File No: STD/1132

July 2006

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)**

# FULL PUBLIC REPORT

## 2,4,6-Tris(2,4,6-tribromophenoxy)-1,3,5-triazine (FR-245)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Heritage.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
Australian Safety and Compensation Council
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1162 or email ascc.library@dewr.gov.au

This Full Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:


| | |
|---|---|
| Street Address: | 334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA. |
| Postal Address: | GPO Box 58, SYDNEY NSW 2001, AUSTRALIA. |
| TEL: | + 61 2 8577 8800 |
| FAX | + 61 2 8577 8888 |
| Website: | www.nicnas.gov.au |


**Director**
**NICNAS**

# TABLE OF CONTENTS

# FULL PUBLIC REPORT

## 2,4,6-Tris(2,4,6-tribromophenoxy)-1,3,5-triazine (FR-245)

### 1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Marchem Australasia Pty Ltd (ABN 34 055 411 133)
38-40 Cromer Ave
Sunshine North, VIC, 3020

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

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

NOTIFICATION IN OTHER COUNTRIES
EU, Level 1a & 1b notification, UK1037 (ELINCS # 426-40-2)

### 2. IDENTITY OF CHEMICAL

CHEMICAL NAME
2,4,6-Tris(2,4,6-tribromophenoxy)-1,3,5-triazine

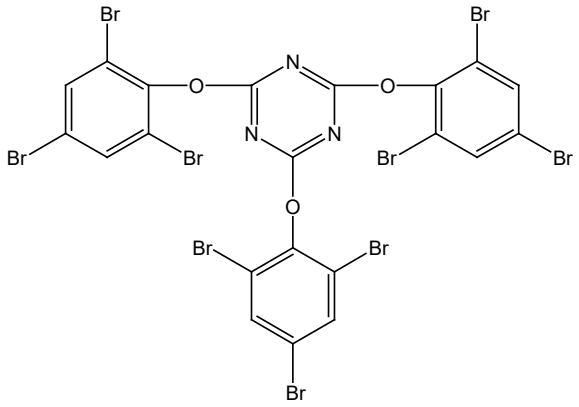
OTHER NAME(S)
1,3,5-Triazine, 2,4,6-tris(2,4,6-tribromophenoxy)-
Tris(2,4,6-tribromophenoxy)-s-triazine
Tris(tribromophenoxy)-s-triazine
Tris(tribromophenyl) cyanurate
SR 245
3-TBPC

MARKETING NAME(S)
FR-245

CAS NUMBER
25713-60-4

MOLECULAR FORMULA
$C_{21}H_6Br_9N_3O_3$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
1067.43

METHODS OF DETECTION AND DETERMINATION

| | |
|---|---|
| METHOD | High Performance Liquid Chromatography (HPLC) |
| Remarks | Identification is performed by comparison of peak retention times of the standard and a sample. Purity of the notified chemical was also determined using this method. |
| TEST FACILITY | ICL (2005) |

## 3. COMPOSITION

DEGREE OF PURITY
99.5%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

| | | | |
|---|---|---|---|
| *Chemical Name* | Tribromophenol | | |
| *CAS No.* | 118-79-6 | *Weight %* | < 300 ppm |
| *Hazardous Properties* | Classification (CICAD)<br>Harmful: R22 Harmful by if swallowed<br>Irritant: R36 Irritating to eyes<br><br>Concentration cut-off<br>Conc ≥ 25%: Xn; R22; R36<br>≥ 20% Conc < 25%: Xi; R36 | | |

| | | | |
|---|---|---|---|
| *Chemical Name* | Bis (Tribromophenoxy) Triazine | | |
| *CAS No.* | Unknown | *Weight %* | <0.45 |
| *Hazardous Properties* | Unknown | | |

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
None

ADDITIVES/ADJUVANTS
None

## 4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Import

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

| *Year* | *1* | *2* | *3* | *4* | *5* |
|---|---|---|---|---|---|
| *Tonnes* | 1 – 10 | < 50 | < 50 | < 50 | < 50 |

USE
Flame retardant additive in styrenic copolymers such as high-impact polystyrene (HIPS) and Acrylonitrile-butadiene-styrene (ABS) and polyethylene. The notified chemical is incorporated at 10 - 20%.

Recommended applications for plastics containing the notified chemical are computer monitors, televisions, videos, remote controls, mobile phones and office equipment

## 5. PROCESS AND RELEASE INFORMATION

### 5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
The notified chemical will be supplied to compounding facilities in Victoria. The compounded pellets containing the notified chemical may be supplied to approximately 6 moulding manufacturers.

TRANSPORTATION AND PACKAGING
The notified chemical is packed in 25 kg paper bags with inside liner. The compounded pellets are usually packed in 25 kg bags or to customer request packaging. This packaging is then palletised and shrink wrapped to be transported usually by road to the moulding manufacturers.

### 5.2. Operation description

*Compounding (typical operation description)*
Workers will open the containers and manually weigh and or add the powdered notified chemical into a hopper which mixes and feeds the plastic resin and required plastic additives automatically into an extruder. In the extruder, the raw materials are melted and mixed. The melted mixture is extruded through die holes in long spaghetti-like strings and passed through a cooling water bath into a pelletiser. Following quality control testing, a packaging operator will bag the compounded pellets ready for distribution to customers.

*Moulding of plastic articles (typical operation description)*
The compounded pellets containing 10-20% notified chemical are either transferred by vacuum or manually tipped into the feeding hopper of the injection-moulding machine. Once heated, the molten pellets are moulded to form the shape of the plastic article, and then cooled within the closed mould, prior to ejection into a suitable receptacle. The moulded article is removed from moulds either manually or automatically ejected.

Moulding machine operators typically prepare and maintain the machine, e.g., installing machine parts such as dies, screws and sizing rings, connecting transfer/conveyor hoses, regulating and synchronizing the machine and examining the moulded products for defects such as wrinkles, bubbles, and splits. During the process, moulding-machine operators may adjust speed and weight controls or turns hot and cold water, air, oil, or steam valves to obtain the plastic product of the specified dimensions. In addition, moulding-machine operators may reel extruded products into rolls of specified length and or weight. Quality control workers may also test the moulded products for conformance to product

specifications.

*Recycling*
Recycling of composite finished articles (e.g. home and office IT and audiovisual equipment) containing the notified chemical may occur in Australia. No specific information was available regarding recycling in Australia. Recycling may involve only the dismantling of equipment manually with the plastic housing landfilled, or granulators, shredders and extruders could be used to convert the plastic article into a form that is amenable for further processing. Shredders and granulators cut up the plastic into small chips that can be reheated. Extruders melt the plastic on site.

## 5.3. Occupational exposure

*Compounding*
It is estimated that compounding will occur at each compounding facility once a week for 2-4 hours and is usually performed by two workers. Exposure is anticipated only in the initial phases of the manufacturing process when raw materials are loaded into hoppers. Dermal, ocular and inhalation exposure to the notified chemical in powder form could occur. The blending and extrusion processes are fully enclosed and automated, therefore further exposure would be limited. Dust containing the notified chemical is not expected during the pelletising process as any fine material generated during this process is expected to remain in the cooling water bath. Due to the low vapour pressure of the notified chemical and the presence of extraction systems release of fumes is unlikely to be a significant source of exposure. Compounding facilities will have equipment with venting systems and air collectors able to collect dust and separate it via filters. Personal protective equipment (PPE) should include protective gloves, goggles, coveralls and dust respirator if required.

*Moulding of plastic articles*
Although dermal contact with the pellets containing 10-20% of the notified chemical could occur during their manual transfer, exposure to the notified chemical is not expected as it not considered to be available in this form. The generation of dust during handling pellets is likely to be negligible. The delivery, mixing and dispensing processes used in moulding operations are typically automated and purpose built facilities fitted with vacuum extraction equipment, to minimise release of fugitive particulate material. Due to the low vapour pressure of the notified chemical and the presence of extraction systems release of fumes is unlikely to be a significant source of exposure. Occupational exposure to the notified chemical after the articles are made is not expected, as it not considered to be available in this form.

*End use and disposal of plastic articles*
There is potential for extensive worker exposure to plastics such as office equipment containing the notified chemical. The notified chemical is physically bound within the polymer matrix, however it is not chemically bound and could theoretically migrate overtime. Other brominated flame retardants have been detected in dusts as a result of blooming, leaching or abrasion from a wide range of finished products. Because there is a theoretical risk that dust from these plastics could become airborne or that the notified chemical may leach or vaporise from plastics containing it, inhalation and dermal exposure could occur to low levels of the notified chemical over extended periods of time.

Exposure by inhalation of dusts and dermal contact with articles could occur during the recycling/dismantling of plastic articles. Exposure is expected to be greatest at recycling sites where electronic equipment/plastic is shredded.

## 5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified chemical will not be manufactured in Australia but will be imported for compounding into the matrix of styrenic copolymers such as ABS polymers [Poly(Acrylonitrile, Butadiene, Styrene)], high impact polystyrene (HIPS) and polyethylene for use in various electronic products. Levels of dosage for polystyrenes and polyethylene polymers are around 10-20%. There are about half a dozen moulding manufacturers interested in the flame retardant compounded materials. The potential compounding facilities are in Victoria. Environmental release of the notified chemical is unlikely during accidental spillage of imported containers containing the notified chemical due to established emergency response procedures and environmental controls. Imported container size (25

kg bags) 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 Victoria for storage prior to compounding. Compounding is mostly undertaken using automated pumping and mixing procedures in enclosed systems and spillage is not expected. The compounding facilities will have safe equipment with venting systems and air collectors able to collect dust and separate it via filters whenever powders are processed. The waste resulted from compounding are usually dust-free as the notified chemical is already encapsulated in the plastic pellets. The import containers containing the residues at 0.4% (200 kg based on 50 tonnes usage volume per annum) will likely be disposed of to landfill.

