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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Blue MGi 1037

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Clariant (Australia) Pty Ltd (ABN 30 069 435 552)
675 Warrigal Road
Chadstone, Vic 3148

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
- Details of notification in other countries
- Chemical identity (chemical name, CAS number, molecular formula, structural formula, molecular weight, chemical spectra, details of methods of detection)
- Identity of impurities
- Percentage of notified chemical in the products
- Details of use
- Introduction volume
- Potential users of the notified chemical

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
- Adsorption/desorption
- Acute inhalation toxicity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Commercial Evaluation Permit No. 584 (CEC/624)

NOTIFICATION IN OTHER COUNTRIES
EU, USA, Canada, Korea, Japan, Switzerland

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Blue MGi 1037
Drimarene Blue CL-2RL
Drimarene Blue HF-RL CDG

3. COMPOSITION

DEGREE OF PURITY
55-70%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
To be imported as a component (65-70%) of the commercial product Drimarene Blue CL-2RL. This product is in the form of blue granules, and is packed in plastic bags inside 25 kg fibreboard boxes.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<10	<10	<10	<10	<10

USE
Textile dye.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
No repackaging of the notified chemical will take place before distribution to the end-user.
A contracted trucking company will transport the notified chemical to the end-user.

5.2. Operation description

The notified chemical will be imported as a component of a commercial dye product for the dyeing of cotton fabric.

The dyestuff containing the notified chemical (0.01-4 kg) is dissolved in 50 kg of water in an open vat at 40°C. The dye solution is then piped to an open side tank, where it is held for between 5 and 20 minutes before it is transferred directly to the enclosed dyeing vessel by piping.

Dyeing of fabric takes place in a vessel containing 6,000 L of water at 60°C over approximately 120 mins. After dyeing is completed, the residual unfixed dyestuff is rinsed away with three washes, once at 40°C, once at 60°C, and then again at 40°C. The fabric is then softened at 40°C, and the vessel is drained via an internal drain.

The dyed fabric now contains the dye in a fixed state, bound to the fabric. It is removed from the dyeing vessel by an automated reel and transferred to the hydroextractor by forklift. The damp fabric undergoes hydroextraction to remove the bulk of water and water-soluble dye components, followed by a continuous dryer, where the fabric is dried at 160°C for up to 5 minutes.

The batch of fabric is then sewn onto the previous batches of fabric.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (hrs/day)*	*Exposure Frequency (days/year)*
Warehouse/stores personnel	4	1	4-10
Dye operators	20	1	150-200

Exposure Details
Warehouse/stores personnel will wear protective equipment (overalls/industrial clothing and gloves as appropriate) when receiving/handling consignments of the commercial product containing the notified chemical. The notified chemical will be handled in the warehouse by forklift handling of pallets or manual handling of individual packages. These workers are unlikely to be exposed to the notified chemical, except in the event of an accident where rupture of the packaging occurs.

Dye operators will wear appropriate skin, eye and respiratory protection. These workers perform a

variety of duties during the dyeing process. The principle exposure of the workers will be dermal, and will occur prior to the fabric dyeing process, when dyestuffs are directly handled:

- The dye operators weigh the batch quantity of the granulated dye containing the notified chemical and add it to open vessels for dissolving in water and blending with other dyes if necessary. These procedures are performed in an enclosed, ventilated weighing room with an exhaust hood. These measures, combined with the use of the granulated product, will reduce the probability of exposure of workers to dusts containing the notified chemical.
- The liquid dye may then be manually poured via a delivery chute into the dyeing machine or poured into a holding tank for pumping into the dyeing machine. Dermal/ocular exposure to the notified chemical is possible during these processes, but appropriate use of PPE should minimise any exposure to workers.

The dyeing process after transfer of dye liquids will take place in enclosed and fully sealed dyeing machines. Dye operators are involved in controlling valves to pump dyes into the machines and to remove wastewater at the end of the process, but they will have no contact with the notified chemical during these processes.

After dyeing, the damp fabric contains the notified chemical fixed to the fabric fibres in an inaccessible form. Operator exposure to any residues of the notified chemical on the dyed fabric (wet or dry) is expected to be negligible.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The product containing the new dyestuff is to be used in dyeing operations in cotton fabric dyeing mills at concentrations up to 3% (i.e., up to 2.1% notified chemical) based on weight of fabric. The end-use concentration depends on cost requirements and the shade of colour required in the dyed fabric. The notified chemical will be used in normal batch dyeing operations in which 400 kg of fabric is dyed in each batch. Accordingly, up to 12 kg of the product (or <8.4 kg of the notified chemical) will be used per batch. Current plant operation of the dyeing mill dyes 150-200 batches (<80 tonnes of fabric) over a 6-day week, across 20 dye machines. The proposed use of the new dye will require on average 2-3 batches per day.

The dye will be exhausted onto cotton fibre at a rate of 80%; the remainder will be rinsed off into wastewater. Recovery for recycling of the remaining substance is not reasonably practicable. Typically, 6000 L of wastewater is generated in each of eight separate process stages (pre-bleach, rinse, dyeing, cold rinse, warm rinse, soap off, cold rinse, and softener), resulting in a total of 48,000 L of wastewater for each 400 kg batch of fabric. 12 kg of dye product is used per 400 kg of fabric; therefore 2400 g (20%) is lost to wastewater from the dye bath. Therefore, the worst-case concentration of residual dyestuff in wastewater is:

$$\frac{\text{2400 g (dye) x 0.70 (notified chemical)}}{\text{48000 (total volume)}} = 35 \text{ mg/L (ppm)}$$

Based on the annual import quantity of up to 10 tonnes of the new chemical and 80% fixation during dyeing processes, up to 2000 kg of the notified chemical per year will be required to be processed and diluted through the end-user's waste water treatment and through the local sewerage system. Current treatment processes at the end-user involves all discharged water being held in large effluent tanks.

The waste liquid from the dyeing and washing processes is always pH >10 (dye bath pH ~11). The wastewater from dyeing and washing processes (total 48000 L per batch) passes through 7000 L pH measurement and dosing tanks where the pH is reduced to <10 (normally to pH 9-9.5). The temperature of the effluent is reduced to below 38°C. Wastewater is then moved to 250,000 L holding tanks where a further dilution takes place (~1:5 dilution per batch) before pumping to the sewerage system. Discharged wastewater therefore contains 7 ppm of notified chemical, and this is released to the sewerage treatment plant to undergo biological treatment before discharge to the ocean.

RELEASE OF CHEMICAL FROM USE

The end use of dyed fabrics will be for either manufacture into garments or home textiles. The dyed fabric will contain the notified chemical levels at <2% based on weight of fibre. However, once the dye is reacted with the fabric, it is bound in a near-permanent fashion, making significant releases to the environment unlikely. Leaching of minute quantities of the hydrolysed, non-reactive form of the

notified chemical may occur during domestic and commercial washing of articles, diluted many fold in waters used in washing and rinsing, and subsequently by release of these waters to the sewer. Some release may also occur from dyed articles disposed of in landfill, but this is likely to occur in a dispersed fashion, and unlikely to occur at levels of any significance.

