File No: STD/1035

17 April 2003

# NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

# FULL PUBLIC REPORT

# HFE-7200/8200 3M™ Novec™ Engineered Fluid

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.

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**Director**
**Chemicals Notification and Assessment**

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# FULL PUBLIC REPORT

# HFE-7200/8200 3M™ Novec™ Engineered Fluid

## 1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
3M Australia Pty Ltd (ABN 000100096) 2 – 74 Dunheved Circuit ST MARYS NSW 2760.

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, CAS No., molecular and structural formulae, spectral data, import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: hydrolysis as a function of pH, dissociation constant, particle size.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
No.

NOTIFICATION IN OTHER COUNTRIES
USA, Canada.

## 2. IDENTITY OF CHEMICAL

The notified chemical is a reaction products mixture containing two structural isomers.

MARKETING NAME(S)
HFE-7200 and HFE-8200 3M™ Novec™ Engineered Fluid

MOLECULAR WEIGHT
264.1

SPECTRAL DATA

| | |
|---|---|
| METHOD | $^1$H and $^{19}$F nuclear magnetic resonance (NMR) spectroscopy |
| Remarks | Accurate determination of components and their relative percentages in HFE-7200/8200 was possible. |
| TEST FACILITY | 3 M Specialty Adhesives & Chemicals Analytical Laboratory (1996). |

| | |
|---|---|
| METHOD | Ultraviolet/Visible (UV/Vis) light spectroscopy. |
| Remarks | A UV/Vis spectrum was provided. |
| TEST FACILITY | 3 M Specialty Adhesives & Chemicals Analytical Laboratory (1997). |

| | |
|---|---|
| METHOD | Infrared (IR) spectroscopy. |
| Remarks | An IR spectrum was provided. |
| TEST FACILITY | SA and C Analytical Laboratory (1996). |

METHODS OF DETECTION AND DETERMINATION

| | |
|---|---|
| ANALYTICAL METHOD | UV/Vis, IR and NMR spectroscopy |

## 3. COMPOSITION

DEGREE OF PURITY
99.9%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None.

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
By importation in 120 or 200 kg metal drums in shipping containers.

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

| *Year* | *1* | *2* | *3* | *4* | *5* |
|---|---|---|---|---|---|
| *Tonnes* | < 30 | < 30 | < 30 | < 30 | < 30 |

USE
The notified chemical will be used for movie film cleaning, vapour degreasing and as a heat transfer agent.

## 5. PROCESS AND RELEASE INFORMATION

### 5.1. Distribution, Transport and Storage

PORT OF ENTRY
Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS
Unknown.

TRANSPORTATION AND PACKAGING
In 120 and 200 kg metal drums.

### 5.2. Operation Description

Movie film cleaning: The solvent is pumped into the cleaning tank of a dedicated machine. A reel of film is placed in the cleaning machine and automatically run through the solvent. The residue is removed with air knives and rollers. Chiller coils are present to contain the solvent in the bath and solvent is removed from air within the machine via condensers.

Vapour degreasing: Parts to be degreased are lowered into solvent vapour and also immersed in the solvent in a specially designed vapour degreasing tank. The vapour is retained within the tank by condensing coils. The operator places baskets of parts into the tank where they are lowered into the solvent.

Cold cleaning: Cold cleaning refers to the process of cleaning by dipping or soaking articles in a cleaning liquid, or spraying, brushing, or wiping the cleaning liquid onto articles at temperatures below boiling point. Processes may be manual, such as in wipe cleaning, or semi- or fully automated, such as in some in-line cleaning systems in which parts carried by conveyor lines are dipped into one or more tanks of solvent. Immersion cleaning can involve manual, mechanical or ultrasonic agitation of the solvent in the tank.

Heat transfer agent: As a refrigerant in supermarkets, walk-in freezers and industrial processes. The notified chemical is transferred to an enclosed system by pump.

## 5.3. Occupational exposure

*Number and Category of Workers*

| *Category of Worker* | *Number* | *Exposure Duration* | *Exposure Frequency* |
|---|---|---|---|
| Unloading, transport and storage | 6 – 18 | 2 – 5 hours/day | 10 – 40 days/year |
| Movie film cleaning | < 5 | Up to 8 hours/day* | Up to 230 days/year |
| Solvent cleaning | 200 | 2 – 8 hours/day | 100 – 200 days/year |
| Heat transfer | 400 | 2 – 5 hours/day | 100 – 200 days/year |

*10 times or 20’/hour

*Exposure Details*

Movie film cleaning: filling and draining of the tank is carried out by pump during which there is a possibility of spillage. Once in the machine exposure is limited to inhalation exposure to the vapour on opening the cabinet. The cabinet does not open until the solvent vapour in the cabinet has been drawn off to condensation. Chiller coils are present to contain solvent in the bath. Eye protection and gloves are worn when handling solvent.

Solvent cleaning: inhalation exposure to vapour is dependent on diffusive loss and release during removal of parts. Measurements of atmospheric concentration of a surrogate substance demonstrated that the exposure level would be approximately 44 ppm during use of the machine. As the vapour pressure of the notified chemical is less than that of the surrogate (0.014 vs 0.026 kPa), its atmospheric concentration is expected to be correspondingly lower. Local exhaust ventilation is used to reduce inhalation exposure. Approximately 3 kg of notified chemical will be removed per day. Chiller coils are used to keep the solvent in the bath.

Less than 1 hour per day is spent putting parts into the degreaser and removing them. Exposure may occur while pumping solvent to the degreasing machine. As much as possible the solvent is reclaimed and recycled by a solvent reclamation company with little loss to the environment. Workers will wear skin and eye protection when handling the solvent to minimise exposure.

