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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Firemaster BZ-54

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
International Sales & Marketing Pty Ltd (ABN 36 467 259 314)
262 Highett Road
Highett VIC 3190

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:
Identity of chemical;
Composition;
Exact import volume; and
Specific use

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None known

NOTIFICATION IN OTHER COUNTRIES
UK and USA

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
CN-2699 CN-
1348
CN-2065

MARKETING NAME(S)
Firemaster BZ-54

3. COMPOSITION

DEGREE OF PURITY
High

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. It will be imported as a neat substance or in a diluted form contained in 340 kg steel drums. The notified chemical will form part of a polyol component for use in polyurethane foam manufacture.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	30-60	30-60	30-60	30-60	30-60

USE
The notified chemical will be used as a flame retardant in polyurethane foam production.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney and Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
International Sales & Marketing Pty Ltd (ABN 36 467 259 314)
262 Highett Road
Highett VIC 3190

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in 340 kg steel drums, 4 per pallet in containers. The imported chemical is stored at warehouses in Sydney or Melbourne prior to distribution to customers by road.

5.2. Operation description

Following importation, the notified chemical will be stored at warehouses in receiving ports prior to distribution to customers for use in polyurethane manufacture.

At the customers site, the imported chemical is either stored in its original packaging or the drums are decanted into tanks prior to use.

Polyurethane foams are made by reacting two-component systems. Component A is typically an isocyanate and Component B is a polyol or polyether. During polyurethane manufacture, the notified chemical will be added to a mixing tank to form a polyol blend containing <20% notified chemical. Alternatively, the notified chemical is directly added into the foam manufacturing line using a metering device. The polyol blend containing the notified chemical is converted to foam as soon as it mixes with the isocyanate. The majority of polyurethane foam is manufactured using highly automated and enclosed processes. Transfer operations involves dedicated lines, pumps and metering devices. For small companies, manual weighing and transfer operations of the notified chemical into the polyol mixing are involved. The notified chemical is incorporated into the polyurethane foam at <20% concentration. Offcuts from foam activities mostly go to lower grade applications such as carpet underlay.

5.3. Occupational exposure

Dermal contact, and limited ocular and inhalation exposure to the notified chemical is possible when handling open containers of the notified chemical, and manually weighing and adding the notified chemical into the polyol tank during polyol blending. Skin contact from spillages of the polyol blend is also possible when overfilling containers.

The manufacturing process for polyurethane foam is described to be highly automated and enclosed. However, it is possible that skin contamination to the notified chemical may occur if pumps and metering device malfunctions during foam manufacture. Skin and eye contamination during cleaning and repair of the equipment may also occur. Workers will wear chemical resistant gloves, impervious protective clothing, splash goggles or safety glasses with side shield. Organic cartridge respirators should also be worn if vapour or misting occurs. Local exhaust ventilation is in place to minimise vapour and misting. Since isocyanate is used during foam manufacture, special precautions

on the safe handling of isocyanate should also be observed.

There is no potential for direct exposure to the notified chemical after foam manufacture, since the notified chemical is entrained into the foam.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured in Australia but will be imported for blending into flexible polyurethane foam for use in various furniture products. Environmental release of the notified chemical is unlikely to occur following accidental spillage of imported containers containing the notified chemical during importation (shipping), handling, storage or domestic transportation due to established emergency response procedures and environmental controls. Directions are provided on the label and Safety Data Sheet for handling, bunded storage, emergency response and spill clean up to minimise the environmental impact of a spill incident. Imported container size (340 kg) and construction specifications (steel drums) will also limit the extent of a spill.

Containers holding the notified chemical will be transported directly from the port facility to various customer sites in Australia for storage prior to blending into foam products. Blending is mostly undertaken using automated pumping and mixing procedures in enclosed systems and spillage is not expected. Manual handling/pumping of drums containing the notified chemical may occur at smaller manufacturing facilities. Waste residues of notified chemical may be generated in batch mixing equipment and the notifier estimates <65 kg/y of notified chemical may be generated Australia-wide, which would either be used in the next batch or collected by waste disposal contractor for landfill disposal.

During incorporation of the notified chemical and manufacture of products, water is not used in the process and generation of aqueous waste streams containing the notified chemical is not anticipated. Imported containers are not rinsed after use at customer sites; but are collected by an approved waste management contractor for reconditioning and/or disposal. Off-specification products and scrap materials (3-5% of the import volume of the notified chemical) is likely to be recycled into other indoor products (eg. carpet underlay) and/or sent to landfill for disposal.

RELEASE OF CHEMICAL FROM USE

The notified chemical will be entrained in the flexible foam products and tends not to leach, and foam products containing the notified chemical are unlikely to be exposed to water. Degradation of the foam matrix may occur, usually giving a friable dusty surface, if exposed to sunlight over a long period; however, foam products are likely to be covered and/or used indoors and therefore stable. No information on the stability of finished foam products, their potential outdoor use pattern, or long term fate of the notified chemical in finished foam products was provided in the submission. Products containing the notified chemical will have widespread and diffuse use pattern, but mostly in developed areas in Australia.

5.5. Disposal

Residues of the notified chemical in emptied imported drums will not be rinsed but will be collected by waste management contractors for either disposal, metal recycling, or drum reconditioning. No wastewaters containing the notified chemical are generated during manufacture of foam products. A small quantity of waste may be generated after each foam batch is produced (eg. <65 kg/y), which will be reused in the next batch or collected by waste disposal contractor for solid waste disposal. Products containing the notified chemical will have widespread and diffuse disposal pattern in Australia and waste finished products will be mostly sent to landfill for disposal.

5.6. Public exposure

Public exposure during polyurethane manufacture is negligible. Public exposure to formed polyurethane can occur in the form of automotive or home furnishings. At this stage, the notified chemical is contained within the polymer matrix and the potential for public exposure to the notified chemical during all phases of its life cycle is considered low.

The potential for exposure of the public to the notified polymer during normal industrial storage, handling and transportation is negligible, except in the case of an accident. The packaging will protect the contents from being released during normal handling.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Amber liquid

Freezing Point <25°C

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Freezing point was determined using a standard crystallising apparatus
TEST FACILITY Huntingdon Life Sciences Ltd. (1997a)

Boiling Point 317-331°C at 101.3 kPa

METHOD EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Ebulliometric Method
TEST FACILITY Huntingdon Life Sciences Ltd. (1997a)

Density 1710 kg/m^3 at 20°C

METHOD EC Directive 92/69/EEC A.3 Relative Density.
Remarks Pycnometer Method
TEST FACILITY Huntingdon Life Sciences Ltd. (1997a)

Vapour Pressure $1.3X10^{-7}$ kPa at 25°C

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Vapour Pressure Balance Method. The temperature of the sample was maintained at <94.5°C and the chemical appears not to have undergone decomposition. Mass readings (±0.1 µg) and temperature (±1°C) were recorded. Tests were performed in triplicate. The notified chemical is slightly volatile (Mensink et al., 1995).
TEST FACILITY University of Leeds (1997)

Surface Tension 72.2 mN/m at 20°C

METHOD EC Directive 92/69/EEC A.5 Surface Tension.
Remarks The surface tension of a 90% saturated aqueous solution of the notified chemical was determined using the OECD harmonised ring method. The notified chemical was not considered to be surface active.
TEST FACILITY Huntingdon Life Sciences Ltd. (1997a)

Water Solubility 2.01 mg/L at 20°C

METHOD EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Flask Method, with HPLC detection. The notified chemical is slightly soluble in water (Mensink *et al*., 1995).
TEST FACILITY Huntingdon Life Sciences Ltd. (1997a)

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)*	*$t_{½}$ year*
4	25	>1
7	25	>1
9	25	>1

Remarks After 5 days at 50°C, the notified chemical did not hydrolyse at either pH 4, 7 or

9, as determined by HPLC. The hydrolysis of the test material was estimated using the following criteria where 50% hydrolysis occurring in 2.4 hours at 50°C is equivalent to a half life time of 1 day at 25°C and 10% hydrolysis occurring in 5 days at 50°C is equivalent to a half life time of 1 year at 25°C. The notified chemical is therefore considered as hydrolytically stable at pH 4, 7 and 9.