During the manufacture of plastic articles, the notified chemical is expected to melt during the injection moulding process, but there is no indication that any chemical reaction takes place. The notified chemical is said to act as a thermally stable plastic additive in the processing window of the polymer in which it is used as long as the processing temperature is below the decomposition temperature. The scraps coming from the injection moulding operations are plastics parts that are ground and recycled on line in the moulding machine. The remaining waste could be easily incinerated. The notifier indicates that the total waste from compounding to manufacture of plastic articles should not exceed 0.1% notified chemical.

RELEASE OF CHEMICAL FROM USE

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. The majority of the notified chemical will be incorporated within a polymer matrix, hence it will share the fate of electrical products. Products containing the notified chemical will have widespread and diffuse use pattern, but mostly in developed areas in Australia. It is anticipated that at the end of their useful life the products will either be recycled and made into new consumer products or disposed of to landfill. The notifier has provided a report showing that plastics containing the notified chemical are amenable to recycling (Heijboer et al, date unknown).

The notified chemical is physically bound within the plastic matrix, however it is not chemically bound and could theoretically bloom (migration of the additives present in a polymer matrix to the surface of the plastics and crystallisation on the surface) from the plastic. The notifier claims that due to the expected low vapour pressure as indicated in the Thermogravimetric Analysis (TGA) data (see under thermal stability) where only small amount of weight is lost when the material is heated to above 350ºC (due to decomposition rather than volatility). Further, the notified chemical is soluble in polymer matrixes such as polystyrene, impact polystyrene, ABS and polycarbonate and becomes transparent proving that the material is a one phase solution with the polymer matrix.

The notifier also provided a report on an ABS which is flame retarded by the notified chemical, which is characterised by a high level of fire retardation (Wells 2001) and has excellent recycling characteristics (Heijboer et al, date unknown). The results show that following 6 recycling operations (moulding and regrind of even 100% scrap and or thermal aging up to 1500 h at high temperature up to 220ºC), the reprocessed ABS keeps its high level of fire retardation but no indication of how much is being lost in the process. This appears to indicate that the notified chemical is well inside the plastics and does not leave the ABS matrix. It is also claimed that no surface migration of the notified chemical was observed even after thermal ageing conditions due to the excellent compatibility of the notified chemical with styrene. However, again no amount of the notified chemical migrated was measured.

The notifier also indicates that the notified chemical should not be compared with the liquid PVC plasticisers as the notified chemical only melts at 230 ºC and returns to its solid state when it cools to room temperature.

The degree to which blooming may occur is dependent of a number of physicochemical and structural factors, including size and shape of molecule, molecular weight, geometry of the polymer matrix, compatability with the plastic polymer and volatility. No studies citing the degree of migration for the notified chemical were available and as such, blooming of the notified chemical cannot be ruled out.

### 5.5. Disposal

Incineration of the notified chemical in manufactured materials may result in the formation of low concentrations of a range of compounds including polybrominated dibenzo-p-dioxins (PBDDs) and polybrominated dibenzofurans (PBDFs). The notifier has provided reports indicating that no polybrominated dioxins or furans are formed in the notified chemical itself (Institut Fresenius 1998, 2001b and 2001d), in its incineration gases, in the end product plastics (ABS and HIPS) or in the incineration gas of the end product plastics (Institut Fresenius 1999, 2001a, 2001c and 2001e). The notified chemical was incinerated under conditions simulating a modern municipal solid waste incinerator at a temperature of 900°C with an afterburning temperature of 1200°C. The results indicate that no polybrominated dibenzodioxins and dibenzofurans were present in the incineration gas of the notified chemical at a level higher than the limits of quantitation specified by the US EPA Toxic Substance Control Act, and were always well below these limits. 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.

### 5.6. Public exposure

Public exposure to imported powder preparations will only occur in the unlikely event of a transport accident involving breach of import packaging. The notified chemical will not be sold to the public except in the form of finished plastic products.

There is potential for extensive public exposure to plastics containing the notified chemical. The notified chemical is physically bound within the polymer matrix, however it is not chemically bound and could theoretically migrate over time. Other brominated flame retardants have been detected in dusts as a result of blooming, leaching or abrasion from a wide range of finished products. Because there is a theoretical risk that dust from these plastics could become airborne or that the notified chemical may leach or vaporise from plastics containing it, inhalation and dermal exposure could occur to low levels of the notified chemical over extended periods of time. The public could also be exposed to low levels of the notified chemical and/or its breakdown products via environmental routes

## 6. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance at 20ºC and 101.3 kPa** White Powder

**Melting Point/Freezing Point** 228-229ºC

| | |
|---|---|
| METHOD | EC Directive 92/69/EEC A.1 Melting/Freezing Temperature. |
| Remarks | Determined by Differential Scanning Calorimetry. The melting process started at a lower temperature of 216-218ºC probably due to impurities. At temperatures above 275 ºC reaction or decomposition of the test substance was observed. |
| TEST FACILITY | NOTOX (1997a) |

**Density** 2440 kg/m$^3$ at 20ºC

| | |
|---|---|
| METHOD | OECD TG 109 Density of Liquids and Solids.<br>EC Directive 92/69/EEC A.3 Relative Density. |
| Remarks | Determined using a gas (helium) comparison pycnometer. |
| TEST FACILITY | NOTOX (1997b) |

**Vapour Pressure** 1.52x10$^{-23}$ kPa at 25ºC

| | |
|---|---|
| METHOD | OECD TG 104 Vapour Pressure.<br>EC Directive 92/69/EEC A.4 Vapour Pressure. |
| Remarks | Estimated using the modified Watson Correlation with the boiling point calculated using Meissner's method. |
| TEST FACILITY | NOTOX (1997c) |

**Water Solubility** < 1 µg/L at 20ºC

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks A previous water solubility test indicated a water solubility of <0.013 mg/L using a flask method with 26 days stirring. The test was further performed using column elution/HPLC and supports the previous finding. No significant protocol deviations. Statement of GLP compliance.
TEST FACILITY Huntingdon (2005)

**Hydrolysis as a Function of pH** Not determined

Remarks The notified chemical is practically insoluble in water and contains no hydrolysable groups. Therefore, it is unlikely to hydrolyse at the environmental pH of 4-9.

**Partition Coefficient (n-octanol/water)** log Pow >5.85 at 20ºC

METHOD OECD TG 107 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks The value of the partition coefficient was estimated by the use of the solubilities of the test substance in n-octanol and water. The solubility of the test substance in n-octanol was determined to be 679 mg/L using the shake flask method of OECD TG 105 (Huntingdon 2005b). Based on the water solubility of <1 µg/L, the Pow was estimated to be >6.79 X $10^5$ (log Pow >5.85). The partition coefficient was also calculated to be 3.9 X $10^{13}$ (log Pow = 13.6) using the Rekker calculation method.
TEST FACILITY NOTOX (1997d)

**Adsorption/Desorption** log $K_{oc}$ = 7.6

METHOD Estimation model PCKOC
Remarks The notifier indicates that due to the hydrophobic property of the notified chemical, it is expected that the notified chemical will adsorb to soil. The predicted log Koc value of 7.6 (calculation not seen) indicates potential for very strong sorption to organic carbon.

**Dissociation Constant** Not applicable

Remarks The notified chemical is insoluble in water and contains no dissociable groups.

**Particle Size** Range 0.8 – 316 µm

METHOD Determined using the Mastersizer 2000 which uses low angle laser light scattering and is based on the principal that diffraction angle is inversely proportional to particle size.

| *Range (µm)* | *Mass (%)* |
|---|---|
| < 10 | 4 |
| 10-100 | 63 |
| 100-200 | 31 |
| 200-400 | 2 |

Remarks Inhalable fraction: 67%
Respirable fraction: 4%
TEST FACILITY DSBG (2004)

**Flash Point** Not determined.

| | |
|---|---|
| Remarks | Notified chemical is a low volatility solid. |

**Flammability Limits** Not considered as highly flammable

| | |
|---|---|
| METHOD | EC Directive 92/69/EEC A.10 Flammability (Solids). |
| Remarks | In a preliminary screening test the notified chemical emitted orange sparks and black smoke in contact with the ignition source. After removal of the ignition source the spark extinguished immediately, therefore, no further testing was required. |
| TEST FACILITY | NOTOX (1997e) |

**Autoignition Temperature** > 400°C

| | |
|---|---|
| METHOD | 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids. |
| Remarks | No self-ignition of the test substance was observed. The test substance had melted and changed into a black residue. |
| TEST FACILITY | NOTOX (1997f) |

**Explosive Properties** Not predicted to be explosive

| | |
|---|---|
| METHOD | EC Directive 92/69/EEC A.14 Explosive Properties. |
| Remarks | From examination of the structure, there are no chemical groups that would infer explosive properties, therefore the result has been predicted to be negative. |
| TEST FACILITY | NOTOX (1997g) |

**Oxidising Properties** Not predicted to have oxidising properties.

| | |
|---|---|
| METHOD | EC Directive 92/69/EEC A.17 Oxidising Properties (Solids). |
| Remarks | From examination of the structure, there are no chemical groups that might act as an oxidising agent, therefore the result has been predicted to be negative. |
| TEST FACILITY | NOTOX (1997h) |

**Reactivity**

| | |
|---|---|
| Remarks | The notified chemical is expected to be stable under normal conditions of use. The notified chemical will decompose at approximately 375°C, releasing poisonous and corrosive fumes of hydrogen bromide, carbon monoxide, carbon dioxide and nitrogen oxides. |

**Thermal Stability**

| | |
|---|---|
| METHOD | Thermogravimetric Analysis (TGA) |
| Remarks | 10 mg of the notified polymer was heated from 25°C to 650°C at a rate of 10°C/min.<br><br>2%, 5% and 10% weight loss at 360°C, 385°C and 400°C, respectively. 2%, 5% and 10% weight loss at 360°C, 385°C and 400°C, respectively. 80% and 100% decomposition was observed at approximately 450 °C and 550 °C, respectively. |
| TEST FACILITY | ICL (2005) |