Heat transfer agent: transfer of the notified chemical into and out of the refrigeration apparatus can potentially result in spillage. Once in the apparatus exposure is unlikely. Typically workers wear gloves and eye protection when loading or unloading chemical in case of spills or emissions.

## 5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified polymer is not manufactured or reformulated in Australia.

RELEASE OF CHEMICAL FROM USE

*Movie Film Cleaning (50-70% of the total import volume)*

Expected release is to the atmosphere, mainly from losses through the cabinet. Small quantities of soil in the tank may be condensed on the cabinet’s refrigerator coils and would be discarded with some solvent through an appropriate waste stream. Spills should be absorbed and sent to waste treatment. While the process is operating contaminated solvent will be distilled within the equipment to generate a waste stream. The waste stream, which includes approximately 5% of the annual solvent used, will be incinerated.

*Cleaning Solvent Use (10-30% of the total import volume)*

The high cost of the material will require that the material be recovered and recycled. The primary mode of emission of the notified substance will be into the air due to evaporation during cleaning operations. Vapour degreasers have room temperature and sub-zero cooling coils to condense and contain solvent vapours, and will shut off in the event of a refrigerator failure. Based on field data using perfluorinated materials it has been estimated that approximately 0.25 to 0.5 kg/h/m$^2$ (area of vapour air interface) of the notified substance will be lost. This will result in the release of approximately 3 kg per day from a typical 0.5 $m^2$ vapour degreaser operated for 16 hours per day. It is proposed that contaminated mixtures containing the notified material will be reclaimed by a solvent reclamation company in Australia.

The soil containing ca. 25% notified substance may be returned by customers to a third party for distillation/recovery. Exposure at the third company would be limited to adding soil to the distillation column and packaging the recovered material from the columns. The recovery efficiency should be about 96%. The transfers would occur in an area provided with a vapour recovery system so releases to air would be quite small. Distillation bottoms containing the notified substance would be incinerated. Smaller quantities of solvent will be disposed as hazardous waste with concentrated soils. Nothing is expected to enter the sewerage system.

*Heat Transfer Agent (10-30% of the total import volume)*
The notified substance will be imported as part of an azeotrope blend used in secondary loop heat transfer systems. Such systems are low pressurised and closed and the imported product would be in the form of a low viscosity liquid. Losses from such systems are minimal. Normally such coolant systems are only filled once and the coolant is not replaced or purged during the life of the equipment. Draining and topping off are infrequent and low duration events. Losses to the environment as a result of this use are therefore likely to be minimal. Spills during filling may occur, however, this is unlikely to be significant and is difficult to estimate. Decommissioned units would have refrigerant reclaimed and recycled as described above for solvent use.

It is anticipated that given cleaning equipment generally loses its fill volume per year the annual emissions will closely approximate the previous year's sales. Therefore, it is expected that over time the entire import volume (up to 30 tonnes per annum) will be released to the environment.

### 5.5. Disposal

For most applications the notified substance will be reclaimed and recycled. If this is not possible, recommended disposal would be to a licensed liquid disposal facility. It is expected that the small quantity of the notified substance that is not recycled or wastes from the recycling process will be released to the atmosphere in partly burnt form when the wastes are disposed of by incineration at a facility permitted for halogenated wastes.

### 5.6. Public exposure

The public should not be exposed to the notified chemical except in the event of a transport accident.

## 6. PHYSICAL AND CHEMICAL PROPERTIES

Physical and chemical properties were determined for T-6333 and combustion characteristics were also determined for L-13556. Both names are given as other names for the notified chemical.

**Appearance at 20°C and 101.3 kPa** Clear, colourless liquid.

**Melting Point/Freezing Point** < -25°C

| | |
|---|---|
| METHOD | EC Directive 92/69/EEC A.1 Melting/Freezing Temperature. |
| Remarks | Test substance was a slightly viscous liquid at -25°C. |
| TEST FACILITY | Huntingdon (1997a). |

**Boiling Point** 76°C at 101.3 kPa

| | |
|---|---|
| METHOD | EC Directive 92/69/EEC A.2 Boiling Temperature. |
| Remarks | The test substance distilled as a clear liquid at 77 °C. |
| TEST FACILITY | Huntingdon (1997a). |

**Density** 1435 $kg/m^3$ at 20°C

| | |
|---|---|
| METHOD | EC Directive 92/69/EEC A.3 Relative Density. |
| TEST FACILITY | Huntingdon (1997a). |

**Vapour Pressure** 16.8 kPa at 25°C.

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.

Remarks The vapour pressure was determined using the vapour pressure isoteniscopic method. A sample was introduced into the isoteniscope tube and boiled at approximately 80ºC under atmospheric pressure for 10 minutes. After further boiling for 5 minutes the tube was allowed to cool and the vapour pressure was monitored over a temperature range of 76.7 to 26.2ºC. This process was repeated twice more and the values for vapour pressure obtained via extrapolation for runs 1, 2 and 3 were 18.5, 15.4 and 16.6 Kpa, respectively. The vapour pressure for the notified chemical was presented as the rounded mean of these three values. The value obtained indicates that the notified chemical is highly volatile (Mensink *et al*. 1995). The Henry's Law constant calculated for the notified chemical based on the vapour pressure determined above and a water solubility of 2.56 mg/L (see below) is $1.738 \times 10^6$ Pa $m^3$/mole.

TEST FACILITY Huntingdon (1997a).

**Water Solubility** < 1.44 mg/L at 20ºC

METHOD EC Directive 92/69/EEC A.6 Water Solubility.