TEST FACILITY Huntingdon Life Sciences Ltd. (1997b)

Partition Coefficient (n-octanol/water) log Pow = >6.2 at 20°C

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks HPLC Method. The notified chemical eluted after DDT, the last eluting reference substance used.
TEST FACILITY Huntingdon Life Sciences Ltd. (1997a)

Adsorption/Desorption log K_{oc} = >4.46 at 20°C

METHOD OECD TG 106 Adsorption - Desorption Using a Batch Equilibrium Method.
Remarks OECD Draft Guideline TGP/94.75 (April 1994) by HPLC. The notified chemical (97.2% purity) eluted later than sulprofos, the latest eluting reference substrate used. The test result is unlikely to be mobile in soils.
TEST FACILITY Huntingdon Life Sciences Ltd (1997c)

Dissociation Constant Not determined

Remarks The notified chemical has no dissociable groups.

Particle Size Not determined

Remarks The notified chemical is imported as liquid.

Flash Point 215°C

METHOD EC Directive 92/69/EEC A.9 Flash Point.
Remarks Closed cup
TEST FACILITY Huntingdon Life Sciences Ltd. (1996a)

Flammability Limits Non-flammable

Remarks The notified chemical does not possess flammable properties.

Autoignition Temperature 350°C at 1016 mbar

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
TEST FACILITY Huntingdon Life Sciences Ltd. (1997a)

Explosive Properties Not explosive

Remarks A Koenen test apparatus was used for thermal sensitivity (effect of a flame) and a fall hammer determination pf mechanical sensitivity. The notified chemical does not possess explosive properties
TEST FACILITY Huntingdon Life Sciences Ltd. (1997a)

Reactivity

Remarks The notified chemical is not reactive in water. Strong alkalis can hydrolyse bromine. The notified chemical is stable under normal conditions. Thermal decomposition may produce hydrogen bromide, bromine, carbon monoxide and carbon dioxide.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 2000 mg/kg bw	low toxicity
Rat, acute oral LD50 >5000 mg/kg bw	low toxicity
Rat, acute dermal LD50 2000 mg/kg bw	low toxicity
Rat, acute inhalation	not conducted
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – non-adjuvant test.	limited evidence of sensitisation.
Rat, repeat dose oral toxicity – 28 days.	NOEL <160 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration test	non genotoxic

7.1 Acute toxicity – oral

7.1.1. Acute toxicity – oral – Initial Test

TEST SUBSTANCE: Notified chemical

METHOD: EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.
- Species/Strain: Rat/Sprague-Dawley (CD)
- Vehicle: None
- Remarks - Method: No significant protocol deviations. A preliminary study was carried out on a female rat dosed at 500 or 2000 mg/kg bw, and as a result, 2000 mg/kg bw was chosen as the dose level for the main study.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	0/10

- LD50: 2000 mg/kg bw
- Signs of Toxicity: Piloerection in all animals were observed almost immediately after dosing and was accompanied by hunched posture on Day 1. All animals recovered by Day 4.
- Effects in Organs: Macroscopic examination of all animals at termination kill revealed no abnormalities.
- Remarks - Results: Two male animals had slightly low body weight gain on Day 8 and Day 15. All other animals had normal body weight gains through out the study.

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

TEST FACILITY: Huntingdon Life Sciences Ltd (1996b)

7.1.2. Acute toxicity – oral – Repeat Test

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 401 Acute Oral Toxicity – Limit Test.
EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.
Toxic Substances Control Act (TSCA) Health Effects Test Guidelines (40 CFR 798.1175).

Species/Strain	Rat/Sprague-Dawley (Crl:CD BR)
Vehicle	None
Remarks - Method	A preliminary study was carried out in 10 (1 animal/sex/dose) rats dosed at 500, 1000, 2000, 3500 or 5000 mg/kg bw. All animals survived, and 5000 mg/kg bw was selected as the dose level for the main study.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	5000	0/10

LD50	>5000 mg/kg bw
Signs of Toxicity	Wet and/or dried yellow staining on the urogenital area and/or limb(s) was observed in all animals. A single male had soft stool on the day of dosing. All animals recovered by Day 6 or earlier.
Effects in Organs	Macroscopic examination of all animals at termination kill revealed no abnormalities.
Remarks - Results	There were no remarkable changes or differences observed in body weights during the study when compared with the control group.

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

TEST FACILITY WIL Research Laboratories, Inc (1997a)

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.
Toxic Substances Control Act (TSCA) Health Effects Test Guidelines (40 CFR 798.1100)

Species/Strain	Rat/Albino (Crl:CD®BR)
Vehicle	None
Type of dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	0/10

LD50	2000 mg/kg bw
Signs of Toxicity - Local	Very slight erythema and desquamation were observed in two females. All erythema subsided by day 8 and, all desquamation has disappeared by Day 10.
Signs of Toxicity - Systemic	Dried red material around the nose and/or mouth in eight animals, and wet and/or dried yellow urogenital staining were observed on the day of dosing. All animals appeared normal by Day 1.
Effects in Organs	None.
Remarks - Results	There were no significant body weight changes during the study period. The red material around the nose and/or mouth and, wet and/or dried yellow urogenital staining were often observed in rats that have been bandaged/collared.

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

TEST FACILITY WIL Research Laboratories, Inc (1997b)

7.3. Acute toxicity - inhalation

The acute inhalation toxicity test was not conducted.

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).
Toxic Substances Control Act (TSCA) Health Effects Test Guidelines (40 CFR 798.4470).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3/sex
Vehicle	None
Observation Period	7 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0.33	1	4 days	0
Oedema	0	0	-	0

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

Remarks - Results Very slight erythema in five animals, which persisted up to 4 days in one animal, was observed. There was no oedema observed.

There were no remarkable body weight changes during the study.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY WIL Research Laboratories, Inc (1997c)

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).
Toxic Substances Control Act (TSCA) Health Effects Test Guidelines (40 CFR 798.4500).

Species/Strain	Rabbit/New Zealand White
Number of Animals	4 males and 2 females
Observation Period	4 days
Remarks - Method	Sodium fluorescein was used to detect any corneal abnormalities prior to initiation of dosing and at 72-hour observation period.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.44	2	72 hours	0
Conjunctiva: chemosis	0	1	1 hour	0
Conjunctiva: discharge	0	1	1 hour	0
Corneal opacity	0	0	-	0
Iridial inflammation	0	0	-	0

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

Remarks - Results

Conjunctival redness and clear discharge were apparent in all animals 1 hour after instillation. Conjunctival redness persisted up to 72 hours for one female animal. All animals appeared normal by the end of the observation period.

There were no corneal (no fluorescein staining) or iridal effects observed, and no remarkable body weight changes seen during the study.

CONCLUSION

The notified chemical is slightly irritating to the eye.

TEST FACILITY

WIL Research Laboratories, Inc (1997d)

7.6. Skin sensitisation

7.6.1. Skin sensitisation – Buehler Method

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 406 Skin Sensitisation – Buehler Test.
EC Directive 96/54/EC B.6 Skin Sensitisation – Buehler Test.
Toxic Substances Control Act (TSCA) Health Effects Test Guidelines (40 CFR 798.4100).

Species/Strain

Guinea pig/Hartley (Hsd:DH)

PRELIMINARY STUDY

Maximum Non-irritating Concentration:
topical: 100%

MAIN STUDY

Number of Animals

Test Group: 10/sex Control Group: 6/sex (naïve); 6/sex (positive)

INDUCTION PHASE

Induction Concentration:
topical: 100%

Signs of Irritation

Very slight to slight dermal reactions were observed in all animals.

