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3 February 2000

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

RED RA 10463

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

RED RA 10463

1. APPLICANT

Clariant (Australia) Pty Ltd of 675 – 685 Warrigal Road CHADSTONE VIC 3148 has submitted a standard notification statement in support of their application for an assessment certificate for RED RA 10463.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of impurities, composition and import volume have been exempted from publication in the Full Public Report and the Summary Report.

Marketing Name: RED RA 10463

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa: Fine, red brown powder

Melting Point: 171°C (see comments below)
(NOTOX B.V, 1996a)

Specific Gravity: 1.42 at 20°C
(NOTOX B.V, 1996b)

Vapour Pressure: $(1.0\pm0.1) \times 10^{-4}$ kPa at 20°C
(NOTOX B.V, 1996c)

Water Solubility: <9 µg/L at 20°C
(NOTOX B.V, 1996d)

Partition Co-efficient (n-octanol/water): $\log P_{ow} = 4.1$
(NOTOX B.V, 1996e)

Hydrolysis as a Function of pH: not applicable; the substance has low water solubility

Adsorption/Desorption: no information available

Dissociation Constant: not applicable; the substance has low water solubility

Particle Size Distribution:
NOTOX B.V., (1996f)

<2	µm	2.6% w/w
2-5	µm	14.4% w/w
5-10	µm	15.0% w/w
10-20	µm	31.6% w/w
20-50	µm	36.4% w/w

Dusting Properties: Low dusting
(Clariant, 1999)

Flash Point: not applicable; the substance is a solid

Flammability Limits: not highly flammable (see comments below)
(NOTOX B.V, 1996h)

Autoignition Temperature: not self-ignitable
(NOTOX B.V, 1996i)

Explosive Properties: not explosive under conditions of thermal and mechanical stress
NOTOX B.V., (1996j)

Reactivity/Stability:
NOTOX B.V., (1996k) the substance has no oxidising properties

Surface Tension:
NOTOX B.V., (1996l) 73.4 mN/m at 20°C (90% saturated concentration)

Comments on Physico-Chemical Properties

Tests were performed according to corresponding EEC and OECD test guidelines (European Economic Commission, 1992a; Organisation for Economic Co-operation and Development, 1981) at the NOTOX B.V. Testing Facilities, The Netherlands. These facilities comply with the OECD principles of good laboratory practice and full test reports were submitted. All tests were performed on the notified chemical, with its impurities still present.

Because of impurities, the notified chemical commences melting at about 149°C. At temperatures above 232°C the substance is not stable and decomposes. No boiling point was determined.

The notified chemical contains an ester linkage that could be expected to undergo hydrolysis in extreme pH conditions. However, due to its very low water solubility, this is unlikely in the usual environmental pH range (4-9).

Adsorption/desorption data were not available for the notified chemical. Given its low water solubility, mobility of the substance in the environment is not likely to occur. Solid waste consigned to landfills, either from spillages or residues in packaging, are expected to be retained at the landfill sites and not be mobile.

Flammability testing indicated that the notified chemical does not ignite spontaneously at room temperature. It is also incapable of developing a dangerous amount of (flammable) gas when in contact with air, damp air or water.

A commercial product containing RED RA 10463 was reported as low dusting, Rank 5, (on a scale of Rank 1 to 5, Rank 5 being the lowest dusting) on a laser based method.

4. PURITY

Degree of Purity:	High
Impurities:	An identified impurity (1.4%) contains functionalities of two classes of chemical which are classified as skin sensitisers according to the National Occupational Health and Safety Commission *List of Designated Hazardous Substances* (NOHSC, 1999a)
Additives/Adjuvants:	none

5. USE, VOLUME AND FORMULATION

The notified chemical is an azo dye.

Red RA 10463 will be imported as a component of a commercial product in the form of red-brown granules and will be packed in 25kg fibreboard boxes lined with plastic. This product will be used industrially by dyehouses for dyeing polyester and polyester blend fibres by the exhaust dyeing method. It will not be available for use by the public.

No manufacture of the notified chemical will take place in Australia. It will be imported from Clariant (Switzerland) Ltd as a component of a dyestuff product. Imports of the notified chemical are projected to be less than five tonnes per year for each of the first five years.

6. OCCUPATIONAL EXPOSURE

The notifier estimates that 14 workers will potentially be exposed to the notified chemical during the storage, handling and dyeing processes. This number includes both Clariant store workers and dyehouse operators.

Transport and Storage

Following import, the dyestuff product, in 25 kg packs, will be delivered directly to the Clariant Australia warehouse by road transportation. Two store workers will handle the packaged product. Their duties are to include forklift handling of palletised packages and manual handling of individual packages. The maximum duration of these tasks is estimated as one hour, four times per year. The product packs are then delivered to six dyehouses. Exposure of transport and storage workers should only occur in the event of a spill.