5.5. Disposal

It is intended that all of the imported substance will be used in dyeing processes, with eventual release to the sewer through wastewater (see *Release of Chemical at Site*, above). The need for disposal of the substance will be limited to waste residues in plastic-lined boxes, or if spillage occurred.

Some minimal release may occur from residues of the notified chemical remaining in packaging after emptying, as some dyestuff will adhere to the plastic lining of the packaging electrostatically. It is estimated that <10 g of the product (i.e., <7 g of the notified chemical) will be retained per package. If the maximum expected quantity of the substance is imported (up to 10000 kg), ~400 packages would be imported and a total of ~2.8 kg of the notified chemical would be retained in packaging. All packaging will be disposed in secure landfill sites, by licensed waste disposal operators.

Waste dyestuff containing the notified chemical will be disposed of by a licensed contractor, or recycled if possible.

5.6. Public exposure

The imported product, Drimarene Blue CL-RL is in the form of blue granules and will be packed in 25 kg boxes. This product will not be available for use by the general public. The potential for exposure of the general public to the product during normal industrial storage, handling, transportation and manufacturing processes will be negligible. Only in extreme cases of inappropriate handling or accidents during transportation would there be any likelihood of the notified chemical being released from the packaging and the public being exposed.

The notified chemical will be used industrially for dyeing cotton towelling fabrics. The end use of dyed fabrics will be for either manufacture into garments or home textiles. The dyed fabric is estimated to contain the notified chemical levels at <2% of the weight of fibre, based on the exhaustion rate and the quantity used in dyeing. Once the dye is reacted with the fabric, it is generally inaccessible to cause exposure to the public. Leaching of minute quantities of a hydrolysed, non-reactive form of the notified chemical has been observed from dyed cotton fabric in contact with simulated perspiration.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Black-violet powder

Melting Point/Freezing Point >400°C

METHOD OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks A Differential Thermal Calorimeter was used. An undefined exothermic process was observed between 55°C and 210°C, possibly indicating a change in crystalline structure. A second exothermic process was observed beginning at 320°C, indicating possible decomposition. After the experiment, the sample had lost 10% of its mass, but remained a blue powder. No melting was observed.
TEST FACILITY RCC Ltd. (2000*a*)

Boiling Point 608°C at 101.3 kPa (calculated)

METHOD The boiling point was estimated using Meissner's method (Lyman *et al*., 1990).
TEST FACILITY RCC Ltd. (2000*c*)

Density 1887 kg/m^3 at 20°C

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks The relative density was measured using a gas comparison pycnometer.
TEST FACILITY RCC Ltd. (2000*b*)

Vapour Pressure 3.80 x 10^{-20} kPa at 25°C (calculated)

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
OECD TG 104 Vapour Pressure Curve
Remarks The vapour pressure was estimated from the boiling point using the free acid form of the notified chemical and using the Modified Watson Correlation. The vapour pressure of the salt must be lower than the calculated value.
TEST FACILITY RCC Ltd. (2000*c*)

Water Solubility 135 g/L at 20°C

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks The Flask Method was used, and the concentration of notified chemical was determined by HPLC.
TEST FACILITY RCC Ltd. (2000*d*)

n-Octanol Solubility 4.82 mg/L n-octanol at 20°C

METHOD Two amounts of ~0.50 g of the notified chemical were weighed, mixed with 20 mL of n-octanol, and stirred at room temperature for ~24 hours. After centrifugation at ~2900 *g* for 10 minutes, the supernatant was filtered and diluted 1:1 with acetonitrile. Quantification of the notified chemical content was by HPLC with respect to a calibration curve.
Remarks Analytical Method: HPLC
TEST FACILITY RCC Ltd. (2000*f*)

Hydrolysis as a Function of pH

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

pH	*T (°C)*	*$t_{½}$ (hours)*
4	25	2250
	50	236
	60	113
	70	50
7	25	>8760
9	25	3536
	50	123
	60	36
	70	7

Remarks The concentration of the notified chemical was determined by HPLC. The notified chemical is stable to hydrolysis at neutral pH.

TEST FACILITY RCC Ltd. (2000*e*)

Partition Coefficient (n-octanol/water) log P_{ow} = - 4.5 at 20°C (calculated)

METHOD The partition coefficient of the notified chemical was estimated using the water and n-octanol solubility data (as above).

Remarks Neither the HPLC Method OECD TG 117, nor the Flask Method OECD TG 107 was used, as neither applied to the notified chemical (as it has high water and low n-octanol solubility).

TEST FACILITY RCC Ltd. (2000*f*)

Adsorption/Desorption Not determined.
The notified chemical has a low partition coefficient (log P_{ow} = -4.5) due to high water solubility (135 g/L) and low n-octanol solubility (4.82 mg/L). Therefore, the notified chemical is not expected to adsorb to soils.

Dissociation Constant Not determined.
The notified chemical has two sulfonic acid groups that are strongly acidic. Therefore it may be assumed that the pKa will be very low (negative).

Particle Size

METHOD European Commission, Particle Size Distribution, Fibre Length and Diameter Distribution. Guidance document, ECB/TM/February 1996.

Range (µm)	*Mass (%)*
< 5	0.58
5-8	0.48
8-10	0.41
10-20	3.39
20-40	6.87
40-60	3.90
60-80	2.34
80-100	1.35
100-150	6.71
150-250	15.52
250-500	28.42
500-1000	26.85
>1000	3.18

Remarks Inhalable fraction (<100µm): 19.32%
Respirable fraction (<10 µm): 1.47%
Mass median aerodynamic diameter: 309 µm

TEST FACILITY RCC Ltd. (2000*g*)

Surface Tension 72.3 mN/m at 20°C

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.
Remarks The surface tension was accomplished by means of tensiometer, using the ring method. Concentration: 0.101% (w/v)
Not surface active (as surface tension >60 mN/m).
TEST FACILITY RCC Ltd. (2000*j*)

Flash Point Not applicable.

The notified chemical is a solid substance, which is not expected to release vapours during normal storage and handling (Boiling point = 608°C (calculated) and Vapour pressure = 3.80 x 10^{-20} kPa at 25°C (calculated)).

Flammability Limits Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks Notified chemical combusted in a smokeless manner on application of a flame. Black ash remained after the test.
TEST FACILITY RCC Ltd. (2000*h*)

Autoignition Temperature 277°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks An exothermic reaction was observed, starting at around 270°C. Black ash remained after the test was complete.
TEST FACILITY RCC Ltd. (2000*i*)

Explosive Properties Not considered to have explosive properties. Not thermally sensitive, not shock sensitive, and not sensitive to friction.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
TEST FACILITY Institute of Safety and Security (2000)

Reactivity Not reactive to water or air at temperatures under normal conditions.

Remarks No hazardous reactions or decomposition are expected to occur under normal usage. In case of fires, hazardous combustion gases can be formed: carbon monoxide (CO), carbon dioxide (CO_2), nitrogen oxides (NO_x), sulfur oxides, copper oxides, and hydrogen fluoride (HF).

