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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Acid Brown 4126

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

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, Worksafe Australia, 92-94 Parramatta Road, Camperdown NSW 2050, between the hours of 10.00 a.m. and 12.00 noon and 2.00 p.m. and 4.00 p.m. each week day except on public holidays.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Acid Brown 4126

1. APPLICANTS

BASF Australia Ltd, 500 Princes Highway, Noble Park Vic 3174

ICI Australia (Operations) Pty Ltd, 1 Nicholson Street, Melbourne Vic 3001

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, the notified chemical is considered to be non-hazardous. Therefore, the chemical name, CAS number, molecular formula, structural formula, molecular weight and spectral data have been exempted from publication in the Full Public Report and the Summary Report.

Other names:	Acid Brown 4126; Säurebraun 4126; Reaktiv-braun 4126; Reactive Brown 4126; Zeneca Red Brown H-EXL
Trade names:	BASILEN BROWN E-RA notified chemical } in granulated PROCION RED BROWN H-EXL form

3. PHYSICAL AND CHEMICAL PROPERTIES

The following data were provided for the commercial product.

Appearance at 20°C and 101.3 kPa:	dark brown granulated powder
Melting Point:	>300°C
Relative Density:	1.71 @ 20/4°C
Water Solubility:	72-77 g/L @ 23°C
Fat Solubility:	<0.03 g/100g fat @ 37°C
Surface Tension:	0.0711 N/m @ 20°C (1 g/L solution)
Partition Co-efficient (n-octanol/water) log $P_{O/W}$:	<-5.4 @ 24°C
Flammability Limits:	not flammable
Ignition Temperature:	280°C
Explosive Properties:	not expected to be explosive based on the chemical structure
Reactivity/Stability:	not expected to have any oxidising properties based on the chemical structure

Particle size:	the granulated commercial product has an average particle size of 104 µm with 84% > 68 µm and 0.2% < 10 µm the undusted chemical (as used in the toxicity studies) has a MMAD 50% (mass median aerodynamic diameter 50%) of 1.5 µm and a respirable fraction of 95% (1)

Comments on physico-chemical data:

No test was performed for vapour pressure. The notifier argues that the vapour pressure of a substance with high MW is expected to be negligible. This is acceptable for a high MW salt.

Hydrolytic stability was not tested. The notifier argues that in view of the chemical stability of the notified substance a measurable hydrolysis can be excluded. This is acceptable based on the substance's chemical structure.

Adsorption/Desorption data were not provided. The notifier argues that the method of use will not present any opportunities for release of any significant quantity of the substance into the environment which could result in contamination of soil.

The dissociation constant was not provided. The dye contains sulphonate groups and basic aromatic amines and is expected to have a dissociation constant typical for these functionalities.

4. PURITY OF THE CHEMICAL

The notified chemical contains no hazardous impurities which are hazardous according to the criteria of Worksafe Australia (2). Therefore, information on the purity of the chemical has been exempted from publication in the Full Public Report and the Summary Report.

5. INDUSTRIAL USE

The notified chemical will be imported into Australia by BASF Australia Ltd as the principal component of BASILEN BROWN E-RA and by ICI Australia Limited as the principle component of PROCION RED BROWN H-EXL. These products will be used in the textile industry only. Textiles that will be treated include cotton, wool, silk and blended fabrics.

Up to 10 tonnes of the notified chemical will be imported per annum during the first five years. Products containing the notified chemical will be marketed throughout Australia.

The notified chemical was listed in the European Listing of New Chemical Substances (ELINCS) in 1990. It has also been registered in the USA, Austria (<1 tonne), Japan (<1 tonne; full notification pending), Switzerland, and Canada (transitional substance). The notified chemical is a variant on dyes already in use in Australia.

6. OCCUPATIONAL EXPOSURE

The notified chemical will not be manufactured in Australia. BASILEN BROWN E-RA and PROCION RED BROWN H-EXL, both granulated forms of the notified chemical, will be imported in sealed polyethylene bags within cardboard boxes or high density polyethylene drums (25 kg/package) and transported by road to the applicants stores. Approximately 3 transport drivers and 6 storepersons will be involved in transporting the products from the dock to the stores and from the stores to the customers. Occasionally (if the outer package is damaged) storepersons will be required to transfer the sealed inner polyethylene package into other outer packages. Exposure of the transport workers or storepersons should only result in the event of accidental spillages. At each supplier, laboratory personnel (~1/site) will test fabrics for dyeing performance. The procedure will be conducted approximately 80 days/year, and will involve the use of ~100g of product (in powder form) on each occasion.

