). In rabbits, it was not considered as a skin irritant but was slightly irritant to the eyes. Although the latter study described transient redness and chemosis of the conjunctiva during the observation period, there was resolution over 7 days and the mean scores were below the threshold for classification.

The Magnusson and Kligman Maximization test provided histological evidence that Acid Red HT 3728 is an extreme sensitizer, as valid visual reading could not be made.

In a 28-day repeated dose oral study, the principal effect observed was a dose-related incidence of congestion and haemosiderosis of the spleen, in both sexes at 200 and 1 000 mg/kg/d. Increases in relative liver weight, kidney weight and elevated blood cholesterol are suggestive of generalised toxicity; however, no corresponding microscopic changes were observed. The increase in cholesterol concentration was reversible; however, the relative liver and kidney weight increases were only partially reversed in the 4-week recovery period. Based on the increased incidence of splenic effects, the NOEL for the study was 50 mg/kg/d.

There was no evidence of genotoxic activity by the notified chemical following negative results in bacterial mutagenicity assays and a mammalian cell chromosomal aberration assay *in vitro*.

Based on the data provided and specifically the results of the skin sensitisation study, Acid Red HT 3728 is classified as a "Sensitiser (Xn)" according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational health and Safety Commission, 1999) with the relevant risk phrase "R43 May Cause Sensitisation By Skin Contact".

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were carried out according to OECD test methods and according to OECD Principles of Good Laboratory Practices.

Table 1: Summary of Ecotoxicity Test Results

Test	***Species***	***Nominal Test Concentrations (mg/L)***	***Results (mg/L)***
acute toxicity (static test) (OECD TG 203)	zebra fish *(Brachydanio rerio)*	17.8, 32.0, 56.0, 100.0, 178.0, 316.0	96 h LC_{50}: 79 NOEC: 35
acute toxicity – immobilisation (semi-static test) (OECD TG 202)	water flea *(Daphnia magna)*	10.0, 18.0, 32.0, 58.0, 100.0, 180.0 L	48 h EC_{50}: 28.1 NOEC:< 11.0
Acute toxicity (14 days)	Earthworm *(Eisenia foetida)*	0.1, 1.0, 10.0, 100.0, 1000.0 (mg/kg)	EC_{50}: >1000 (mg/kg)
growth inhibition - (OECD TG 201)	green algae *(Scenedesmus subspicatus)*	4.6, 10.0, 21.4, 46.3	E_RC_{50}: 46.9 E_BC_{50}: 19.3 NOEC: 4.6
respiration inhibition (OECD TG 209)	activated sludge-aerobic waste water bacteria	10, 32, 100, 320 (test substance)	IC_{50} test substance: >320 mg/L
		3.2, 10, 32 (reference substance)	IC_{50} reference substance: 10.5 mg/L

[a]All reported results are based on nominal concentrations.

Fish (Bottcher J, 1993)
The acute toxicity of the notified chemical to Zebra fish, *Brachydanio rerio,* was determined in a 96h static test (OECD TG 203). The reported results are related to the analytical concentrations of the test article. The test substance concentrations in the test media were in the range of 101 and 113% of the nominal values. In the control and the two lowest test concentrations (actual means 19 and 35 mg/L), no mortalities or abnormal symptoms were observed. After 96h at 59 mg/L (actual) there was 20% mortality but at 105 mg/L (actual), 80% mortality and moderate changes in the swimming behaviour of fish were observed. At 192 mg/L (actual mean), 100% mortality was observed. The LC_{50} was ascertained using the Spearmann-Kärber Method.

Aquatic Invertebrates (Matzler P, 1992)
The acute toxicity of the notified chemical to *Daphnia magna* was determined in a 48 hour static test in accordance with OECD guidelines TG 202. The report indicated that the EC_{50} (28.1 mg/L) was calculated directly from the test results rather than through Probit analysis (not available). From the test results, 30% of the daphnia were immobilised at 10 mg/L, 40% at 18 mg/L, 65% at 32 mg/L and 100% at 58 mg/L. Therefore it can be confirmed that the EC_{50} lies between 18 and 32 mg/L. The reproduction part of the test was not conducted. This is acceptable because of the slight toxicity of the notified chemical, and the large safety margin (see below).