Dyehouse

At the dyehouse two operators (a dye store worker and a dye operator) will handle the packages in each case, following standard work practices. The dye store worker is responsible for the weighing of dye quantities (500 to 700 g), to be carried out at a weighing station that is equipped with an exhaust hood to capture dusts. In addition, the imported dyestuff is stated to be low dusting. Therefore, dust clouds should not accumulate and persist in the weighing area. Exposure during weighing is estimated as 0.5 hour, twelve times per year. The dye operator is responsible for dispersing the dye in water, then adding it to a dyebath. Dispersing involves adding the weighed quantity of dye into a bucket to which cold water is added before being poured into the dye tank. Alternatively, weighed dye is poured into a stirred funnel containing water from which the dye mix directly enters the dye tank. Skin contact from drips and spills may occur during dispersing. The maximum exposure for these workers is estimated as one hour, twelve times per year.

Although no details were provided, it is expected that laboratory staff may have contact with the dyestuff for quality control purposes.

The notifier states that workers should wear personal protective equipment, that is protective gloves, clothing, footwear, safety goggles and breathing apparatus that comply with the corresponding Australian Standards to avoid contact with the notified chemical.

The notifier did not describe occupational exposure during the dyeing and drying stages. However, it is expected that after completion of the dyeing process, operators may make skin contact with wet cloth as it removed from the dye machine for drying or when untangling is required. It is expected that protective gloves would be worn during handling of the wet cloth.

7. PUBLIC EXPOSURE

The notified chemical is imported and delivered to the notifiers site as described above. The notifiers MSDS lists procedures to follow for containment and spillage clean-up in the event of a transport accident.

Release to the environment of the notified chemical is expected to be minimal.

There is little potential for exposure of the public to the notified chemical, as it is not available for retail sale. The public will only come into contact with the dyed polyester fibres where the notified chemical will be trapped inside the matrix. The low exposure indicates a low risk to public health.

8. ENVIRONMENTAL EXPOSURE

Release

The most significant environmental exposure to the notified chemical will come from dyehouse effluents and wastewater treatment systems. Other releases will be limited to trace residues in empty packaging and spillage.

Based on a maximum annual import of five tonnes of the chemical and 98% exhaustion during the dye process, up to 100 kg of the chemical would be processed through industrial wastewater treatments over six different sites or through sewerage systems. Dilution of the dye process wastewater in the internal wastewater treatment plant and purification of the wastewater in an external plant, results in the concentration of the notified chemical lost to the sewerage system of <<1ppm (see section 10, *Assessment of Environmental Hazard* for calculations). Purification of the wastewater can be achieved by membrane filtration, flocculation or treatment with ozone. All solids collected in these treatment processes would be disposed of to landfill.

Residual chemical may remain in the packaging after use. It is estimated that between 0.3 to 0.6 g of the notified chemical will be retained. Given a maximum import volume of 5 tonnes (in 200 packages) between 72 to 120 g of the notified chemical) will be retained in the packaging. The packaging and residue will be disposed of to landfill.

Fate

The bulk of the notified chemical will become chemically fixed to polyester fibres, given a fixation performance of 98%, while the remainder would be rinsed into wastewater. The fate of the majority of the notified chemical is therefore linked with the fate of the particular item and in this state is not expected to impact on the environment. Eventually the polyester fibres will enter the waste disposal stream for recycling or landfill. Once in a landfill site, movement by leaching is not expected because the chemical has low water solubility and high binding affinity to soil.

Dye wastes, normally released into water ways as dyehouse effluents, may either partition to sediment or remain in the aqueous phase. Due to its very low water solubility and high P_{ow}, the notified chemical is expected to become associated with the organic component of sediments. While azo dyes are generally not biodegraded under aerobic conditions they are susceptible to reductive degradation under anaerobic conditions, such as those found in sewage, sediments and soils (Yen, 1991). Any dye that binds to the sludge during the waste treatment process would be disposed of to landfill.

Residues that persist after sewage treatment will enter marine or freshwater environments (city and country wastewater treatment systems, respectively) in suspension. The concentrations are expected to be very low because of the very high fixation rate in the initial process, the expected movement to sediment/sludge and the high dilution in the release processes. Accordingly, no significant increase in dissolved concentrations over time is predicted, while residues bound to sediment are expected to undergo reductive degradation.

In the event of accidental spillage of the notified chemical into waterways, it is not expected to disperse into the water, but to settle out onto sediments after adsorbing to the organic fraction. If the dyestuff is spilt on land, either during usage or transport, it is expected that the chemical would become immobilised in the soil layer. Contaminated soil can then be collected and disposed to landfill.

A CO_2 Evolution Test (modified Sturm test, OECD TG 301) was performed with the notified chemical to determine the degree of ready biodegradability (NOTOX B.V, 1997a). At 39.4 mg per 2 litres, corresponding to 11 mg TOC/L, the theoretical CO_2 production was estimated to be 2.1 mg CO_2/mg. The relative degradation values calculated for the test period revealed no significant degradation. The study also indicated that the notified chemical was non-inhibitory. In conclusion, the notified chemical was not readily biodegradable.

The log P_{ow} of 4.1 for the notified chemical, coupled with a low level of biodegradability, suggests potential bioaccumulation. However, low environmental exposure and high affinity for soil/sediment would limit any bioaccumulation of this chemical.