Remarks Distilled water was spiked with varying amounts of the notified chemical (10, 1 and 1.5 μL in 1, 1 and 2 L, respectively) and shaken vigorously for one minute The phases were allowed to separate before being placed into a water bath at 20ºC. Throughout the 48 h incubation period, the solutions were shaken and inspected visually. After 48 h, two phases were present in the solutions with nominal test substance concentrations above 1 μL in 1 L. No phase separation was observed in the solution containing a nominal test substance concentration of 1.5 μL in 2 L and therefore the solubility is < 1.44 mg/L based on the above relative density.

It should be noted that saturated solutions of the notified chemical were used in the toxicity test reports supplied in the submission by the notifier. The test substance concentrations in the solutions used in the fish, Daphnid and algal studies as determined by gas chromatography were 2.75, 2.62 and 2.32 mg/L, respectively. Closed loop saturator column systems were used to achieve these concentrations.

TEST FACILITY Huntington (1997a).

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

Remarks The notified chemical is not expected to undergo hydrolytic degradation due to its low water solubility, high volatility and lack of any functionality generally considered to be hydrolysable. The notifier indicates that the notified chemical is highly volatile and exhibits virtually no solubility in water. It use, disposal and any accidental spills of the notified chemical are therefore expected to result in release or rapid partitioning to the atmosphere. While hydrolysis is an important removal process for volatile chemicals that partition into the condensed liquid phase of the atmosphere, a high Henry's Law constant and inherent stability of the fluorochemical ether from a chemical standpoint make hydrolysis in the atmosphere at most an extremely minor removal process.

**Fat (or n-octanol) Solubility** 9452 mg/100 g Standard Fat at 37°C.

METHOD EC Directive 84/449/EEC (OJ No. L251), Part A, Method A7.

Remarks Liquefied and mixed standard fat (ca. 10 g) and the test substance (4 mL of a mixture of the two isomers of the notified chemical) were combined in glass flasks (four in total) were stirred at 30ºC (two flasks) and 50ºC (two flasks) for 1 h. The four flasks were then stirred for a further 24-48 h at 37ºC and then allowed to equilibrate for 37ºC. The test solutions were allowed to separate, dissolved in dichloromethane and analysed by GC. The fat solubility obtained indicates that the notified chemical is moderately fat soluble.

TEST FACILITY Huntingdon (1997c).

**Partition Coefficient (n-octanol/water)** Log P = 3.95 at 20ºC (Isomer 1)
Log P = 4.04 at 20ºC (Isomer 2)

| | |
|---|---|
| METHOD | EC Directive 92/69/EEC A.8 Partition Coefficient. |
| Remarks | The retention times for two solutions of the notified chemical prepared in methanol were determined on a C18 HPLC column. From these averages the log of the capacity factor was determined which was then used in the calculated regression equations to determine the partition coefficient for the notified chemical. These values are indicative of a hydrophobic molecule that will partition into the organic phase. |
| TEST FACILITY | Huntington (1997a). |

**Adsorption/Desorption** Log Koc = 2.11 at 20ºC

| | |
|---|---|
| METHOD | OECD Draft Document TGP/94.75 (HPLC Method) |
| Remarks | The retention times for two solutions of the notified chemical prepared in methanol were determined on a cyano HPLC column. From these averages the log of the capacity factor was determined which was then used to deduce the partition coefficient using a calibration plot of log k versus log Koc of selected reference compounds.<br>The result for Koc (=130) indicates that the notified chemical has a low affinity for soil and sediment and, as such, will be mobile in both aquatic and terrestrial compartments. This is consistent with the notified chemical's volatility that suggests it will not remain dissolved in water bodies or associated with soil under normal atmospheric pressures. |
| TEST FACILITY | Huntington (1997b). |

**Dissociation Constant** Not determined

| | |
|---|---|
| Remarks | The notified chemical does not contain any groups which are expected to dissociate in the environmental pH range of 4-9. |

**Particle Size** Not applicable.

**Flash Point** None below 77°C (T-6333, closed cup) or at 76°C (L-13556, closed cup); 41°C (open cup).

| | |
|---|---|
| METHOD | T-6333: EC Directive 92/69/EEC A.9 Flash Point; L-13556: ASTM D 92-85 and ASTM D 56-87. |
| TEST FACILITY | T-6333: Huntingdon (1997a); L-13556: Safety Consulting Engineers (1996). |

**Flammability Limits** Upper: 1070 mg/L
Lower: 210 mg/L

| | |
|---|---|
| METHOD | ASTM E681-94 |
| Remarks | L-13556 was the test substance. |
| TEST FACILITY | Safety Consulting Engineers (1996). |

**Autoignition Temperature** 358ºC (T-6333); 375ºC (L-13556).

| | |
|---|---|
| METHOD | 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases) (T-6333); ASTM E659-78 (L-13556). |
| TEST FACILITY | T-6333: Huntingdon (1997a); L-13556: Safety Consulting Engineers (1996). |

**Sustained Burning Test** At 76ºC L-13556 ignited but did not sustain burning.

| | |
|---|---|
| METHOD | ASTM D 4206. |
| TEST FACILITY | Safety Consulting Engineers (1996). |

**Explosive Properties** Not explosive.

| | |
|---|---|
| METHOD | EC Directive 92/69/EEC A.14 Explosive Properties. |
| TEST FACILITY | Huntingdon (1997a). |

## 7. TOXICOLOGICAL INVESTIGATIONS

| *Endpoint and Result* | *Assessment Conclusion* |
|---|---|
| Rat, acute oral LD50 > 2000 mg/kg bw | low toxicity |
| Rat, acute inhalation LC50 > 9.2%/4 hour | low toxicity |
| Rabbit, skin irritation | non-irritating |
| Rabbit, eye irritation | slightly irritating |
| Guinea pig, skin sensitisation - non-adjuvant test. | no evidence of sensitisation. |
| Rat, oral repeat dose toxicity - 28 days. | NOEL = 40 mg/kg/day bw in males; 200 mg/kg/day bw in females |
| Rat, inhalation repeat dose toxicity - 28 days. | No NOEL established |
| Genotoxicity - bacterial reverse mutation | non mutagenic |
| Genotoxicity – in vitro chromosomal aberrations in Chinese Hamster Lung (CHL) cells. | non genotoxic |