At each dye house 1-2 store persons as well as 4-6 dye equipment operators may be exposed to the product. The dye stuff solution will be prepared by either storepersons (~60 hours/year/worker) or operators (40 hours/year/plant) depending on the plant. In a typical situation, the dye stuff will be scooped and weighed and added to a stock tank with water to form a 2% solution. The solution will be pumped to a thermally insulated dye vessel where the solution will be diluted further (to 0.2%) and mechanically mixed with the fabric. The dyeing vessel will be heated to 80°C during the dyeing operation. Operators may also be exposed to the dye in liquid form as samples are taken during the dyeing operation for colour checking. After the treatment is complete, the dye solution will be drained and the fabric rinsed in hot water (70°C). A further wash and rinse will be conducted in a separate vessel before the fabric is dried.

The principal source of exposure will occur during the handling of dye stuff powder. Workers will be instructed to wear protective clothing and gloves during these operations. Additionally, a dust respirator will be worn where local exhaust ventilation is not available or insufficient. Workers exposed to treated fabrics will be instructed to wear waterproof gloves and protective clothing.

7. PUBLIC EXPOSURE

The potential for public exposure to the notified chemical during dye mixing and treatment of fabrics is low. Minor spills will be contained with a dust binding material (eg. sand) and later incinerated. Residual dye is drained to the factory waste water system, and depending on the plant, will result in a concentration of 0.003 to 0.2 mg/L in receiving waters after discharge to the effluent. There should be negligible public health effects as a result of these operations.

As BASILEN BROWN E-RA and PROCION RED BROWN H-EXL will only be sold to the dyeing industry, the potential for public exposure to the notified chemical during dyeing operations is minimal, but once incorporated into fabrics, there is a potential to come into contact with the notified chemical. However, the dyeing process fixes the dye to the fabric (by covalently bonding to cellulose) and it is claimed that the process is wetfast and not removed by contact with moist skin or water. Overall, there should be minimal public exposure.

8. ENVIRONMENTAL EXPOSURE

. Release

The dye is to be used to colour cellulosic textiles in commercial dyehouses only. It will be chemically bound to the fibres via triazine links between the hydroxyl group of the cellulose fibres and the displaceable chlorine of the dye.

The notifier has indicated that the dye has a 85-90% level of fixation on the fibres. This level of fixation is within the normal range for reactive dyes. The remainder will be discharged into the sewer.

Spills that occur during transport or handling will be cleaned up according to the MSDS and consigned to secure landfill or incinerated.

. Fate

The bulk of the dye will become chemically bound to fibres and in this state is not expected to adversely impact on the environment.

The unfixed residues from dyeing operations will enter the aquatic environment after discharge from the textile mills and subsequent treatment at sewage treatment plants. As a result of the dye's low K_{OW}, and hydrolytic stability, it is likely that significant quantities will remain in the aquatic phase. Furthermore, reactive dyes have been found not to strongly adsorb to sludge (3) in model systems.

The dye was not tested for its biodegradability but based on its chemical structure it is not expected to show any appreciable degradation. The BOD/COD ratio was determined to be <1%, using a BOD (5 day) test according to German Standard DIN 38 409, part 43.

Residues that survive treatment in the sewage plant, which is likely, will enter either freshwater or marine environments in solution. The dye is stable to aerobic conditions but azo dyes are susceptible to reductive degradation under anaerobic conditions, characteristic of sediments (4). The half life of this degradation was found to be between 2 and 16 days for several sulfonic azo dyes (5), thus no significant increase in concentration over time is expected. One possible route for the dye to enter the sediments is by precipitation of its calcium salts, as several calcium salts of sulfonic dyes are known to be insoluble (5) at modest concentrations. However, apart from precipitation as the calcium salt, the hydrophilic nature of the notified chemical should limit the affinity for soil and sediment and thus the dye should remain mainly in the aquatic compartment.