9. EVALUATION OF TOXICOLOGICAL DATA

Tests were performed according to corresponding EEC and OECD test guidelines at the NOTOX B.V. Testing Facilities, The Netherlands, except for the 'Skin Compatibility (Sensitisation) in Human Adults' test, which was performed at the GTLF Therapy and Performance Research Institute, Erlangen, Germany. These facilities comply with the OECD principles of good laboratory practice and full test reports were submitted. All tests were performed on the notified chemical, in powder form, with its impurities present.

9.1 Acute Toxicity

Summary of the acute toxicity of the notified chemical:

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2000 mg/kg	NOTOX B.V, 1996m
acute dermal toxicity	rat	LD_{50} > 2000 mg/kg	NOTOX B.V, 1996n
skin irritation	rabbit	Non irritating	NOTOX B.V, 1996o
eye irritation	rabbit	Mildly irritating	NOTOX B.V, 1996p
skin sensitisation:			
Maximisation test*	guinea pig	Sensitising	NOTOX B.V, 1996q
Buehler test*	guinea pig	Non sensitising	NOTOX B.V, 1996r
Repeat Patch test**	human	Non sensitising	Fink 1997

* 20% challenge concentration.
** Test fabric stained with 2% dyestuff product containing RED RA 10463.

9.1.1 Oral Toxicity (NOTOX B.V, 1996m)

Species/strain:	rat/Wistar
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	gavage
Test method:	OECD TG 401 limit test
Clinical observations:	purple staining of the back, tail and tail base region noted in all females between days 5 and 9 and among the males from day 2 onwards and persisting at termination in one male; two females showed reduced body weight gain over the second week of the study; body weight gain shown by the other animals was considered to be similar to that expected of normal untreated animals of the same age and strain
Mortality:	no deaths observed during the study
Morphological findings:	no abnormalities observed on day 15
LD_{50}:	>2 000 mg/kg

Result:	the notified chemical was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity (NOTOX B.V,1996n)

Species/strain:	rat/Wistar
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	A single dermal application of 2 000 mg/kg body weight for 24 hours
Test method:	OECD TG 402 limit test
Clinical observations:	purple staining of several parts of the body (e.g. snout, back, tail, abdomen, flank, chest) observed in all animals and some staining persisted at termination in the majority of animals; red staining of the snout and/or neck noted in one male and four females and persisted at termination in two females; body weight gain was within the range expected for rats used in this type of study
Mortality:	No deaths observed during the study
Morphological findings:	No abnormalities observed on day 15
LD_{50}*:*	> 2 000 mg/kg
Result:	The notified chemical was of low acute dermal toxicity in rats

9.1.3 Inhalation Toxicity

An acute inhalation toxicity study was not available. The notifier stated that the imported product is to be sold in a low dusting formulation and under normal dyehouse practices (e.g. exhaust hood ventilation, use of dusk masks etc.), members of the workforce would not be expected to be exposed to airborne quantities of the substance.

9.1.4 Skin Irritation (NOTOX B.V,1996o)

Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	3/male

Observation period:	3 days
Method of administration:	A single, topical application of 0.5g to clipped skin for 4 hours using semi-occlusive dressing
Test method:	OECD TG 404
Comment:	no skin irritation was caused by 4 hours exposure to the notified chemical – all Draize scores were zero; no symptoms of systematic toxicity were observed; purple staining of the treated skin was observed
Result:	the notified chemical was not irritating to the skin of rabbits

9.1.5 Eye Irritation (NOTOX B.V,1996p)

Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	3/male
Observation period:	7 days
Method of administration:	A single ocular dose of approximately 28mg (in 0.1mL) to one eye
Test method:	OECD TG 405

Draize scores for individual ocular changes:

	Time after instillation														
Animal	***1 hour***			***1 day***			***2 days***			***3 days***			***7 days***		
Cornea	***o***		***a***	***o***		***a***	***o***		***a***	***o***		***a***	***o***		***a***
1	0		0	0		2	0		0	0		0	0		0
2	0		0	0		0	0		0	0		0	0		0
3	0		0	0		1	0		0	0		0	0		0
Iris															
1		0			1			0			0			0	
2		1			0			0			0			0	
3		0			0			0			0			0	
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	1	3	2	3	2	2	2	1	1	1	0	0	0	0	0
2	1	2	2	2	2	1	2	1	0	3	0	0	0	0	0
3	1	2	1	2	1	1	2	1	0	1	0	0	0	0	0

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

Irrigated eyes:

effects on the cornea, iris and conjunctivae among the animals; slight dulling of the normal lustre of the cornea (opacity Grade 0) and epithelial damage (10% or 35% of the corneal area) were observed in two animals, 24 hours after instillation only;
iridic irritation Grade 1 observed in one animal one hour after instillation and in another 24 hours after instillation;
irritation of the conjunctivae consisted of redness, chemosis and discharge and had completely resolved within 7 days in all animals;
a haemorrhage in the sclera of the eye, where remnants of the test substance had been present, was observed in one animal 72 hours after instillation;
remnants of the test substance were present in the eyes, up to 24 hours in two animals and up to 48 hours in the third animal; the test substance remained in the lower eye-sac after rinsing the eyes with tap-water 24 hours after instillation;
purple staining of the fur on the head and paws, caused by the test substance, was noted during the observation period;
no symptoms of systemic toxicity were observed and no mortality occurred