## 7. TOXICOLOGICAL INVESTIGATIONS

| *Endpoint and Result* | *Assessment Conclusion* |
|---|---|
| Rat, acute oral | low toxicity, LD50 > 2000 mg/kg bw |
| Rat, acute dermal | low toxicity, LD50 > 2000 mg/kg bw |
| Rat, acute inhalation | not determined |
| Rabbit, skin irritation | non-irritating |
| Rabbit, eye irritation | slightly irritating |
| Guinea pig, skin sensitisation – adjuvant test | limited evidence of sensitisation |
| Rat, repeat dose oral toxicity – 28 days. | NOAEL 1000 mg/kg bw/day |
| Genotoxicity – bacterial reverse mutation | non mutagenic |
| Genotoxicity – in vitro chromosome aberration test | non clastogenic |
| Genotoxicity – in vitro gene mutation test | non clastogenic |
| Genotoxicity – in vivo | not determined |

### 7.1. Acute toxicity – oral

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.
Species/Strain Rat/Wistar
Vehicle 1% Aqueous carboxymethyl cellulose
Remarks - Method No significant protocol deviations

RESULTS

| *Group* | *Number and Sex of Animals* | *Dose mg/kg bw* | *Mortality* |
|---|---|---|---|
| I | 5 per sex | 2000 | 0 |

LD50 >2000 mg/kg bw
Signs of Toxicity Hunched posture was noted in all females and one male and piloerection in two females and one male, 2 hours after dosing. All signs had reversed by day 2. There were no remarkable body weight changes during the study period.
Effects in Organs There were no remarkable necropsy findings.

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

TEST FACILITY NOTOX (1997i)

### 7.2. Acute toxicity – dermal

TEST SUBSTANCE Notified chemical

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain Rat/Wistar
Vehicle 1% Aqueous carboxymethyl cellulose
Type of dressing Occlusive
Remarks - Method No significant protocol deviations

RESULTS

| *Group* | *Number and Sex of Animals* | *Dose mg/kg bw* | *Mortality* |
|---|---|---|---|

| | | | |
|---|---|---|---|
| I | 5 per sex | 2000 | 0 |

| | |
|---|---|
| LD50 | >2000 mg/kg bw |
| Signs of Toxicity - Local | There were no dermal reactions reported. |
| Signs of Toxicity - Systemic | Red staining of the snout was noted in one female on day 2. There were no other clinical signs or remarkable body weight changes during the study period. |
| Effects in Organs | There were no remarkable necropsy findings. |

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

TEST FACILITY NOTOX (1997j)

### 7.3. Acute toxicity – inhalation

Not determined. The chemical as introduced has only 4% of particles having less than 10µm diameter.

### 7.4. Irritation – skin

TEST SUBSTANCE Notified chemical

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

| | |
|---|---|
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 3 |
| Vehicle | Test substance moistened with distilled water. |
| Observation Period | 72 hours |
| Type of Dressing | Semi-occlusive. |
| Remarks - Method | No significant protocol deviations |

RESULTS

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

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

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

TEST FACILITY NOTOX (1997k)

### 7.5. Irritation – eye

TEST SUBSTANCE Notified chemical

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

| | |
|---|---|
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 3 |
| Observation Period | 72 hours |
| Remarks - Method | No significant protocol deviations. Fluoroscein was used to facilitate corneal observations |

RESULTS

| *Lesion* | *Mean Score* Animal No.* | | | *Maximum Value* | *Maximum Duration of Any Effect* | *Maximum Value at End of Observation Period* |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | | | |
| *Conjunctiva: redness* | 0.3 | 0.3 | 0.3 | 2 | < 48 hours | 0 |
| *Conjunctiva: chemosis* | 0 | 0 | 0 | 1 | < 24 hours | 0 |
| *Conjunctiva: discharge* | 0 | 0 | 0 | 0 | N/A | 0 |
| *Corneal opacity* | 0 | 0 | 0 | 0 | N/A | 0 |
| *Iridial inflammation* | 0 | 0 | 0 | 0 | N/A | 0 |

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

Remarks - Results: Remnants of the test substance were present in the eyes of all animals on day 1.

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

TEST FACILITY: NOTOX (1997l)

### 7.6. Skin sensitisation

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 406 Skin Sensitisation – Magnusson and Kligman Method
EC Directive 96/54/EC B.6 Skin Sensitisation - Magnusson and Kligman Method

Species/Strain: Guinea pig/Himalayan

PRELIMINARY STUDY: Maximum Non-irritating Concentration:
intradermal: 5% in Corn Oil
topical: 50% in Corn Oil

MAIN STUDY

Number of Animals: Test Group: 20 Control Group: 10

INDUCTION PHASE: Induction Concentration:
intradermal: 5% in Corn Oil
topical: 50% in Corn Oil

Signs of Irritation: Intradermal injection: Mild to moderate erythema was recorded at sites receiving Freund's complete adjuvant in test and control animals. Mild erythema was seen in one test animal at sites receiving the test substance. There were no signs of irritation in the other nineteen test animals at sites receiving the test substance.

Topical induction: The test sites were pre-treated with 10% sodium lauryl sulphate 24 hours before topical induction. Mild to moderate erythema was observed in test and control animals following topical induction.

CHALLENGE PHASE

1st challenge: topical: 50%

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* | 0% (vehicle) | 1/18 | 0/18 | - | - |
| | 50% | 1/18 | 0/18 | - | - |
| *Control Group* | 0% (vehicle) | 0/18 | 0/18 | - | - |
| | 50% | 0/18 | 0/18 | - | - |

| | |
|---|---|
| Remarks - Results | Two test animals died on days 6 and 7. Signs of ill health, deep respiration, dark eyes and weakness were observed on the day prior to death. Macroscopic post-mortem of both animals showed dark red discolouration of the lungs.<br><br>The reaction to the vehicle in an experimental animal is unexpected. Sensitisation to the vehicle is ruled out based on the absence of responses in the control group to the vehicle.<br><br>The reaction to the 50% concentration noted in the same experimental animal may be indicative of skin sensitisation, based on the absence of any responses to the test substance in the control animals. However, the possibility that this animal showed a general, non-specific response cannot be rules out.<br><br>The results indicate a sensitisation rate of 0-6%. A response in at least 30% of the animals is required for classification as a skin sensitiser according to the Approved Criteria (NOHSC, 2004) |
| CONCLUSION | There was limited evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test. |
| TEST FACILITY | NOTOX (1997m) |

### 7.7. Repeat dose toxicity

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | '28-day Oral Toxicity Study in Mammalian Species' prescribed in 'Notification on Partial Revision of Testing Methods Relating to the New Chemicals Substances (Notification No. 700 of the Planning and Coordination Bureau, EA, No. 1039 of the Pharmaceutical Affairs Bureau, MHW & No. 1014 (1986) of the Basic Industries Bureau, MITI. |
| Species/Strain | Rats/Crj: CD(SD) |
| Route of Administration | Oral – gavage |
| Exposure Information | Total exposure days: 28 days<br>Dose regimen: 7 days per week<br>Post-exposure observation period: 14 days |
| Vehicle | 0.5% carboxymethylcellulose sodium solution. |
| Remarks - Method | Doses selected based on results of 14 day preliminary toxicity study.<br><br>Deviations from OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.<br><br>– Sensory reactivity to stimuli not reported.<br>– The organ weights of epididymis, heart and thymus were not reported.<br>– Histopathological examinations were performed on the heart, liver, spleen, adrenals, kidneys stomach and small intestines. |

RESULTS

| *Group* | *Number and Sex of Animals* | *Dose mg/kg bw/day* | *Mortality* |
|---|---|---|---|
| I (control) | 6 per sex | 0 | 0 |
| II (low dose) | 6 per sex | 10 | 0 |

| | | | |
|---|---|---|---|
| III (mid dose 1) | 6 per sex | 50 | 0 |
| IV (mid dose 2) | 6 per sex | 250 | 0 |
| V (high dose) | 6 per sex | 1000 | 0 |
| VI (control recovery) | 6 per sex | 0 | 0 |
| VII (high dose recovery) | 6 per sex | 1000 | 0 |

*Mortality and Time to Death*

No mortality was observed during the treatment or recovery phases.

*Clinical Observations*

Clinical signs included loss of hair, tail wound and scab formation. These were seen in control, treated and recovery animals and hence are considered not to be treatment related. There was no significant difference in body weight gain and food and water consumption in treated animals when compared to controls.

*Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis*

*Clinical Chemistry*

There were no significant difference of any of the clinical chemistry parameters in group II-V animals compared with controls. A significant decrease (33%, $P<0.05$) in gamma glutamyl transpeptidase levels was noted in high dose recovery male animals when compared to controls. A significant decrease (10%, $P<0.05$) in the Albumin/Globulin ratio was noted in high dose recovery female animals when compared to controls.

*Haematology*

A significant decreased (43%, $P<0.01$) (but not dose related) reticulocyte count was noted in group II-V females, when compared to group I females. No similar decrease was noted in treated males and levels noted were similar to those in the vehicle control recovery group. Decreased mean corpuscular haemoglobin levels were noted in group II (4%, $P<0.05$) and group III (6%, $P<0.01$) females with increased mean corpuscular volume (6%, $P<0.01$) and mean corpuscular haemoglobin levels (6%, $P<0.05$) noted in group VII females, when compared to their respective controls.

*Urinalysis*

There were no significant findings in any of the parameters in any of the treated or recovery animals.

*Effects in Organs*

*Organ weights*

A significant decrease (13%, $P<0.05$) in relative adrenal weight was noted in the group III females. Increased relative liver weight (7%, $P<0.05$) and decreased relative kidney weight (7%, $P<0.05$) were noted in high dose recovery males.

*Macroscopic Findings*

A map-like brownish region in the lung was noted in one group V male and one group IV female. Dilatation of pelvis in the kidney (1/6) depressed region of cerebrum of the brain (1/6) and depressed region of right parietal bone (1/6) was noted in the group III females. Whitish region of the liver was noted in one group I female and one high dose recovery group female.