The bioaccumulation potential of the dye was not investigated due to its very low partition coefficient ($\log P_{OW} < -5$), as allowed by the *Industrial Chemicals (Notification and Assessment) Act 1989.* This, together with the high water solubility and low fat solubility, indicate that bioaccumulation should not occur.

9. EVALUATION OF TOXICOLOGICAL DATA

The following toxicity studies were conducted using Säurebraun 4126/Acid Brown 4126 (the notified chemical in ungranulated form).

9.1 Acute Toxicity

Table 1Summary of the acute toxicity of the notified chemical

Test	Species	Outcome	Reference
Oral	Rat	LD_{50} >2200 mg/kg	6
Dermal	Rat	LD_{50} >2000 mg/kg	7
Inhalation	Rat	LC_{50} >5.3 mg/L/4h	1
Skin irritation	Rabbit	non-irritant	8
Eye irritation	Rabbit	slight irritant	9
Skin sensitisation	Guinea pig	non-sensitising	10

9.1.1 Oral Toxicity (6)

This study was conducted in accordance with OECD guideline No: 401 (11).

The notified chemical was administered to 10 Wistar rats (5/sex) by oral gavage, at a single dose of 2200 mg/kg (in 0.5% aqueous carboxymethylcellulose (CMC), corresponding to 10 ml/kg). Clinical observations were made over a 14-day period.

No deaths occurred during the observation period. All rats were sacrificed on day 14 and necropsy performed. No clinical effects or pathologic findings were noted.

Results of this study indicate an acute oral LD_{50} of >2200 kg/mg in rats of both sexes for the notified chemical.

9.1.2 Dermal Toxicity (7)

This study was conducted in accordance with OECD guideline No: 402 (12).

A single dose (2000 mg/kg) of the notified chemical, was prepared as a 50% solution in 0.5% aqueous CMC, and applied (at a volume of 4 ml/kg) by the cutaneous route to Wistar rats (5/sex). The treated areas were covered with a semi-occlusive dressing for 24 hours. Clinical observations were made over a 14 day period. All rats were sacrificed on the last day and necropsy performed.

No deaths occurred during the observation period. No clinical effects or pathologic findings were noted. Skin reactions could not be assessed due to the staining of the test substance.

Results of this study indicate an acute dermal LD_{50} of >2000 kg/mg in rats of both sexes for the notified chemical.

9.1.3 Inhalation Toxicity (1)

This study was conducted in accordance with OECD guideline No: 403 (13).

Wistar rats (5/sex) were exposed to the notified chemical as an aerosol dust (MMAD50 1.5 μm) at a concentration of 5.3 mg/L for 4 hours. Clinical observations were made over a 14 day period.

No mortalities were reported during the study. Weight gain was unaffected by treatment. Clinical effects were observed during the first 9 days of the study and included irregular respiration, respiratory sounds, closed eyelids, changes in posture and gait as well as deterioration of general state. Necropsy revealed no pathological changes.

The results of this study suggest an LC_{50} of >5.3 mg/L/4h (5300 mg/m^3/4h) for acute inhalation toxicity in rats of both sexes.

9.1.4 Skin Irritation (8)

This study was conducted in accordance with OECD guideline No: 404 (14).

A single dose of 0.5 g the notified chemical was applied by semi-occlusive application to the intact skin of 3 White Vienna rabbits for 4 hours. Skin reactions were assessed 4, 24, 48 and 72 hours after dressing application.

No erythema or oedema was apparent at any of the observation times. Erythema, however, could not be assessed in 2 of the animals at 4 or 24 hours due to the staining by the test substance.

The results of this study suggest that the notified chemical is not a skin irritant in White Vienna rabbits.

9.1.5 Eye Irritation (9)

This study was conducted in accordance with OECD guideline No: 405 (15).

A single dose of 0.1 ml (~73 mg) of the notified chemical was instilled in the conjuctival sac of the right eye of each of 3 White Vienna rabbits. The left eye served as the control. The eyes were examined 1, 24, 48 and 72 hours after treatment.

Erythema was observed at 1 hour (well defined, all animals), 24 hours (slight, all animals) and 48 hours (slight, 1 animal). All effects had subsided by 72 hours. Slightly increased discharge was observed in all animals at 1 hour only. No corrosion was observed during the study.