Result:

the notified chemical was mildly irritating to rabbit eye

9.1.6 Skin Sensitisation – Maximisation Test (NOTOX B.V,1996q)

Species/strain:	guinea pig/Himalayan strain
Number of animals:	10 test, 5 control (all females)
Induction procedure:	Day 1 (intradermal injections) to a clipped area of the scapular region, each animal received 3 pairs of intradermal injections (0.1 mL/site) as follows: • Freund's Complete Adjuvant (FCA): distilled water (1:1 ratio) • 1% w/v of test substance • 1:1 mixture of FCA and 2% w/v test substance Day 3 dermal reactions caused by the intradermal injections were assessed for irritation Day 7 scapular area between the injection sites was clipped and subsequently rubbed with 10% sodium dodecyl sulfate in vaseline Day 8 (topical application) the 10% SDS treated area was treated with 0.5mL of 20% test substance using a Scotchpak-non-woven patch (2x3cm) mounted on Micropore tape and secured with Coban elastic bandage; dressing was removed after 48 hours exposure, the skin cleaned and the dermal reactions were assessed; control animals treated as described above, except instead of the test substance the vehicle was administered
Challenge procedure:	Day 22 epidermal application of 20% w/v test substance and the vehicle (0.5mL each) to one flank (clipped), using Scotchpak-non-woven patch (2x3cm) mounted on Micropore tape and secured with Coban elastic bandage; dressing was removed after 24 hours exposure, the skin cleaned and the treated sites were assessed for challenge reactions 24 and 48 hours after removal of dressing
Test method:	OECD TG 406 Magnusson and Kligman maximisation test,

Challenge outcome:	purple staining was observed in the treated skin areas 24 hours after the challenge exposure in all animals; skin reactions varying between Grades 1 and 2 were observed in eight out of ten animals, 48 hours after the challenge exposure; scaliness also observed in four of these eight animals; no skin reactions were evident in the control animals
Result:	the notified chemical was sensitising to guinea pig skin

9.1.7 Skin Sensitisation – Buehler Test (NOTOX B.V,1996r)

Species/strain:	albino guinea pig/Himalayan strain
Number of animals:	20 test, 10 control (all females)
Induction procedure:	Days 1, 8 and 15 the left flank of each animal was clipped and treated epidermally with 0.5 mL of 20% test substance using a Scotchpak-non-woven patch (2x3cm) mounted on Micropore tape and secured with Coban elastic bandage; dressing was removed after 6 hours exposure, the skin cleaned and the dermal reactions were assessed; immediately after removal of the last induction application (Day 15), the treated skin area was assessed for irritation; control animals treated as described above, except instead of the test substance the vehicle was administered
Challenge procedure:	Day 29 epidermal application of 20% w/w test substance and the vehicle (0.5mL each) to the right flank (clipped), using the same type of occlusive dressing as in the induction phase; dressing was removed after 24 hours exposure, the skin cleaned and the treated sites were assessed for challenge reactions 24 and 48 hours after removal of dressing
Test method:	Buehler test, OECD TG 406
Challenge outcome:	no skin reactions were evident after the challenge exposure; purple staining was observed in the treated skin areas 24 and 48 hours after the challenge exposure
Result:	the notified chemical was non sensitising to guinea pig skin

9.1.8 Repeat Patch Test for Skin Compatibility (Sensitisation) in Human Adults (Fink, 1997)

Number of humans:	27 females, 5males
Test articles:	Polyester Interlock 1880 synthetic fabric A = untreated B = treated (with staining aid) C = treated and stained with 2% dyestuff product containing RED RA 10463
Application:	under firm occlusion, 3 x weekly for 48 hours, for 3 weeks on the same spot of skin of upper arm or back (induction); challenge application once for 48 hours to a naive site on the back or arm after a free interval of 14 days
Readings:	Induction immediately after each patch removal and always prior to the next application; Challenge immediately, 24 and 48 hours after patch removal
Test method:	repeat patch test of Kligman and Epstein (1975)
Outcome:	no skin reactions were observed in any of the volunteers at any stage during the test
Result:	there is no, or only minimal, risk of skin sensitisation for humans in contact with Polyester Interlock 1880, stained with 2% dyestuff product containing RED RA 10463

9.2 Repeated Dose Toxicity (NOTOX B.V, 1997b)

Species/strain:	rat/Wistar
Number/sex of animals:	30/sex one control group and three treated groups tested, each consisting of 5 males and 5 females; an extra 5 animals per sex in the control and high dose groups were allowed 14 days of recovery
Method of administration:	Oral, gavage
Dose/Study duration::	0, 50, 200 or 1 000 mg/kg/day for 28 days (males) or 29 days (females)
Test method:	EEC Directive 92/69/EEC No. B7