Oxygen in the notified substance is in deficit in relation to carbon atoms. It is reasonable to conclude that the substance is not capable of causing a fire or of increasing the risk when in contact with combustible materials.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral toxicity	low toxicity; LD50 >2000 mg/kg bw
Rat, acute dermal toxicity	low toxicity; LD50 >2000 mg/kg bw
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test.	no evidence of sensitisation.
Rat, oral (gavage) repeat dose toxicity - 28 days.	NO(A)EL = 50 mg/kg bw/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* chromosome aberration assay	inconclusive
Genotoxicity – *in vivo* mammalian erythrocyte micronucleus test	non-genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.

Species/Strain	Rat/HanIbm: WIST (SPF)
Vehicle	Distilled water
Remarks - Method	The animals received a single a 2000 mg/kg bw dose of the notified chemical by oral gavage, and the animals observed for 14 days.

RESULTS

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

LD50	>2000 mg/kg bw
Signs of Toxicity	No clinical signs were observed during the study period.
Effects in Organs	No macroscopic findings were observed at necropsy.
Remarks - Results	No deaths occurred during the study. The body weight of the animals was within the range commonly recorded for this strain and age.

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

TEST FACILITY RCC Ltd. (2000*k*)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Notified chemical

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

Species/Strain	Rat/HanIbm: WIST (SPF)
Vehicle	Distilled water
Type of dressing	Semi-occlusive
Remarks - Method	Five male and five female rats were treated with 2000 mg/kg bw notified chemical (suspended in distilled water at 0.5 g/mL) by application to skin for 24 hours.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	Slight focal erythema was observed in 3 male and 3 female animals on test day 2 after removal of the dressing. This persisted in 2 male animals until test day 5 and in 2 female animals until test days 3 and 4, respectively.
Signs of Toxicity - Systemic	No clinical signs were observed during the observation period. Two female animals showed a marginal loss in body weight one week after treatment, but all other animals were within the normal range.
Effects in Organs	No macroscopic findings were observed at necropsy.
Remarks - Results	No death occurred during the study.

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

TEST FACILITY RCC Ltd. (2000*l*)

7.3. Acute toxicity – inhalation

An acute inhalation toxicity study has not been conducted. Inhalation hazards are not expected to occur with the use and handling of the notified chemical. It is a non-volatile powder with a proportion of particles of inspirable size; however, the commercial product that will be imported is in a granular non-dusting form.

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White (1M, 2F)
Number of Animals	3
Vehicle	Distilled water
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks - Method	Topical semi-occlusive application of 0.5 g to 6 cm^2 intact left flank of each of three rabbits. The duration of treatment was four hours, and thereafter the animals were scored at 1, 24, 48 and 72 hours.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0.33	0	0	1	1 h	0
Oedema	0	0	0	0	0	0

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

Remarks - Results

- → Very slight erythema was observed in one male animal one hour after treatment. Local signs (mean values from 24 to 72 hours) consisted of grade 0.00 erythema and grade 0.00 oedema.
- → Light blue staining of the treated skin was observed in all animals after removal of the dressing and during the whole study period.
- → No corrosive effects were noted on the treated skin of any animal at any measuring interval.

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

TEST FACILITY RCC Ltd. (2000*m*)

7.5. Irritation – eye

TEST SUBSTANCE: Notified chemical

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

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	21 days
Remarks - Method	The primary eye irritation potential of The notified chemical was investigated by instillation of 0.1 g into one eye of each of three young adult New Zealand White rabbits. Scoring of irritation effects was performed approximately 1, 24, 48 and 72 hours, as well as 7, 10, 14, 17 and 21 days after notified chemical application.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.67	1.00	1.00	1.00	72h	0
Conjunctiva: chemosis	1.00	1.00	1.00	3.00	72h	0
Conjunctiva: discharge	-	-	-	-	1h	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	0	0	0

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

Remarks - Results

- → Marked (at 1 hour only) to slight blue staining produced by the notified chemical was observed in all animals up to the end of the study (wholly blue eye). Blue staining prevented examination of the redness of the conjunctivae (in two animals) and nictitating membrane (in three animals) at the 1-hour reading.
- → When visible, the conjunctivae or nictitating membrane was observed with some hyperaemic blood vessels in the first animal at the 24 and 72-hour observations, in the second from 1-72 hours and in the third from 24-72 hours. Slightly reddened sclera were noted for all animals at 24 hours and for two animals at 48 hours.
- → Slight to marked swelling of the conjunctivae and/or nictitating membrane was recorded for all animals at the 1-hour examination. From 24 to 72 hours, the swelling was slight (above normal) in all animals before clearing in all animals due to swelling (moderate to marked) and marked blue staining produced by the notified chemical.
- → Slight to marked watery discharge were observed in all animals at the 1-hour examination (not scored).
- → No corneal or iridal effects was observed in the treated eyes of any animals.
- → No corrosion was observed at any of the measuring intervals.

CONCLUSION: The notified chemical is slightly irritating to the eye.

TEST FACILITY: RCC Ltd. (2000*n*)

7.6. Skin sensitisation

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 406 Skin Sensitisation – Guinea pig Maximisation test.
EC Directive 96/54/EC B.6 Skin Sensitisation – Guinea pig Maximisation test).

Species/Strain: Guinea pigs/Ibm: GOHI (SPF-quality) (synonym: Himalayan spotted)

PRELIMINARY STUDY: Maximum Non-irritating Concentration:
- ➞ intradermal: 10%
- ➞ topical: 10% under an occlusive dressing.

MAIN STUDY

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

INDUCTION PHASE: Induction Concentration:
- ➞ intradermal injection 10%
- ➞ topical application 50%

Signs of Irritation: As skin was stained blue, it was not possible to determine whether erythema was present or not. However, no oedema was observed.

CHALLENGE PHASE

1st challenge: topical application: 10%

Remarks - Method
- ➞ In order to assess the cutaneous allergenic potential of the notified chemical, the Maximisation Test was performed in 15 (10 test and 5 control) female albino guinea pigs.
- ➞ The intradermal induction of sensitisation in the test group was performed in the nuchal region with a 10% dilution of the notified chemical in distilled water and in an emulsion of Freund's Complete Adjuvant (FCA)/physiological saline, The epidermal induction of sensitisation was conducted for 48 hours under occlusion with the notified chemical at 50% in distilled water one week after the intradermal induction. The animals of the control group were intradermally induced with bi-distilled water and FCA/physiological saline and epidermally induced with bi-distilled water under occlusion.
- ➞ Two weeks after epidermal induction the control and test animals were challenged by epidermal application of the notified chemical at 10% in distilled water and distilled water alone under occlusive dressing.
- ➞ Cutaneous reactions were evaluated at 24-48 hours after removal of the dressing.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after1st challenge*	
		24 h	*48 h*
Test Group	0	0	0
	10%	0	0
Control Group	0	0	0
	10%	0	0

Remarks - Results
- ➞ No positive control was used.
- ➞ Blue discolouration of the skin caused by the notified chemical was observed directly after removal of the patch.
- ➞ No deaths or any signs of systemic toxicity were observed. The body weight of the animals was within the normal range throughout the duration of the test.