Algae (Memmert U & Knoch E, 1992)
The influence of the notified chemical on the growth (biomass and growth rate) of the green alga *Scenedesmus subspicatus* was investigated in a 72 h static test (OECD TG 201). The report indicated that all test media, even the lowest concentrations, were colored by the test substance and that the toxic effect was due to reduced light quality and intensity rather than the notified chemical *per se*. However, these results still indicate the notified chemical has a toxic effect on algal growth regardless of whether this toxicity is direct or indirect. It should also be noted that solution pH greatly increased during the course of the experiment. This was evident for both the control and the lowest test concentrations (4.6 and 10 ppm). The stability of pH at higher concentrations suggests that the test substance acts either directly or indirectly as a photosynthetic inhibitor.

Microorganisms (Dietschy A, 1992a)
An activated sludge respiration inhibition test (OECD TG 209) was conducted using the notified chemical and compared with a known sludge inhibitor (3,5-dichlorophenol). The respiration rate of each test concentration was calculated and plotted on a logarithmic graph. The IC_{50} for the notified chemical was reported to be >320 mg/L because inhibition did not reach the 50% level. However, the results indicated that bacterial respiration inhibition was evident at the lowest concentration (4.4% at 10 ppm). Inhibition increased to 40% at 100 ppm, then declined to 31% at 320 mg/L.

Earthworms (Dietschy A, 1992b)
The acute toxicity of the notified chemical to earthworms was tested according to OECD (TG 207). In all test concentrations, body weights of surviving worms decreased slightly due to starvation during the test period. No behavioural abnormalities could be observed. During the course of the experiment, two of 60 test animals died. These mortalities were declared to be unrelated to the presence of the notified chemical. The EC_{50}could not be determined because mortality did not reach 50%. It was estimated, therefore, that the EC_{50} would be greater than 1000 mg/kg of artificial soil.

Conclusion

From the test results summarised above, it can be concluded that the notified chemical is slightly toxic to fish, aquatic invertebrates, algae and very slightly toxic to microorganisms and earthworms.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard presented by the importation and use of the dyestuff containing the notified substance is expected to be low. The product will be used at a limited number of dyehouse sites in Australia. The majority of the dye will become chemically fixed to the fibres of the fabric and in this state is not expected to impact on the environment. The major environmental exposure to the substance will come from the effluent discharge from dyehouses and waste water treatment systems.

Predicted Environmental Concentration (PEC) calculations for release of the notified chemical from the textile mill in effluent and from a rural sewage treatment plant after further dilution. These calculations assume that a 5% of the dye batch is released as effluent from the textile mill and represents a worst case scenario.

Calculation Factor	*City Dyehouse*	*Country Dyehouse*
Typical use of dyestuff containing notified chemical	8 kg/day	8 kg/day
Quantity of notified chemical in dyestuff	2.24 kg	2.24 kg
Fixation rate	95%	95%
Quantity of dyestuff unfixed	0.112 kg	0.112 kg
Mill effluent	1000000 L	1000000 L
Chemical concentration in mill wastewater	0.112 mg/L	0.112 mg/L
Dilution rate in STP	1:250	1:50
Chemical concentration in STP	0.448 µg/L	2.24 µg/L
Degree of bioelimination adsorption to sludge	0%	0%
Dilution factor in receiving waters	1:10	1:2
Predicted Environmental Concentration	0.05 µg/L	1.12 µg/L
Most sensitive aquatic organism - Alga for biomass	19.3 mg/L	19.3 mg/L

Safety Margin	386,000	17,232

Note: the dilution factors above may vary from the actual dilution levels achieved in the Sewage Treatment Plant and receiving waters. Therefore, the PEC may vary from the value calculated above. The daily usage rate has been provided by the notifier and is likely to be less than the 1 000 kg cited.