Clinical observations:	no deaths were observed during the study period; brown/purple discolouration of fur, tail and urine was ascribed to the staining properties of the powder; no other significant treatment-related observations were observed during the study period
Clinical chemistry:	slight increases in serum sodium were observed in males after four weeks at all doses; however, the effect was not dose-related and in the absence of a similar observation in females this was not considered to be of toxicological significance by the authors; no other treatment-related differences were observed between control and treated animals
Haematology:	slight reductions in red blood cell count, haemoglobin and haematocrit, along with slightly high red cell distribution width were observed after four weeks in high dose females, however, nearly all values remained within the range of historical data and no treatment-related effect was expected
Pathology:	the relative liver weights of high dose males were slightly increased compared with the controls, however, liver weights were normal at the end of the recovery period; no other significant findings were observed, including microscopic examination
Comment:	no treatment related abnormalities (macroscopic or microscopic) were observed; no morphologic or functional alterations were found in the liver; no deaths observed;
Result:	No signs of systemic toxicity were observed with the notified chemical when administered orally at 1000 mg/kg/day to rats over a 28 day period; Based on the increase in relative liver weight at 1 000 mg/kg/day, the No Observable Effect Level (NOEL) is 200 mg/kg/day. The No Observable Adverse Effect Level (NOAEL) was determined at 1 000 mg/kg/day based on the absence of morphological or functional alterations in the liver.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium/Escherichia coli* Reverse Mutation Assay (NOTOX B.V, 1996s)

Strains:	*Salmonella typhimurium* TA1535, TA1537, TA98 and TA100 *Escherichia coli* WP_2uvrA
Metabolic Activation System:	Liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Concentration range:	up to 1 000 μg/plate, in the absence and presence of S9
Test method:	OECD TG 471 and 472
Comments/Observations:	With S9 TA1535 : 10- and 14-fold dose-related increases in the number of revertant (His^+) colonies in experiments 1 and 2, respectively TA1537 : 139- and 159-fold dose-related increases in experiments 1 and 2, respectively TA98 : 138- and 177-fold dose-related increases in experiments 1 and 2, respectively TA100 : 15- and 14-fold dose-related increases in experiments 1 and 2, respectively WP_2uvrA : 9- and 7-fold dose-related increases in the number of revertant (Trp^+) colonies in experiments 1 and 2, respectively Without S9 TA1535 : 14-fold dose-related increases in the number of revertant (His^+) colonies in both experiments 1 and 2 TA1537 : 168- and 135-fold dose-related increases in experiments 1 and 2, respectively TA98 : 80- and 92-fold dose-related increases in experiments 1 and 2, respectively TA100 : 17- and 16-fold dose-related increases in experiments 1 and 2, respectively WP_2uvrA : 5- and 13-fold dose-related increases in the number of revertant (Trp^+) colonies in experiments 1 and 2, respectively
Result:	The notified chemical was mutagenic in the *Salmonella typhimurium* reverse mutation assay and in the *Escerichia coli* reverse mutation assay

9.3.2 *In vitro* Mammalian Cell Gene Mutation Test (NOTOX B.V, 1997c)

Species/culture:	mouse/L5178Y lymphoma cells
Metabolic Activation System:	Liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Doses:	0.3, 1, 3 and 10 µg/mL exposition medium, in the absence and presence of S9
Test method:	OECD TG 476
Comments/Observations:	No dose-related increase in the mutant frequency at the TK-locus in the absence and presence of S9, in two independently repeated experiments. Results from positive control experiments indicated that the test conditions functioned properly
Result:	The notified chemical was not mutagenic in the mouse lymphoma L5178Y test system under the experimental conditions

9.3.3 Chromosomal Aberration Assay in Human Lymphocytes (NOTOX B.V, 1999a)

Cells:	Human Peripheral Lymphocytes
Metabolic activation system:	1.8% liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Dosing schedule:	<u>Experiment 1:</u> without metabolic activation, 1, 3 and 10 µg/mL; treatment/fixation time = 3/24 hours; positive control: 0.5 µg/mL MMC; with metabolic activation, 1, 3 and 10 µg/mL, treatment/fixation time = 3/24 hours, positive control: 15µg/mL cyclophosphamide; <u>Experiment 2:</u> without metabolic activation, 1, 3 and 10 µg/mL; (1) treatment/fixation time = 24/24 hours; positive control: 0.2 µg/mL MMC;

(2) treatment/fixation time = 48/48 hours;
positive control: 0.1 µg/mL MMC;

with metabolic activation,
1, 3 and 10 µg/mL;
treatment/fixation time: 3/48 hours,
positive control: 15 µg/mL cyclophosphamide;

Test method: OECD TG 473

Comment: Tests were carried out in duplicate in two independent experiments.

Experiment 1:
The test substance did not induce a statistically significant increase in chromosomal aberrations, both in the absence and presence of metabolic activation, compared with negative controls.