### 7.1. Acute toxicity – oral

| | |
|---|---|
| TEST SUBSTANCE | T-6333 |
| METHOD | EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test. |
| Species/Strain | Rat/Sprague-Dawley. |
| Vehicle | None. |

RESULTS

| *Group* | *Number and Sex of Animals* | *Dose mg/kg bw* | *Mortality* |
|---|---|---|---|
| 1 | 5/sex | 2000 | None |

| | |
|---|---|
| LD50 | > 2000 mg/kg bw |
| Signs of Toxicity | Piloerection, hunched posture, pallor of the extemeties in males. |
| Effects in Organs | None. |
| CONCLUSION | The notified chemical is of low toxicity via the oral route. |
| TEST FACILITY | Huntingdon (1997d). |

### 7.2. Acute toxicity - dermal

Data not provided.

### 7.3. Acute toxicity - inhalation

| | |
|---|---|
| TEST SUBSTANCE | T-6333 |
| METHOD | OECD TG 403 Acute Inhalation Toxicity – Limit Test.<br>EC Directive 92/69/EEC, 93/21/EEC B.2 Acute Toxicity (Inhalation) – Limit Test. |
| Species/Strain | Rat/Sprague-Dawley |
| Vehicle | None. |
| Method of Exposure | Whole-body exposure. |
| Exposure Period | 4 hours |
| Physical Form | Vapour. |

RESULTS

| *Group* | *Number and Sex of Animals* | *Concentration % v/v* | | *Mortality* |
|---|---|---|---|---|
| | | *Nominal* | *Actual* | |
| 1 | 5/sex | 10 | 9.2 | 1 female |

| | |
|---|---|
| LC50 | > 9.2% v/v 4 hours |
| Signs of Toxicity | Staggering gait, brown staining on the body on day 1 and exaggerated respiratory movements; brown staining persisted for a further 2 days in females. One female died 1 hour and 15 minutes into the 4-hour exposure. |
| Effects in Organs | None. |

CONCLUSION The notified chemical is of low toxicity via inhalation.

TEST FACILITY Huntingdon (1997e).

### 7.4. Irritation – skin

TEST SUBSTANCE T-6333.

| | |
|---|---|
| METHOD | EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation). |
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 3 |
| Vehicle | None. |
| Observation Period | 72 hours. |
| Type of Dressing | Semi-occlusive. |
| Remarks - Results | Neither erythema nor oedema was observed in any animal at any time point. |

CONCLUSION The notified chemical is non-irritating to skin.

TEST FACILITY Huntingdon (1996a).

### 7.5. Irritation - eye

TEST SUBSTANCE T-6333.

| | |
|---|---|
| METHOD | 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 |

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* | 0.7 | 0 | 0 | 1 | 48 hours | 0 |
| *Conjunctiva: chemosis* | 0 | 0 | 0 | 0 | | 0 |
| *Conjunctiva: discharge* | | | | | | |
| *Corneal opacity* | 0 | 0 | 0 | 0 | | 0 |
| *Iridial inflammation* | 0 | 0 | 0 | 0 | | 0 |

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

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Huntingdon (1996b).

### 7.6. Skin sensitisation

TEST SUBSTANCE T-6333.

METHOD EC Directive 96/54/EC B.6 Skin Sensitization - Buehler.
Species/Strain Guinea pig/Dunkin-Hartley.
PRELIMINARY STUDY Maximum Non-irritating Concentration: undiluted

MAIN STUDY
Number of Animals Test Group: 20 Control Group: 10
INDUCTION PHASE Induction Concentration: undiluted topical application
Signs of Irritation None.
CHALLENGE PHASE
1st challenge topical application: undiluted

RESULTS

| *Animal* | *Challenge Concentration* | *Number of Animals Showing Skin Reactions after: 1st challenge* | |
|---|---|---|---|
| | | *24 h* | *48 h* |
| *Test Group* | undiluted | 0 | 0 |
| *Control Group* | undiluted | 0 | 0 |

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

TEST FACILITY Huntingdon (1997f)

### 7.7. Repeat dose toxicity

### 7.7.1 28-day oral toxicity

TEST SUBSTANCE T-6333

METHOD Japanese Guidelines on Industrial Chemicals (1986).
Species/Strain
Route of Administration Oral – gavage.
Exposure Information Total exposure days: 28 days;
Dose regimen: 7 days per week.
Vehicle 0.1% Tween 80 in water.

RESULTS

| *Group* | *Number and Sex of Animals* | *Dose mg/kg bw/day* | *Mortality* |
|---|---|---|---|
| I (control) | 6/sex | 0 | 0 |
| II (low dose) | “ | 8 | 0 |
| III (low mid dose) | “ | 40 | 0 |
| IV (high mid dose) | “ | 200 | 0 |
| V (high dose) | “ | 1000 | 0 |
| VI (control recovery) | “ | 0 | 0 |
| VII(high mid dose recovery) | “ | 200 | 0 |
| VIII (high dose recovery) | “ | 1000 | 0 |

*Clinical Observations*

Irregular respiration in all high dose males after day 9 and in 5 females after day 10; salivation in 3 high dose males after day 21. No effects were observed on body weights or food consumption for all groups.

*Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis*

*Clinical chemistry:* Lower triglyceride and elevated Albumin/Globulin ratio were observed in high mid and high dose males but elevated globulin was only observed in high dose males.

*Haematology:* Decreased RBC counts in high dose males

*Urinalysis:* No effects.