*Histopathology*

Perilobular lipid droplets in the liver (2/6), basophilic change of tubular epithelium in the kidney (1/6), congestion and thickening of alveolar walls (1/1) in the lung were noted in group V males. Cell infiltration in Glissons capsule in the liver was noted in one group I male.

Perilobular lipid droplets (2/6) and formation of granulation tissue (1/6) in the liver was noted in group I females. Pelvic dilatation in the kidney (1/1) and deformity of the skull was noted in group II females. Thickening of alveolar walls in the lung was noted in one group IV female. Perilobular lipid droplets in the liver was noted in two group V females. Necrosis of hepatocytes (1/1) was noted in group VII females.

Remarks – Results

The decreased reticulocyte count noted was considered to have no toxicological significance due to a lack of dose response and as no other related changes were noted.

The histopathological findings in the lung were considered to be due to an administration error.

The other changes and statistically significant differences noted in haematology, blood chemistry, organ weights, clinical signs, gross pathological findings and histopathological findings were not considered to be test substance related, since there was no dose response relationship and similar changes were also noted in the control groups.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study, based on the absence of treatment related effects.

TEST FACILITY Hita (1997)

### 7.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified Chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure

Species/Strain: *S. typhimurium*: TA1535, TA1537, TA98, TA100,
Metabolic Activation System: S9-Mix from Aroclor 1254 induced rat liver.
Concentration Range in Main Test:
Test 1
a) With metabolic activation: 10-1000 µg/plate (TA1535, TA1537, TA98), 3-5000 µg/plate (TA100)
b) Without metabolic activation: 10-1000 µg/plate (TA1535, TA1537, TA98), 3-5000 µg/plate (TA100)

Test 2
a) With metabolic activation: 10-1000 µg/plate (all strains)
b) Without metabolic activation: 10-1000 µg/plate (all strains)

Vehicle: Dimethylsulphoxide
Remarks - Method: The testing of TA100 in test 1 was used as the dose range finding test. The concentrations used for the rest of the strains in test 1 and in test 2 was based on the precipitation observed in this test.

Deviations from Protocol:
Neither *S. typhimurium* strain TA102 or *E.coli* WP2 strains which may detect cross-linking mutagens were included in the assay.

2-Aminoanthracene was used as the sole indicator of the efficacy of the S9-mix.

The following positive controls were used in the absence of S9-mix:
methylmethanesulfonate (TA100)
daunomycine (TA98)

RESULTS

| *Metabolic Activation* | *Test Substance Concentration (µg/plate) Resulting in:* | | | |
|---|---|---|---|---|
| | *Cytotoxicity in Preliminary Test* | *Cytotoxicity in Main Test* | *Precipitation* | *Genotoxic Effect* |
| *Absent* | | | | |
| Test 1 | >5000 (TA100) | > 1000 | 1000 | negative |
| Test 2 | | > 1000 | 1000 | negative |
| *Present* | | | | |
| Test 1 | > 5000 (TA 100) | >1000 | 1000 | negative |

| | | | |
|---|---|---|---|
| Test 2 | > 1000 | 1000 | negative |

Remarks - Results

The test substance did not cause a marked increase in the number of revertants per plate of any of the tester strains either in the presence or absence of activation. No signs of toxicity (reduction of the bacterial lawn or decrease in the number of revertants) were observed.

Negative controls were within historical limits, except for TA1535 in the presence of activation (test 2). However, since this value was just below the lower limit of the range, the validity of the test was considered not to be affected. Positive controls confirmed the sensitivity of the test system

CONCLUSION

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

TEST FACILITY

NOTOX (1997n)

### 7.9.1 Genotoxicity – in vitro Chromosome Aberration Test

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.

Species/Cell Type: Cultured peripheral human lymphocytes
Metabolic Activation System: S9-Mix from Aroclor 1254 induced rat liver.
Vehicle: Dimethylsulphoxide
Remarks - Method: No significant protocol deviations.

| *Metabolic Activation* | *Test Substance Concentration (µg/mL)* | *Exposure Period* | *Harvest Time* |
|---|---|---|---|
| *Absent* | | | |
| Preliminary test | 0.1, 0.3, 1, 3, 10 (a + b) | 24 h (a)<br>48 h (b) | 24 h (a)<br>48 h (b) |
| Test 1 | 0.1, 0.3, 1*, 3*, 10* | 24 h | 24 h |
| Test 2a | 1*, 3*, 10* | 24 h | 24 h |
| Test 2b | 10* | 48 h | 48 h |
| *Present* | | | |
| Preliminary test | 0.1, 0.3, 1, 3, 10 | 3 h | 24 h |
| Test 1 | 0.1, 0.3, 1*, 3*, 10* | 3 h | 24 h |
| Test 2a | 1*, 3*, 10* | 3 h | 24 h |
| Test 2b | 10* | 3 h | 48 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* | > 10 | | | |
| Test 1 | - | > 10 | 10 | negative |
| Test 2a | - | > 10 | 10 | negative |
| Test 2b | - | > 10 | 10 | negative |
| *Present* | > 10 | | | |
| Test 1 | - | 10 | 10 | negative |
| Test 2a | - | 10 | 10 | negative |

| | | | | |
|---|---|---|---|---|
| Test 2b | - | > 10 | 10 | negative |

* based on > 50% decrease in mitotic index

Remarks - Results: The test substance did not cause any significant increases in the incidence of cells with chromosomal aberrations, polyploidy or endoreplication, at the concentrations analysed in the presence or absence of metabolic activation compared to the solvent controls.

Negative controls were within historical limits. Positive controls confirmed the sensitivity of the test system

CONCLUSION: The notified chemical was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY: NOTOX (1997o)

### 7.9.2 Genotoxicity – in vitro Gene Mutation Test

TEST SUBSTANCE

METHOD: OECD TG 476 In vitro Mammalian Cell Gene Mutation Test.
EC Directive 2000/32/EC B.17 Mutagenicity - In vitro Mammalian Cell Gene Mutation Test.

| | |
|---|---|
| Species | Mouse |
| Cell Type/Cell Line | Lymphoma cells/L5178Y |
| Metabolic Activation System | S9-Mix from Aroclor 1254 induced rat liver (Test 1: 8% v/v, Test 2: 12% v/v) |
| Vehicle | Dimethylsulphoxide |
| Remarks - Method | No significant protocol deviations. |

| *Metabolic Activation* | *Test Substance Concentration (µg/mL)* | *Exposure Period* | *Expression Time* | *Selection Time* |
|---|---|---|---|---|
| *Absent* | | | | |
| Preliminary test | 3, 10, 33, 100, 333 (a + b) | 3 h (a)<br>24 h (b) | 24 + 48 h (a)<br>24 h (b) | - |
| Test 1 | 0.025, 0.1, 1, 2.5, 10, 25, 100 | 3 h | 48 h | 11-12 days |
| Test 2 | 0.03, 0.1, 0.3, 1, 3, 10, 33, 100 | 24 h | 48 h | 11-12 days |
| *Present* | | | | |
| Preliminary test | 3, 10, 33, 100, 333 | 3 h | 24 + 48 h | - |
| Test 1 | 0.025, 0.1, 1, 2.5, 10, 25, 100 | 3 h | 48 h | 11-12 days |
| Test 2 | 0.03, 0.1, 0.3, 1, 3, 10, 33, 100 | 3 h | 48 h | 11-12 days |

RESULTS

| *Metabolic Activation* | *Test Substance Concentration (µg/mL) Resulting in:* | | | |
|---|---|---|---|---|
| | *Cytotoxicity in Preliminary Test* | *Cytotoxicity in Main Test* | *Precipitation* | *Genotoxic Effect* |
| *Absent* | > 333 | | | |
| Test 1 | | >100 | 100 | negative |
| Test 2 | | >100 | 100 | negative |
| *Present* | >333 | | | |
| Test 1 | | >100 | 100 | negative |
| Test 2 | | >100 | 100 | negative |

Remarks - Results: The test substance did not cause any significant increases in the mutant frequency at the TK locus, at the concentrations analysed in the presence or absence of metabolic activation compared to the solvent controls. The numbers of small and large colonies in the treated cultures were comparable to the numbers of small and large colonies of the solvent

| | |
|---|---|
| | controls. The positive controls confirmed the sensitivity of the test system |
| CONCLUSION | The notified chemical was not clastogenic to L5178/mouse lymphoma cells treated in vitro under the conditions of the test. |
| TEST FACILITY | NOTOX (2005) |

**7.10. Genotoxicity – in vivo**

Not determined.