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

TEST FACILITY: RCC Ltd. (2000*o*)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral). Japanese Guidelines for Screening, Toxicology Testing of Chemicals: Testing Methods for new Substances, enacted July 13, 1974, amended December 5, 1986.
Species/Strain	Rat/Hanlbm: WIST (SPF)
Route of Administration	Oral – gavage.
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: 14 days
Vehicle	Distilled water
Remarks - Method	➞ The notified chemical was administered daily to SPF-bred Wistar rats of both sexes for a period of 28 days. A control group was treated with vehicle only. ➞ An additional 5 rats per sex and group were treated at 0 and 1000 mg/kg bw/day. These animals were treated for 28 days and then allowed a 14-day treatment-free recovery period after which they were sacrificed. ➞ From the animals of the low and middle dose groups, the kidney and stomach were examined to establish a no-effect level.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
1 (control)	5/sex	0	0
2 (low dose)	5/sex	50	0
3 (mid dose)	5/sex	200	0
4 (high dose)	5/sex	1000	0
5 (control recovery)	5/sex	0	0
6 (high dose recovery)	5/sex	1000	0

Mortality and Time to Death

➞ All animals survived until scheduled necropsy.

Clinical Observations

➞ No clinical signs of toxicity were noted at any dose level during daily or weekly observations (weeks 1-3) or during the functional observational battery (week 4).

➞ Dark faeces were noted during daily observations in males and females treated with 200 and 1000 mg/kg bw/day. These findings were considered to be findings that commonly occur following oral administration of a dyestuff, rather than an indication of toxicity.

➞ The fore- and hind limb grip strength of the notified chemical-treated animals was unaffected.

➞ A transient reduction of locomotor activity was noted in males and females treated with 1000 mg/kg/day when compared with the controls most strongly in males during the first 30 minutes and in females during the first 15 minutes of the 60-minute measurement interval. These differences were considered to be related to the treatment with the notified chemical.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Haematology

Notified chemical-related findings, generally indicative of very slight anaemia with compensatory reticulocytosis, were noted in males treated with 1000 mg/kg bw/day. These changes were not seen in males treated with 50 or 200 mg/kg bw/day, nor in any females treated with the notified chemical, and were no longer present after the 2-week recovery period.

Clinical Biochemistry

Lower total protein levels and lower globulin levels were noted in males and females treated with 1000 mg/kg bw/day when compared with the controls. Albumin levels were lower in females treated with 1000 mg/kg bw/day when compared with the control values, whereas the males were unaffected. Although these findings

were largely reversible after the 2-week recovery period, some differences remained. All other parameters were unaffected by the treatment with the notified chemical after 4 weeks' treatment and 2 weeks' recovery.

Urinalysis

Changes in the urinalysis parameters (higher specific gravity, osmolality and pH) noted in males and females treated with 1000 mg/kg bw/day were generally commensurate with effects upon the ability of the kidney to concentrate urine. In males treated with 1000 mg/kg bw/day (but not females), ketone was present in the urine. These findings were reversible after 2 weeks' recovery. The urinalysis parameters of animals treated with 50 or 200 mg/kg bw/day were unaffected after 4 weeks' treatment and 2 weeks' recovery.

Effects in Organs

Organ Weights

Notified chemical-related increases in kidney weights (accompanied with changes in urinalysis parameters and morphology) were restricted to the males treated with 1000 mg/kg bw/day. The absolute and relative kidney weights of the females treated with 1000 mg/kg bw/day compared favourably with those of the controls. Although minor differences were noted in some absolute and relative organ weights of males and females at 50 or 200 mg/kg bw/day, these were not accompanied by corroborating evidence in related parameters and therefore considered to be incidental. All other organ weights and ratios compared favourably after two weeks' recovery.

Macroscopic/Microscopic Findings

In the kidneys of treated animals, discoloured kidneys were recorded at necropsy. There was no histological correlate to the discoloration, and therefore, this finding was likely due to colouration from the notified chemical or a metabolite. Tubular basophilia and lymphoid cell focus/foci increased in incidence in animals treated with 1000 mg/kg bw/day. These findings were accompanied by minor degrees of tubular cell swelling consisting of small vacuolated tubular cells in some females. The latter finding may contribute to higher kidney weights, although this finding was not recorded in males. Treatment with the notified chemical led to a slightly osmotic tubular nephrosis, supported by the minor increases in uric acid and minor decreases in bilirubin, albumin and protein levels in the high dose groups after the treatment period. Moreover, urine osmolality increased significantly in males after the treatment period.

In the stomach, a higher incidence of hyaline droplets in the glandular mucosa was found after four weeks' treatment and two weeks' recovery. This finding was accompanied by an increased incidence and severity of limiting ridge vacuolation in animals treated with 1000 mg/kg bw/day. Furthermore, increased inflammatory cell foci in the glandular submucosa were recorded in all animals and one recovery animal treated with 1000 mg/kg bw/day. These findings are indicative for a minor irritative potential of the notified chemical.

Remarks – Results

- Oral administration of the notified chemical to Wistar rats at doses of 50, 200 and 1000 mg/kg bw/day, for 28 days resulted in no effects upon mortality, daily or weekly clinical signs, functional observational battery, grip strength, food consumption or body weights. Treatment-related findings were generally restricted to males and females treated with 1000 mg/kg bw/day, manifested by transient reductions of locomotor activity, changes in haematology parameters, changes in clinical biochemistry parameters and increased absolute and relative kidney weights. These findings were noted after four weeks' treatment, but were reversible after two weeks' recovery.
- Discolouration was noted macroscopically in the kidneys of animals treated with 1000 mg/kg bw/day after four weeks. Historically, the incidence of lymphoid cell foci increased slightly in animals treated with 1000 mg/kg bw/day after four weeks' treatment and two weeks' recovery. These findings were accompanied by minor degrees of tubular cell swelling, consisting of small vacuolated tubular cells in two females after four weeks of treatment.
- In the stomach, the findings consisted of a higher incidence and severity of hyaline droplets in the glandular mucosa accompanied by an increased incidence and severity of epithelial vacuolation in the limiting ridge at 200 or 1000 mg/kg bw/day, as well as increased inflammatory cell foci at 1000 mg/kg bw/day. These findings are indicative of a minor irritant potential of the test article.

CONCLUSION

The No Observed (Adverse) Effect Level (NO(A)EL) was established as 50 mg/kg bw/day in this study based on the treatment-related histological changes in stomach mucosa seen at doses of both 200 and 1000 mg/kg bw.