CHALLENGE PHASE

1st challenge

topical: 100%

Remarks - Method

Two vehicles (acetone and dimethylsulfoxide) were identified as acceptable diluents for the test material. In the range finding experiment, use of these vehicles did not result in a non-irritating dilution of the test material. Therefore, a 100% (undiluted) concentration of the test material was selected for challenge dosing although this concentration was identified as a slight to moderately irritating.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	100%	20/20	17/20
Control Group	100%	12/12	12/12

Remarks - Results	There were no remarkable changes observed in body weights. Animals in the test and control groups showed comparable skin reactions of slight to moderate erythema on the 24 hour observation. The degree of erythema subsided at the 48 hour observation period in all animals, while the test control groups remained comparable. The positive control showed a much more intense skin reactions compared to the test and control groups, indicating that the test system responded appropriately.
CONCLUSION	The notified chemical may have skin sensitising ability but the test conditions employed are inadequate. Therefore, on the basis of inadequate evidence, no conclusion is made.
TEST FACILITY	WIL Research Laboratories, Inc (1997e)

7.6.2. Skin sensitisation – Magnusson & Kligman Method

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 406 Skin Sensitisation – Magnusson and Kligman Test. EC Directive 96/54/EC B.6 Skin Sensitisation – Magnusson and Kligman Test.
Species/Strain	Guinea pig/Dunkin Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 80% v/v in Alembicol D topical: 96% (as supplied)
MAIN STUDY	
Number of Animals	Test Group: 10 females Control Group: 5 females
INDUCTION PHASE	Induction Concentration: intradermal: 80% v/v Alembicol D topical: 96% (as supplied)
Signs of Irritation	Necrosis at intradermal injection sites of Freunds's Complete Adjuvant (FCA) in test and control animals was reported. Slight to well-defined irritation at injection was seen in test animals receiving 80% notified chemical in Alembicol D, and slight irritation was observed in control animals receiving Alembicol D. Slight erythema was observed in most test animals following topical application of the notified chemical as supplied. Slight erythema was seen in one control animal.
CHALLENGE PHASE	
1st challenge	topical: 96% (as supplied) and 50% v/v in Alembicol D
2nd challenge	topical: 50% and 25% v/v in Alembicol D
Remarks - Method	No significant protocol deviations.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group					
	as supplied	9/10	9/10		
	50% v/v in Alembicol D	3/10	3/10	4/10	3/10
	25% Alembicol D			1/10	2/10

Control Group				
as supplied	2/5	2/5		
50% v/v in Alembicol D	1/5	1/5	0/5	0/5
25% Alembicol D			0/5	0/5

Remarks - Results

There were no signs of toxicity observed during the study. Bodyweight increases were recorded for all animals over the study period.

1st challenge

Erythema and/or oedema were observed in 40% of the control animals and 90% of the test animals when challenged with the test material as supplied. Dryness and sloughing of the epidermis were observed in 7 test animals.

Erythema and/or oedema were observed in 20% of the control animals and 30% of the test animals when challenged with 50% v/v test material in Alembicol D.

Due to the above reactions seen in both control and test groups, a 2nd challenge using lower concentrations of the test material was conducted.

2nd challenge

Dermal reactions similar to those observed in the 1st challenge, persisted in 30% of the test animals compared to none in the control animals. One test animal gave an inconclusive response and the remaining test animals gave negative responses.

The positive control (2-mercaptobenzothiazole) produced evidence of skin sensitisation in all of the positive control animals, indicating the sensitivity and reliability of the experimental technique.

CONCLUSION

There was evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY

Huntingdon Life Sciences Ltd (1999)

7.7. Repeat dose toxicity

TEST SUBSTANCE

Notified chemical

METHOD

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

Species/Strain	Rat/Sprague-Dawley (Crl:CD®BR)
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	Corn oil
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	6/sex	0	
II (low dose)	6/sex	160	
III (mid dose)	6/sex	400	

IV (high dose)	6/sex	1000
V (control recovery)	6/sex	0
VI (high dose recovery)	6/sex	1000

Mortality and Time to Death
There were no unscheduled deaths during the study.

Clinical Observations
Salivation was observed in most animals of the high dose group (4/12 males and 8/12 females) and in one female in the mid dose group. Relaxed vaginal openings were noted in a number of females in all dose groups. Other findings in treated groups, which occur at low incidence, include scabbing, relaxed scrotum, wet yellow material on the urogenital area and ocular discharge.

Statistically significant decrease in mean body weight gains was observed in high dose animals and in mid-dose females, through out the dosing period. Decreased in mean body weight gains were also observed in the female low dose group on Week 3 of the study. As a result, the overall body weight gains of all animals in the high dose group and females in the mid dose group were significantly decreased from Week 1 to the end of the dosing period, and in low dose female group from week 2 to the end of the dosing period. The mean body weights of the high dose recovery group were comparable to the control recovery group.

Food consumption was consistently reduced in the high dose males during Week 1 and 2, and in high, mid and low dose females from Week 1 to end of the dosing period. During the recovery period, food consumption was similar to or greater than the control group.

No significant differences were seen in the functional observational battery and motor activity tests in animals at all dose groups.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Clinical chemistry
Significant increase in mean albumin/globulin ratio was observed in high dose group. Mean chloride was also significantly increased in all high dose, in female mid dose, and in female low dose groups.

Other observations, which were slight and non-dose related changes, include increased mean creatinine in high dose group, mean chloride in male mid dose group, and mean sodium in female low and mid dose groups. Mean calcium was decreased in female low dose group. Decreased mean urea nitrogen in male high dose recovery, and decreased mean albumin and total proteins were observed in female high dose recovery group.

Haematology
Mean platelet and lymphocyte counts were statistically decreased in female high dose group in Week 4. During recovery, female high dose recovery group had increased mean total leukocyte and absolute lymphocyte count, and decreased mean red blood cell, haemoglobin and hematocrit count.

Urinalysis
Urine analysis was not conducted.

Effects in Organs
No treatment-related organ effects were seen at the scheduled necropsy. Enlarged Peyer's patches, clear fluid contents of the uterus, small/soft testis were observed sporadically or at a similar incidence to the control group.

Several statistically significant differences in organ weights when compared with the control group were observed including decreased mean absolute heart, ovary and adrenal gland weights in high dose females. Differences in organ weights relative to final body weight means consisted of increased mean relative liver weights in high dose groups and in the male mid dose group, increased mean relative brain weights in female low, mid and high dose groups, and increased mean relative heart and kidney weights in the female mid dose group.

Cortical tubular epithelial regeneration in the kidneys was observed in all treated groups at necropsy. Other

microscopic changes in the kidney, which were observed in both control and treated groups, include nephropathy, tubular mineralisation, hydronephrosis, and nonsuppurative inflammation. Pulmonary osseous metaplasia, cerebral haemorrhage and histiocytosis were observed either in both control and treated groups or in single animals. Similar microscopic abnormalities were reported for the high dose recovery group and again the occurrence of the effects were comparable to the control group and occurred at low incidence.

Remarks – Results

The occurrences of salivation observed at the dosing time were mainly in the high dose group and was more common in females. Relaxed vaginal opening was also observed in some treated females. Both effects were reversible, as these did not persist into the recovery period. Other clinical observations occurred sporadically and are typical findings in laboratory animals.

Statistically significant decrease in body mean weight gains and consequently mean body weights were observed in treated animals. Again, females were mostly affected. However, during recovery period, mean body weight gains of high dose group were similar or increased compared with the control group. Mean body weights of the recovery high dose group were within 7% of the control group values at the end of the recovery period.

Food consumption was slightly, but consistently reduced in the high dose males, and in high, mid and low dose females. During the recovery period, food consumption was similar to or greater than the control group values.

Significant increase in mean albumin/globulin ratio was observed but limited to high dose group only. Mean chloride was significantly increased in high dose, in female mid dose, and in female low dose groups, and was potentially treatment related.

Differences in haematology parameters although statistically significant when compared with the control group were not considered as treatment related because the changes were confined to high dose females only and/or the values were within the historical control data.