Experiment2:
In the 48 hour treatment/fixation experiment, there was a statistically significant increase in chromosomal aberrations, particularly at the highest test concentration of 10 µg/mL where there was also evidence of precipitation. In the 24 hour treatment/fixation experiment, no evidence of increased chromosomal aberrations was seen.
In the 3 hour treatment/48 fixation experiment, there was an elevated incidence of double minutes[1] at 3 µg/mL test concentration. Since this occurred only at the intermediate dose level, and in only one of the duplicate cultures, it was considered to have little biological relevance.

The lack of any chromosomal aberrations in the solvent control makes interpretation of the data difficult. The testing facility quotes a historical control range of 0 to 5, with a mean of 0.9. It is considered that the mean, 0.9, is more representative of a true historical control value than the range. A higher weighting is therefore placed on the finding of significant chromosome aberrations at the highest concentration of 10µg/L and accordingly the test substance is considered to be a weak *in vitro* clastogen.

[1] Double minutes – two, usually circular, parts of a chromatid lacking a centromere.

	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 notified chemical was considered to be a weak clastogen under the conditions of the test.

9.3.4 Micronucleus Assay in the Bone Marrow Cells of the Mouse (NOTOX B.V, 1998; NOTOX B.V, 1999b)

Species/strain:	Mouse/NMRI BR
Number and sex of animals:	5/sex/group
Doses/Method of administration:	Test substance: 50, 250, 500 and 1 000 mg/kg in corn oil; the substance was administered twice, with a 24 hour interval Positive control was 50 mg/kg cyclophosphamide, administered once on the second day of the test.
Sampling schedule:	Animals were sacrificed 24 and 48 hours after the last dosing.
Clinical observations:	No mortality; No clinical signs of toxicity;
Test method:	OECD TG 474
Result:	The original data supplied by the testing facility indicated that the test substance was a weak inducer of micronuclei, with statistically significant increases being detected in male mice at 1 000 and 500 µg/mL at the 48 and 24 hour sampling time, respectively, and in female mice at 500 µg/mL at the 48 hour sampling time. These data were based on an evaluation of micronucleus incidence in 2000 polychromatic erythrocytes. A reevaluation of micronucleus incidence, performed in 5 000 polychromatic erythrocytes, did not show statistically significant differences in any of the test doses. Because of the greater statistical power afforded by the reevaluation experiment, the test substance was considered to be non-clastogenic in bone marrow cells of the mouse *in vivo*, under the conditions of the assay

9.4 Overall Assessment of Toxicological Data

The notified chemical displayed very low acute oral toxicity and low dermal toxicity in the rat. It was not a skin irritant in rabbits. It was a mild irritant to rabbit eyes; however, the reaction was insufficient to warrant classification as an eye irritant. It was a skin sensitiser in a Magnusson and Kligman maximisation test in guinea pigs, but was negative in a Buehler test. A human patch test using fabric stained with 2% dyestuff product containing RED RA 10463 was also negative.

In a 28 day repeat dose oral rat study, the notified chemical caused a slight increase in relative liver weights in males at the highest dose (1 000 mg/kg/day); however, the animals in the recovery group were normal and no corresponding histopathological changes were observed. Based on this finding, the NOEL for the study is 200 mg/kg/day. The NOAEL was determined at 1 000 mg/kg/day based on the absence of morphological or functional alterations in the liver.

Reverse mutation assays in *Salmonella typhimurium* and *Escherichia coli* were positive, with and without S9 metabolic activation. An *in vitro* gene mutation assay in mouse lymphoma cells was negative.

In a chromosomal aberration assay in peripheral human lymphocytes, a 48 hour treatment/fixation experiment showed a statistically significant increase in chromosomal aberrations, particularly at the highest test concentration of 10 µg/mL where there was also evidence of precipitation. However, no evidence of increased chromosomal aberrations was seen in the 24 hour treatment/fixation experiment. In a 3 hour treatment/48 fixation experiment, there was an elevated incidence of double minutes at the 3 µg/mL test concentration. Since this occurred only at the intermediate dose level, and in only on of the duplicate cultures, this finding was considered to have little biological relevance. Based on this evidence alone, the notified chemical was considered to be a weak clastogen *in vitro*. In an *in vivo* mouse micronucleus test, original data supplied by the testing facility indicated that the notified chemical was a weak inducer of micronuclei, with statistically significant increases being detected in male mice at 1 000 and 500 µg/mL at the 48 and 24 hour sampling time, respectively, and in female mice at 500 µg/mL at the 48 hour sampling time. These data were based on an evaluation of micronucleus incidence in 2 000 polychromatic erythrocytes. A reevaluation of micronucleus incidence, performed in 5 000 polychromatic erythrocytes, did not show statistically significant differences in any of the test doses. Because of the greater statistical power afforded by the reevaluation experiment, the notified chemical was considered to be non-clastogenic in bone marrow cells of the mouse *in vivo*, under the conditions of the assay.