TEST FACILITY RCC Ltd. (2000*q*)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Assay EC Directive 92/69, L383A Annexe V, B14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure / Pre incubation procedure.
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102.
Metabolic Activation System	Phenobarbital/β-naphthoflavone-induced S9 rat liver microsomes (test 1); non-induced S9 hamster liver microsomes (test 2).
Concentration Range in Main Test	a) With metabolic activation: 33-5000 µg/plate. b) Without metabolic activation: 33-5000 µg/plate.
Vehicle	Deionised water
Remarks - Method	The test was performed in triplicate at the following concentrations of notified chemical: 0, 33; 100; 333; 10000; 2500; and 5000 µg/plate.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>5000	333	>5000	>5000
Test 2		5000	>5000	>5000
Present				
Test 1	>5000	1000	>5000	>5000
Test 2		>5000	>5000	>5000

Remarks - Results

- The plates incubated with the notified chemical showed normal background growth up to 5000 µg/plate with and without S9 mix in all strains used. No substantial increase in revertant colony numbers of any of the five tester strains was observed following treatment with the notified chemical at any dose level, neither in the presence nor absence of metabolic activation.
- Slight toxic effects, evident as a reduction in the number of revertants, were observed in test 1 without metabolic activation in strains TA1535 (33 µg/plate), with metabolic activation in strain TA1537 (333 and 1000 µg/plate), and at 5000 µg/plate with metabolic activation in strain TA1537 in test 2.
- Appropriate reference mutagens were used as positive controls and showed the expected increases in revertant colonies.

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

TEST FACILITY RCC Cytotest Cell Research GmbH (2000*a*)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 473 *In vitro* Mammalian Chromosomal Aberration Test. EC Directive 2000/32, L 1362000, Annex V, B10, dated May 19, 2000. Japanese Guidelines: "Kanpoan No.287 – Environment Protection Agency" "Eisei No.127 – Ministry of Health & Welfare" "Heisei 09/10/31 Kikyoku No.2 – Ministry of International Trade & Industry".
Cell Type/Cell Line	Chinese hamster V79 cells
Metabolic Activation System	Phenobarbital/β-naphthoflavone-induced S9 rat liver microsomes

Vehicle	Deionised water
Remarks - Method	Per culture, 100 metaphase plates were scored for structural chromosome aberrations. The highest applied concentration in the pre-test on toxicity (5000 µg/mL) was chosen for the main test. Dose selection of the cytogenetic experiments was performed considering the toxicity data of the pre-experiment.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	156.3, 312.5, 625*, 1250*, 2500*, 5000	4	18
Test 2a	25, 50*, 100*, 150*, 200*, 300	18	18
Test 2b	100, 150, 200*, 300	28	28
Test 3a	25, 50, 100, 150*, 200*, 300*	18	18
Test 3b	25, 50, 100, 150*, 200*, 300*	18	28
Present			
Test 1	250, 500, 1000, 2000*, 3000*, 4000*	4	18
Test 2	312.5, 625, 1250*, 2500*, 3750, 5000*	4	28

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥2500	≥2500	>5000	negative
Test 2a		>300	>300	positive
Test 2b	>156.3[1]	>300	>300	positive
Test 3a		>300	>300	positive
Test 3b		>200	>300	negative
Present				
Test 1	≥625	≥4000	>4000	negative
Test 2		>5000	>5000	negative

[1] Preliminary test was of 24 hours exposure.

Remarks - Results

- In the absence and presence of S9 mix, clear toxic effects indicated by strongly reduced cell numbers or mitotic indices below 50% of control were observed. In the absence of S9 mix the mitotic indices were reduced only after continuous treatment whereas reduced cell numbers were observed after 4 and 18 h pulse treatment.
- Reproducibly increased aberration frequencies were observed after continuous exposure in the absence of S9 mix. Pulsed exposure followed by a recovery period yielded no relevant increases when tested up to cytotoxic concentrations. Therefore, in the absence of a mechanistic explanation, the notified chemical should be regarded as weakly clastogenic.
- No increase in the frequencies of polyploid metaphases was found after treatment with the notified chemical as compared to the frequencies of the controls.
- Appropriate mutagens were used as positive controls. They induced statistically significant increased aberration frequencies ($P < 0.05$).

CONCLUSION The clastogenic potential of the notified chemical is found to be weakly clastogenic in this chromosome aberration test.

TEST FACILITY RCC Cytotest Cell Research GmbH (2000*b*)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
EC Directive 2000/32/EC Annex 4C, Mammalian Erythrocyte Micronucleus Test.

Species/Strain: Mouse/NMRI
Route of Administration: Oral – gavage
Vehicle: Deionised water
Remarks - Method:
- ➞ This study was performed to investigate the potential of The notified chemical to induce micronuclei in polychromatic erythrocytes (PCE) in the bone marrow of the mouse.
- ➞ Ten animals (5 per sex) were evaluated for the occurrence of micronuclei. At least 2000 polychromatic erythrocytes (PCEs) per animal were scored for micronuclei.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
Vehicle	6/sex	0	24
Low dose	6/sex	500	24
Medium dose	6/sex	1000	24
High dose	6/sex	2000	24
High dose	6/sex	2000	48
cyclophosphamide	6/sex	40	24

RESULTS

Doses Producing Toxicity: ≥2000 mg/kg bw
Genotoxic Effects: >2000 mg/kg bw
Remarks - Results:
- ➞ After treatment with the notified chemical the number of NCEs was not substantially increased as compared to the mean value of NCEs of the vehicle control (rather, it was decreased slightly at maximal dose). This indicates that the notified chemical was not cytotoxic to bone marrow erythrocytes.
- ➞ In comparison to the corresponding vehicle controls there was no biologically relevant or statistically significant enhancement in the frequency of the detected micronuclei at any preparation interval after administration of the notified chemical and with any dose level used.
- ➞ Cyclophosphamide administered orally was used as positive control, and it showed the expected substantial increase of induced micronucleus frequency.
- ➞ A change in urine colour was observed, indicating systemic distribution of the notified chemical.

CONCLUSION: The notified chemical was not clastogenic under the conditions of this *in vivo* mouse micronucleus assay.

TEST FACILITY: RCC Cytotest Cell Research GmbH (2001)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Notified chemical

METHOD
- Inoculum: Aerobic activated sludge from a domestic sewage treatment plant (ARA Ergolz II, Zwitzerland).
- Exposure Period: 28 days
- Auxiliary Solvent: Test Water- prepared according to the testing guidelines.
- Analytical Monitoring: DOC analyses on a Shimadzu TOC-500 Analyser.
- Remarks - Method: The notified chemical and/or reference item were dissolved in test water. No emulsifier or solvent was used. To each flask (with the exception of abiotic control) activated sludge was added and made up to a total volume of 1000 mL with test water. The test flasks were incubated in a dark room and continuously stirred.

  The reference sodium benzoate was employed as a control at concentration of 50 and 51 mg/L. Samples were poisoned with mercury dichloride ($HgCl_2$) at a concentration of 10 mg/L. Test water was inoculated with defined volumes of dilute activated sludge to give a final concentration of 30 mg/L of dry material. The notified chemical was employed at concentration of 150 and 151 mg/L. The inoculated flasks were incubated in temperature-controlled room at 22-23°C. Prior to test start the pH was 7.4, measured in all test flasks before the addition of activated sludge. At the end of the incubation the pH ranged from 7.2 to 7.4. One sample of ~10 mL was taken from each test flask per sampling date. Sampling was done on day 0, 3, 7, 10, 14, 21, 27 and 28 of the incubation period for DOC.