The results of this study suggest that the notified chemical is a slight eye irritant in rabbits.

9.1.6 Skin Sensitisation (10)

This study was conducted in accordance with OECD guideline No: 406 (16) using the Magnusson-Kligman Maximisation Test.

Test animals were female Pirbright White guinea pigs (4/treatment).

Induction

In a preliminary study the notified chemical applied occlusively as a 10% preparation in distilled water was determined to be the maximum non-irritant concentration. In the same study a 25% preparation produced distinct erythema.

On day one, 20 test animals were injected intradermally (in duplicate) with:

. 0.1 ml Freund's Complete Adjuvant diluted 50:50 in distilled water (50:50 FCA),

. 0.1 ml 5% notified chemical in distilled water, and

. 0.1 ml 5% notified chemical in 50:50 FCA.

On day 8, topical applications of 25% notified chemical in distilled water (equivalent to 0.30 g; occluded for 48 hours) were made to the injection sites of all test animals. Two control groups (10 animals/group) were given similar injections and topical applications with test material excluded.

1st Challenge

After 14 days both test and control group 1 animals were challenged with topical applications of 5% notified chemical in distilled water (equivalent to 0.15 g; occluded for 24 hours). Sensitisation reactions were assessed 24, 48 and 72 hours after patch removal.

No oedema was observed in test or control animals. Erythema, if any, was masked by compound staining at 24 hours (all animals), 48 hours (8/10 controls, 17/20 test animals) and 72 hours (8/10 controls, 17/20 test animals). In the remaining animals no erythema was observed at any of the observation times.

2nd Challenge

After 7 days, all animals, including control group 2, were challenged with 5% notified chemical in distilled water and skin reactions assessed 4, 48 and 72 hours later.

Again no oedema was observed in any of the animals. Skin staining resulted at 24 hours (all animals), 48 hours (15/19 controls, 14/20 test animals) and 72 hours (7/19 controls, 8/20 test animals). No erythema was observed in the remaining animals.

The results of this study suggest that the notified chemical is not a skin sensitiser in guinea pigs. However, skin staining may have masked any positive reactions.

9.2 Repeated Dose Toxicity (17)

A 28-day oral toxicity study was conducted in accordance with OECD guideline No: 407 (18).

The notified chemical was administered daily in drinking water to Wistar rats (5/sex/dose) at 0 (control group), 1000 (low dose), 5000 (mid dose) or 15000 (high dose) ppm for 4 weeks. These doses corresponded to an average of 0, 97, 497 or 1739 mg/kg/day. Clinical observations were recorded weekly. Blood samples were collected on day 28 and necropsy performed on day 29.

All animals survived to scheduled necropsy. The animals treated with the low and mid dose showed no treatment-related changes in food or water consumption or liver enzymes. Blood clotting time was increased in the mid dose females, though this effect was not dose dependent. Changes in clinical chemistry included decreased potassium levels in low dose females and increased triglicerides in mid dose males. Again these effects were not dose dependent.

High dose animals showed decreases in food consumption (both sexes), water consumption (females only) and body weight (females only). These effects were seen only at week 1. High dose males showed a significant increase (~45%) in alkaline phosphatase activity.

Gross pathology conducted at necropsy revealed the relative liver weights to be significantly decreased in high dose males. No other treatment-related effects were observed on organ weights. Discoloured gastrointestinal organs due to substance staining were noted.

Microscopic examination showed no treatment-associated effects.

The results of this study suggest the target organ for toxicity to be the liver in males.

9.3 Genotoxicity

9.3.1 Salmonella typhimurium and Escherichia coli Reverse Mutation Assays (19)

This study was conducted in accordance with OECD guideline No: 471 (20) and OECD guideline No: 472 (21).

The notified chemical was tested in the *Salmonella typhimurium* test strains TA 98, TA 100, TA 1535 and TA 1537 as well as *Escherichia coli* strain WP2*uvr*A, both with and without metabolic activation.