*Effects in Organs*

*Organ weights:* The absolute and relative liver weights were elevated in high dose males and the relative liver weight was elevated in high mid dose males. Absolute and relative kidney weights were elevated in high dose males. The kidney weight increases had no histopathological correlates but the livers were enlarged and exhibited centrilobular hepatocyte hypertrophy.

Remarks – Results

The liver toxicity was interpreted to be an adaptive response and all changes resolved by the end of the recovery period.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 40 mg/kg bw/day in males and 200 mg/kg bw/day in females in this study, based on liver and kidney effects in males and irregular respiration in high dose females.

TEST FACILITY Mitsubishi Chemical Safety Institute (1996a).

### 7.7.2 28-day inhalation toxicity

TEST SUBSTANCE T-6333

METHOD OECD TG 412 Repeated Dose Inhalation Toxicity: 28-day or 14-day Study.

| | |
|---|---|
| Species/Strain | |
| Route of Administration | Inhalation – whole body. |
| Exposure Information | Total exposure days: 28 days;<br>Dose regimen: 5 days per week;<br>Duration of exposure (inhalation/dermal): 6 hours/day. |
| Physical Form | Vapour. |

RESULTS

| *Group* | *Number and Sex of Animals* | *Concentration ppm* | | *Mortality* |
|---|---|---|---|---|
| | | *Nominal* | *Actual* | |
| I (control) | 5/sex | 0 | 0 | None |
| II (low dose) | “ | 1000 | 1066 | “ |
| III (mid dose) | “ | 3000 | 3006 | “ |
| IV (high mid dose) | “ | 9000 | 8844 | “ |
| V (high dose) | “ | 25000 | 24386 | “ |

*Clinical Observations*

No treatment related effects except for an increase in bodyweight and food consumption in high mid and high dose animals. In high dose males there was an increased incidence where assessment of gait was not possible and a slight reduction in activity and rearing counts. However, these effects were judged not to indicate neurotoxicity.

*Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis*

No treatment related effects on clinical chemistry, haematology or urinalysis except for a dose-related increase in urinary fluoride at all doses.

*Effects in Organs*

Enlarged livers were seen in 4/5 high dose males and 1/5 high mid dose males and increased liver weights, palmitoyl CoA activity and increased 3000 x g supernatant protein were recorded in these groups. Increased trace hyperplasia of the larynx was observed in high dose animals, centrilobular hepatocyte hypertrophy in mid, high mid and high dose males and tubular basophilia with nuclear clustering in the inner cortex of the kidney in high mid and high dose males.

Remarks – Results

An adaptive response was observed in mid, high mid and high dose males as indicated by the liver effects. Elevated palmitoyl CoA and 3000 x g supernatant protein were considered indicative of biotransformation of the notified chemical. Slight irritant effects were observed in the larynx of high dose animals and a slight hyperplasia as a response to minor damage in high mid and high dose males.

CONCLUSION

No No Observed Effect Level (NOEL) was established as in this study, based on the increase in urinary fluoride in all dose groups.

| | |
|---|---|
| TEST FACILITY | Huntingdon (1997g). |

### 7.8. Genotoxicity - bacteria

| | |
|---|---|
| TEST SUBSTANCE | T-6333 |
| METHOD | OECD TG 471 Bacterial Reverse Mutation Test.<br>Pre incubation procedure modified for volatiles. |
| Species/Strain | *S. typhimurium*:<br>TA1535, TA1537, TA98, TA100.<br>*E. coli*: WP2 uvrA. |
| Metabolic Activation System | S9 fraction from phenobarbital/5,6-benzoflavone induced rat liver. |
| Concentration Range in Main Test | a) With metabolic activation: 1250 - 20000 µg/plate.<br>b) Without metabolic activation: 1250 - 20000 µg/plate. |
| Vehicle | Acetone. |
| Remarks - Results | No cytotoxicity or precipitation was observed and no increase in the number of revertants per plate was observed in any strain. |
| CONCLUSION | The notified chemical was not mutagenic to bacteria under the conditions of the test. |
| TEST FACILITY | Mitsubishi Chemical Safety Institute (1996b). |

### 7.9. Genotoxicity – in vitro

| | |
|---|---|
| TEST SUBSTANCE | T-6333 |
| METHOD | Guidelines for Screening Toxicity Testing of Chemicals. MITI. Japan (1986) |
| Cell Type/Cell Line | Chinese Hamster Lung (CHL) cells. |
| Metabolic Activation System | S9 fraction from phenobarbital/5,6-benzoflavone induced rat liver. |
| Vehicle | carboxymethylcellulose |

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

| | | | |
|---|---|---|---|
| *Absent* | | | |
| Test 1 | 630, 1300, 2500, 5000, 10000 | 24 hours. | 24 hours. |
| Test 2 | 630, 1300, 2500, 5000, 10000 | 48 hours. | 48 hours. |
| Test 3 | 630, 1300, 2500, 5000, 10000 | 6 hours. | 24 hours. |
| *Present* | | | |
| Test 1 | 630, 1300, 2500, 5000, 10000 | 6 hours. | 24 hours. |

All cultures selected for metaphase analysis.

| | |
|---|---|
| Remarks - Results | No cytotoxicity or precipitation was observed and no increase in the number of chromosomal aberrations was observed at any dose point. |
| CONCLUSION | The notified chemical was not clastogenic to CHL cells treated in vitro under the conditions of the test. |
| TEST FACILITY | JBRC (1996). |