RESULTS

Notified chemical		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	1	7	98
14	6	14	100
21	1	21	103
28	4	28	103

- Remarks - Results: In the test flasks containing the notified chemical and activated sludge the mean concentration of DOC varied between 29.3 and 31.9 mg/L over a period of 28 days and were not significantly different from the initial concentration of 31.2 mg/L measured on day 0.

  The reference item sodium benzoate was completely biodegraded within 7 days of exposure, confirming suitability of the activated sludge. In the toxicity control containing the notified chemical, reference item (sodium benzoate) and activated sludge (inoculum), the initial DOC decreased by 49% within 14 days of exposure.

  Thus, according to the test guidelines the notified chemical can be assumed to not be inhibitory to activated sludge microorganisms because degradation was >35% within 14 days.

CONCLUSION: The notified chemical was not ready biodegradable under the test conditions.

TEST FACILITY: RCC Ltd. (2000*v*)

8.1.2. Bioaccumulation

No bioaccumulation studies have been carried out.

CONCLUSION

It is considered that the notified chemical bioaccumulation potential is low. The partition coefficient, log P_{ow}, was calculated to be -4.5. The notified chemical is soluble in water (135 g/L) but has low solubility in n-octanol (4.82 mg/L). Therefore, it is not expected to partition into lipids.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 203 Fish, Acute Toxicity Test -static non-renewal test to an aqueous test medium.

Species: Rainbow Trout
Exposure Period: 96 hours
Water Hardness: 250 mg $CaCO_3$/L
Analytical Monitoring: HPLC-UV/VIS Analyser
Remarks – Method: Symptoms of intoxication could not be determined in the test medium during the test period due to intense coloration by the notified chemical. Therefore, the test fish were placed into control water at the end of the test for the observation of intoxication symptoms.

A limit test was performed in accordance with the guidelines to demonstrate that the notified chemical has no toxic effect on the test organisms up to and including the concentration of 100 mg/L and control.

The analytically determined notified chemical concentration in the test medium was 90% of the nominal value at the start and the end of the test. The notified chemical was stable under the test conditions during the test period of 96 hours. Therefore, all reported biological results are related to nominal concentration of the notified chemical.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
100	90	7	0	0	0	0	0
Control	0	7	0	0	0	0	0

LC50: > 100 mg/L at 96 hours.
NOEC: 100 mg/L at 96 hours.
Remarks – Results: In the control and at the test concentration of 100 mg/L, no mortality or other signs of intoxication were determined at the test fish at the end of the test.

CONCLUSION

The notified chemical was found not to be toxic to fish up to a nominal 100 mg/L.

TEST FACILITY

RCC Ltd. (2000*r*)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - immobilization acute static test.
Species	*Daphnia magna*
Exposure Period	48 hours
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC-UV/VIS Analyser
Remarks - Method	The test was performed in 250 mL glass beakers filled with 50 mL test medium. Since the test medium was intensively coloured by the notified chemical and the daphnids were hardly observable, beakers with large diameter were chosen to keep the test medium level low. A limit test was performed to demonstrate that the notified chemical has no toxic effect on the test organisms up to and including the nominal concentration of 100 mg/L. Thus, the only concentration tested was nominal 100 mg/L and a control

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
100	93 - 94	20	0	0
Control	0	20	0	0

LC50	> 100 mg/L at 48 hours
NOEC	100 mg/L at 48 hours
Remarks - Results	The analytically determined notified chemical concentration in the test medium at the start and the end of the test was 94 and 93% of the nominal value, respectively. Under the test conditions, the notified chemical was stable during the test period of 48 hours. Therefore, all the reported results are related to the nominal concentration of the notified chemical. At the test concentration of 100 mg/L no immobilized or dead test organisms were observed during the test period of 48 hours.
CONCLUSION	The notified chemical is very slightly toxic to *Daphnia magna*.
TEST FACILITY	RCC Ltd. (2000*s*)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test
Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 1.0, 3.2, 10, 32 and 100 mg/L Actual: 0.84, 2.93, 9.34, 30.5, 97.6 mg/L
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	HPLC-UV/VIS Analyser Coulter Counter, Model ZM
Remarks - Method	The test was modified to quantify the algicidal effect of the notified chemical, but also the growth inhibition effect caused by reduce light intensities in the coloured test solution.

RESULTS

Biomass Experiment A		*Growth Experiment A*	
E_bC50 (95% CL) mg/L (0-72 h)	*NOEC* mg/L	*E_uC50 (95% CL)* mg/L (0-72 h)	*NOEC* mg/L
33 (25-44)	3.2	> 100	100

Biomass Experiment B		*Growth Experiment B*	
E_bC50 (95% CL) mg/L (0-72 h)	*NOEC* mg/L	*E_uC50 (95% CL)* mg/L (0-72 h)	*NOEC* mg/L
47 (23-172)	-	> 100	100

Remarks - Results

The analytically determined notified chemical concentrations in the analysed test media varied in the range from 84 to 98% of the nominal values. The notified chemical was sufficiently stable in the test media under the test conditions during the test period of 72 hours. Therefore, all the biological results are related to the nominal concentrations of the notified chemical.

Experiment part A corresponds to the usual algal toxicity test. Therefore, the algal growth inhibition in this experimental part was caused by a possible toxic effect of the notified chemical and/or by the reduced light intensities due to light absorption in the coloured test media.

In experimental part B, the algal growth inhibition caused by the reduced light intensities of the coloured test media was quantified. In this experimental part a very similar inhibition effect on algal growth was observe compared to experimental part A.

CONCLUSION

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

TEST FACILITY

RCC Ltd. (2000*t*)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 209 Activated Sludge, Respiration Inhibition Test.

Inoculum

Aerobic activated sludge from a domestic sewage treatment plant (ARA Ergolz II, Zwitzerland).

Exposure Period

3 hours

Concentration Range

Nominal: 10, 32, 100, 320, 1000 mg/L

Remarks – Method

Notified chemical, together with two controls (deionized water, synthetic wastewater and activated sludge) and the reference item 3,5-dichlorophenol (positive control) at nominal concentrations of 5, 16 and 50 mg/L were tested in parallel under identical test conditions.