Doses tested were 0, 20, 100, 500, 2500 or 5000 µg/plate. Two experiments were conducted: a standard plate test and a preincubation test (3 plates/strain/dose/experiment). The reference mutagens N-methyl-N'-nitro-N-nitrosoguanidine (TA 100, TA 1535; - S9), 4-nitro-o-phenylendiamine (TA 98; - S9), 9-aminoacridine chloride monohydrate (TA 1537; - S9), N-ethyl-N'-nitrosoguanidin (WP2*uvr*A; - S9) and 2-aminoanthracene (all strains; + S9) were used as positive controls.

At the doses studied no increases were observed in revertant colonies, in either the presence or absence of metabolic activation. Significant increases in revertant colonies were observed when tested with the positive controls.

The results of this study indicate that the notified chemical is not mutagenic against *Salmonella typhimurium* or *Escherichia coli* in this test.

9.3.2 Ames Salmonella Assay - Prival Test (22)

The Ames Salmonella assay was performed according to OECD guideline No: 471 (20) with some modifications. The notified chemical was preincubated with flavin mononucleotide and hamster liver uninduced S9 to facilitate azo reduction.

Experiments were conducted in duplicate at compound doses of 0, 20, 100, 500, 2500 or 5000 µg/plate using *Salmonella typhimurium* tester strains TA 98, TA 100, TA 1535 and TA 1537 with and without hamster liver S9 mix (3 plates/strain/dose/ experiment). The reference mutagens N-methyl-N'-nitro-N-nitrosoguanidine (TA 100, TA 1535; - S9), 4-nitro-o-phenylendiamine (TA 98; - S9), 9-aminoacridine chloride monohydrate (TA 1537; - S9), 2-aminoanthracene (all strains; + S9), Congo red (TA 98: + S9) and benzidine (TA 98: + S9) were used as positive controls.

No increases were observed in the number of revertant colonies, in either the presence or absence of metabolic activation for any of the concentrations tested. The positive controls produced significant increases in revertant colonies.

The results of this study indicate that the notified chemical and its metabolites are not mutagenic against *Salmonella typhimurium* under the conditions of this test.

9.3.3 Chromosome Aberration Assay in Chinese Hamster V79 Cells (23)

This study was conducted in accordance with OECD guideline No: 473 (24).

Chinese hamster V79 cells were exposed to the notified chemical with and without exogenous metabolic activation. Experiments were conducted in duplicate. Cells were incubated with the notified chemical at concentrations of 0, 10, 50 or 100 µg/ml and harvested after either 18 hours (all doses) or 28 hours (high dose only). Cells exposed to S9 mix were treated with notified chemical at 0, 500, 2000 or 4762 µg/ml for 4 hours and harvested after a 14 hour (all doses) or 24 hour (high dose only) recovery period. The reference mutagens cyclophosphamide (+ S9) and ethylmethanesulfonate (- S9) were used. Stained chromosome preparations were examined for chromosomal aberrations (100 metaphases per treatment group; 25 metaphases per positive control).

In both the absence and presence of metabolic activation the notified chemical produced no significant increases in cells with structural aberrations at any of the dose levels tested.

The positive controls showed marked increases in the number of cells with structural chromosome aberrations. Cytotoxicity of the notified chemical, measured as a decrease in mitotic index, was observed at both high doses.

Under the conditions of this test the notified chemical is not clastogenic *in vitro*.

9.3.4 Micronucleus Assay in the Mouse Bone Marrow Cells (25)

This study was in accordance with OECD guideline No: 474 (26).

Mice (CD-1) were administered orally with notified chemical suspended in CMC (5 mg/ml distilled water) at dose levels of 1250, 2500 or 5000 mg/kg (dose volume 25 ml/kg). They were killed at 24, 48 or 72 hours after treatment (5 mice/sex/dose/treatment time with an additional 5 mice/sex at 72 hours). Negative control mice were given CMC alone (5 mice/sex/treatment time). Positive control mice (5/sex) were given cyclophosphamide (80 mg/kg) and killed after 24 hours treatment only.

At the end of each treatment period bone marrow cells were collected for micronuclei analysis from each group. One slide was prepared from each animal and the number of micronucleated polychromatic erythrocytes (PCE) per 1000 PCEs were scored.

Cytotoxic effects were described by the ratio of PCEs to normochromatic erythrocytes (NCE) for each animal.