### 7.10. Genotoxicity – in vivo

TEST SUBSTANCE

| | |
|---|---|
| METHOD | OECD TG 474 Mammalian Erythrocyte Micronucleus Test. |
| Species/Strain | Mouse/Swiss CD-1. |
| Route of Administration | Intraperitoneal. |
| Vehicle | 1% methylcellulose/0.5% Tween 80. |

| *Group* | *Number and Sex of Animals* | *Dose mg/kg bw* | *Sacrifice Time hours* |
|---|---|---|---|
| 1 | 15/sex | 0 | 24, 48, 72 hours |
| 2 | “ | 1250 | “ |
| 3 | “ | 2500 | “ |
| 4 | “ | 5000 | “ |

RESULTS

| | |
|---|---|
| Doses Producing Toxicity | Only slight clinical signs were seen at 5000 mg/kg. |
| Genotoxic Effects | None. |
| CONCLUSION | The notified chemical was not clastogenic in this in vivo mouse micronucleus test under the conditions of the test. |
| TEST FACILITY | Huntingdon (1997h). |

### 7.11. Developmental toxicity

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical. |
| METHOD | OECD TG 414. |
| Species/Strain | |
| Route of Administration | Inhalation – whole body. |
| Exposure Information | Exposure period: Days 6 to 19 *post coitum*.<br>Duration of exposure, inhalation: 6 hours/day. |
| Physical Form | Vapour. |

RESULTS

| *Group* | *Number of Animals* | *Dose/Concentration ppm* *Nominal* | *Dose/Concentration ppm* *Actual* | *Mortality* |
|---|---|---|---|---|
| 1 | 25 mated | 0 | | None |
| 2 | " | 1000 | 1012 | " |
| 3 | " | 3000 | 3074 | " |
| 4 | " | 9000 | 8919 | " |
| 5 | " | 25000 | 24082 | " |

*Effects on Dams*

No clinical signs were observed. There was a reduction in mean bodyweight at the top dose from days 6 to 8 and food consumption was down from days 6 to 19 *post coitum*.

*Effects on Foetus*

No treatment-related finding were observed on litter parameters, sex ratio, skeletal and visceral malformations and variants. The proportions of foetuses with supernumerary ribs was higher at 25000 ppm and to a lesser extent at 9000 ppm.

CONCLUSION

The no effect level was 3000 ppm.

| | |
|---|---|
| TEST FACILITY | Huntingdon (1997i) |

## 7.12. Cardiac sensitisation to adrenaline

| | |
|---|---|
| TEST SUBSTANCE | T-6333 |
| METHOD | Based on the methods of Reinhart (1971; 1973) |

STUDY DESIGN

| | |
|---|---|
| Species/Strain | Dog/Beagle |
| Study Design | Six dogs were selected on the basis of administration of adrenaline alone and inspection of the ECG for ectopic beats. During challenge, each dog received snout only exposure to the test substance. Test dogs were rested for at least 24 hours between each exposure session. |

Challenge Procedure

| *Time* | *Event* |
|---|---|
| 0 min | Start ECG recording. |
| 2 min | Blood sample collected.<br>1st adrenaline challenge (iv) (baseline). |
| 7 min | Test substance introduced into air supply line. |
| 12 min | Blood sample collected.<br>2nd adrenaline challenge (iv). |
| 17 min | Test substance supply discontinued.<br>Stop ECG recording. |

RESULTS

*Summary of Cardiac Response*

| *Dog Number* | *Adrenaline Dose (µg/kg)* | *Test Substance Concentration % v/v* | *Number of Ectopic Beats: 1st Adrenaline Challenge* | *Number of Ectopic Beats: 2nd Adrenaline Challenge* | *Clinical Response* |
|---|---|---|---|---|---|
| 1355 | 12 | 0.97 | 0 | 0 | N |
| 1359 | 12 | " | 1 | 2 | N |
| 1361 | 8 | " | 6 | 21 | N |
| 1365 | 2 | " | 23(3) | 37(1) | N |
| 1369 | 4 | " | 0 | 0 | N |
| 1371 | 4 | " | 0 | 6 | N |

| | | | | | |
|---|---|---|---|---|---|
| 1355 | 12 | 1.89 | 0 | 2 | N |
| 1359 | 12 | “ | 2 | 10 | N |
| 1361 | 8 | “ | 10 | 9 | N |
| 1365 | 2 | “ | 17 | 38 | N |
| 1369 | 4 | “ | 0 | 8 | N |
| 1371 | 4 | “ | 0 | 0 | N |
| | | | | | |
| 1355 | 12 | 4.90 | 1 | > 50 VT | P |
| 1361 | 8 | “ | 1(1) | 0 | N |

() values in parentheses indicate abnormal beats of uncertain origin – typically escape beats
P = positive response; N = negative response; VT = ventricular tachycardia

| | |
|---|---|
| Signs of Toxicity | Restlessness, limb rigidity, agitation and tremors were observed at the top concentration and to a lesser extent at 1.89%. |
| Myocardial Effects | One animal at the top dose exhibited a series of ventricular premature complexes concomitant with marked tachycardia. |
| EC50 or NO(A)EL | |
| Remarks - Results | The severity of the clinical signs at the top dose was such that exposure to higher concentrations of the test substance could not be justified. |

CONCLUSION There was evidence of cardiac sensitisation under the conditions of the test.

TEST FACILITY Huntingdon (1997j).