Predicted environmental concentration calculations indicate that the exposure to fish, aquatic invertebrates, algae and wastewater treatment microorganisms will be at levels unlikely to cause significant effect. Swift dilution will further reduce environmental concentrations. The chemical is not expected to bioaccumulate.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical in Acid Red HT 3728 was of very low acute oral toxicity and low acute dermal toxicity (LD50 >2 000 mg/kg). The notified chemical was not a skin and eye irritant in rabbits. The notified chemical was an extreme skin sensitiser in guinea pigs. The application site of all treated animals at challenge showed prominent changes indicative of contact dermatitis.

In a 28-day repeated dose oral study, the principal effect observed was a dose-related incidence of congestion and haemosiderosis of the spleen, observed in both sexes at 200 and 1 000 mg/kg/d. Increases in relative liver weight and elevated cholesterol concentrations at 1 000 mg/kg/d may indicate an effect on the liver, however, no corresponding microscopic changes were observed. Similarly, the increases in relative kidney weight at 1 000 mg/kg/d were not accompanied by any correlating histopathological findings. However, the relative liver and kidney weight increases were only partially reversed in the 4-week recovery period. Based on the increased incidence of splenic effects, the NOAEL for the study was 50 mg/kg/d.

The notified chemical was considered non-mutagenic to the bacterial strains tested and non-clastogenic *in vitro* in a chromosomal aberration assay.

The notified chemical is classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999) based on skin sensitisation observed in an adjuvant type test. The overall classification is Sensitiser (Xn) and the risk phrase R43 - May Cause Sensitisation by Skin Contact, is assigned. The safety phrases S22 – Do Not Breathe Dust, is suitable as a warning against inhalation of the particulate dye, S24 and S25 – Avoid Contact with Skin and Eyes, is suitable as a warning of possible eye irritation.

The submission indicates that cases of skin and respiratory sensitisation have been observed with reactive dyes and care should be taken to avoid skin contact and inhalation. However, no work related injuries or diseases related to the notified chemical have been reported from the notifier's overseas plants.

Occupational Health and Safety

Transport and Storage
Exposure to the notified chemical is not expected during transport or storage as long as the packaging remains intact. Exposure after a spill would be controlled by use of the recommended practices for spillage clean up given in the MSDS supplied by the notifier. The risk of adverse health effects for transport and storage workers is considered low.

Formulation and Dyeing
The greatest potential for exposure to the notified chemical is during weighing and mixing of the powdered chemical and during disposal of empty used liner bags. There exists potential for exposure by inhalation and/or skin and eye contact with dust particles with the associated health effects of skin sensitisation, possible respiratory sensitisation and possible eye irritation. The notified chemical comprises 50 – 60% Acid Red HT 3728, with a large percentage of particles within the inspirable size range (20% <200μm and 2% <40μm). These particles may be deposited in the nose, pharynx and larynx. They may be transported to the gastrointestinal tract by secondary ingestion, hence absorbed into the body. Mixtures containing Acid Red HT 3728 at concentrations of ≥1% are hazardous substances. Although significant absorption through the skin is expected to be low, given the molecular weight of 717, the hazardous nature of the chemical necessitates strict controls during handling.