Hazard Classification

Based on the positive findings in the adjuvant type skin sensitisation study the notified chemical is considered a hazardous substance, skin sensitising, according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b). The overall hazard classification is Harmful (Xi) with risk phrase R43 “May Cause Sensitisation by Skin Contact”.

The notified chemical does not meet the criteria for classification as a mutagen. Although it was mutagenic in bacteria, it was not considered to be a clastogen because (a) it cannot be excluded that the *in vitro* effects, occurring predominantly at the high dose where precipitation was evident, may have been artefactual and (b) in the *in vivo* experiment, greater statistical power failed to detect any evidence of clastogenic potential.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Tests were performed in compliance with EEC/OECD test methods and according to OECD Principles of Good Laboratory Practice.

Summary of the ecotoxicity tests for the notified chemical

Species	*Test*	*Test conc.s (nominal) mg/L*	*Result*
Carp (*Ctenopharyngodon*)	Acute Toxicity (static) (OECD TG 203)	0.1, 1.0	96h LC_{50} > 0.26 mg/L
Water Flea (*Daphnia magna*)	Acute Toxicity - Immobilisation Test (Static Test) (OECD TG 202)	0.1, 1.0	48h EC_{50} > 0.18 mg/L
Green Algae (*Selenastrum capricornutum*)	Growth Inhibition (Static Test) (OECD TG 201)	0.1, 1.0, 10	EC_{50} > 0.07 mg/L
Aerobic Wastewater Bacteria	Activated Sludge Respiration Inhibition (OECD TG 209)	100[a]	EC_{50} > 100 mg/L

[a] prepared using Tween-80 as additive

Ecotoxicological tests used nominal concentrations of 0.1, 1.0 and 10 mg/L. Precipitation of the notified chemical, however, was observed at 1.0 and 10 mg/L. The low water solubility of the notified chemical meant that it was not possible to maintain a stable dispersion at concentrations higher than 1.0 mg/L, although for algae, results were still reported. The fish and water flea tests, therefore, used the highest available test concentration of 1.0 mg/L, while the wastewater bacteria test used a concentration of 100 mg/L and a surfactant to disperse the dye.

10.1 Fish Acute Toxicity (NOTOX B.V, 1997d)

Analysis of the solution at the completion of the test showed that the concentration of the notified chemical had decreased to 0.26 mg/L, due to deposition of the chemical out of the water phase. Fish showed no visible effects during the 96 hour test period. Hence, concentrations toxic to carp could not be reached because the limit of solubility of the notified chemical was below any effect concentration. Therefore, the 96 hour LC_{50} for carp was beyond the maximum solubility of the notified chemical in the water (i.e. LC_{50} > 0.26 mg/L).

10.2 Aquatic Invertebrate Acute Toxicity (NOTOX B.V, 1997e)

Analysis of the solution at the completion of the test showed that the concentration of the notified chemical had decreased to 0.18 mg/L. Hence, as with the fish toxicity study, concentrations of the chemical that were acutely toxic to *Daphnia magna* could not be reached because of its low water solubility. Therefore, the 48 hour EC_{50} for effect on mobility was beyond the maximum solubility of the notified chemical in the water (that is, $EC_{50} > 0.18$ mg/L).

10.3 Alga Growth Inhibition Test (NOTOX B.V, 1997f)

Hardly any cell growth of the green algae, *Selenastrum capricornutum*, was observed at 10 mg/L of notified chemical, but these algal suspensions contained undissolved test substance in an unstable dispersion. The notified chemical did not significantly inhibit cell growth or reduce growth rate of green algae at nominal concentrations up to 1.0 mg/L. Therefore, the EC_{50} for algal growth was greater than the maximum solubility of the notified chemical in the water (that is, $EC_{50} > 0.07$ mg/L). The NOEC of the notified chemical for fresh water algal growth corresponded with the maximum solubility of the test substance.

10.4 Activated Sludge, Respiration Inhibition Test (NOTOX B.V, 1997g)

A suspension of 0.5 g/L was prepared using Tween-80 as an additive. A 0.1 g/L dilution was subsequently tested, in duplicate. No significant inhibition in respiration rate of the sludge was recorded at 0.1 g/L of the notified chemical. The respiration rates of the controls and additive controls were within 15% of each other. Therefore, under the conditions used for the test the notified chemical was not toxic to wastewater bacteria at a nominal concentration of 0.1 g/L.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified chemical, when fixed to the polyester fibre, is rated as negligible, with the chemical sharing the same fate as the fibre. The most significant environmental exposure would be from the discharge of the chemical in aqueous dyehouse effluents. The aquatic hazard has been estimated for two dyehouses located in two general locations, one metropolitan-based dyehouse and the other country based. The notifier supplied a typical rate of use of the dye based on one kg per 100 kg of fabric. The Predicted Environmental Concentration (PEC) was calculated assuming 700 kg of cloth per day is processed, and typical mill effluent is 2 ML per day. The PEC calculated for a city dyehouse was 0.03 ppb and, for a country dyehouse, 5 ppb. The calculations assume that no dye is removed in treatment of the different waste effluents and represent the worst case scenario for dyehouses.