Cyclophosphamide produced a significant increase in the micronuclei frequency. Micronuclei frequency and PCE/NCE ratios were no different for the test compound and the vehicle control.

The results of this study indicate that the notified chemical is not clastogenic *in vivo*.

9.4 Overall Assessment of Toxicological Data

The notified chemical was shown to have low acute oral, dermal and inhalation toxicity (rat oral LD_{50} >2200, rat dermal LD_{50} >2000, rat inhalation LC_{50} >5300 mg/m^3/4h respectively). It was non-irritating to rabbit skin and non-sensitising to guinea pig skin, however it was shown to be a slight irritant in the rabbit eye.

After administration of 1739 mg/kg/day of the notified chemical to rats for 4 weeks, treatment-related effects included decreased food and water consumption, decreased body weight (females only) and decreased relative liver weights (males only). Administration of 497 mg/kg/day produced no treatment-related effects. The target organ for toxicity is likely to be the liver in males.

The notified chemical was not found to cause point mutations in *Salmonella typhimurium* or *Escherichia coli.* The chemical was not clastogenic *in vitro* (Chinese hamster V79 cells) or *in vivo* (mouse micronuclei).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Ecotoxicity tests were performed using technical grade (73%) notified chemical and the results (table 2) were provided by the notifier. No precipitates or other irregularities were noted in these tests and the concentrations were measured (HPLC) at regular intervals for the fish studies. The Daphnia and bacteria toxicity studies used nominal concentrations. These tests were performed in accordance with standard OECD test methods, unless otherwise stated, and at facilities complying with OECD principles of GLP.

Table 2 Ecotoxicity summary for the notified chemical

Species	Test	Result*	Reference
Zebra fish, *Brachydanio rerio*	96 hour acute TG 203	NOEC >500 mg/L LC_{50} >1000 mg/L	27
Daphnia, *Daphnia magna*	48 hour immobilisation TG 202	NOEC >500 mg/L LC_{50}> 500 mg/L	28
Bacterial Inhibition *Pseudomonas putida*	30 minutes respiration (29)	IC $_{50}$> 100 mg/L	30

* Concentrations are actual.

The above results show that the notified chemical is practically non-toxic to fish and daphnia. Based on these results, chronic effects would not be expected at the estimated environmental concentrations and the lack of daphnia reproduction tests results is therefore acceptable.

Toxicity tests on algae were not performed, but toxic effects are not expected because of the dye's high water solubility and large molecular weight. Note that at a concentration of approximately 1 ppm, the dye is likely to be visible, which is of concern as algal growth will be inhibited in coloured water due to the reduced light intensity.

The dye does not affect bacterial respiration at 100 mg/L, indicating that it is non-toxic to bacteria likely to be encountered in the sewage system.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

As indicated above, 85-90% of the dye is fixed in the exhaust dyeing process, thus 15% of the dye used could be discharged into effluents of the dyehouses where it is used. The notifier has calculated the concentration of discharge for two model dyehouses, one in a regional centre (Type A) and the other city based (Type B). These were chosen to represent a range of situations. The calculations presented by the company are as follows:

Use of notified chemical per batch = 8 kg

Amount of dye used per batch (71% pure) = 5.68 kg

Fixation rate of 85%, quantity passing to effluent = 0.852 kg

Total volume of dyehouse wash waters:
Type A = 3,000,000 L
Type B = 1,500,000 L

Effluent concentration
Type A = 0.29 ppm
Type B = 0.57 ppm

Dilution in sewage treatment plants for:

Rural treatment plant 5 ML per day = 170 ppb (100% discharged),

City based 290 ML per day = 3.0 ppb (100% discharged)

CEPA has extended the calculation to the receiving waters.

Inland waterway (3:1 dilution) = 60 ppb

Ocean discharge from city (10:1 dilution) = 0.3 ppb

These calculations are based on no removal of notified chemical in the sewage treatment plant due to its high water solubility (>72 g/L) and low partition coefficient (log P_{OW} =<-5). The calculations give expected environmental concentrations significantly below the NOEL for fish and daphnia (>500 mg/L) and unlikely to significantly affect algae.

The dye is not expected to accumulate in the sediment nor bioaccumulate.