At the start of the test 200 mL activated sludge inoculum with a sludge concentration of 2.5 g dry weight/L (corresponding to about 1.0 g dry material per L test medium) was added. The sludge was added in time intervals of 15 minutes first to control, then to the test solutions of the reference item, then to the test solution of the notified chemical, and finally to the second control. During incubation period all test media and the controls were continuously aerated with compressed air at a flow of

	approximately 1 L/min. The concentration of dissolved oxygen did not drop below 2.5 mg/L during the incubation period, and just before the measurements of the respiration rates the dissolved oxygen concentration was at least 7.1 mg/L. The temperature in the test media, measured in one control, was 20°C at the start and at the end of the incubation period.
RESULTS	
IC50	> 1000 mg/L
NOEC	1000 mg/L
Remarks – Results	Up to and including the concentration of nominal 1000 mg/L the notified chemical had no significant inhibitory effect (<15%) on the respiration rate of activated sludge after the incubation period of 3 hours. The inhibition of the respiration rates was in the range of 1.5 to 9.1% compared to controls. Thus, the 3 hours NOEC of the notified chemical to activated sludge microorganisms was at least 1000 mg/L. The reference item had an ECSO of 26.8 mg/L, within the acceptable range of 5-30 mg/L, thus validating the test.
CONCLUSION	The test substance had no significant inhibitory effect on the respiration rate of activated sludge.
TEST FACILITY	RCC Ltd. (2000*u*)

8.2E. Inherent biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 302 B Zahn-Wellens/EMPA Test.
Inoculum	Aerobic activated sludge from a domestic sewage treatment plant (ARA Ergolz II, Zwitzerland).
Exposure Period	28 days
Auxiliary Solvent	Test Water- prepared according to the testing guidelines.
Analytical Monitoring	DOC analyses on a Shimadzu TOC-500 Analyser.
Remarks - Method	The notified chemical and/or reference item were dissolved in test water. No emulsifier or solvent was used. To each flask (with the exception of abiotic control) activated sludge was added and made up to a total volume of 2000 mL with test water. The test flasks were incubated under diffuse illumination. The reference sodium benzoate was employed as control at concentration of 120 mg/L. Test water was inoculated with defined volumes of dilute activated sludge to give a final concentration of 200 mg/L of dry material. The ratio between activated sludge and notified chemical was 2.9:1. The notified chemical was employed at concentrations of 300 and 300.5 mg/L. The inoculated flasks were incubated in temperature-controlled room at 21-22°C. The temperature was checked at the start of the test (0 h) and at each sampling interval. During the test the pH was in the range of 7.0 to 7.6. The oxygen concentration was checked at the start of the test (0 h) and at each sampling interval, and was in the range of 7.4 to 8.6 mg/L. One sample of 30 mL was taken from each test flask per sampling date. Sampling was done on Day 0, 3, 7, 10, 14, 21, 27 and 28 of the incubation period for DOC.

RESULTS

Notified chemical		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	-1	7	100
14	-3	14	97
21	0	21	99
28	2	28	100

Remarks - Results	In the test flasks containing the notified chemical and activated sludge the mean concentration of DOC was constant, during the exposure period of 28 days, 67.8 and 70.9 mg/L. No significant DOC removal was observed the first three hours of exposure indicating that the notified chemical did not adsorb on activated sludge. The reference item sodium benzoate was ultimately and completely degraded by 100% within the first three days of exposure, thus confirming suitability of the activated sludge.
CONCLUSION	The notified chemical cannot be classed as inherently biodegradable under the test conditions.
TEST FACILITY	RCC Ltd. (2000*w*)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

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

The major environmental exposure to the notified chemical will be from release to the communal sewer via the dye house effluent discharge. The dye containing the notified chemical will be used in one city dye house only. However, based on the typical use of the dye expected per day, worst-case predicted environmental concentration (PEC) values are estimated for the identified city dye house and one country dye house (one discharging into a large sewage treatment works and the other into a small sewage treatment works) assuming no partitioning to sludge within the sewage treatment works.

Process or Dilution Factor	City Dye house	Country Dye house
Typical notified chemical use expected per day	34 kg	5.8 kg
Quantity in wash water (at a fixation rate of 80%)	6.8 kg	1.2 kg
STP daily Volume	100 ML	4 ML
Concentration in effluent from sewage treatment plant	77 µg/L	288 µg/L

Predicted environmental concentrations (PECs) in receiving waters

	City Dye house	Country Dye house
Ocean PEC (Dilution Factor 1:10)	7.7 µg/L	29 µg/L
River PEC (Dilution Factor 1:1)	77 µg/L	288 µg/L

The low K_{oc} value and the inherent biodegradability test results indicate that the test substance is not likely to adsorb to sludge. Therefore, the notified chemical will remain in the water column and no further mitigation is possible.

The potential for bioaccumulation is low due to the notified chemical's very high water solubility, high molecular weight and low $\log K_{ow}$.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests are summarised below:

Organism	*Duration*	*End Point*	*mg/L*
Fish	96 h	LC_{50}	>100
Daphnia	48 h	LC_{50}	>100
Algae	0-72 h	E_bC_{50}	33
		E_uC_{50}	>100

Using the No Effect test concentration of 33 mg/L and a safety factor of 100 (based on 3 experimental results) for fish/Daphnia/algal acute toxicity endpoints, a Predicted No Effect Concentration (PNEC) for aquatic ecosystems of 0.33 mg/L is estimated. The Algal endpoint is derived from an effect of reduced light rather than an action of the notified chemical.

9.1.3. Environment – risk characterisation

The Risk Quotient PEC/PNEC is < 1 in a city dye house, indicating a low risk to the aquatic environment. However, the Quotient PEC/PNEC can be > 1 for freshwater in a country dye house, indicating a high risk to the freshwater aquatic environment.

Location	Receiving waters	PEC (µg/L)*	PNEC (µg/L)	Risk Quotient (RQ)*
City Dye house	Ocean outfall	7.7	330	0.02
	Inland River	77	330	0.23
Country Dye House	Ocean outfall	29	330	0.09
	Inland River	288	330	0.87

* The worst-case PEC and the RQ values calculated assuming the notified chemical is not removed during the wastewater treatment at the dye houses or the STP process.

The resulting risk quotient (RQ = PEC/PNEC) values for the aquatic environment, assuming that the chemical is not removed in the communal STP, are all below 1 for both freshwater and marine water for a city and country dyehouse, indicating no immediate concern to the aquatic compartment.

Based on the proposed use pattern the notified chemical is expected to pose an acceptable risk to the health of aquatic life for a city or country dye house.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Warehouse/stores personnel will wear protective equipment (overalls/industrial clothing and gloves as appropriate) when receiving/handling consignments of the commercial product containing the notified chemical. Exposure to the notified chemical should not occur except in the case of an accident or spill where the packaging is ruptured.

Dye operators have the greatest chance of exposure to the notified chemical. Weighing of the batch quantity of the notified chemical and dissolving it in water will be performed in an enclosed, ventilated weighing room, which has an exhaust hood in case the granulated dye materials generate dust. The dye operators will wear appropriate skin, eye and respiratory protection to reduce the possibility of exposure. Dye operators are also involved in controlling machine valves during the dyeing process, but during these processes they will have no contact with the notified chemical.

Damp fabric after dyeing contains the notified chemical fixed to the fabric fibres in an inaccessible form. Operator exposure to any residues of the notified chemical on the dyed fabric (wet or dry) is expected to be negligible.