The calculations show that exposure to fish, daphnia, algae and wastewater treatment bacteria is at levels unlikely to cause any significant effect. At higher release rates or lower achieved dilutions, there is still unlikely to be any significant effect on these species, since the concentration of the dye would still be limited by its low solubility. Once in the aquatic environment, the chemical is also expected to swiftly dilute to undetectable concentrations, and undergo biotic and abiotic degradation.

In the event of accidental spillage of the dyestuff into waterways, the chemical is not expected to disperse into the water, but settle out onto sediments. If the dyestuff is spilt on land, either during usage or transport, it is expected that the chemical would become immobilised in the soil layer. Contaminated soil can then be collected and disposed to landfill.

Solid waste consigned to landfill, either from spillages or residues in packaging, would be expected to be retained at the landfill sites and not be mobile. Movement of the chemical by leaching from landfill sites is not expected because of its lack of mobility due to its low water solubility and high binding affinity to soil.

The dye is not readily biodegradable and the log Pow of 4.1 would suggest potential for bioaccumulation. However, low exposure and adsorption to the sediment in the sewage treatment processing of dyehouse waste would reduce the quantity of notified substance eventually released to the aquatic environment and limit the potential for bioaccumulation.
Given the above, environmental exposure and the overall environmental hazard is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

From the toxicological data supplied, the notified chemical is not likely to be acutely toxic nor to cause systemic toxic effects on repeated or prolonged exposure. It is not likely to be a skin irritant but may be mildly irritating to eyes. Skin sensitisation was observed in an adjuvant type study in guinea pigs. The notified chemical induced both base-pair substitution and frameshift mutations in *S. typhimurium* and base pair substitution mutations in *E. coli*. In further investigations of mutagenicity, it was negative in an *in vitro* gene mutation assay in mouse lymphoma cells. In an *in vitro* chromosome aberration assay, the notified chemical was weakly clastogenic, but similar activity was not seen in an *in vivo* mouse micronucleus test. These findings suggest the mutagenicity of the notified chemical appears to be limited to *in vitro* systems.

The notified chemical is classified as hazardous according to NOHSC (1999b). The overall hazard classification is Harmful (Xi) with risk phrase R43 – May Cause Sensitisation by Skin Contact, assigned.

Occupational Health and Safety

Transport and Storage

Transport and storage workers would only be exposed to the notified chemical in the event of a spill. 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.

Dyehouse

RED RA 10463 will be imported as a component of a dyestuff product which is in granular form and is reportedly a low dusting formulation. The main groups of workers likely to be exposed to the notified chemical on a regular basis are those involved in dye weighing and those handling the dyed fabric after the exhaust dyeing is completed when the cloth is lead off to dry. The notified chemical has a proportion of particles of respirable size (15.0%) and it is expected that the granular form and low dusting properties in addition to local exhaust ventilation should minimise inhalation exposure and contamination (or indirect skin contact) in the workplace. Personal protective equipment, namely, elbow length gloves, coveralls and face shield would be required to control skin exposure given that the notified chemical is a skin sensitiser. In the absence of measured exposure data, respiratory protection would also be required to control inhalation exposure during use of the notified chemical. The adherence to strict control measures during the use of the notified chemical will be required to minimise the risk of sensitising effects.

Public Health

There is negligible potential for public exposure to the notified chemical arising from its use industrially by dyehouses for dyeing polyester and polyester blend fibres by the exhaust dyeing method. There will be public contact with the notified chemical when incorporated into polyester fibre products, but since the notified chemical is strongly incorporated into dyed fibres, no significant exposure should occur and the pattern of exposure would be intermittent. Based on this information, it is considered that the notified chemical will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to products containing the notified chemical the 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 sensitisation exists the notifier's MSDS should be provided to the authorised medical practitioner responsible for health surveillance in the workplace;
- A copy of the MSDS should be easily accessible to all employees.

- Respiratory protection to conform to Australian/New Zealand Standard 1715-1994 (Standards Australia 1994a): *Use and Maintenance of Respiratory Protective Devices* and Australian/New Zealand Standard 1716-1991 (Standards Australia 1994b): *Respiratory Protective Devices*;

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia 1994c) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia 1992) and industrial clothing should conform to the specifications detailed in AS 3765.2 (1990). Impermeable gloves or mittens should conform to AS 2161 (Standards Australia, 1998) and all occupational footwear should conform to AS/NZS 2210 (Standards Australia, 1994d); and

- Products containing the RED RA 10463 should be handled in manner that avoids spillages. Spillages should be collected mechanically in a manner that avoids generating dust. Personnel involved in a clean-up should wear suitable eye, respiratory and skin protective equipment.

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

The notified chemical may be recommended to the National Occupational Health and Safety Commission for consideration for inclusion in the NOHSC *List of Designated Hazardous Substances*.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical and a product containing the notified chemical were provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994). It contains adequate instructions for dealing with occupational and environmental emergencies.

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

Under the Act, secondary notification of The notified chemical shall be required if 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.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	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