Spills of granulated powdered dyestuff should not present an environmental hazard when cleaned up according to the Material Safety Data Sheets.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Exposure by inhalation is likely to be the major route of exposure during the use of the notified chemical in solid form especially as a finely divided powder. The results of an acute inhalation study suggest that the chemical is not a primary respiratory irritant, although, as it is a reactive dye, respiratory sensitisation may be possible. The notified chemical, however, will be imported and used as a granulated solid which has a size distribution where 87% is greater than 68 µm and less than 0.2% is below 10 µm. With conformation to the Australian exposure standard for nuisance dusts 10 mg/m^3 inspirable (31), risks to workers via the inhalational route should be negligible.

Exposure to eyes and skin is also possible during use. The toxicity profile suggests that eye exposure may result in irritation, however exposure via the dermal route should not present a major concern to workers.

The engineering controls and personal protective equipment which the applicants have in place should minimise all routes of exposure to the notified chemical (both granulated powder and solution) to a safe level. Therefore, under normal use conditions the risk to occupational health and safety should be minimal.

There is low potential for public exposure to the notified chemical. Therefore there should be negligible risk to public safety.

13. RECOMMENDATIONS

To minimise occupational exposure to Acid Brown 4126 the following guidelines and precautions should be observed.

. Atmospheric concentrations of Acid Brown 4126 should be kept below the recommended exposure standard for nuisance dusts:

  TWA 10 mg/m^3 (31);

. Engineering controls such as enclosed systems should be used where possible;

. The work place should be well ventilated and if necessary local exhaust ventilation should be used;

. If work practices and engineering methods are insufficient to reduce exposure to the notified chemical to a safe level the following personal protection equipment which comply with Australian Standards should be worn:

  . dust mask (AS 1715, AS 1716) (32,33);

- goggles (AS 1336, AS 1337) (34,35);
- gloves (AS 2161) (36);
- protective clothing (AS 2919) (37);

- Good housekeeping and maintenance should be practised. Spills should be cleaned up promptly. Personal protective equipment should be worn during cleaning;
- Good personal hygiene practices, such as washing of hands prior to eating food, should be observed; and
- A copy of the Material Safety Data Sheet (MSDS) should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for BASILEN BROWN E-RA (Attachment 1) and PROCION RED BROWN H-EXL (Attachment 2) were provided in Worksafe Australia format (38) as part of the notification statement. These MSDS were provided by the applicants BASF Australia Ltd and ICI Australia (Operations) Pty Ltd, respectively. They are reproduced here as a matter of public record. Each of the applicants remains responsible for the accuracy of the information contained in their MSDS.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of Acid Brown 4126 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

1. Project No.: 13I0494/887058. *Study on the Acute Inhalation Toxicity LC_{50} of Säurebraun 4126 P 3 as a Dust Aerosol in Rats (4 Hour Exposure).* BASF Aktiengesellschaft, 1989.
2. National Occupational Health and Safety Commission, *Approved Criteria for Classifying Hazardous Substances*, Australian Government Publishing Service Publ., Canberra, 1994.
3. Hobbs S. Industry Category Document: UK Dye Production and Use in the Textile Industry, UK Department of the Environment (CR36/38), July 1988.
4. Yen C-P C., Perenich T. A. and Baughman G.L. *Environmental Toxicology and Chemistry*, **10**, 1009-1017, 1991.
5. Weber E. J. *Environmental Toxicology and Chemistry*, **10**, 609-618, 1991.
6. Project No.: 10A0494/881140. *Study on the Acute Oral Toxicity Study of Säurebraun 4126 on the Rat.* BASF Aktiengesellschaft, 1989.
7. Project No.: 11A0494/881141. *Report on the Study of Acute Dermal Toxicity of Säurebraun 4126 in Rats*. BASF Aktiengesellschaft, 1989.
8. Project No.: 18H0494/882204. *Study on the Acute Dermal Irritation/Corrosivity to the Intact Dorsal Skin of Säurebraun 4126 in White Rabbits*. BASF Aktiengesellschaft, 1989.

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10. Project No.: 30H0494/882206. *Report on the Maximization Test for the Sensitizing Potential of Säurebraun 4126 in Guinea Pigs*. BASF Aktiengesellschaft, 1989.

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