Renal tubular epithelial regeneration was observed in all treated groups. Substantial to full recovery from all kidney effects was observed by the end of the recovery period.

CONCLUSION

The No Observed Effect Level (NOEL) was not established in this study. Based on the kidney effects and increased levels of mean serum chloride observed at all dose levels, the lowest observed effect level (LOEL) was 160 mg/kg bw/day.

TEST FACILITY WIL Research Laboratories, Inc (1997f)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471/472 Bacterial Reverse Mutation Test:
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Salmonella typhimurium and Escherichia coli.
US Environmental Protection Agency, Method: HG-Gene Mutation – S. typhimurium: The Salmonella typhimurium reverse mutation assay.
Japanese Ministry of Agriculture, Forestry and Fisheries (JMAFF): Notification of Director General, Agricultural Production Bureau, NohSan 4200.
Japanese Ministry of Health and Welfare (JMOHW), Notification Yakushi 1 No.24, Guidelines for Toxicity Study of Drugs, 4 I, Bacterial Reverse Mutation Test.
Japanese Ministry of International Trade & Industry (JMITI), 61 Kikyoku No. 1014, and 62 Kikyoku No.303.
Japanese Ministry of Labour (JML), Guidebook of Mutagenicity Tests.

	Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2uvrA.
Metabolic Activation System	Aroclor 1254 induced rat liver S9 fraction
Concentration Range in Main Test	a) With metabolic activation: 0 - 5000 µg/plate. b) Without metabolic activation: 0 - 5000 µg/plate.
Vehicle	Dimethyl sulphoxide (DMSO)
Remarks - Method	A preliminary test was conducted on the five tester strains with or without S9 using test concentrations 5, 50, 500 and 5000 µg/plate. No toxicity was observed in any tester strain at any dose level; therefore 5000 µg/plate was chosen as the top doe level in the mutation tests.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	None	None	None	None
Test 2	-	None	None	None
Present				
Test 1	None	None	None	None
Test 2	-	None	None	None

Remarks - Results	No cytotoxicity, precipitation and genotoxic effect observed in all tester strain at any dose. Appropriate positive controls induced marked increases in the number of revertant colonies, indicating that the test system responded appropriately.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Huntingdon Life Sciences Ltd (1997d)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test. EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test. Joint Directives of the JEPA, JMOHW and JMITI. EPA (TSCA) Health Effects Testing Guidelines. 40 CFR 798, 50 FR 39252 Subpart F – Genetic Toxicity 798.5375 *In vitro* mammalian cytogenetics.
Cell Type/Cell Line	Human lymphocyte
Metabolic Activation System	Aroclor 1254 induced rat liver S9 fraction
Vehicle	DMSO
Remarks - Method	Two tests were conducted. Test 1 includes 4 sets of treatments (1 set with S9 and 3 sets without S9). Test 2 includes 3 sets of treatment (1 set with S9 and 2 sets without S9). Each treatment set was conducted in duplicate.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			

Test 1			
Set 2	39.1, 78.1, 156.3, 312.5, 625*, 1250*, 2500* and 5000	6 h	18 h
Set 3 (24 h continuous)	39.1, 78.1, 156.3*, 312.5*, 625*, 1250, 2500 and 5000	24 h	-
Set 4 (48 h continuous)	39.1, 78.1*, 156.3*, 312.5*, 625, 1250, 2500 and 5000	48 h	-
Test 2			
Set 6 (24 h continuous)	156.3, 312.5*, 470*, 625, 940* and 1250	24 h	-
Set 7	156.3, 312.5, 625, 1250*, 2500* and 5000*	6 h	42 h
Present			
Test 1			
Set 1	39.1, 78.1, 156.3, 312.5*, 625*, 1250*, 2500 and 5000	6 h	18 h
Test 2			
Set 5	156.3, 312.5, 625*, 1250*, 2500* and 5000	6 h	18 h

*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				
Set 2	Not conducted	None	≥ 78.1	Negative
Set 3	Not conducted	>625	≥ 78.1	Negative
Set 4	Not conducted	>312.5	≥ 78.1	Negative
Test 2				
Set 6	Not conducted	>1250	≥ 156.3	Negative
Set 7	Not conducted	None	≥ 156.3	Negative
Present				
Test 1				
Set 1	Not conducted	None	≥ 78.1	Negative
Test 2				
Set 5	Not conducted	None	≥ 156.3	Negative

Remarks - Results	The notified chemical did not cause a statistically significant increase in the proportion of aberrant cells or polyploid cells either in the presence or absence of S9. The result of the vehicle and positive controls confirm the sensitivity of the test systems.
CONCLUSION	The notified chemical was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.
TEST FACILITY	Huntingdon Life Sciences Ltd (1997e)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1a Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	Directive 92/69/EEC Part C Method 4-E Determination of Ready Biodegradability – Closed Bottle Test; and OECD TG 301D Ready Biodegradability: Closed Bottle Test
Inoculum	Activated sludge filtrate from a domestic sewage treatment plant, Anglian Water plc (Godmanchester, UK)
Exposure Period	28 days
Auxiliary Solvent	Chloroform
Analytical Monitoring	Dissolved oxygen levels were measured electrochemically on days 0, 4, 7, 11, 14, 18, 21, 25 and 28 (in duplicate).
Remarks - Method	Degradation of test material was determined by comparing oxygen depletion to a Theoretical Oxygen Demand (ThOD). Tests included controls (nutrient medium with inoculum; nutrient medium with inoculum and filter paper), test substance (5 mg/L) plus filter paper, Standard substance (sodium benzoate 3 mg/L) and test substance (5 mg/L) plus filter paper and Standard Substance (3 mg/L). Test temperature was 20°C.

RESULTS

	% Degradation (DOC Removal)		
Incubation time Days	*Notified Substance Mean*	*Standard Mean*	*Abiotic Control Mean*
4	4	45	
7	1	48	
11	2	57	
14	6	71	40
18	2	66	
21	3	79	
25	2	77	
28	1	65	28

CONCLUSION	The notified chemical is not readily biodegradable as only 6% was eliminated after 28 days. At the tested concentrations and conditions, the notified chemical had no inhibitory effect on sewage sludge micro-organisms.
TEST FACILITY	Huntington Life Sciences Ltd (1998d)

8.1.1b Higher Tier Testing

TEST SUBSTANCE	Notified chemical
METHOD	USEPA (1998) Series 835-Fate, Transport and Transformation Test Guidelines. January 1998, OPPTS 835-3170: Shake Flask Die-away Test.
Inoculum	Natural microbial populations in freshly collected surface water (filtered 0.3 μm) and sediment, Schuylkill River, PA, USA. Collected 60 mm below water surface the day before tested. Surface water pH 6.9 and temperature 11.2°C. Sediment consisted of the upper 5-10 mm (sieved 2mm, sand removed).
Exposure Period	34 days
Auxiliary Solvent	Methanol
Analytical Monitoring	Duplicate test chambers from each group were sampled on days 0, 7, 11, 18, 26 and 34 to determine by HPLC/MS the total concentration of test substance remaining in total and soluble fractions. Suspended sediment vessels were also analysed for soluble concentrations of test substance. Total organic carbon (TOC), pH (range 6.7-7.6) and bacterial counts (~10^5 cells/mL at day 0) in test solutions were analysed periodically over the duration of the test. Method LOQ was 3.33 μg/L.
Remarks - Method	Aerobic biodegradation of the test substance in freshly collected natural surface waters, with and without sediment, was assessed. Two control groups (control water [CW] and control sediment [CS]) not dosed with the test substance, and four treatment groups (active water [AW], active sediment [AS], sterile water [SW], sterile sediment [SS]) dosed with 16 μg/L (nominal). Water test groups vessels contained filtered river water and sediment test group vessels contained filtered river water amended with sediment slurry at a nominal total suspended solids concentration of 500 mg/L. A stock solution (40 mg/L nominal) was prepared in methanol for volumetric addition (methanol also added to controls). The sediment/water slurry was prepared at 1:1 ratio. Test chambers consisted of 500 mL Teflon bottles and these were incubated at 25±1°C. Sterile water and sediment was prepared by addition of formalin (37% formaldehyde) to test media. 13-19 test chambers were tested per treatment and control.

RESULTS

	% Remaining		
Incubation time Days	*Active Water/Sediment*	*Sterile Water/Sediment*	*Control Water/Sediment*
Waters (total test substance)			
0	100	100	Not applicable
7	26.2	96.3	"
11	8.9	84.6	"
18	4.1	100	"
26	<2.5	68.4	"
34	<2.5	69.0	"
Sediments (total test substance)			
0	100	100	Not applicable
7	50.9	100	"
11	35.2	87.5	"
18	25.6	76.2	"
26	17.0	69.1	"
34	9.8	71.7	"
Sediments (soluble test substance)			
0	37.3	41.5	Not applicable
7	None present	≤22.4	"
11	"	None present	"
18	"	"	"

26	“	“	“
34	“	“	“

CONCLUSION

Mean analytical recovery from HPLC/MS analyses of water and sediment were 87±10% and 94±9% (acceptable), and sample concentrations were not corrected for mean procedural recovery. Microbial analysis of sterile water and sterile sediment indicated no active aerobic or facultative anaerobic cells at day 34. No interaction between the formalin and test substance was observed. Results indicate <2.5% and <10% of the test substance remained in waters and sediments after 34 days, primarily due to biodegradation. Some abiotic degradation was evident in sterile waters and sediments (~30% abiotically degraded after 34 days). The notified chemical had high affinity to bind to sediment (sorption distribution coefficient Kd ≥7611). The partitioning of the test substance to sediment matter likely contributed to the longer half life of the test substance in the suspended sediment matrix. First order kinetic analyses indicate half lives of the test substance in active water and sediment of 3.49 and 8.48 days, respectively. It is however likely that degradation will proceed via removal of the carbon side chains to form a brominated product.

TEST FACILITY

Wildlife International Ltd (2002)

8.1.2. Bioaccumulation

TEST SUBSTANCE

Notified chemical

METHOD

USEPA (1996) Series 850-Ecological Effects Test Guidelines (draft) OPPTS 850.1730: Fish BCF; OECD TG 305C Bioconcentration: Flow-through Fish Test; and ASTM Standard E1022-84 (1988). Standard Practice for Conducting Bioconcentration Tests with Fishes and Saltwater Bivalve Molluscs.

Species

Rainbow Trout (*Oncorhynchus mykiss*), juveniles, mean length 63 mm and weight 22.1 g.

Exposure Period

Exposure: 35 d Depuration: 14 d

Auxiliary Solvent

Dimethylformamide (DMF)

Concentration Range

Nominal

1.0 and 10 µg/L (and solvent control)

Actual

0.96 and 8.9 µg/L (mean measured)

Analytical Monitoring

Test water samples were collected for chemical analysis 8, 3 and 1 days prior to the test, uptake phase days 0, 0.5, 1, 4, 7, 14, 21, 28 and 35, and depuration days 1, 4, 7, 11 and 14 (replicate samples were collected and analysed). Fish tissue samples (~120 g) were collected on days 0, 0.5, 1, 4, 7, 14, 21, 28 and 35 of the uptake phase, and days 1, 4, 7, 11 and 14 of the depuration phase (replicate samples were collected and analysed). Lipid content of selected samples was analysed on days 0 (uptake) and 14 (depuration). Tissue solids content (dry weight) of selected samples was analysed on days 0 and 35 (uptake) and 14 (depuration). All samples were analysed by reverse-phase HPLC/MS.

Remarks - Method

A continuous flow-through diluter system was used to deliver the test substance and solvent control (turn over 6.3 times/day). 90 fish were distributed to each test chamber. Dilution water consisted of moderately hard (test water hardness range 128-148 mg/L as $CaCO_3$) groundwater (filtered 0.45 µm and aerated). Test water had a total organic carbon (TOC) concentration of 0.7-53.6 mg/L (mean 38.8 mg/L). Test chambers consisted of 106 L stainless steel aquaria containing 80 L of test solution (depth 19.6 cm).

Test chambers were siphoned daily to remove excess feed faecal matter,

algae and bacterial growth. Test concentrations (1.0 and 10.0 µg/L nominal) were prepared from a primary stock solution by dissolving test substance in DMF (0.100 mg/mL). An aliquot of the primary stock solution was diluted with DMF to prepare an additional stock solution (0.020 mg/mL). The 2 stock solutions and DMF control were injected into the diluter mixing chamber (0.035 µL/minute) to achieve the nominal test concentrations. Stock solutions were prepared weekly. Calibration Standards of the test substance were prepared in the range of 1.0-10.0 µg/L. The limit of quantitation (LOQ) was 0.500 µg/L (water) and 1.00 µg/kg (tissues). Fish were fed and observed for adverse effects daily during the test. Water temperature range: 11.3-12.2°C. Water pH range 7.8-8.2. Dissolved oxygen range: 6.3-9.9 mg/L (acceptable). Photoperiod 16 h light: 8 hours dark (226 Lux).

Tissue concentrations were evaluated for normality and homogeneity of variance using Shapiro-Wilk's Test and Bartlett's Test (passed) and ANOVA was used to determine statistically significant differences among the groups. Significantly different treatments were identified using Tukey's Test ($p \leq 0.05$) using TOXSTAT Version 3.5 or SAS Version 8.02 software.

RESULTS

Bioconcentration Factor (BCF)	*Concentration (µg/kg wet wt)*	*Steady-state BCF (0-35 d)*	*Estimated Time to Reach 50% Clearance (days)*
Exposure 0.96 µg/L			
Edible portions	5.93	6.18	Not determined
Non-edible portions*	5.94	6.19	"
Whole Fish	5.92	6.17	"
Exposure 8.9 µg/L			
Edible portions	15.5	1.74	6.2
Non-edible portions*	20.2	2.27	7.4
Whole Fish	18.0	2.02	6.5

* Non-edible portions included head, fins and viscera.

Remarks - Results

Test concentrations were not adjusted for the purity of the test substance (89.4%). Test substance recoveries were acceptable (ie. 92.1-113% of nominal). Tissue sample stability was assessed over a 51 day period using spiked fish samples (100 µg/kg), and only for the non-edible portion were recoveries low (~53% of nominal). No fish exposed to the test substance died or showed any treatment-related effects during the test, and this is consistent with the acute fish toxicity test (see Section 8.2.1). Steady-state conditions for the 0.96 µg/L treatment were achieved at day 7 of the uptake phase, and during the depuration phase almost all samples were below LOQ, therefore calculations of the times to reach 90% steady state (t_{90}), 50% clearance ($t_{1/2}$) and kinetic bioconcentration factor (BCFK) in fish tissues were not determined for the 0.96 µg/L treatment group. Steady-state conditions in the higher concentration treatment group were achieved at day 4. On days 0 (uptake) and 14 (depuration), test fish had lipid contents of ~0.0-0.1 g and 0.13-0.7g, respectively. Fish dry weight was 21.2-30.1% of wet weight.

CONCLUSION

BCF (whole fish) values of 2.0-6.2 resulted after 35 days exposure to the notified chemical at concentrations of 0.96-8.9 µg/L. The notified chemical has a low potential to bioconcentrate in fish. At the cessation of exposure, depuration of the notified chemical is relatively rapid ($t_{1/2} \leq 7.4$ days).

TEST FACILITY Wildlife International Ltd (2003)

8.1.3. Incineration

Incineration of the notified chemical in manufactured materials is expected to result in the formation of low concentrations of a range of compounds including polybrominated dibenzo-p-dioxins and polybrominated dibenzofurans (PBDD/Fs). Battelle (2002) conducted a simulated incinerator test using seven replicates of the notified chemical. The method used followed the *Guidelines for the Determination of Polyhalogenated Dibenzo-p-Dioxins and Dibenzofurans in PMN Substances, Selected Waste Streams, and Simulated Incinerator Emissions* (MRI Report 29 March 1991), and was conducted according to USEPA TSCA GLP Standards. Incinerator temperatures at pre-, peak and post-combustion regions were 350-1200°F (177-649°C), 1200-1750°F (649-954°C) and 600-1200°F (316-649°C), respectively (measured at 4 locations within the furnace recorded at 5 minute intervals). The incineration was allowed to continue for approximately 15 minutes. Samples were analysed by HRGC/HRMS after extraction. Seventeen 2,3,7,8-substituted PBDD/F congeners were detected during the incineration of the notified chemical. PBDFs were detected in the concentration range 94-9500 µg/kg (ppb) of notified chemical incinerated. PBDDs were detected in the concentration range 20-8300 µg/kg notified chemical incinerated. During incineration, 2,3,7,8-PBDD and 2,3,7,8-PBDF were detected at concentrations of 2000±770 and 20±9.4 µg/kg of notified chemical, respectively. While these concentrations are relatively high, it is unlikely that the finished products containing the notified chemical would be incinerated given their use and disposal pattern, which predominantly involves recycling of finished products or landfill methods of disposal in Australia.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE Notified chemical

METHOD OECD TG 203 Fish, Acute Toxicity Test and EEC Directive 92/69/EEC C.1 Acute Toxicity for Fish, Static Renewal Conditions

Species	Rainbow Trout (*Onchorhynchus mykiss*), 4.75 cm (SD±0.8) length, 2.12 g (SD±0.87) mass.
Exposure Period	96 h
Auxiliary Solvent	Dimethylformamide (DMF)
Water Hardness	137-159 mg (as $CaCO_3$/L)
Analytical Monitoring	Test conditions (satisfactory): temperature 14±1°C, pH 7.7, dissolved oxygen 9.5-9.7 mg/L. Fish were observed at 3, 6, 24, 48, 72 and 96 hours.
Remarks – Method	Range finding and definitive tests were performed. No toxicity was evident at the highest range finding test concentration (20 mg/L). No fish died within 2 weeks prior to the definitive test during the acclimation period. Test solutions were renewed daily. DMF solvent control was tested at a concentration of 100 µL/L. Test chambers consisted of 20 L glass aquaria. Photoperiod 16 light: 8 dark.

RESULTS No mortalities or adverse signs were observed in exposed fish.

Concentration mg/L		*Number of Fish*	*Percent Mortality (%)*
Nominal	*Actual*		*96 h*
Control	0	10	0
Solvent control	0	10	0
10	12	10	0

LC50	>12 mg/L at 96 hours (95% CI).
NOEC	12 mg/L

CONCLUSION	The notified chemical is not toxic to fish up to the level of its water solubility (2.01 mg/L; enhanced by DMF present). No mortality or adverse effects were observed in fish exposed to 12 mg/L.
TEST FACILITY	Huntington Life Sciences Ltd (1998b)

8.2.2a. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	Directive 92/69/EEC C.2 Acute Toxicity to *Daphnia*, and OECD 202.I. *Daphnia* Acute Immobilisation Test.
Species	Freshwater Cladoceran *Daphnia magna* (neonates <24 h old).
Exposure Period	48 h
Auxiliary Solvent	Dimethylformamide (DMF)
Water Hardness	<180 mg/L (as $CaCO_3$)
Analytical Monitoring	Temperature, DO and pH were monitored daily. Test temperature 20±1°C, pH 7.7-7.8, DO 8.7-8.9 mg/L. 16:8 h light:dark cycle. (Within acceptable limits throughout the test).
Remarks - Method	Range finding and definitive tests were performed. A solvent solution incorporating DMF was also used. Test solutions were renewed at 24 h. Test concentrations were verified by chemical analysis of a variable number of duplicate 100 mL samples collected at 0 and 24 h (fresh media) and 24 and 48 h (expired media; replicates pooled). Test chambers (250 mL glass beakers containing 200 mL test solution) were not aerated during the tests and were covered in plastic film to minimise volatilisation. Exposed adults were not fed during the tests. EC50 values and 95% confidence limits were calculated using the Thompson and Weil model (Thompson and Weil, 1952). Adult mortality was monitored during the tests at 24 h intervals. The highest 3 test concentrations were considered higher than the test material water solubility (2.1 mg/L), but there is no indication that solutions were cloudy, had precipitates or oily surface layer.

RESULTS

Concentration mg/L		*Number of Daphnids*	*Iimmobilisation (%)*
Nominal	*Actual*		*48 h*
Control	0	20 (2 replicates of 10 animals)	0
Solvent control	0	"	5
0.10	0.12	"	0
0.22	0.22	"	25
0.46	0.55	"	70
1.0	0.93	"	100
2.2	2.0	"	100
4.6	3.4	"	100
10	7.2	"	100

EC50 (immobilisation)	0.42 mg/L at 48 h (95% CI 0.35-0.51) (mean measured concentration).
NOEC	0.12 mg/L at 48 h (mean measured concentration)
Remarks - Results	At the 3 highest concentrations, 100% immobilisation occurred with 24 h.
CONCLUSION	Very acutely toxic (L(E)C50 <1 mg/L; Mensink *et al.*, 1995) to cladocerans.
TEST FACILITY	Huntington Life Sciences Ltd (1998a).

8.2.2b. Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	Chronic Toxicity/Reproductive Test with *Daphnia carinata* – Static Renewal Test
Species	Freshwater Cladoceran *Daphnia carinata* (neonates <24 h old)
Exposure Period	15 d
Auxiliary Solvent	Acetone (AR grade)
Water conductivity	228-292 µS/cm
Analytical Monitoring	None. Test results are based on nominal test concentrations.
Remarks - Method	Test chambers were not aerated during the tests and were covered in plastic film to minimise volatilisation. Ten replicates per test concentration were conducted. One adult was placed in each test chamber. Test solution was renewed 48 hourly. Adult mortality and neonate production was monitored during the tests at 24 h intervals. Significant differences to control were determined using Fisher's Exact Test and Dunnett's Test. Tests were run over 3 broods. Temperature, DO and pH were monitored 48 hourly. Test temperature 20±1°C (19.8-21.8), pH 7.55-8.30, DO >90% saturation. 16:8 h light:dark cycle.

RESULTS

Concentration (µg/L) *Nominal*	*Actual*	*Number of D. magna*	*% Mortality*	*Mean Brood Size*** Per treatment (± SD)***
Solvent Control: 0.02% v/v acetone	Not determined	10 (1/rep. X 10 reps.)	0	11.2±0.76
Dilution Control	"	"	10	11.07±1.42
7.8	"	"	10	10.87±1.57
15.6	"	"	10	9.47±1.63
31.3	"	"	30	6.83±1.78*
62.5	"	"	30	7.53±1.73*
125	"	"	80*	1.97±1.34*
250	"	"	100*	0*
500	"	"	100*	0*

* Denotes significantly different from the solvent control. ** Significance (P<0.05) based on raw data supplied and t-test assuming equal variances. ***The average brood size per adult per treatment.

LC50	79.3 µg/L at 15 days (95% CI 57.3-109.9 µg/L)
NOEC (mortality)	62.5 µg/L at 15 days
LOEC (reproduction)	31.3 µg/L
NOEC (reproduction)	15.6 µg/L
Remarks- Results	Time to first brood not reported. The test report incorrectly stated that "at a concentration below 125 µg/L, there was no significant effect of Firemaster BZ-54 on the reproductive output of the cladocerans" as the total number of young produced was significantly reduced at this exposure concentration as only 2 of 10 daphnids survived to reproduce. A NOEC for reproduction of 15.6 µg/L has been calculated based on raw test data provided.
CONCLUSION	Very chronically toxic (L(E)C50 <1 mg/L; United Nations, 2003) to cladocerans.
TEST FACILITY	Access:UTS Pty Ltd (2003)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test and EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	Green alga *Selenastrum capricornutum*
Exposure Period	96 hours
Concentration Range Nominal	0 and 10 mg/L
Concentration Range Actual (mean)	<0.05 and 5.1 mg/L
Auxiliary Solvent	DMF
Analytical Monitoring	HPLC
Remarks – Method	Test substance (1000 mg) was dissolved in 10 mL DMF to give an initial stock solution of 100 mg/mL. An aliquot (100 µL) was added to 1 L of algal pre-culture to give the intended concentration of 10 mg/L. Flasks (250 mL) with 100 mL of test solution were incubated for 96 h under constant illumination (7000 lux) and slow stirring. Temperature: 23±1°C. Initial algal biomass ~10000 cells/mL test medium. Final cell densities for controls were ~$4X10^6$ cells/mL (acceptable).

RESULTS	
E_bC50	>5.1 mg/L at 96 h
NOEC	5.1 mg/L
Remarks – Results	No inhibition of growth was measured at a mean measured concentration of 5.1 mg/L under the test conditions.
CONCLUSION	The notified chemical is not toxic to the algae species tested up to the level of its water solubility (2.01 mg/L; enhanced by DMF present).
TEST FACILITY	Huntington Life Sciences Ltd (1998c).

8.2.4. Inhibition of sewage sludge organisms

No test report was submitted though it is noted that the MSDS states that sludge digestion is inhibited at ≥100 mg/L, 30%, 3 hours.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The proposed use and disposal pattern for the notified chemical suggests that direct release to the aquatic and terrestrial environmental compartments of the environment is unlikely and therefore no predicted environmental concentration (PEC) has been estimated for the notified chemical.

The international literature indicates that brominated flame retardants with a similar manufacturing, use and disposal pattern have been identified in sewage sludge and biota (eg. marine organisms), including polar regions due to long range atmospheric transport, due to unknown, unforseen or apparently insignificant sources of environmental releases (Danish EPA, 2001; de Witt *et al*., 1999, de Witt, 2001; Hale, *et al*., 2001; Ikonomou *et al*., 2002; Boon *et al*., 2002; Law *et al*., 2003; Eljarrat, *et al*., 2004; Lebeuf *et al*., 2004). Decomposition of the foam polymer matrix and release of dusts containing the brominated compounds is one source of environmental release identified. Direct volatilisation from finished products has also been investigated (Prevedouros *et al*., 2004). Although the notified chemical has a high log P_{ow} (>6.2) suggestive of a high affinity to lipids, bioaccumulation test results with fish (BCF 2.0-6.2 after 35 days exposure to the substance at concentrations of 0.96-8.9 µg/L) and modelling using PBT Profiler (USEPA, 2004; BCF 3.2 for one component) indicate that the notified chemical has a low potential to bioaccumulate in the food chain. Limited persistence in the environment is expected based on biodegradability testing in natural waters and sediments (aquatic half life of ~3-8 days), and this will also reduce the potential for biological exposure and bioaccumulation. Degradation is likely to occur by removal of hydrocarbon sidechains to yields a brominated product. Testing on a high production volume (HPV) chemical, which also breaks down to the main brominated product in aqueous systems, has shown an average partition coefficient of 96 (log Kow of 1.9) (Yu, 1978) and lack of bioaccumulation in bluegill sunfish (Nye, 1978).

9.1.2. Environment – effects assessment

In the event of a spill of the notified chemical into the environment, local adverse effects to organisms may potentially occur due to the very high toxicity of the notified chemical. Given the anticipated short persistence of the notified chemical in the environment, long lasting effects to aquatic invertebrates would not be expected.

Aquatic ecotoxicity data were available for 4 taxonomic levels of freshwater species (fish, invertebrate, algae and sewage sludge micro-organisms). The notified chemical is not acutely toxic to freshwater fish or algae or activated sewage sludge micro-organisms (based on a ready biodegradability test) at its limit of water solubility (2.01 mg/L); however, freshwater cladocerans (*Daphnia* sp.) were very sensitive to the notified chemical with acute (lethality)

and chronic (reproduction) L(E)C50 values of 420 µg/L and 80 µg/L, respectively. Chronic NOEC values of 62 and 15.6 µg/L were obtained for mortality and reproduction, respectively. A predicted no effect concentration ($PNEC_{aquatic}$) of 1.6 µg/L has been derived by dividing the lowest NOEC by an assessment factor of 10 used to account for interspecies sensitivity and other adverse factors that may potentially arise in the environment if organisms are exposed to the notified chemical.

A Material Safety Data Sheet from the manufacturer states that activated sludge digestion is inhibited by 30% at >100 mg/L after 3 hours exposure. However, this concentration is unlikely in the sewerage system based on the use and disposal pattern for the notified chemical.

No terrestrial toxicity data or results were available. Terrestrial exposure may potentially occur through sewerage system disposal and re-use of sludge/biosolids by application to land, but again this is expected to be low due to the anticipated low release and persistence of the notified chemical in aqueous solutions.

9.1.3. Environment – risk characterisation

Brominated flame retardants (eg. pentabrominated diphenyl ether or Penta-BDE) are widely used globally in the manufacture of flexible polyurethane foam products (content 5-30% by weight). However, health and environmental concerns due to the occurrence of this chemical in the environment and people have led to the banning/disuse of several compounds in some countries. As indicated by the notifier, a market for chemicals such as the notified chemical has developed. However, the notified chemical raises similar environmental concerns as other brominated flame retardants with similar use pattern as it may also be released to the environment through similar routes. The limited information available for the notified chemical indicates that it is very toxic to aquatic organisms, but is not persistent (based on an aquatic sediment test) and not bioaccumulative. If released into the environment or landfill, the notified chemical is likely to degrade over time, and is most likely to partition to sediments, soils and organic carbon (Log Koc >4.46). It is unlikely to be mobile in soils/sediments and is unlikely to percolate and affect groundwater. Due to its low vapour pressure ($1.3X10^{-7}$ kPa at 25°C), volatilisation to the atmosphere is unlikely to be a significant migration pathway. With an estimated Henry's Law Constant of ~$3.5X10^{-2}$ $Pa.m^3$/mole, the notified chemical is essentially non-volatile from waters. PBT Profiler (USEPA, 2004) indicates that the notifier chemical is estimated to have a half life in air of 0.75 days. Within a wastewater treatment plant or sewerage system, the notified chemical is likely to partition to suspended particulates and sludge and degrade over time (USEPA, 2004). Site-specific treatment processes will determine the quantity collect as sludge or released with effluent. Due to its low persistence, the notified chemical is unlikely to enter a terrestrial environment (eg. soils) where sewage sludge or effluent is collected and reused as biosolids or irrigation water, respectively.

Incineration of the notified chemical is likely to produce low concentrations of PBDD/Fs. No information was provided on the potential for formation of PBDD/Fs during its use to manufacture foam products or PBDD/F content of these products, which is known to occur with Penta-BDFs. (Ebert and Bahadir, 2003).

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

As the chemical is available in liquid form, skin and eye contact will be the main source of occupational exposure during polyurethane foam manufacture. The majority of polyurethane manufacture involves fully automated and enclosed processes using dedicated lines for transfer operations. In small polyurethane manufacturing company, manual intervention is required for transfer operations and therefore, there is increased likelihood of exposure to the notified chemical. Inhalation exposure during these activities is unlikely due to the low vapour pressure.

During polyurethane manufacture, the use of personal protective equipment is mandatory to prevent exposure to the isocyanate component as well as any other additives such as the notified chemical. Where possible, automation and enclosed processes are preferred when handling and

using the product. There are a number of regulatory controls for isocyanate in place in Australia and these should be implemented during polyurethane foam manufacture. The use of local exhaust ventilation would further minimise worker exposure during mixing of the ingredients. Precautions against continued exposure to ingredients other than the notified chemical, such as isocyanate, should be observed. The controls implemented as described in the submission are adequate to mitigate occupational exposure to the notified chemical and isocyanate. Because the notified chemical is bound to the cured foams, the chemical is not available for absorption by dermal contact with the foam products.

Exposure to waterside, warehouse and transport workers is low considering the handling of sealed packages containing the notified chemical.