# 8. ENVIRONMENT

## 8.1. Environmental fate

### 8.1.1. Ready biodegradability

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 301 D Ready Biodegradability: Closed Bottle Test. |
| Inoculum | Effluent from the Kitakyushu City Kohgasaki Sewage Treatment Plant |
| Exposure Period | 28 days |
| Auxiliary Solvent | None |
| Analytical Monitoring | Gas Chromatography |
| RESULTS | The notified chemical was incubated for 28 days at a nominal test substance concentration of 2.37 mg/L. Analysis of the test substance solutions at day 0 found an average recovery rate of 83.5% of the nominal concentration. |

| *Test substance* | | *Aniline* | |
|---|---|---|---|
| *Day* | *% degradation* | *Day* | *% degradation* |
| 14 | 0 | 14 | 79 |
| 28 | 0 | 28 | 97.5 |

| | |
|---|---|
| Remarks - Results | The biodegradation of the reference substance, aniline, was 97.5% after 28 days, indicating the test conditions were valid. After 28 days at 20°C, the test substance underwent 0% biodegradation (based on BOD removal and GC) which indicates the notified chemical is not readily biodegradable in aerobic environments. |
| CONCLUSION | The notified chemical is not readily biodegradable. |
| TEST FACILITY | Mitsubishi Chemical Safety Institute (1996c). |

### 8.1.2. Bioaccumulation

| | |
|---|---|
| TEST SUBSTANCE | The notified chemical |
| METHOD | OECD TG 305C Bioconcentration: Flow-through Fish Test. |
| Species | Carp (*Cyprinus carpio*) |
| Exposure Period | Exposure: 56 days Depuration: Not done |
| Auxiliary Solvent | |
| Concentration Range Nominal | 0, 0.05 and 0.5 µg/mL |
| Concentration Range Actual | 0, 0.0434 and 0.486 µg/mL |
| Analytical Monitoring | Gas Chromatography |
| Remarks - Method | The bioconcentration test was conducted with a total of 15 fish per test concentration and at a water temperature of 25ºC for a period of 8 weeks. |
| RESULTS | |
| Bioconcentration Factor | 158-624 (high exposure limit) and 136-91 (low exposure limit). |
| Remarks - Results | The concentrations of the test substance in fish were calculated to be 76-302 µg/g at the high exposure limit of 0.5 mg/L and 5.9-39.9 µg/g at the lower exposure limit of 0.05 mg/L. The results gave bioconcentration factors for the high exposure limit and the low exposure limit of 158-624 and 136-919, respectively. Depuration was not measured. A preliminary test with Orange killfish (*Oryzias latipes*) gave a 48 h LC50 of greater than 50 mg/L. |

| | |
|---|---|
| CONCLUSION | The notified chemical can be considered to be moderately concentrating (Mensink *et al*. 1995). |
| TEST FACILITY | Mitsubishi Chemical (1996d). |

### 8.2. Ecotoxicological investigations

### 8.2.1. Acute toxicity to fish

TEST SUBSTANCE

| | |
|---|---|
| METHOD | OECD TG 203 Fish, Acute Toxicity Test – 96 h static test. |
| Species | Fathead minnow (*Pimephales promelas*) |
| Exposure Period | 96 h |
| Auxiliary Solvent | None |
| Water Hardness | 42 mg $CaCO_3$/L |
| Analytical Monitoring | Gas chromatography |

RESULTS

| *Mean Measured Concentration mg/L* | *Number of Fish* | *Mortality* | | | |
|---|---|---|---|---|---|
| | | *24 h* | *48 h* | *72 h* | *96 h* |
| 0 | 20 | 0 | 0 | 0 | 0 |
| 2.75 | 20 | 0 | 0 | 0 | 0 |

| | |
|---|---|
| EC50 | > 2.75 mg/L at 96 hours (based on mean measured concentration). |
| NOEC | 1.9–2.50 mg/L at 96 hours (based on the range finding and definitive studies) |
| Remarks – Results | The tests were performed under static conditions in sealed flasks with observations performed at 24, 48, 72 and 96 hours using 20 specimen fish per test concentration at a temperature of 21°C. The tests were conducted using a mean measured test substance concentration of 2.75 mg/L. This was achieved through use of enclosed loop saturator column systems. There were no mortalities during the study. After 96 h at the test substance concentration of 2.75 mg/L, fish exhibited sub-lethal effects such as an erratic swimming motion and remained near the top of the test chamber. The 96-hour EC50 for the notified chemical to Fathead minnow is therefore greater than 2.75 mg/L. |
| CONCLUSION | The ecotoxicity data indicates the notified chemical is non-toxic to fish up to the limit of its solubility, though some sub-lethal effects were noted. |
| TEST FACILITY | AscI Corporation (1997a). |

### 8.2.2. Acute/chronic toxicity to aquatic invertebrates

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical. |
| METHOD | OECD TG 202 Daphnia sp. Acute Immobilisation Test – 48 h test |
| Species | *Daphnia magna* |
| Exposure Period | 48 hours |
| Auxiliary Solvent | None |
| Water Hardness | 63 mg $CaCO_3$/L |
| Analytical Monitoring | Gas chromatography |

RESULTS

| *Concentration mg/L Actual* | *Number of D. magna* | *Number Immobilised* | |
|---|---|---|---|
| | | *24 h* | *48 h* |
| 0 | 20 | 0 | 0 |
| 2.55 | 20 | 0 | 1 |

| | |
|---|---|
| LC50 | > 2.55 mg/L at 48 hours (based on mean measured concentration). |
| NOEC (or LOEC) | 2.55 mg/L at 48 hours. |
| Remarks - Results | The immobilisation tests with *Daphnia* were performed using 5 daphnids per flask at a temperature of 21°C with observations performed at 24 and 48 hours. The tests were conducted using a mean measured test substance concentration 2.55 mg/L. After 48 h, one immobilised daphnid was observed in one of the four replicates at a test substance concentration of 2.55 mg/L. No sub-lethal effects were observed during the study. The 48-hour LC50 for the notified chemical to *Daphnia magna* is greater than 2.55 mg/L. The 48-hour NOEC for the notified chemical to *Daphnia magna* is 2.55 mg/L. |

CONCLUSION The ecotoxicity data indicates the notified chemical is non-toxic to daphnia up to the limit of its solubility.

TEST FACILITY AscI Corporation (1997b).