**7.11. Toxicity profile of potential breakdown products**

A detailed review of the source data for this summary has not been conducted, this summary has been provided to give a brief overview of the toxicity profile of the potential breakdown products and is not intended to be a hazard assessment. No degradation products or pathways of the notified chemical have been identified. A summary of the available toxicological data for the theoretical potential breakdown product 2,4,6-tribromophenol (IPCS, 2005) is as follows:

| *Endpoint and Result* | *Assessment Conclusion* |
|---|---|
| Rat, acute oral | harmful, LD50 1486 mg/kg bw (several studies reported, lowest value used) |
| Rat, acute dermal | low toxicity, LD50 > 2000 mg/kg bw |
| Rat, acute inhalation | low toxicity, LC50 50000 mg/m$^3$/4 hour |
| Rabbit, skin irritation | non-irritating |
| Rabbit, eye irritation | irritating |
| Guinea pig, skin sensitisation – adjuvant test. | evidence of sensitisation |
| Rat, repeat dose oral toxicity – 48 days (male), 41-45 days (females). | NOAEL 100 mg/kg bw/day |
| Genotoxicity – bacterial reverse mutation | non mutagenic (3 studies) |
| Genotoxicity – in vitro chromosome aberration test | positive |
| Genotoxicity – in vitro gene mutation test | non clastogenic |
| Genotoxicity – in vivo mouse micronucleus test | negative |
| Developmental and reproductive effects | <u>Study 1 (Rat, oral reproduction/developmental combined with repeat dose)</u><br>Parental NOEL 1000 mg/kg bw/day<br>Foetal NOEL 300 mg/kg bw/day<br><br><u>Study 2 (Rat, oral developmental)</u><br>Maternal NOEL 1000 mg/kg bw/day<br>Foetal NOEL 300 mg/kg bw/day<br><br><u>Study 3 (Rat, inhalation developmental)</u><br>Maternal NOAEL 0.1 mg/m$^3$<br>Foetal NOAEL < 0.03 mg/m$^3$ |

# 8. ENVIRONMENT

## 8.1. Environmental fate

### 8.1.1. Ready biodegradability

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | Testing methods for new chemical substances, Kanpogyo No.5, Planning and coordination Bureau, Environment Agency, Yakuhatu No. 615, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, and 49 Kikyoku No. 392, Basic Industries Bureau, Ministry of International Trade and Industry, Japan. |
| Inoculum | Mixture of activated sludge from 10 locations in Japan |
| Exposure Period | 28 days |
| Auxiliary Solvent | None |
| Analytical Monitoring | HPLC and BOD |
| Remarks - Method | The concentration of the test substance used was 100 mg/L. The medium was inoculated with micro-organisms derived from the activated sludge. Five treatment groups were established in the system: a control consisting of sludge with reference (aniline), sludge with test substance (triplicate), water with the test substance and a blank. The % biodegradation of the test substance was measured by BOD and HPLC on days 7, 14, 21 and 28. The results of the BOD and HPLC determinations are shown below. |

RESULTS

| *Test substance* | | | *Aniline* | |
|---|---|---|---|---|
| *Day* | *% Degradation* | | *Day* | *% Degradation* |
| | *HPLC* | *BOD* | | |
| 7 | 6 | 0 | 7 | 59 |
| 14 | 6 | 0 | 14 | 71 |
| 21 | 4 | 0 | 21 | 73 |
| 28 | 6 | 0 | 28 | 74 |

| | |
|---|---|
| Remarks - Results | The test substance was neither soluble in water nor in sludge at the initiation of cultivation. At the completion of the cultivation, transformation was not observed compared with the initiation of cultivation for test substance in water. The test solutions were cloudy and the growth of the sludge was not observed at the completion of the cultivation. The test substance was stable during the cultivation based on the HPLC of the test substance before the start and after the termination of the cultivation. The reference substance underwent 74% biodegradation after 28 days thus validating the test. |
| CONCLUSION | The test substance is considered to be not readily biodegradable. |
| TEST FACILITY | Kurume Research Laboratories (1990a) |

### 8.1.2. Inherent biodegradability

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD guideline 302D for testing of chemicals: 'Inherent biodegradability – Concawe test (October 2001), using a pre-exposed inoculum. |
| Inoculum | A mixture of activated sludge from Haifa municipal wastewater treatment |

| | |
|---|---|
| | plant and sludge from a bioreactor treating BCL industrial wastewater. |
| Exposure Period | 72 days |
| Auxiliary Solvent | THF |
| Analytical Monitoring | GC |
| Remarks – Method | The test substance at approximately 20 mg C/L was incubated in a buffer-mineral salts medium that had been inoculated with a pre-exposed inoculum. The test substance was first dissolved in a solvent, dispensed on glass fibre filters and then introduced into the reaction mixture following the evaporation of the solvent. The test was performed in sealed bottles for a period of 74 days by periodical measurements of $CO_2$ evolution in the bottles. The $CO_2$ values were translated to inorganic carbon produced and the extent of biodegradation was expressed as % of the maximum theoretical IC (ThIC) production, based on the initial quantity of test substance. The pre-exposure stage was performed with the mixed inoculum in flasks consisting of identical reaction mixtures. The test system consisted of (a) blank controls containing the inoculated medium, (b) reference substance 1-octanol, (c) test mixture containing the test substance, (d) inhibition control containing both the test substance and reference (e) abiotic control where the inoculum was poisoned by mercuric chloride and (f) a solvent control. |

RESULTS

| *Test substance* | | *1-octanol* | |
|---|---|---|---|
| *Day* | *% Degradation* | *Day* | *% Degradation* |
| 5 | 0 | 5 | 49 |
| 11 | 2 | 11 | 63 |
| 19 | 3 | 19 | 84 |
| 33 | 3 | 33 | 90 |
| 46 | 1 | 46 | 82 |
| 60 | 2 | 60 | 73 |
| 74 | 4 | 74 | 114 |

| | |
|---|---|
| Remarks – Results | The results indicate that the test substance is not inherently biodegradable. Only 4% of its initial carbon content was transformed to $CO_2$ during the test period. The study met the acceptability criteria and therefore was valid. The mean amounts of IC produced from the blank and the solvent control was <15% of the organic carbon added initially as the test substance. The degradation% of the reference reached over 60% after 11 days of the test period. The test substance was not inhibitory to the inoculum since in the inhibition control a transformation of 45% of the total carbon content to $CO_2$ was achieved by the end of the test. |
| CONCLUSION | The notified chemical is considered not inherently biodegradable. |
| TEST FACILITY | IMI-TAMI (2004) |

### 8.1.3. Bioaccumulation

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | Test methods for new chemical substances (Kanpogyo No. 5 Yakuhatsu No. 615, 49 Kikyoku No. 392, 1974) |
| Species | Carps |
| Exposure Period | 8 weeks |
| Auxiliary Solvent | None |
| Concentration Range | Nominal: Level 1 concentration = 0.5 mg/L; Level 2 concentration = 0.05 mg/L |

| | |
|---|---|
| Analytical Monitoring | HPLC |
| Remarks - Method | A continuous flow-through test was used for the test. 15 fish were used for Levels 1 and 2 concentrations and 5 fish for the control. These levels were based on a 48 h preliminary test using Red Killifish (*Oryzias Latipes*). Test water analysis was conducted for both levels 1 and 2 concentrations 2 times per week for a total of 16 times during the exposure period of 8 weeks. In addition test fish analysis was conducted for both levels before and after exposure at weeks 2, 4, 6 and 8 for a total of 4 times, with 2 fish samples analysed each time. Analysis of the target range was conducted prior to initiation and at termination of exposure, with 2 fish samples analysed each time. The concentration was determined by HPLC. Temperature and dissolved oxygen concentration were measured during the test. |

RESULTS

| | |
|---|---|
| Bioconcentration Factor | The bioconcentration factors were determined to be <0.8 to 9 and 8.0 to 18 for level 1 and level 2 concentrations, respectively. |
| CT50 | The 48 h LC50 was determined to be >500 mg/L |
| Remarks - Results | Observation of the external appearance of the test fish revealed no abnormalities. The stability of the test substance under storage and testing conditions were validated. Temperatures and dissolved oxygen concentrations were within acceptable limits. The concentrations of the test substance were maintained during the course of exposure. |

| | |
|---|---|
| CONCLUSION | The test substance was considered to be not bioaccumulative in the food chain as the BCF criteria are not exceeded. Further, the notified chemical high molecular weight and low water solubility suggests that it is unlikely to cross biological membranes and bioaccumulate (Connell 1990). Release to the aquatic environment will be very limited from the proposed uses and thus aquatic toxicity is unlikely to occur. |
| TEST FACILITY | Kurume Research Laboratory (1990b) |

### 8.2. Ecotoxicological investigations

#### 8.2.1. Acute toxicity to fish

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 203 Fish, Acute Toxicity Test - Static conditions.<br>EC Directive 92/69/EEC C.1 Acute Toxicity for Fish |
| Species | Carp (*Cyprinus carpio*) |
| Exposure Period | 96 h |
| Auxiliary Solvent | None |
| Water Hardness | 250 mg $CaCO_3$/L |
| Analytical Monitoring | HPLC |
| Remarks – Method | After a range finding test, a limit test was performed with carp exposed to a filtrate of a supersaturated solution of 100 mg/L prepared without any additive. The study started with the preparation of a solution by exposing the test medium to 100 mg/L for ca 3 days prior to testing to ensure the highest obtainable concentration in the water phase. These supersaturated solutions were stirred for ca. 65 h. The solution was filtered through a paper filter to remove the larger undissolved test substance particles. The filtrate was a clear and colourless solution. The test was performed under static condition with 7 fish per concentration and control. No mortality was observed at 3.5, 24, 48, 72 and 96 h following the start of exposure. A 96 h acute toxicity study in the carp with pentachlorophenol was also performed to check the sensitivity of the fish. |

RESULTS

| *Concentration mg/L* *Nominal* | *Number of Fish* | *Mortality* *3.5h* | *24h* | *48h* | *72h* | *96h* |
|---|---|---|---|---|---|---|
| 100 (filtered) | 7 | 0 | 0 | 0 | 0 | 0 |
| Control | 7 | 0 | 0 | 0 | 0 | 0 |

| | |
|---|---|
| LC50 | > 0.37 mg/L at 96 hours. |
| NOEC | 0.37 mg/L at 96 hours. |
| Remarks – Results | No fish were found dead in the control. The carp originating from this batch can be considered as sensitive to toxic substances based on the toxicity study with the reference pentachlorophenol. The actual concentration could not be maintained at > 80% of the initial concentration. The concentration initially measured included an undissolved but dispersed fraction, while the measured concentration at the end of the test period represented the concentration after further deposition of the hydrophobic material. Therefore, the decrease in measured concentration is largely due to precipitation of the hydrophobic molecule rather than degradation. The measured concentration in the sample taken from the filtrate at the start of the test was between 0.33-0.37 mg/L. During the exposure period the measured concentration decreased to below detection (< 0.016 mg/L). The temperature, pH and dissolved oxygen were found to be within acceptable limit at the end of the test. |

CONCLUSION The notified chemical is considered to be practically not toxic up to its limit of water solubility.