Inhalation exposure is expected to constitute a minor source of exposure because the notified chemical is taken as having low vapour pressure, and it will be imported as a component in a non-dusting solid product. Local exhaust ventilation and dust extraction need to be maintained over mixing areas to capture dust and aerosols at source, and minimise exposure to fine particles generated from the notified chemical and any other ingredients. Good hygiene and work practices are required in these areas to minimise the generation and subsequent settling of dusts on work surface areas and floors; this is also recommended in the MSDS for the commercial dye products Neolan Red A-G and Erionyl Red A-3G. Based on data reported to be from a US air monitoring study, the notifier estimated that the average lifetime exposure of a 70 kg worker during weighing would be 0.000838 mg/kg/day. This estimate assumes only one weighing operation per shift for a total duration of 0.15 hours/day. Other assumptions used in the exposure estimate were 1.25 m^3/hr inhalation rate, 125 days weighing/year, 40 years work and 70 years life expectancy. Using the same data but not correcting for lifetime expectancy, the average daily exposure is 0.0043 mg/kg/day. Based on the NOEL of 50 mg/kg/day from a 28-day oral repeat dose study in rats, a margin of exposure (MOE) for this estimate is 11 628, which indicates that the risk of adverse health effects resulting from inhalation exposure is of low concern. However, these estimates are conservative because the estimation of exposure excludes any contamination via the dermal route. In addition, the study methodology or the complete parameters/assumptions used in calculating exposure were not provided.

Given that an airborne exposure dose cannot be related to the health effects anticipated, that is, skin and may be respiratory sensitisation, the wearing of an air purifying dust respirator (with P2 particulate filter) and other protective equipment such as overalls, protective gloves, and goggles during these operations, is needed.

Exposure to the notified chemical at <0.108% may occur after dissolution, when mixing with other dyes, during connection/disconnection of metering pump hoses from the mixing vessel to the dyeing vessel, during the dyeing process, and during cleaning and maintenance of

equipment. Inhalation exposure is not expected as any aerosols would be within enclosed automated operation systems. Skin and/or eye contact will be the main routes of exposure. The wearing of safety glasses, protective gloves and overalls are needed to reduce the risk of irritation and sensitisation when handling the dyestuff and wet dyed textiles. The notifier stated that workers will be trained in the safe handling of hazardous substances.

Once the dye is fixed and the fabric washed and dried, workers are not anticipated to be at risk of experiencing skin sensitisation.

Exposure to dusts may also occur during laboratory testing, however, given the smaller quantities handled, the potential for skin sensitisation effects and eye irritancy is reduced. Local exhaust ventilation and the routine wearing of laboratory coats, impervious gloves and safety glasses would be expected to further reduce these risks.

Measures should also be implemented in the disposal of the notified chemical to ensure that exposure is avoided.

Public Health

Public contact will occur from touching the dyed fabric treated with the notified chemical. The dyeing process fixes the dye firmly to the fabric. While the fabric is used for clothing, the dyestuff is wetfast and will not be removed by contact with the skin or with water. This renders the notified chemical biologically unavailable. Hence the potential for public exposure to the notified chemical is considered to be low.

13. RECOMMENDATIONS

To minimise occupational exposure to the notified chemical following guidelines and precautions should be observed:

- Workers receive regular education and training on handling techniques, good hygiene practices and potential adverse health effects associated with hazardous substances used in dyeing.

- As potential for skin and respiratory sensitisation exist, the notifier's MSDS should be provided to the authorised medical practitioner responsible for health surveillance in the workplace. Sensitised persons should not continue to handle the notified chemical and should be transferred to another workplace.

- The notified chemical may be recommended to the National Occupational Health and Safety Commission for consideration for inclusion in the List of Designated Hazardous Substances with the risk phrase R43 – May Cause Sensitisation by Skin Contact.

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia/Standards New Zealand, 1994a) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.1 (Standards Australia, 1990);

impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia, 1998); and all occupational footwear should conform to AS/NZS 2210.1 (Standards Australia/Standards New Zealand, 1994b);

- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

If the conditions of use are varied, then greater exposure to the public may occur. In such circumstances, further information may be required to assess the hazards to public health.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Secondary notification under Section 64 (1) of the Act will be required if:

i) the method of use changes in such a way as to greatly increase the environmental exposure of the notified chemical; or

ii) additional information becomes available on adverse environmental effects of the chemical; or

iii) any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

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Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	3 severe	Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe