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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Iodotrifluoromethane

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**Iodotrifluoromethane****1. APPLICANT**

Pacific Dynamics Pty Ltd of 23 Ben Boyd Rd NEUTRAL BAY NSW 2089 has submitted a standard notification statement in support of their application for an assessment certificate for iodotrifluoromethane.

2. IDENTITY OF THE CHEMICAL

Chemical name: iodotrifluoromethane

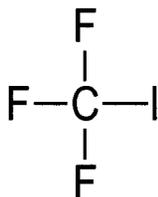
Chemical Abstracts Service (CAS) Registry No.: 2314-97-8

Other names: trifluoroiodomethane
trifluoromethyl iodide
FIC-13I1

Trade name: Triiodide

Molecular formula: CF₃I

Structural formula:



Molecular weight: 195.91

Method of detection and determination: infrared spectroscopy and mass-selective gas chromatography

Spectral data: Infrared: major characteristic peaks are at 260, 284, 539, 743, 1076 and 1185 cm⁻¹ (1)

3. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|--|--|
| Appearance at 20°C and 101.3 kPa: | colourless gas |
| Boiling Point: | -22.5°C |
| Vapour Density: | 8.051 kg/m ³ at 20°C |
| Liquid Density: | 2096 kg/m ³ at 25°C |
| Vapour Pressure: | 541 kPa at 25°C |
| Water Solubility: | 0.00862 g /g H ₂ O |
| Partition Co-efficient (n-octanol/water): | log P _{ow} = 0.27 - 0.41 |
| Hydrolysis as a function of pH: | does not contain hydrolysable functional groups and is only slightly soluble in water |
| Flammability Limits: | nonflammable |
| Decomposition Products: | hydrogen fluoride, hydrogen iodide |
| Reactivity/Stability: | incompatible for use as a fire extinguisher agent on burning metals such as magnesium, sodium, lithium, or potassium |

Comments on Physico-Chemical Properties

Due to the gaseous nature of the chemical, solubility was determined (by Deepwater Iodides, Inc, USA) by bubbling CF₃I through 125 mL deionised water, and weighing every 30 minutes until a constant weight was maintained. In the submission and the Material Safety Data Sheet (MSDS), water solubility is stated by the notifier as "very slightly soluble; 0.00862 g CF₃I / g H₂O". This equates to 8620 mg/L, making the chemical quite soluble in environmental terms.

There are no readily hydrolysable groups on the notified chemical.

Partition coefficient (octanol/water) was determined using a method analogous to OECD Guideline 107. A coefficient was determined (0.41), but it was found that the chemical was decomposing in the octanol as a function of time. An alternative method for determining the partition coefficient was used and a second value of 0.27 derived. Both these values were used by the notifier in the modelling of aquatic toxicity data.

The notifier states adsorption/desorption was insignificant due to the gaseous nature of the chemical. This is acceptable.

The notified chemical would not be expected to dissociate in water under environmental conditions.

4. PURITY OF THE CHEMICAL

Degree of purity: 99.9% minimum

Toxic or hazardous impurities:

Chemical name: hydrofluoric acid
CAS No.: 7664-39-3
Weight percentage: $< 5 \times 10^{-6}\%$
Toxic properties: human poison by inhalation; experimental poison by inhalation, subcutaneous and peritoneal routes; corrosive irritant to skin, eyes and mucous membranes; experimental teratogen; experimental reproductive effects; mutagenic data (2)

Chemical name: hydroiodic acid
CAS No.: 10034-85-2
Weight percentage: $< 5 \times 10^{-6}\%$
Toxic properties: poisonous by ingestion and inhalation; corrosive and poisonous irritant to skin, eyes and mucous membranes (2)

Non-hazardous impurities (> 1% by weight): none

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured or reformulated in Australia. It will be imported (at a rate of up to 100 tonnes/annum) into Australia in pressurised tanks and/or ready-to-use pressurised cylinders. It will be distributed to fire protection companies, aircraft service companies and the Australian military, and then to end users. The chemical is intended to be used in both fixed and portable systems. The uses for total flooding (fixed) systems are limited to normally unoccupied spaces such as aircraft engine compartments and auxiliary power units and unmanned engine and power compartments in ships, railway locomotives, mining equipment, switch rooms, racing cars and military vehicles. Explosion suppression in grain silos, gluten formulation facilities and starch processing plants are also uses for which the notified chemical will be employed. Portable extinguishers will only be used to fight high risk fires such as in aircraft engines and aircraft refuelling fires on the ground.

The estimated quantities to be used per annum for different applications are approximately 20 tonnes for land-based applications, 30 tonnes for maritime applications, 30 tonnes for aerospace applications and 20 tonnes for streaming applications.

6. OCCUPATIONAL EXPOSURE

The notified chemical is to be imported in tanks or ready-to-use cylinders (up to 70 kg capacity). Transportation will be most likely by sea, but may be by air for urgent shipments. The notified chemical will be transported to a Department of Defence depot or to a single (at present) service centre.

Exposure of dock workers, warehouse and transportation workers is possible in the rare event of tank or cylinder rupture.

The notified chemical is intended to be used either in total-flooding or streaming applications. Total flooding agents are chemicals manually or automatically discharged from a fixed piping system in sufficient quantities so the agent totally floods the space being protected. Fixed systems for total flooding applications normally comprise cylinders attached to the requisite piping and control systems. The notified chemical will replace Halon 1301 in these systems. Cylinders will be removed and taken to a single service centre.

The nature of the filling operation involves attaching hoses and valves to cylinders and tanks, transferring the notified chemical between containers and pressurising cylinders with nitrogen. A filled and sealed bottle will be taken to the fixed system to which it is to be coupled and attached. The seal is broken only after the fire suppression activator is initiated. Exposure during bottle filling is expected to be low given that local exhaust ventilation through the floor is to be used. The notifier estimates that leaks may occur about 2 to 3 times a year and involve exposure to 1000 ppm - 15 minutes time weighted average.

Exposure during use is not expected to occur in the space which is flooded and leakage is expected to be minimal in most cases given the need to maintain the design concentration during fire suppression.

Following release of the notified chemical and suppression of the fire or explosion, systems designed to initiate ventilation and exhaust procedures are activated before personnel can enter the hazard zone. Exhaust systems and practices following fire suppression are expected to take account of possible exposure of personnel to hazardous products of combustion and unconsumed extinguishant.

Streaming applications involve portable extinguishers and will only be used for high risk fires such as aircraft engine and refuelling fires on the ground. Portable units only will be used by trained firefighters. In these cases the notified chemical is a volumetric drop-in replacement for Halon 1211, the portable extinguishers have a discharge throw range of between 4.5 and 6.0 meters and workers trained in the use of Halon 1211 extinguishers will use the same procedures and precautions for extinguishers containing the notified chemical. Based on breathing zone personnel monitoring studies of Halon 1211 and other halon replacement agents, personnel are exposed to less than 1000 ppm in simulated aircraft hangar exposures during discharge of nominal 9 kg fire extinguishers in T-dock aircraft hangars (3), in open pit, outdoor fire scenarios fought with 9 kg fire extinguishers (4) and in 22 m³ room tests during discharge of a nominal 1.5 kg extinguisher (5). Exposure time during streaming scenarios is of short duration - less than 1 minute - and is infrequent - the notifier estimates about 1 in a working life on average. An exposure study for use of the notified chemical itself in hand-held fire extinguishers was also submitted (6) in which extinguisher sizes ranged from about 1 kg to about 6 kg in rooms of 25.8 m³ to 145.2 m³ in volume. The room

sizes were designed to simulate a telephone or electrical control room, a small laboratory or shop and an industrial setting. The maximum measured concentration in the breathing zone of the firefighter was 1700 ppm for the 6 kg extinguisher in the simulated industrial setting (145.3 m³).

A further use for the notified chemical is in engine strangler systems which are required to be fitted to diesel engines on vehicles transporting dangerous goods. As the amount of extinguishant is approximately 0.25 kg, exposure following release is expected to be low.

7. PUBLIC EXPOSURE

No public exposure to the notified chemical is expected to occur during its storage or distribution.

The notified chemical will be used in non-domestic situations where total flooding of the space to be protected is required or where streaming is appropriate.

Public exposure during total-flooding scenarios will not occur as the notified chemical will be used in unoccupied areas where occupancy is either physically impossible (eg. engine nacelle) or procedures have been taken to prevent entry. Given that the public would be removed from areas threatened by fires, public exposure to trifluoroiodomethane during its use as a streaming fire extinguishing agent for aircraft engine fires would not be expected to occur. However, use of trifluoroiodomethane as a streaming agent to control aircraft cabin fires could be expected to lead to public exposure.

Disposal of any waste notified chemical is expected to be in accordance with Local, State and Federal regulations and as such no public exposure is expected to occur.

8. ENVIRONMENTAL EXPOSURE

Release

The notified chemical will be used as a volumetric drop-in replacement for Halons 1301 and 1211. As with halons, the notified chemical suppresses fires primarily by chemical mechanisms whereby the production of free radicals from the agent interrupt the combustion chain reaction. Total flooding applications may include marine vessel machinery spaces and telecommunication switching stations. They also include explosion suppression uses in grain silos, gluten formulation facilities and starch processing plants. Streaming agents are chemicals that are manually discharged from portable fire extinguishers directly onto the fire hazard.

There is no manufacturing or reformulating of the notified chemical in Australia. The chemical is stored and transported in pressurised cylinders or tanks. Bulk chemical will be transported in containers ranging in size from 30 kg to 1 tonne. It will also be transported in end-use containers such as aircraft fire extinguishers. Based on the notifier's knowledge of historical discharge rates, it is estimated that a maximum of 2.5% of the import volume (up to 2.5 tonnes) will be discharged or emitted to the environment annually. Chemical not used for fire fighting or explosion suppression purposes can be reclaimed using existing halon reclamation technologies and recycled.

If disposal of small quantities of the notified chemical is necessary, it is likely to be vented to the atmosphere in a hood or remote area. Large quantities of the

chemical are likely to be disposed of by incineration.

Fate

The level 1 fugacity model estimates up to 99.73% of the chemical is expected to partition to air, with around 0.25% to water at equilibrium. The remaining negligible portion of the chemical is likely to associate with the soil compartment.

Chemical discharged into the atmosphere will decompose via photolytic breakdown into other materials which will readily dissipate and dilute in the atmosphere. The notified chemical has an atmospheric lifetime of less than 1 day (7): $\text{CF}_3\text{I} \rightarrow \text{CF}_3 + \text{I} \cdot (< 1 \text{ day})$

The ultimate products of degradation are CO_2 , HI and HF.

Ozone depletion potential (ODP) of CF_3I is expected to be far lower than that for halons due to the lower atmospheric lifetime, and the notified chemical is not expected to readily reach the stratosphere (7). In addition to the ODP of the notified chemical, the global warming potential (GWP) could be of concern. Solomon et al, 1993 concluded that the GWP (relative to CO_2) of CF_3I would be extremely small, even for a 20-year time horizon (7).

CF_3I is relatively water soluble (8620 mg/L), and the fugacity model indicates around 0.25% will reach the aquatic compartment at equilibrium. Due to the short half life and the fact there is no manufacture of the chemical in Australia, contamination of groundwater is improbable, and bioaccumulation is unlikely to occur.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Given that iodotrifluoromethane is a gas at ambient conditions, no acute oral toxicity study has been conducted.

Summary of the acute toxicity of Iodotrifluoromethane

| <i>Test</i> | <i>Species</i> | <i>Outcome</i> | <i>Reference</i> |
|---|----------------|---|------------------|
| inhalation toxicity (nose only) | rat | $\text{LC}_{50} > 1.02 \times 10^6 \text{ mg/m}^3$ (15 minute) | (8) |
| inhalation toxicity (whole body/ nose only) | rat | $\text{LC}_{50} > 2.0 \times 10^6 \text{ mg/m}^3$ (4 hour/ 15 minutes) | (9) |
| inhalation toxicity (nose only) | rat | $\text{LC}_{50} > 8.0 \times 10^4 \text{ mg/m}^3$ (4 hour) | (10) |

9.1.1 Dermal Toxicity

No acute dermal toxicity study was provided. The notifier has argued that trifluoroiodomethane is a gas at ambient temperature and is not easily absorbed in biological tissues.

9.1.2 Inhalation Toxicity (8, 9, 10)

Study 1

Five male and five female CD Sprague-Dawley rats were exposed (nose-only) to vapours containing trifluoroiodomethane at 1018312 mg/m³ (127289 ppm) for fifteen minutes. There were no deaths during the study. When removed from the chamber all rats exhibited severe salivation and two male rats also had rales; all rats had recovered within one-hour of exposure. There were no gross pathological changes attributed to treatment.

Study 2

Groups (5/sex/gp) of CD Sprague-Dawley rats were exposed to vapours containing trifluoroiodomethane at 803752, 1023752, 1602224, or 2572128 mg/m³ (100469, 127969, 200278, or 321516 ppm) by whole body exposure for 4 hours or at 1933400 or 2305840 (241675 or 288230 ppm) by nose-only exposure for 15 minutes. Although, all rats exposed to trifluoroiodomethane at 2572128 mg/m³ died within 20 minutes of exposure, the test material was found to be contaminated with hydrogen fluoride. Remaining exposures were conducted in the absence of hydrogen fluoride. Exposure to trifluoroiodomethane at 1602224 mg/m³ also resulted in the death of all animals within 20 minutes of exposure. No deaths occurred following whole body exposure to lower concentrations. Nose-only exposure to trifluoroiodomethane at 1933400 mg/m³ resulted in the death of one rat, however exposure to 2305840 mg/m³, resulted in the death of 2/5 males and all females. Surviving animals had recovered within 14 days of exposure. At necropsy, only the lungs ('puffy' and/or red) were found to be affected by treatment. On the basis of deaths occurring following nose-only exposure the acute LC₅₀ was estimated to be greater than 2000000 mg/m³ (27.4%).

Study 3

The objective of this study was to determine whether inhalational exposure to trifluoroiodomethane interferes with thyroid function. Groups (30/gp) of male Fischer 344 rats were exposed (nose-only) to vapours containing trifluoroiodomethane at 0, 40000, or 80000 mg/m³ (0, 0.5% or 1.0 %) for 4 hours. Sacrifices (10/gp) were conducted immediately following exposure, and at day 3 and day 14 post exposure. Criteria to assess toxicity included mortality, bodyweights, clinical observations, biochemical and haematological examinations, and pathological findings. Serum levels of thyroxine (T₄) and thyroxine-binding globulin (TBG) were determined.

There were no deaths or clinical signs attributed to trifluoroiodomethane. Transient reductions in bodyweights occurred at both exposure levels. At the high exposure level, a statistically significant 2-fold increase in the mean serum level of AST occurred on post exposure day 3, and although the mean level was also increased at day 14, it did not attain statistical significance. Also at the high level, the mean serum level of ALT was lower up to day 3 post-exposure, but was increased at day 14 post-exposure. Although, there were a number of other statistically significant changes in a number biochemical (including mean TBG and T₄ levels) and haematological parameters, changes were small and/or were stated to be within normal ranges for F-344 rats. There were no pathological changes attributed to trifluoroiodomethane.

9.1.3 Skin Irritation

No skin irritation studies were submitted. However, based on the information provided in the MSDS for a structurally similar compound, bromochlorodifluoromethane, trifluoriodomethane is expected to cause slight irritation and chilling of the skin.

9.1.4 Eye Irritation

No eye irritation studies were submitted. However, based on the information provided in the MSDS for a structurally similar compound, bromochlorodifluoromethane, trifluoriodomethane is not expected to be irritating to the eye.

9.1.5 Skin Sensitisation

No skin sensitisation studies were submitted.

9.2 Repeated Dose Toxicity (11)

Ninety-day inhalational study in rats

Groups (15/sex) of Fischer 344 rats were exposed (nose-only) to vapours containing trifluoriodomethane at 0, 2.0%, 4.0% or 8.0% (0, 160000, 320000 and 640000 mg/m³ respectively) for 2 hours/day, 5 days/week for 13 weeks. Interim (5/gp/sex) and terminal sacrifices were conducted at day 30 and day 90. Tests to assess toxicity included mortality, bodyweights, clinical observations, biochemical and haematological examinations, and pathological findings. Thyroid function and the potential for trifluoriodomethane to induce micronuclei in polychromatic erythrocytes obtained from bone marrow were also assessed.

Deaths occurring at 160000 (7 male rats) and 640000 mg/m³ (1 male rat) were not attributed to trifluoriodomethane but were attributed to accidents for the restraint system employed. Bodyweights of rats (both genders) were lower following exposure to trifluoriodomethane at 640000 mg/m³, and at 320000 mg/m³, male bodyweights were also lower. There was a dose-related increase in the activity of rats during exposure from 160000 mg/m³, and following exposure, rats at 640000 mg/m³ were reported to be lethargic.

Following 30 days of treatment, statistically significant changes in haematological parameters included a reduction in Hb concentration and RBC counts and an increase in the number of neutrophils in males at 640000 mg/m³, and the number of lymphocytes were reduced at and above 320000 mg/m³ in males and at 640000 mg/m³ in females (no blood haematological values were reported for male rats exposed to trifluoriodomethane at 160000 mg/m³). Following 90 days of treatment, RBC counts were reduced in males, and the number of lymphocytes were reduced in both genders at 640000 mg/m³. Following 30 days of treatment, significant changes in biochemical parameters included decreased calcium, glucose, and triglycerides (males) and increased ALT at 640000 mg/m³ (no results were presented for low dose male rats). Calcium, glucose (females) and triglyceride (males) levels remained lower after 90 days of treatment, and ALT levels were decreased at 640000 mg/m³.

There were dose-related increases in thyroglobulin from 160000 mg/m³ following treatment of females for 30 days (also increased in males but only at the high dose), and from 160000 mg/m³ for both genders following treatment for 90 days. T3 levels were decreased in males from 320000 mg/m³ (no results provided for females) at 30 days, and after 90 days dose-related decreases occurred from 160000 mg/m³ in both genders. T4 levels were increased from 320000 mg/m³ in males and from 160000 mg/m³ in females following treatment for both 30 and 90 days. T4 levels were also increased in males at 160000 mg/m³ following 90 days of treatment. rT3 levels were increased at 640000 mg/m³ in males and from 320000 mg/m³ in females after 30 days, and from 320000 mg/m³ in both genders after 90 days. Dose-related increases in TSH levels were reported from 160000 mg/m³ in males after 90 days of treatment and from 160000 mg/m³ in females following treatment for 30 and 90 days. TSH was also elevated in males at 640000 mg/m³ following treatment for 30 days.

Although statistically significant changes for some mean absolute organ weights occurred at 640000 mg/m³, they were associated with reduced mean bodyweights. Significant organ weight changes included lower absolute and relative thymus weights from 320000 mg/m³ in males at both sacrifices, and from 320000 mg/m³ and 160000 mg/m³ in females at interim and terminal sacrifices, respectively. Absolute and relative testicular weights were lower at 640000 mg/m³.

Histopathological findings at interim sacrifice included a dose-related increase in the incidence and severity (minimal to moderate) of inflammation of nasal turbinates in males from 320000 mg/m³, and in females at 640000 mg/m³, and a dose-related increase in the severity (mild to marked) of testicular atrophy and degeneration of spermatogonia in all males from 320000 mg/m³.

At terminal sacrifice, minimal necrosis of nasal turbinates occurred in all male treatment groups with the incidence increasing from approximately 10% at exposure levels of 160000 and 320000 mg/m³, to 56% at the highest exposure level; no male controls were affected. In female rats, the incidence of necrosis of nasal turbinates was increased at 160000 (22%) and 640000 (40%) mg/m³, but not at 320000 mg/m³; 10% of female controls were also affected. The number of males exhibiting minimal dilation of thyroid follicular cells increased from approximately 10% at exposure levels of 160000 and 320000 mg/m³, to 100% at the highest exposure level, and in females, there was a dose-related increased incidence from 160000 mg/m³ (0%, 10%, 20% and 100%, at the respective exposure levels). At the highest exposure level, the dilation of follicular cells was associated with an increase in colloidal content, and although the follicular lumen area was increased at all exposure levels, statistical significance was only attained for females treated at the highest exposure level; no follicular lining cell hypertrophy or hyperplasia were reported. Effects to the testes (atrophy and degeneration of spermatogonia) were reported at all exposure levels increasing from approximately 30% at exposure levels of 160000 and 320000 mg/m³, to 78% at the highest exposure level. Although testicular effects were reported to be incidental to treatment, no data was submitted to support this claim.

Treatment with trifluoroiodomethane resulted in dose-related increases in the frequency of micronuclei from 320000 and 160000 mg/m³ in male rats exposed for 30 and 90 days, respectively, and from 320000 mg/m³ in females treated for both 30 and 90 days. Cytotoxicity (as indicated by a

decrease in the PCE/NCE ratio) was evident at all doses that induced increased frequencies of micronuclei.

Note: - Doses were selected on the basis of a 2-week range-finding study in which groups of 5 male Fischer 344 rats were exposed (nose-only) to vapours containing trifluoriodomethane at 0, 240000, 480000, or 960000 mg/m³ (0, 30000, 60000, or 120000 ppm) for 2 hours/day, 5 days/week for 10 exposures. In this study, no deaths occurred, clinical observations reported included lethargy and incoordination from 480000 mg/m³, lower mean bodyweights from 480000 mg/m³, and serum thyroglobulin and reverse T₃ were increased from 240000 mg/m³. There were pathological changes attributed to treatment.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (12)

Cell cultures of *Salmonella typhimurium* TA98, TA100, TA1535, TA1537 and TA1538 (with (+S9) and without (-S9) metabolic activation) were exposed to trifluoriodomethane in exposure chambers at concentrations ranging from approximately 8000 or 680000 mg/m³ (1000 or 85000 ppm). All dose levels were plated in triplicate. For the positive controls, 2-anthramine was used in the presence of S9 in all the strains, and in the absence of S9, 4-nitro-o-phenylenediamine was used in strains TA98 and TA1538, sodium azide in strains TA100 and TA1535, and 9-aminoacridine in strains TA1537. In the absence and presence of metabolic activation, trifluoriodomethane was found to be mutagenic in strains TA98 (> 2 fold dose-related increase from 84688 (-S9) and 185840 (+S9) mg/m³), TA100 (> 2 fold dose-related increase from 22200 mg/m³), TA1535 (> 3 fold dose-related increase from 8480 (-S9) and 22200 (+S9) mg/m³), and TA1537 (> 3 fold dose-related increase from 185840 mg/m³), but not TA1538. No increases in the number of revertant colonies/plate were reported in any of the concurrent negative controls. The positive controls produced marked increases in the number of revertant colonies/plate.

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (13)

Swiss Webster mice (5/sex/group) were exposed (nose-only) to trifluoriodomethane at atmospheric concentrations of 0, 200000, 400000, or 600000 mg/m³ (0, 2.5%, 5.0%, or 7.5%) for 6 hours/day on 3 consecutive days. Animals in a positive control group (5/sex) were given triethylenemelamine by intraperitoneal injection at 0.4 mg/kg on day 3. Peripheral blood was collected 24 hours following the third exposure. Significant dose-related increases in the number of micronuclei/1000 polychromatic erythrocytes were reported for both sexes following exposure to trifluoriodomethane from 5%. The positive control significantly increased the number of micronuclei/1000 PCEs, and the concurrent controls produced the expected results.

9.3.3 Mouse Lymphoma cell Forward Mutation Assay (14)

In a L5178Y mouse lymphoma cell assay cell cultures (in the absence and presence of metabolic activation) were exposed to atmospheric concentrations of trifluoriodomethane ranging from 1000000 to 8000000 mg/m³ (125000 to 1000000 ppm). Duplicate assays were not conducted

The positive controls, hycanthone and cyclophosphamide were used in the absence and presence of metabolic activation, respectively. Exposure of cells to trifluoroiodomethane did not increase the mutation frequency in the absence or presence of metabolic activation. The positive controls produced marked increases in mutation frequencies.

9.4 Other studies

9.4.1 Cardiac sensitisation study in dogs (15)

The objective of this study was to assess the cardiac sensitisation potential of trifluoroiodomethane and iodoheptafluoropropane in dogs. The results with iodoheptafluoropropane are not reported here. Beagle dogs were given injections of adrenaline (ranging from 0.1 µg/kg to 12 µg/kg) prior to and during inhalational exposure (snout-only) to trifluoroiodomethane at concentrations of 0, 8000, 16000, 32000, or 80000 mg/m³ (0.0, 0.1, 0.2, 0.4 and 1.0%) for 10 minutes; a 24-hour recovery period was allowed between exposures. Cardiac sensitisation was assessed on the basis of abnormal ECG activity (multifocal ventricular ectopic activity or ventricular fibrillation). At 8000 and 16000 mg/m³, no cardiac sensitisation occurred, however at 32000 and 80000 mg/m³, the first dog exposed to each level had fatal ventricular fibrillation. No other dogs were treated at 32000 and 80000 mg/m³. In one dog, inhalational exposure to the positive control agent, CFC 11, at a concentration of 2%, resulted in fatal ventricular fibrillation.

9.4.2 Gas uptake kinetics of bromotrifluoromethane (Halon 1301) and trifluoroiodomethane (16)

The objective of this study was to measure tissue:air partition coefficients and to estimate gas uptake and metabolic constants in male Fischer 344 rats. Tissue:air coefficients were determined by incubating samples of liver, muscle, fat, gastrointestinal tract and blood in glass vials with trifluoroiodomethane in the headspace of each vial at concentrations ranging from 800 to 6400 mg/m³ (100 to 800 ppm). Fat samples were incubated for 5 to 8 hours, and other samples for 1 to 7 hours; or until no further change in the concentration of trifluoroiodomethane in the headspace occurred. Gas uptake was determined by exposing rats (via recirculating gas uptake exposure methods) to trifluoroiodomethane at concentrations ranging from 896 to 46936 mg/m³ (112 to 5867 ppm) for 6 hours, and monitoring the concentration of trifluoroiodomethane in the chamber atmosphere every 5 minutes for 30 minutes and then at 15 minute interval for the remaining 5.5 hours. Physiologically-based pharmacokinetic modelling was used to determine metabolic constants based on default parameters and values for tissue/air partition coefficients and gas uptake. Since the findings for bromotrifluoromethane are not relevant to this notification, they are not reported.

The partition coefficients (tissue/air) for most tissues were stated to be low and ranged from 1.22 for liver to 11.24 for fat. The inhalational uptake of trifluoroiodomethane showed two phases: a rapid phase that lasted up to 60 minutes followed by a slow linear uptake phase. On the basis of values obtained from PBPK modelling, it was concluded that some trifluoroiodomethane was metabolised by rats. In addition, the appearance of a second chromatographic peak, suggested that a metabolite or decomposition product of trifluoroiodomethane had been produced.

9.4 Overall Assessment of Toxicological Data

No acute oral or dermal studies, skin and eye irritation studies or skin sensitisation studies have been conducted with trifluoroiodomethane. However, based on information in the MSDS for a structurally similar compound, bromochlorodifluoromethane, iodotrifluoromethane is expected to cause chilling and slight irritation to the skin, but is not expected to be irritating to the eye. Irritation was indicated by inflammation of the nasal passages in rats observed in the 90-day repeat dose inhalation study and inflammation of the lungs was observed following acute inhalation (study 2).

Trifluoroiodomethane was of low inhalational toxicity in rats (nose-only 15-minute exposure) with an LC_{50} estimated to be greater than 2000000 mg/m^3 (27.4%). However, in another study conducted in the same strain of rat, whole-body exposure to trifluoroiodomethane for 4 hours resulted in the death of all animals at 1602224 mg/m^3 (22%) after 20 minutes. In the later study, no deaths occurred at 1023752 mg/m^3 , and therefore the LC_{50} in this study was most likely between 1023752 and 1602224 mg/m^3 .

In rats, inhalational exposure to trifluoroiodomethane at 40000 mg/m^3 for 4 hours, did not produce any significant adverse effects. Although statistically significant changes in thyroglobulin and T_4 levels occurred they were claimed to be within the normal ranges for the strain of rat used.

Trifluoroiodomethane was found to be a cardiac sensitiser in dogs at levels of 32000 (0.4%) and 80000 mg/m^3 (1.0%).

Repeated inhalational exposure to trifluoroiodomethane for 2 hours/day, 5 days/week for 13 weeks at exposure levels ranging from 160000 (2.0%) to 640000 mg/m^3 (8.0%), resulted in reduced RBC (males), lymphocytes, calcium, glucose, and triglyceride (males) levels at both interim (day 30) and terminal (day 90) sacrifices. Although the reduction in the number of lymphocytes may have been associated with reduced thymic weights (which were also reduced at 320000 mg/m^3), the changes in the above haematological and biochemical parameters were not associated with any histopathological findings. Increased levels of thyroglobulin, T_4 , rT_3 , and TSH and a reduction in T_3 , were associated with histopathological changes of the thyroid, and were stated to be consistent with thyroid effects induced by other iodinated compounds. Other findings included lower testicular weights following treatment at 640000 mg/m^3 at both interim and terminal sacrifices which were associated with testicular atrophy and degeneration of spermatogonia (also reported at 320000 mg/m^3), and the number of animals with minimal necrosis of nasal turbinates was increased in all male treatment groups and in females exposed to 160000 and 640000 mg/m^3 . It should be noted that this study was not carried out according to OECD or EU guidelines with respect to the dosing regime used. The usual protocol for a 90 day study involves exposing animals to test substance for 6 hours/day.

Trifluoroiodomethane was mutagenic in 4 of the 5 strains of *S. typhimurium* tested, but was not mutagenic in L5178Y mouse lymphoma cells. It also induced chromosomal damage (increased frequency of micronuclei/1000 polychromatic erythrocytes) in mice and rats following inhalational exposure.

Based on the toxicological data submitted, the notified chemical would not be classified as hazardous in accordance with Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) (17) in relation to acute lethal effects (inhalation) or severe effects after repeated or prolonged exposure (inhalational route) but would be classified

as hazardous in relation to mutagenic effects as a category 3 mutagen.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier has determined toxicity values by means of QSAR (Quantitative Structure Activity Relationships), using their measured values of LogP = 0.41 - 0.27, and following US EPA methods (18). The results obtained are as follows:

| Species | Ecotoxicity Parameter | Result (mg/L) |
|------------------|--|----------------------|
| Sheephead Minnow | 96-h LC ₅₀ | 481 - 613 |
| Freshwater Fish | 14-d LC ₅₀ | > 1000 |
| Daphnia sp. | 48-h LC ₅₀ | > 1000 |
| Daphnia sp. | 16-d EC ₅₀ (Reproduction) | 111 - 141 |
| Green alga | 3-h LC ₅₀ (Inhibition of photosynthesis). | > 1000 |

Toxicity values modelled by ASTER (ASsessment Tools for Evaluation of Risk) are shown in the table below. ASTER provides a much higher (calculated) partition coefficient of LogP = 2.09 which is used to obtain the following results which use a number of QSARs (18).

| Species | Duration (days) | Endpoint | Concentration (mg/L) calculated |
|---|------------------------|------------------|--|
| Water Flea (<i>Daphnia magna</i>) | 2 | LC ₅₀ | 61.952 |
| Bluegill (<i>Lepomis macrochirus</i>) | 4 | LC ₅₀ | 93.251 |
| Fathead minnow (<i>Pimephales promelas</i>) | 4 | LC ₅₀ | 121.764 |
| Channel catfish (<i>Ictalurus punctatus</i>) | 4 | LC ₅₀ | 52.448 |
| Rainbow trout, donaldson trout (<i>Oncorhynchus mykiss</i>) | 4 | LC ₅₀ | 53.983 |

The most sensitive aquatic toxicity predicted result is 96-h LC₅₀ of around 52.4 mg/L for Channel catfish (*Ictalurus punctatus*), obtained from the ASTER calculations in the above table.

Based on the predicted results, the notified chemical could be classed as slightly to practically non-toxic to aquatic species. It should be noted that there is great variability in these calculated results, and they provide a guide only as to the potential toxicity of the notified chemical.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Based on the notifier's knowledge of historical discharge rates, it is estimated that a maximum of approximately 2.5% of the imported volume of the notified chemical will be discharged or emitted to the environment. The remainder will be stored until required or recycled.

The maximum amount of chemical reaching the environment in any year will therefore be 2.5 tonnes. Because of the varied situations where this chemical could be used (ie, aircraft, marine or land-based applications), it is not possible to say where release will occur, except that most, if not all, will partition to the atmosphere. The level 1 Fugacity model predicts that in the order of 99.73% would partition to the atmosphere at equilibrium, with only around 0.25% reaching aquatic systems.

Atmospheric hazard is low as the notified chemical and its atmospheric breakdown products have limited persistence. As a result this substance has a low Ozone Depleting and Global Warming Potential.

Rapid atmospheric degradation will prevent the attainment of equilibrium. Therefore, the estimate of 0.25% partitioning to water is likely to be exaggerated. The environmental hazard associated with aquatic exposures of this magnitude, dispersed across Australia and occurring during the course of a year, would appear to be negligible.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical would be classified as hazardous according to the Approved Criteria in relation to its mutagenic effects. It is expected that mutagenic effects, in addition to other effects (including testicular effects, thyroid dysfunction and necrosis of nasal turbinates) seen in a repeated dose animal inhalational study would be of concern mainly for repeated exposure. However, chronic exposure to the notified chemical is considered unlikely as the fires and explosions it is to be used to suppress are likely to be infrequent events and occupational exposure during transport, storage, cylinder filling and system maintenance is likely to be well below the LOAEL of 2% reported in the repeat dose study (although certain deficiencies have been noted in this study).

The major hazard posed by the notified chemical under its conditions of use is cardiac sensitisation. The NOAEL in dogs was observed to be 0.2% (and the LOAEL 0.4%) whereas the design concentration for total flooding applications is at least 3.6% up to a maximum of 6.8% for a fire involving gaseous propane (19).

During system servicing and maintenance and cylinder filling operations, risks of acute effects are considered to be low as exposures well below the NOAEL are expected. Leaks are estimated by the notifier to result in an exposure level of 0.1% (15 minute TWA) maximum. Valve failure leading to discharge of an entire cylinder may occur rarely - estimated by the notifier at once in a worker's lifetime.

Due to the significant potential risk of cardiac sensitisation at the design concentration, the notified chemical is not recommended for use in total flooding applications for normally occupied spaces. In addition, spaces which can be occupied would be expected to be protected against discharge of the notified chemical during such intermittent occupation.

In total flooding applications leakage during fire or explosion suppression to the surrounding area is expected to be low because of the need to maintain the design concentration of the extinguishant. In marine applications, engine compartments are designed to be watertight and are located on the lowest level of the ship. In rail car applications the engine compartment requires a high air flow rate drawn from outside the compartment. However, on fire system activation the air intakes are automatically blocked by shutters so that leakage is likely to be low. Exhaustion of combustion products and unconsumed extinguishant is required from the hazard area in a controlled manner to atmosphere.

Use of the notified chemical in portable extinguishers is intended for trained firefighters for high risk fire events such as aircraft engine and refuelling fires on the ground. A number of studies have been conducted on exposure levels in the breathing zone of firefighters following discharge of portable extinguishers containing Halon 1211 and other potential halon replacements in aircraft hangar simulations and exterior fires. In no case was a level above 0.1% recorded. The

notified chemical itself has also been monitored following discharge of a variety of cylinder sizes into different room volumes. The maximum level recorded for the notified chemical was 0.17%.

Use of the notified chemical for engine strangler systems is likely to result in low exposure due to the small amount of extinguishant used.

In summary the risk of cardiac sensitisation for workers involved in filling of cylinders containing the notified chemical for use in fixed (total flooding) systems, in service and maintenance of these systems and for workers in surrounding areas following discharge, is expected to be low given the low potential for exposure. Similarly, the risk of cardiac sensitisation for workers following discharge of engine strangler systems is expected to be minimal.

There is a potential for high acute exposure to the notified chemical for firefighters using portable extinguishers, however risks of cardiac sensitisation should be substantially reduced by the deployment of appropriate ppe of which self-contained breathing apparatus is essential.

Finally the risk of cardiac sensitisation for transport and storage workers due to cylinder or tank leakage or rupture is not possible to quantify but may be significant if the notified chemical can accumulate in confined spaces over time.

No public exposure to trifluoroiodomethane is expected to occur when used as a 'total-flooding' fire extinguisher and explosion suppression agent in unoccupied land-based, maritime or aircraft applications, or as a streaming fire extinguishing agent for aircraft engine fires, and therefore such uses are not expected to present risks to public health.

However, use of trifluoroiodomethane as a streaming fire extinguishing agent in aircraft cabins may lead to public exposure. Given that the level of public exposure to trifluoroiodomethane resulting from such use is not known, and that trifluoroiodomethane has potential to induce a number of adverse toxicological effects following acute and repeated exposures in animals, this use may present significant risks to public health.

Conclusions

The US EPA has conducted a risk assessment of iodotrifluoromethane and allowed it to be used as a fire extinguishant for all but residential purposes. The Director of NICNAS recommends use for total flooding applications with the proviso that, where there is a potential for exposure either following discharge or during exhaust procedures, air monitoring studies be conducted. The use of the notified chemical for streaming applications is only recommended for high risk fires such as aircraft engine or refuelling fires on the ground where firefighters are adequately trained and wear the correct ppe including self-contained breathing apparatus for confined spaces.

13. RECOMMENDATIONS

- The notified chemical is recommended for protection of normally unoccupied spaces only with respect to total flooding (fixed systems) applications. Use in portable fire extinguishers is recommended only for high risk fires such as aircraft engine and refuelling fires on the ground and for use by trained firefighters only.

- With regard to exposure to the notified chemical in areas surrounding the 'protected area', human exposure should not exceed the NOAEL (0.2% - 2000 ppm) for cardiac sensitisation; monitoring studies should be conducted to determine the levels after discharge and during exhaust procedures where there is a possibility of exposure of workers or the public; the results of these studies should be forwarded to the Director; in addition, any future toxicological studies should be forwarded to the Director when completed.
- The use of the notified chemical as a streaming fire extinguishing agent for use in aircraft cabins is not recommended due to unknown public health risks.
- To minimise occupational exposure to the notified chemical from both fixed and portable extinguishers, appropriate control measures have been recommended by the Fire Protection Industry Association of Australia and Australia Standards (in particular AS/NZS 1851.12 (20); AS/NZS 4214.1 (21) and AS 1841.1 (22)) and include the following:

Engineering controls and equipment design

- ◆ Extinguishant cylinders to withstand specified pressure.
- ◆ Containers to have a reliable means of indicating pressure of contents.
- ◆ Appropriate fittings/connections for extinguishant transfer/filling operations.
- ◆ Specification for both portable extinguishers & fixed systems to meet the Building Code of Australia and a 'compliance certificate' to be obtained from appropriate local government or competent authority.
- ◆ Correct specification for fixed extinguishant 'distribution system' (e.g., piping, valves, spans & joints and pressure relief devices).
- ◆ Compatible system components (e.g., piping, valves, pressure relief switches and gauges) for retrofitted extinguishing systems.
- ◆ All components to comply with appropriate Australian Standards and to be listed by the Commonwealth Scientific Services Laboratory.
- ◆ Appropriate design, installation and commissioning of detection systems.
- ◆ Installation of automated mechanical ventilation system (with fixed extinguishant systems) for prompt ventilation after discharge.
- ◆ Concentration of discharged extinguishant (for total flooding (fixed) systems) not to exceed specified limits.
- ◆ Extinguishant discharge to comply with distribution & holding requirements.
- ◆ Quantity of extinguishant in system (i.e., primary agent supply) to be the least amount required for the largest single fire hazard protected.
- ◆ Precautions (e.g., sealed openings or automatic closures) to prevent loss of discharged extinguishant to adjacent work areas.
- ◆ Factors resulting in unwanted discharge during testing/service to be thoroughly evaluated and corrected.
- ◆ Adherence to 'protected enclosure requirements'.

Safe work practices

- ◆ Cylinders to be inspected in accordance with government requirements and standards.
- ◆ Correct procedure to be followed for filling of extinguishant cylinders.
- ◆ Extinguishant cylinders to be charged to correct filling ratio/density.
- ◆ Storage of extinguishant containers below specified temperature.
- ◆ Storage of extinguishant containers away from incompatible substances.
- ◆ Prompt clean-up of leaks and spills - procedure to be pre-planned.

- ◆ Disposal of extinguishant to be carried out in accordance with appropriate government legislation.
- ◆ Maintenance of fire protection equipment according to appropriate standards.
- ◆ Extinguishant discharge test carried out according to specified protocol.
- ◆ Commissioning tests for installed systems to be carried out in the presence of occupational safety officer(s).
- ◆ Certification of testing to be provided by installation contractor.
- ◆ Retrofitting of existing fire extinguishing equipment should be approved by the appropriate authority.

Personal protective equipment

- ◆ Appropriate gloves (AS 2161 (23), safety glasses (AS 1336 (24)& AS/NZS 1337 (25)) and safety shoes (AS/NZS 2210 (26)) to be used when handling and/or filling extinguishant containers.
 - ◆ Respiratory protection (including self-contained breathing apparatus) to be available at storage facility/filling site. (AS1319 (27), AS/NZS 1715 (28) and AS/NZS 1716 (29)).
 - ◆ Appropriate equipment for firefighters (including AS/NZS 1715, AS 2375 (30), AS 4067 (31)).
- Extinguishant cylinders should be properly labelled according to Australia Standards requirements and Worksafe Australia's *National Code of Practice for the Labelling of Workplace Substances* (32) and should include the risk phrase R40 - Possible risk of irreversible effects.
 - Notified substance should be classified as *Hazardous - Cat 3 mutagen*.
 - MSDS should be readily available to workers (particularly those involved in storage/filling).
 - In view of its high potential for cardiac sensitisation, it is recommended that advice be sought from the Federal Office of Road Safety's Advisory Committee for the Transport of Dangerous Goods (ACTDG) regarding the suitability of the notified chemical for classification for transportation (i.e., ADG Code classification).
 - Workers who are taking sympathomimetic medication should be warned about potential cardiovascular sensitisation from excessive exposure to the notified chemical.
 - Physicians treating a patient after exposure to high concentrations of the notified chemical should not administer adrenalin or other sympathomimetic amine stimulants.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of a Material Safety Data Sheets* (33).

This MSDS was provided by the applicant as part of their notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise.

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