TEST FACILITY NOTOX (1997p)

### 8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static conditions.
EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia

| | |
|---|---|
| Species | *Daphnia magna* |
| Exposure Period | 48 hours |
| Auxiliary Solvent | None |
| Water Hardness | 250 mg $CaCO_3$/L |
| Analytical Monitoring | HPLC |
| Remarks - Method | After a range finding test, a limit test was performed with daphnids exposed to a filtrate of supersaturated solution of 100 mg/L prepared without any additive. The solution was prepared according to the above (see fish test). The test consisted of two vessels per group containing 10 daphnids per vessel and control. The immobility was observed at 24 and 48 h. A reference test with potassium dichromate was also conducted to determine the sensitivity of the test. |

RESULTS

| *Concentration mg/L* *Nominal* | *Number of D. magna* *(in duplicate of 10)* | *Number Immobilised* *24 h* | *48 h* |
|---|---|---|---|
| 100 (filtered) | 20 | 0 | 0 |
| Blank control | 20 | 0 | 0 |

| | |
|---|---|
| LC50 | > 0.37 mg/L at 48 hours |
| NOEC | 0.37 mg/L at 48 hours |
| Remarks - Results | No daphnia were found immobilised in the control. The actual responses in the reference test are within the ranges of the expected responses at the |

different concentrations for potassium dichromate. Therefore, the sensitivity of this batch of daphnia was within acceptable levels. Similar effects were observed in the solution (see fish test). Therefore, the decrease in measured concentration is largely due to precipitation of the hydrophobic molecule. Analysis of the concentration taken from the filtrate at the start of the test were 0.33 and 0.37 mg/L. After 48 h of exposure the measured concentration decreased to 0.1 mg/L. The temperature, pH and dissolved oxygen were found to be within acceptable limit at the end of the test.

CONCLUSION The notified chemical is considered to be practically not toxic to daphnia up to its limit of water solubility.

TEST FACILITY NOTOX (1997q)

### 8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.
EC Directive 92/69/EEC C.3 Algal Inhibition Test.

| | |
|---|---|
| Species | Fresh water alga (*Selenastrum capricornutum*) |
| Exposure Period | 72 hours |
| Concentration | Nominal: 100 mg/L |
| Auxiliary Solvent | None |
| Water Hardness | 24 mg $CaCO_3$/L |
| Analytical Monitoring | HPLC |
| Remarks - Method | Based on the range finding test, a limit test was performed exposing exponentially growing algal culture to a filtered solution prepared at a supersaturated concentration of 100 mg/L. Before filtration with filter paper to remove the undissolved test substance, the solution was stirred for 93 h to ensure that maximum saturation had been achieved. At the start of the test the filtered solution tested was clear and colourless. During incubation over a period of 72 h the algal cells were kept in suspension by continuous shaking. At the beginning of the test cells were counted using microscope. Thereafter the cell densities were determined by spectrophotometric measurement. The system consisted of 3 replicates of each test concentration, 6 replicates of the blank control and 1 replicate of the highest concentration without algae. A reference test with potassium dichromate was performed to check the sensitivity of the test system. |

RESULTS

| *Biomass* | | *Growth* | |
|---|---|---|---|
| *EbC50* | *NOEC* | *ErC50* | *NOEC* |
| *mg/L at 72 h* | *mg/L* | *mg/L at 72 h* | *mg/L* |
| >1 | 1 | >1 | 1 |

Remarks - Results During the 72 h exposure period no significant inhibition of cell growth or reduction in growth rate was recorded in the filtrate of 100 mg/L. Similar effects were observed in the solution (see fish test). Analysis of samples taken during the final test showed that the actual test concentration at the start of the test corresponded with a measured concentration of 1 mg/L. At the end of the test the concentration was 0.5 mg/L in the sample taken from the test solution with algae, while it was 0.2 mg/L in the sample taken without the algae. The difference between these results could not be explained. The results for the reference were within the expected limits. The pH and temperature were within acceptable limit at the end of the test.

| | |
|---|---|
| CONCLUSION | The notified chemical is considered practically not toxic up to its limit of water solubility. |
| TEST FACILITY | NOTOX (1997r) |

### 8.2.4. Inhibition of microbial activity

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 209 Activated Sludge, Respiration Inhibition Test.<br>EC Directive 67/548/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test |
| Inoculum | Municipal sewage treatment plant |
| Exposure Period | 30 minutes |
| Concentration | Nominal: 100 mg/L |
| Remarks – Method | Activated sludge was added to the mixture of synthetic sewage feed and test substance at a nominal concentration of 100 mg/L in duplicate. Oxygen consumption was measured and recorded. In each test series two controls without test substance were tested. Each batch of activated sludge was checked for susceptibility by testing the reference 3,5-dichlorophenol. |
| RESULTS | |
| IC50 | >100 mg/L |
| NOEC | 100 mg/L |
| Remarks – Results | No significant inhibition in respiration rate of the sludge was recorded at nominal concentration of 100 mg/L. The respiration rates of the controls were within 15% of each other. The EC50 of the reference was within the acceptable range of 5-30 mg/L. |
| CONCLUSION | The notified chemical is considered not toxic to micro-organisms. |
| TEST FACILITY | NOTOX (1997s) |

# 9. RISK ASSESSMENT

## 9.1. Environment

### 9.1.1. Environment – exposure assessment

Brominated flame retardants (BFRs)are widely used globally in the manufacture of electrical products. However, health and environmental concerns due to the widespread occurrence of some BFRs in the environment and people have led to the banning/disuse of several compounds in some countries.

The proposed use of the notified chemical will be of limited exposure in water during its compounding stage and manufacture of the articles. The fate of the majority of the notified chemical will share that of the polymer matrix in which it will be incorporated and ultimately be disposed of to landfill (or recycled) at the end of its useful lifetime. A small amount of the free notified chemical (200 kg per annum) will be disposed of to landfill along with empty import packaging. The low water solubility and volatility of the notified chemical would suggest that it would not be expected to be mobile in landfill.

However, BFRs have been detected in dusts as a result of blooming, leaching or abrasion from a wide range of finished products. In addition, BFRs have been identified in sewage sludges presumably due to breakdown of finished products. The Danish EPA has assumed a conservative release rate of brominated flame retardants of 1.5% per annum of import volume as a result of its use with emission from products in service (Danish EPA 2006). The notified chemical is used as an additive flame retardant for which blooming cannot be ruled out. The data provided and arguments put forward by the notifier to date are not convincing. The recycling study provided appears to confirm only that accelerated aged specimens were tested for flame resistance and other physical properties and does not appear to rule out a percentage of the notified chemical moving to the surface. Taking a release rate of 1.5% leads to the potential release of up to 750 kg per annum of the notified chemical at the maximum import rate. This release1 will be dispersed across Australia and will mainly occur indoors.

### 9.1.2. Environment – effects assessment

The notified chemical is practically insoluble in water (<1 µg/L). Based on the toxicity studies of the notified chemical, it is unlikely to be toxic to aquatic organisms up to its limit of water solubility. Furthermore, the proposed use pattern will be of limited aquatic exposure. Thus the toxic effects in the aquatic compartment are not a consideration and no PNEC can be calculated.

### 9.1.3. Environment – risk characterisation

As noted above, no PEC or PNEC can be calculated and thus a risk assessment in the aquatic environment can not be performed. The majority of the notified chemical will be incorporated as an additive into the matrix of the polymers used for electronic equipment. During the lifetime of the equipment there is the potential for the notified chemical to bloom to the surface of the plastic from where it may be dispersed. However, the rate of emission from the blooming process is likely to be low (a worst case estimate of < 750 kg per annum). This release will be extremely dispersed, occurring throughout Australia and not expected to pose an environmental risk at the proposed levels of import. However, should the proposed level of import exceed 100 tonnes then the notified chemical should become the subject of a secondary notification for which blooming data may be required.

As noted above, the notified chemical exhibits similar physico-chemical properties to decabromodiphenyl ether and the cleavage of the ether linkages within the notified chemical during degradation has the potential to release the theoretical breakdown product tribromophenol (TBP), thereby potentially adding small amounts to the pool of TBP in the environment.

At the end of their useful life equipment containing the notified chemical will most likely be disposed of to landfill along with residues in import containers (< 200 kg per annum). The low water solubility and vapour pressure of the notified chemical would indicate that it should remain immobile within landfill and eventually degrade through a combination of biotic and

abiotic processes to oxides of carbon, water and bromine salts.

The notifier has provided reports indicating that no polybrominated dioxins or furans are formed in the notified chemical itself, in its incineration gases, in the end product plastics (ABS and HIPS) or in the incineration gas of the end product plastics. Furthermore, given the proposed use pattern very little of the notified chemical is expected to be incinerated.

## 9.2. Human health

### 9.2.1. Occupational health and safety – exposure assessment

*Storage and distribution*

Waterside, transport and warehouse workers' exposure to the notified chemical is expected to be negligible except in the event of an accident.

*Compounding*

Dermal and possibly ocular and inhalation exposure to the notified polymer may occur during the transfer of the notified chemical into the hoppers. The estimated reasonable worst case and typical case dermal exposure is 3000 mg and 900 mg respectively using measured data for the exposure scenario 'dumping of powders in a formulation facility' (European Commission, 2003). Therefore, for a 70 kg worker and a 10% dermal absorption factor (based on the high molecular weight and high log $P_{ow}$), reasonable worst-case and typical case dermal exposure is estimated to be 4.3 mg/kg bw/day and 1.3 mg/kg bw/day respectively. Exposure would be limited by the use of PPE (gloves, goggles, and coveralls) and would be further reduced in the presence of local exhaust ventilation (LEV).

The estimated atmospheric concentration of the notified chemical during the transfer due to dust is 5-50 mg/m$^3$, based on EASE model (EASE) using the following inputs: dry manipulation, non-fibrous and LEV absent. Therefore for a 70 kg worker, assuming an inhalation rate of 1.3 m$^3$/hour, 3 hour exposure time (EU, 2002) and 67% inhalable fraction, inhalation exposure is estimated to be 0.18-1.8 mg/kg bw/day. In the presence of effective local exhaust ventilation, inhalation exposure is estimated by the EASE model to be 0.07-0.18 mg/kg bw/day.