The notifier provided information for predicting the workplace exposure using the EASE software model. Dermal and inhalation exposure resulting from handling and compounding the notified chemical was achieved using 2 scenarios: i) Transfer of notified chemical into closed blender by pumps and gravity discharge from drums. Subsequent introduction of the formulation onto the foam-manufacturing line and ii) Direct transfer of notified chemical into the foam-manufacturing line using metering devices. In both scenarios, the use pattern involves "closed system", although significant breaching occurs during drum change-over. There is no significant potential for aerosol generation. The model calculations for workers with no protective clothing predict that dermal exposure to the notified chemical will be very low and that vapour exposure will be negligible. Conversion is also carried out in closed systems, but without the necessity for significant breaching to occur. Similarly, the model predicts that dermal exposure to the notified chemical will be very low and that vapour exposure will be negligible.

9.2.2. Public health – exposure assessment

The notified chemical and the polyol blend containing it are intended for industrial use only. Public exposure to the notified chemical may occur in the unlikely event of transport accident. Dermal contact to polyurethane foams made from the notified chemical is possible; however, at this stage the notified chemical will form part of the polyurethane foam and is not available for separate exposure. Therefore, public exposure to the notified chemical when used as a flame retardant additive in polyurethane manufacture is low.

9.2.3. Human health - effects assessment

The notified chemical is of low acute oral and dermal toxicity.

The eye and skin irritation study showed slight irritation effects; however, the notifier classified the notified chemical as an eye and skin irritant. The sensitisation studies submitted by the notifier provided evidence that the notified chemical is a skin sensitiser. The notifier has classified the notified chemical as a skin sensitiser.

There was some evidence in the acute and sub-acute toxicity studies that the notified chemical is absorbed by the oral route, particularly at high doses. However, there was no evidence for absorption beyond the skin barrier in the acute dermal study. In a 28-day oral repeat dose study, renal epithelial regeneration and increased levels of mean serum chloride in all treated groups were observed, which suggests that the kidney is a target organ. Substantial to full recovery from all kidney effects was observed by the end of the recovery period. No treatment related changes and differences were observed in neurobehavioural, haematology and clinical chemistry parameters. Differences in mean body weight gains with the control group were overcome during the recovery period. No NOEL was established, and the LOEL was 160 mg/kg bw/day.

The notified chemical was not mutagenic in bacterial reverse mutation assay, and did not reveal any genotoxic potential in vitro.

9.2.4. Occupational health and safety – risk characterisation

Given that the majority of polyurethane manufacture is automated and enclosed, the risk of adverse effects arising from exposure to the notified chemical is low. However, due to the skin

and eye irritation, and skin sensitisation potential of the notified chemical, dermal and ocular exposure should be avoided when connecting and disconnecting hoses, during maintenance operations and when manual intervention is required during polyurethane manufacture. Prolonged exposure to the notified chemical by oral route is also of concern; however, swallowing of the notified chemical during normal handling of the notified chemical is improbable. Once the polyurethane foam is formed, the notified chemical forms part of the foam article and will not be available for separate exposure.

The limited contact to the notified chemical during polyol blending and polyurethane manufacture, the presence of adequate ventilation in the workplace and the use of recommended personal protective equipment would ensure that occupational risk posed by the notified chemical is low when used as specified in the notification. Also, the controls in place provide adequate protection from isocyanate exposure.

9.2.5. Public health – risk characterisation

Public exposure to the notified chemical will arise from dermal contact with finished polyurethane articles, such as in automotive and home furnishings. The notified chemical will be encapsulated in the final polyurethane matrix, therefore unlikely to be bioavailable. Consequently, the risk from public exposure to the notified chemical throughout all phases of its life cycle is considered to be low.

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 hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:
R36/38 – Irritating to eyes and skin
R43 – May cause sensitisation by skin contact
R48/22 – Harmful: danger of serious damage to health by prolonged exposure if swallowed.

As a comparison only, the classification of 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.

Skin irritation Category 3:
Symbol: None
Signal Word: Warning
Hazard statement: Causes mild skin irritation

Eye irritation Category 2B:
Symbol: None
Signal Word: Warning
Hazard statement: Causes eye irritation

Skin sensitiser Category 1:
Symbol: Exclamation mark
Signal Word: Warning
Hazard statement: May cause allergic skin reaction

Target organ systemic toxicity following repeat exposure Category 2:
Symbol: Health hazard
Signal Word: Warning
Hazard statement: May cause damage to organs (kidney) through prolonged or repeated exposure (oral)

Acute hazards to the aquatic environment Category 1:
Symbol: Environment
Signal Word: Warning
Hazard statement: Very toxic to aquatic life

10.2. Environmental risk assessment

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

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 fire retardant additive in the manufacture of polyurethane foams.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical and products containing the notified chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2003). The MSDS of the notified chemical 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 and products containing the notified chemical provided by the notifier were 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 health hazard classification for the notified chemical:
  - R36/38 – Irritating to eyes and skin
  - R43 – May cause sensitisation by skin contact
  - R48/22 – Harmful: danger of serious damage to health by prolonged exposure if swallowed

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥20%: R36/38 – Irritating to eyes and skin
  - ≥1%: R43 – May cause sensitisation by skin contact
  - ≥10%: R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed

- The notified chemical should be classified as follows under the ADG Code:
  - Class 9 – Miscellaneous dangerous goods and articles
  - Packaging Group III

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 during weighing and transfer of notified chemical into the mixing tank.
  - Enclosed and automated manufacture of polyol and polyurethane foams.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - During transfer operations and cleaning of equipment, avoid spills and splashing.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - chemical resistant gloves
  - impervious protective clothing which protects the body, arms and legs
  - splash goggles or safety glasses with side shield
  - organic cartridge respirators if vapour or misting occurs

  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.

Environment

- The following water quality assessment benchmark may be used by the notifier and regulatory agencies for assessment of accidental or other release of the notified chemical to the aquatic environment:
  - 1.6 µg/L (based on chronic aquatic toxicity data for freshwater invertebrates)

Disposal

- The notified chemical should be disposed of in a manner consistent with National, State and local jurisdiction waste management regulations to landfill.
- Incineration of the notified chemical may result in the formation of PBDD/Fs and wastes containing the notified chemical should not be disposed of by incineration.
- Waste finished products containing the notified chemical should be sent to landfill for disposal or recycled.
- Emptied drums/containers should be sent to landfill for disposal or metal-recycling, or reconditioned at approved drum reconditioning facilities.
- Fire-damaged materials containing the notified chemical and potentially PBDD/Fs and should be disposed of to landfill in accordance with local jurisdiction waste management regulations.

Emergency procedures

- Spills/release of products containing the notified chemical should not be released to waterways, stormwater, soils or sewerage system. Avoid release to the environment.
- Spills/leaks should be should be contained by applying absorbent materials to the spill and/or pumping to labelled, sealable container(s). Scoop absorbed substance into labelled, sealable containers. Carefully collect all spill/leftover residues. Remove contaminated soil and place in labelled sealable container(s) for appropriate disposal. Clean contaminated surfaces with an excess of water and contain and collect all washwaters for appropriate disposal. Wash equipment and clothing after clean-up and contain washwaters for appropriate disposal and dispose of used PPE appropriately. Dispose of all wastes in a manner consistent with local jurisdiction waste management regulations.
- During fires involving the notified chemical or products containing the notified chemical, release of fire-fighting waters to the environment should be minimised due to the potential for environmental release of the notified chemical or products of combustion (ie PBDD/Fs). Fire-affected areas may require decontamination.

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(1) of the Act; if
- manufacturing of the notified chemical occurs in Australia;
- the notified chemical is proposed to be incorporated into finished products other than those currently proposed;
- significant release to the aquatic environment is proposed;
- significant new information about the adverse environmental effects become available;
- environmental monitoring detects the presence of the notified chemical in the Australian environment above levels of concern (ie. 1.6 µg/L);

or

(2) 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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