Commercial washing of dyed fabrics is not expected to result in any risk to workers, as the notified chemical has been shown to leach from dyed fabric in only minute quantities. This leached form of the notified chemical is hydrolysed and non-reactive, and would be diluted many-fold in the volumes involved in the washing of fabrics. Most often wastewater would be removed from the washing process in an automated fashion.

9.2.2. Public health – exposure assessment

Fabrics dyed with the notified chemical will be manufactured into garments or home textiles. In dyed fabric, the notified chemical is generally inaccessible and there should be little or no exposure to the public. Leaching of minute quantities of a hydrolysed, non-reactive form of the notified chemical has been observed from dyed cotton fabric in contact with simulated perspiration. In addition, exposure to minute quantities of the notified chemical may occur during the washing of dyed fabrics, through leaching of the notified chemical. Therefore, members of the public are only likely to be exposed to the notified chemical through dermal exposure to the hydrolysed form of the notified chemical, leached from dyed fabric.

9.2.3. Human health – effects assessment

Toxicity studies indicate that the substance is generally of low toxicity. Acute and sub-acute repeated dose toxicity studies both showed an absence of serious adverse toxic effects of administration. The oral and dermal LD50 were both found to be >2000 mg/kg bw/day, indicating the classification of low toxicity. Given the notified chemical's high level of water solubility and its low solubility in n-octanol, significant dermal absorption of the notified chemical is unlikely. Absorption from the gastrointestinal tract appears to occur, as the colouration of urine indicated systemic distribution of the notified chemical in the repeat dose toxicity test and in the micronucleus assay. The detailed studies indicate that the notified chemical may have some specific toxic actions.

The No Observed (Adverse) Effect Level established in the repeated dose toxicity study was 50 mg/kg bw/day, based on the incidence of abnormalities in stomach mucosa and increases in stomach inflammatory cell foci. The stomach mucosa is exposed to a localised high concentration of the notified chemical when it is administered orally, without systemic absorption. Therefore, irritation of the stomach is likely following oral exposure to the notified chemical. Dark stained faeces was also observed following oral administration of the notified chemical, as expected for a poorly absorbed dye.

Dermal exposure to the notified compound is unlikely to result in significant toxicity beyond staining of the skin. Only very slight transient erythema was observed in only one animal, suggesting that the notified chemical is of low toxicity by this route. The notified chemical was also found to be not a skin sensitiser. Studies of eye irritation in rabbits indicated that the powder of the notified chemical is a slightly irritating to the eye on the basis of effects observed on the cornea, iris and conjunctivae. However, staining of the eye is persistent and affects the hazard classification.

Inhalation of dusts of the notified chemical is of possible concern, as the powder is of inhalable particle size. The toxicity of inhaled powders is unknown, as inhalation toxicity studies have not been carried out. However, given the relatively low toxicity displayed by the notified chemical in oral and dermal toxicity studies, and the fact that the notified chemical is to be used in a granular form, the impact of inhaled dusts is likely to be minimal.

The small quantity of the notified chemical that is absorbed by whatever route is likely to be cleared by excretion to urine, suggested by the discolouration of kidneys and urine seen in high dose animals. Some alterations in kidney function seen in the subacute study suggest that some toxicity to kidneys occurs during the elimination of the notified chemical. Some metabolism by the liver is likely to occur given the structure of the notified chemical, and this is most likely to consist of oxidation and conjugation processes that would make the compound more easily excreted by the kidneys. It is unlikely to accumulate in tissues because of its lack of fat solubility.

Chromosomal aberrations were observed *in vitro* for cells treated continuously with the notified chemical in solution for >18 hours. This raises some concern regarding the mutagenicity of the notified chemical. However, the results from shorter exposure periods, and from the Ames test and the *in vivo* mouse micronucleus assay, suggest that the notified chemical is unlikely to be significantly mutagenic to humans following a short exposure.

No human health conditions are known which may be affected by use of the notified chemical, and no incidents are known where exposure to the notified chemical resulted in health problems or adverse symptoms.

Based on the available data, the notified chemical is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*

(NOHSC, 2004) and assigned risk phrase R41: Risk of serious damage to eyes on the basis of persistent staining at the end of the observation period.

9.2.4. Occupational health and safety – risk characterisation

The primary route for potential exposure to the notified chemical is dermal. However, given the low dermal toxicity of the notified chemical, the lack of irritant and sensitising effects and its non-dusting granular form together with the use of personal protective equipment (PPE) means that there is a low risk of these effects in the workplace.

The notified chemical is a non-volatile powder with a proportion of inspirable particle size; however, the commercial product will be imported in a granular form. Standard recommendations apply to avoid the formation of dusts during use and local exhaust ventilation is used during weighing and addition to mixing vessels, so workers are unlikely to be at risk of toxicity from the inhalation of the notified chemical.

Powders of the notified chemical also pose a risk of slight eye irritation to workers. Given the use of appropriate PPE (as above) and the use of granulated dye products, this risk is minimal.

The mutagenic potential of the notified chemical (as shown in chronic exposure during *in vitro* studies, but not in the *in vivo* study) is unlikely to affect workers, given the expected exposure scenarios. Any exposure is likely to be of short duration, and dermal.

9.2.5. Public health – risk characterisation

Members of the public will only come into contact with dyed articles containing the notified chemical; therefore, their exposure will be primarily dermal. In dyed fabric, the notified chemical is generally inaccessible resulting in low exposure to the public. Leaching of minute quantities of a hydrolysed, non-reactive form of the notified chemical has been observed, but this is unlikely to cause significant toxicity, irritant or sensitising effects from clothing or other dyed articles.

Therefore, the available data on the notified chemical and the recommended usage in dyeing processes are such that no significant risks are expected to members of the public.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data, the notified chemical is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* and assigned risk phrase R41: Risk of serious damage to eyes on the basis of persistent staining and the end of the observation period.

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

For health effects the chemical is classified as an eye irritant Category 1 (irreversible effects on the eye).

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio, the notified chemical poses no risk to the environment based on the use pattern in city dye houses.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is No Significant Concern to public health when used as a textile dye.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

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

11.2. Label

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

12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following hazard classification for the notified chemical:
  - R41 Risk of serious damage to eyes

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:
  - *Exhaust ventilation should be employed when workers are engaged in operations and airborne dusts of the notified chemical could potentially occur.*

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced, and during use in dyeing operations:
  - *Impermeable gloves, appropriate footwear, protective apron, coveralls, and goggles/face shield.*
  - *An appropriate respirator when dusts of the notified chemical might occur.*

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - *Avoid the formation of dusts.*

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

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of

State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical waste and contaminated packaging should be disposed of as chemical waste to an approved waste disposal facility in accordance with official regulations. Incineration is recommended.

Emergency procedures

- In case of spillage of the product, the material should be removed whilst dry and recycled if possible. Personnel involved in clean up require adequate respiratory, skin and eye protection. The product should be removed mechanically using a shovel or any other suitable equipment. The material should be prevented from entering drains or watercourses. Disposal of spillages should be in accordance with government legislation and recycling should be considered.

12.1. Secondary notification

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

(1) Under Section 64(2) of the Act:

- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

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