Minimal exposure is expected during the extrusion process due to the automated nature of this process, the use of engineering controls (venting systems), the low vapour pressure of the notified chemical and low level of dust generation.

*Manufacture of plastic articles*

Inhalation and dermal exposure to the notified chemical due to the handling of pellets or finished articles is expected to be low due to the incorporation of the notified chemical in the polymer matrix. The generation of dust during handling of the pellets is likely to be negligible. Release of fumes during the injection process may be a source of exposure but the low vapour pressure of the notified chemical and the presence of extraction ventilation will minimise emission.

*End use and disposal of plastic articles.*

*Office workers*

Extensive worker exposure to office equipment containing the notified chemical is expected and as such there is the potential for exposure to the notified chemical in dust or to airborne notified chemical from blooming. Although the low vapour pressure and high molecular weight would indicate negligible migration, another high molecular weight brominated flame retardant (decabromodiphenyl ether) has been shown to be present in air and dust samples from office and buildings albeit at low levels (< 100 pg/m$^3$ (air), < 1 – 7 mg/kg (dust)). The contribution of the different sources e.g. furnishing, electronic equipment could not be established (European Commission (2002)). Therefore for a 70 kg worker and assuming the levels in air may be similar to decabromodiphenyl ether, an inhalation rate of 1.3 m$^3$/hour, and an 8 hour exposure time, exposure to the notified chemical is estimated to be 0.014 ng/kg bw/day. Although the notified chemical is of similar molecular weight to decabromodiphenyl ether and has a low vapour pressure and is incorporated into plastic articles at the same rate as decabromodiphenyl ether, the assumption that the notified chemical will be present in air at the same concentrations has its limitations as it does not take into account other factors that contribute to blooming potential such as the relative compatibility of the two flame retardants, the contribution to the levels from

furnishings (in which the notified chemical is not used) or the longer term and higher volume usage of decabromodiphenyl ether. However, it is considered to give an indication of potential exposure. Workers may also be exposed by dermal contact with dust containing the notified chemical but due to the low expected absorption due to the high molecular weight of the notified chemical, this is not expected to be a major route of exposure. In addition, only low levels (ppm) of other brominated flame retardants have been detected in dust.

*Recycling*
In the assessment of another brominated flame retardant tetrabromobisphenol A (European Commission, 2006), workers involved in plastic recycling were identified as the workers with the second highest potential for exposure to the flame retardant (second to compounding workers). Inhalation exposure to dust during shredding was identified as the major route of exposure.

### 9.2.2. Public health – exposure assessment

Extensive public exposure to electronic equipment containing the notified chemical is expected. Other brominated flame retardants have been detected in dusts as a result of blooming, leaching or abrasion from a wide range of finished products and as such there is the potential for exposure to the notified chemical in dust or to airborne notified chemical. Based on levels of another high molecular weight brominated flame retardant (decabromodiphenyl ether) measured in buildings (<100 $pg/m^3$) (European Commission, 2002), exposure has been estimated to be 0.037 ng/kg bw/day. This assumes a daily inhalation volume for the average adult of 22 $m^3$/day (Enhealth, 2002) and a bodyweight of 60 Kg. Indirect exposure to the notified chemical and/or its breakdown products may occur, however, the notified chemical or the potential breakdown product TBP have not been predicted to bioaccumulate in the food chain.

### 9.2.3. Human health – effects assessment

*Toxicokinetics, metabolism and distribution.*
No toxicokinetic studies were available for the notified chemical. Based on the high molecular weight, the notified chemical is not expected to cross biological membranes, however, another high molecular weight brominated flame retardant decabromodiphenyl ether has been detected in blood and tissues (European Commission, 2002). An oral absorption study in rats is currently being undertaken.

*Acute toxicity.*
The notified chemical is considered to be of low toxicity via oral and dermal routes.

*Irritation and Sensitisation.*
Based on studies in rabbits the notified chemical is considered to be non-irritating to skin and slightly irritating to the eye. There was limited evidence of reactions indicative of skin sensitisation in a guinea pig maximisation test. However, skin reactions were only observed in one animal and an irritant response was also observed in one animal challenged with the vehicle and as such the response may be a non-specific effect.

*Repeated Dose Toxicity*
In a 28-day study in rats the NOAEL was established as 1000 mg/kg bw/day in this study based on the absence of treatment related effects. The chronic toxicity of this chemical has not been investigated.

*Mutagenicity.*
The notified chemical was negative in an Ames test, an *in vitro* chromosome aberration test and in an *in vitro* gene mutation test.

*Hazard classification for health effects.*
Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2002).

### 9.2.4. Occupational health and safety – risk characterisation

Worstcase dermal and inhalation exposure to the notified chemical during compounding was estimated to be 6.1 mg/kg bw/day. Based on a NOAEL of 1000 mg/kg bw/day, derived from a 28-day rat oral study the margin of exposure (MOE) is calculated as 164. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, based on the available toxicological information the risk of systemic effects using modelled worker data is acceptable for workers involved in compounding operations. Exposure to the notified chemical is considered to be greatest for workers involved in the compounding process and as such the risk of systemic effects for all workers is considered to be low.

The notified chemical is a slight eye irritant and as such workers involved in compounding operations should wear eye protection to minimise the risk of an irritation effect.

### 9.2.5. Public health – risk characterisation

Public exposure has been estimated to be of the order of 0.037 ng/kg bw/day. Based on a NOAEL of 1000 mg/kg bw/day, derived from a 28-day rat oral study the margin of exposure (MOE) is calculated as $2.7 \times 10^{10}$. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, based on the available toxicological information the risk to public is considered to be low.

## 9.3. Comparison with Persistent Organic Pollutant (POP) Criteria

The Stockholm Convention on Persistent Organic Pollutants (POPs) is a global treaty to protect human health and the environment. The convention contains criteria which address persistence, bioaccumulation potential, long-range transport and toxicity concerns. These criteria are used to identify substances that may be candidates for inclusion in the treaty. The Stockholm Convention on Persistent Organic Pollutants (POPs) entered into force on 17 May 2004. Australia ratified the Convention on 20 May 2004, and obligations of the POPs Convention entered into force for Australia on 18 August 2004. The Stockholm Convention requires parties under the Convention to take into account POPS characteristics when conducting assessments on new and existing chemicals.

The POPs characteristics of the notified chemical and its potential theoretical breakdown product TBP are as follows:

*Persistence*
The notifier has provided ready and inherent biodegradation studies of the notified chemical. The results indicate that the notified chemical will not biodegrade in the environment. Therefore, the notified chemical is likely to meet the persistence criteria for a POP chemical. TBP has been shown to be degraded by sewage microorganisms when it is the only source of nutrient (IPCS 2005). Therefore, it is unlikely to meet the persistence criteria for a POP chemical.

*Bioaccumulation*
The notifier has provided a bioaccumulation study of the notified chemical on carp. The test substance was considered to be not bioaccumulative in the food chain as the BCF criteria are not exceeded. Further, the notified chemical's number average molecular weight in excess of 1000 suggests that it is unlikely to cross biological membranes and bioaccumulate. Therefore, the notified chemical does not meet this criterion for POP chemicals. The bioconcentration factor of 20 for TBP (IPCS 2005), indicates that the potential breakdown product also does not meet the bioaccumulation criterion for POP chemicals (BCF>5000).

*Potential for long-range environmental transport*
The low solubility, volatility and low bioaccumulation potential of the notified chemical would suggest that it is unlikely to undergo long range environmental transport through air, water or migratory species. Hence the notified chemical would not meet this criterion for a POP

chemical.

*Adverse environmental effects*
Ecotoxicity data have been provided for the notified chemical. The results indicate that there is unlikely to be a toxic effect in the aquatic environment up to its limit of water solubility. Hence, the notified chemical does not meet this criterion for POP chemicals. Its proposed breakdown product TBP has been shown highly toxic to aquatic organisms (IPCS 2005) and would therefore meet the adverse environmental effects criterion of POP chemicals.

*Adverse health effects*
No specific criteria for health endpoints are provided, however based on the available toxicity data there was no evidence of serious damage to health by prolonged exposure and the notified chemical is not mutagenic. The potential breakdown product TBP is not classified as mutagenic, toxic for reproduction/development nor for prolonged exposure effects. Therefore, the notified chemical and its potential breakdown product are not considered to meet the toxicity criteria for POP chemicals.

*Summary*
The notified chemical and its potential breakdown product TBP are not considered to be potential POP chemicals.

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

### 10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

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.

| | ***Hazard category*** | ***Hazard statement*** |
|---|---|---|
| Chronic hazards to the aquatic environment | 4 | May cause long lasting harmful effects 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 and levels of introduction.

### 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 in the proposed manner.

## 11. MATERIAL SAFETY DATA SHEET

### 11.1. Material Safety Data Sheet

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

### 11.2. Label

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

## 12. RECOMMENDATIONS

REGULATORY CONTROLS

Annual Reporting

- Given the current international action on brominated flame retardants, the holder of the certificate should report to NICNAS annually the amount of notified chemical introduced, any known adverse occupational health and safety, public health and environmental effects of the notified chemical and any new information regarding blooming potential.

AICS

- When the notified chemical is added to the Australian Inventory of Chemical Substances (AICS), it should be annotated with the following condition of use:
  - For use only as a flame retardant additive in polymer matrices in electrical/electronic applications.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical during compounding and plastic recycling:
  - Operations should take place under local exhaust ventilation

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical during compounding and plastic recycling:
  - Avoid skin and eye contact
  - Avoid breathing dust

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical during compounding and plastic recycling:
  - Coveralls
  - Impervious gloves
  - Eye protection
  - Suitable respiratory protection where adequate ventilation is not present

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

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

- If products and mixtures containing the notified chemical are classified as hazardous to

health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of by landfill or incineration.

Emergency procedures

- Spills or accidental release of the notified chemical should be contained, collected and stored in a labelled, sealable container ready for disposal.

### 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;
- when the EU risk assessment is finalised
- when the oral absorption study and any data generated for the EU risk assessment becomes available.
- if any new information regarding blooming potential becomes available.

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. Under section 64 (2) of the Act, if the importation volume exceeds one hundred tonnes per annum, additional data will be required on the potential blooming (such as an aging test). In addition, if blooming is shown to be significant a higher tier longer term biodegradability study may be required, with the formation of the expected breakdown product TBP measured.

## 13. BIBLIOGRAPHY

Danish EPA (2006) Brominated Flame Retardants. Environmental Project no. 494 1999. Danish Environmental Agency. Available at http://www.mst.dk/udgiv/Publications/1999/87-7909-416-3/html/indhold_eng.htm Accessed 14 March 2006.

DSBG (2005) Determination of Particle Size Distribution of FR-245 using the Mastersizer 2000 (20 July 2004). Dead Sea Bromine Group. (Unpublished report provided by notifier.)

Enhealth (2002) Environmental Health Risk Assessment: Guidelines for Assessing Human Health Risk from Environmental Hazard, Dept of Health and Aging and EnHealth Council, commonwealth of Australia, June 2002.

Estimation and Assessment of Substance Exposure (EASE). The EASE system was developed by the UK Health and Safety Executive in conjunction with the Artificial Intelligence Applications Institute. For a further description see: Marquart et al., Evaluation of Methods of Exposure Assessment for Premarket Notifications, TNO Report V 94.229 TNO Nutrition and Food Research (Zeist), 1994.

European Commission (2002) European Union Risk Assessment Report: Bis(pentabromophenyl ether). 1st Priority List, Volume 17. European Commission Joint Research Centre, EUR 20402 EN, 2002.

European Commission (2003) Technical Guidance Document on Risk Assessment in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances and Directive 98/8/EC of the European Parliament and

of the Council Concerning the Placing of Biocidal Products on the Market – Part I. Institute for Health and Consumer protection, European Chemicals Bureau, European Communities.

European Commission (2006). European Union Risk Assessment Report: 2,2',6,6'-Tetrabromo-4,4'-isopropylidene diphenol (Tetrabromobisphenol A or TBBP-A) Part II - human health. 4th Priority List, Volume 63. European Commission Joint Research Centre, EUR 22161 EN, 2002.

Heijboer A, Scheinert J, Karp M and Reyes J (Year unknown) Health, safety and environmental aspects of plastics containing brominated fire retardants. (Unpublished report provided by notifier.)

Hita (1997) Twenty-Eight-Day Repeated Dose Oral Toxicity Study of SR-245 in Rats (Report no. D-2367, 30 May 1997) English translation of the final report (study B11-0092, 19 September 1990). Oita, Japan, Hita Research Laboratories. Sponsor: Dai-ichi Kogyo Seiyaku co Ltd. (Unpublished report provided by notifier.)

Huntingdon (2005a) FR-245 Water Solubility (DSV017/043663, 16 March 2005). UK, Huntingdon, Huntingdon Life Sciences Ltd. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

Huntingdon (2005b) FR-245 n-Octanol Solution (DSV017/043664, 16 March 2005). UK, Huntingdon, Huntingdon Life Sciences Ltd. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

ICL (2005) Characterisation of FR-245 (31 May 2005). Israel, ICL Industrial Products, Bromine Compounds Limited.

IMI-TAMI (2004) Inherent biodegradability test for FR-245 (Report No. St 08-15/Sr). IMI-TAMI, Institute for Research and Development Ltd, Haifa Bay, Israel. (Unpublished report provided by notifier.)

Institut Fresenius (1998) Polybrominated dibenzodioxins and dibenzofurans contamination (7 May 1998). Taunusstein, Institut Fresenius, Chemische und Biologische, Laboratorien GmbH. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

Institut Fresenius (1999) FR-245: Polybrominated dibenzodioxins and dibenzofurans in incineration gas (1 March 1999). Taunusstein, Institut Fresenius, Chemische und Biologische, Laboratorien GmbH. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

Institut Fresenius (2001a) FR-245: Polybrominated dibenzodioxins and dibenzofurans in incineration gas (16 July 2001). Taunusstein, Institut Fresenius, Chemische und Biologische, Laboratorien GmbH. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

Institut Fresenius (2001b) FR-245 in ABS after recycling: Polybrominated dibenzodioxins and dibenzofurans contamination (16 July 2001). Taunusstein, Institut Fresenius, Chemische und Biologische, Laboratorien GmbH. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

Institut Fresenius (2001c) FR-245 in ABS after recycling: Polybrominated dibenzodioxins and dibenzofurans in incineration gas (2 August 2001). Taunusstein, Institut Fresenius, Chemische und Biologische, Laboratorien GmbH. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

Institut Fresenius (2001d) FR-245 in HIPS after recycling: Polybrominated dibenzodioxins and dibenzofurans contamination according to TSCA (16 July 2001). Taunusstein, Institut Fresenius, Chemische und Biologische, Laboratorien GmbH. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

Institut Fresenius (2001e) FR-245 in HIPS after recycling: Polybrominated dibenzodioxins and dibenzofurans in incineration gas (1 August 2001). Taunusstein, Institut Fresenius, Chemische und Biologische, Laboratorien GmbH. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

IPCS (International Programme on Chemical Safety) (2005) Concise International Chemical Assessment Document 66: 2,4,6-Tribromophenol and other simple brominated phenols. Geneva, World Health Organization, International Programme on Chemical Safety.

Kurume Research Laboratory (1990a) Biodegradation test of SR-245 by micro-organisms. Test report 11793, Chemicals Biotesting Centre Chemicals Inspection & Testing Institute, Japan. (Unpublished report provided by notifier.)

Kurume Research Laboratory (1990b) Enrichment testing of SR-245 in Carp. Chemicals Evaluation and Research Institute, Japan. (Unpublished report provided by notifier.)

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2002) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2002)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edn [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOTOX (1997a) Determination of the Melting Point of SR-245 (Project 195784, 21 July 1997). Netherlands, s-Hertogenbosch, NOTOX B.V. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier. )

NOTOX (1997b) Determination of the Density of SR-245 (Project 195795, 16 June 1997). Netherlands, s-Hertogenbosch, NOTOX B.V. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

NOTOX (1997c) Calculation of the Vapour Pressure of SR-245 (Project 195806, 27 June 1997). Netherlands, s-Hertogenbosch, NOTOX B.V. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

NOTOX (1997e) Determination of the Flammability of SR-245 (Project 195841, 30 June 1997). Netherlands, s-Hertogenbosch, NOTOX B.V. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

NOTOX (1997f) Determination of the Relative Self-Ignition Temperature of SR-245 (Project 195841, 30 June 1997). Netherlands, s-Hertogenbosch, NOTOX B.V. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

NOTOX (1997g) Statement on the Explosive Properties of SR-245 (Project 217395, 3 November 1997). Netherlands, s-Hertogenbosch, NOTOX B.V. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

NOTOX (1997h) Statement on the Oxidizing Properties of SR-245 (Project 217406, 3 November 1997). Netherlands, s-Hertogenbosch, NOTOX B.V. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

NOTOX (1997i) Assessment of Acute Oral Toxicity with SR-245 in the Rat (Project 195885, 23 June 1997). Netherlands, s-Hertogenbosch, NOTOX B.V. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

NOTOX (1997j) Assessment of Acute Dermal Toxicity with SR-245 in the Rat (Project 195896, 23 June 1997). Netherlands, s-Hertogenbosch, NOTOX B.V. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

NOTOX (1997k) Primary Skin Irritation/Corrosion Study with SR-245 in the Rat (Project 195907, 23 June 1997). Netherlands, s-Hertogenbosch, NOTOX B.V. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

NOTOX (1997l) Acute Eye Irritation/Corrosion Study with SR-245 in the Rat (Project 195918, 23 June 1997). Netherlands, s-Hertogenbosch, NOTOX B.V. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

NOTOX (1997m) Assessment of Contact Hypersensitivity to SR-245 in the Albino Guinea Pig (Maximization Test) (Project 195929, 23 June 1997). Netherlands, s-Hertogenbosch, NOTOX B.V. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

NOTOX (1997n) Evaluation of the Mutagenic Activity of SR-245 in the Salmonella Typhirium Reverse Mutation Assay (With Independent Repeat) (Project 205695, 15 June 1997). Netherlands, s-Hertogenbosch, NOTOX B.V. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

NOTOX (1997o) Evaluation of the Ability of SR-245 to Induce Chromosome Aberrations in Cultured Peripheral Human Lymphocytes (With Independent Repeat) (Project 205706, 23 July 1997). Netherlands, s-Hertogenbosch, NOTOX B.V. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

NOTOX (1997p) 96 Hour acute toxicity study in carp (Project 195931, 25 July 1997). Netherlands, s-Hertogenbosch, NOTOX B.V. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

NOTOX (1997q) Acute toxicity study in Daphnia magna with SR-245 (Project 195942, 25 July 1997). Netherlands, s-Hertogenbosch, NOTOX B.V. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

NOTOX (1997r) Fresh water algal growth inhibition test with SR-245 (Project 195964, 25 July 1997). Netherlands, s-Hertogenbosch, NOTOX B.V. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

NOTOX (1997s) Activated sludge respiration inhibition test with SR-245 (Project 195975, 12 September 1997). Netherlands, s-Hertogenbosch, NOTOX B.V. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

NOTOX (2005) Evaluation of the Mutagenic Activity of FR-245 in an *in vitro* Mammalian Cell Gene Mutation Test with L5178Y Mouse Lymphoma Cells (With Independent Repeat) (Project 412324, 17 February 2005). Netherlands, s-Hertogenbosch, NOTOX B.V. Sponsor: Bromine Compounds Ltd, Israel. (Unpublished report provided by notifier.)

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.

Utracki L A (1989) Polymer Alloys and Blends, Hanser Publishers, p174.

Wells D (2001) FR-245 behaviour during six recycling steps and thermal aging. (Unpublished report provided by notifier.)