### 8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical.

| | |
|---|---|
| METHOD | OECD TG 201 Alga, Growth Inhibition Test. |
| Species | *Selenastrum capricornutum* |
| Exposure Period | 96 hours |
| Concentration Range Actual | 0 and 2.32 mg/L (mean measured concentration). |
| Auxiliary Solvent | None |
| Analytical Monitoring | Gas chromatography |

RESULTS

| *Growth* <br> *$E_r$C50 mg/L at 96 h* | *NOEC* <br> *Growth mg/L at 96 h* |
|---|---|
| > 2.32 | < 2.32 |

Remarks - Results Algae were exposed to the test substance in sealed flasks at the mean measured concentration of 2.32 mg/L for 96 h at 24˚C under constant illumination and shaking. Neither the biomass nor the growth rate of *Selenastrum capricornutum* was adversely affected by the test substance with a maximum of 10% growth rate inhibition after 72 h.

CONCLUSION The ecotoxicity data indicates the notified chemical is practically non-toxic to algae up to the limit of its solubility.

TEST FACILITY AscI Corporation (1997c).

# 9. RISK ASSESSMENT

## 9.1. Environment

### 9.1.1. Environment – exposure assessment

*Exposure*

The notifier has indicated that when the notified chemical is used as a movie film cleaner, vapour degreaser and as a heat transfer agent it is anticipated that given cleaning equipment generally loses it fill volume per year and the annual emissions will closely approximate the previous year's sales. Therefore, it is expected that over time the entire import volume (up to 30 tonnes per annum) will be released to the environment. Empty import drums and the residual chemical they contain will either be disposed of to landfill or incinerated. At the end of its useful life, the notified chemical will be disposed of by incineration.

*Fate*

The notified chemical's volatility suggests that all of the notified chemical released will eventually find its way into the atmosphere.

The notified chemical is a highly fluorinated low molecular weight alkane ether and may persist in this environment. The initial degradation of the notified chemical in the atmosphere will occur through hydrogen abstraction by hydroxy radicals (Christensen *et al.* 1998). These species subsequently react with oxygen to produce the corresponding peroxy radicals which inturn react with oxides of nitrogen to form the corresponding alkoxy radicals. The authors observed that one of these compounds then reacts with oxygen to give the ester while another compound is converted to the formate, with the ester being the major product and the formate the minor product. The authors postulated that give the unreactivity of the ester to attack by chlorine and hydroxyl radical, the main atmospheric removal mechanism will be via wet/dry deposition and possibly photolysis. It is expected that the notified chemical will eventually degrade to HF and $CO_2$. The paper estimates the average atmospheric half-life for the two isomers of the notified chemical in the atmosphere to be 0.77 years, but clearly degradation products are more persistent. Using a 24 h global average OH radical concentration of $7.5 \times 10^5$ $cm^{-3}$, a lower limit estimate of 22 days for the atmospheric lifetime with respect to reaction with OH radicals has been derived.

The rate constant for degradation through hydrogen abstraction may also be estimated using published data from an OECD monograph (OECD, 1992), and using the appropriate procedures described in this document, the rate constant for hydrogen abstraction from the notified chemical is estimated as $k_{abs} = 5.3 \times 10^{-12}$ $cm^3$ molecule/sec. The atmospheric half life may then be estimated through the relation $t_{1/2} = \text{Log}(2)/ ([OH\bullet] \times k_{abs})$ where $[OH\bullet]$ is the average concentration of atmospheric hydroxy radicals which is given as $5 \times 10^5$ radicals/$cm^3$ by Calamari (1993). Using these data and relationships the value of $t_{1/2}$ is estimated as $1.136 \times 10^5$ seconds, or approximately 0.0036 years. The difference between the literature value and the calculated value for $t_{1/2}$ is attributable to the choice of the average concentration of atmospheric hydroxy radicals and the $k_{abs}$ value used.

The ozone depletion potential (ODP) of a gaseous compound is a measure of its ability to migrate to the stratosphere, together with its ability to degrade (through direct and indirect photolysis) to radical species which are able to react with and destroy ozone molecules. The most damaging chemicals in this regard are compounds that contain chlorine and/or bromine, which is a characteristic of various chlorinated hydrocarbons (CFC and HCFC) and brominated hydrocarbons (halon). The ODP of such compounds is roughly related to the content of chlorine (or bromine) in the compounds together with its atmospheric lifetime. Since the notified chemical contains no chlorine or bromine it is expected to have zero or very low ODP.

The Global Warming Potential (GWP) of a gaseous compound is a composite measure of its ability to absorb radiation in the infrared (IR) spectral region (typically 500-1200 $cm^{-1}$), together with its expected atmospheric lifetime. Effectively the GWP of a chemical compares the amount of IR radiation absorbed by unit weight (eg 1 tonne) of the chemical over a given time (taking into account its removal through degradation processes) with that absorbed by an equivalent weight of emitted $CO_2$. Because of atmospheric degradation of compounds (eg through reaction with $OH\bullet$ radicals) the GWP decreases with time, it is usual to estimate the GWP using 20, 100 and 500 year horizons. By determining the IR absorption cross section from the measured IR spectrum of the notified chemical between 600 and 1500 $cm^{-1}$ together with an estimation of the atmospheric half life, Christensen *et al.* (1998) derived 20 and 100 year global warming potentials for the notified chemical of 0.036 and 0.014 compared with CFC-11, respectively. However, the International Committee on Climate Change (IPCC 2001) has revised these values indicating the 20, 100 and 500 year global warming potentials for the notified chemical are 190, 55 and 17 when compared with $CO_2$, respectively. The introduction of the new compound as a replacement for existing products is expected to be beneficial in respect of global warming.

Although these GWP figures are subject to some uncertainty they may nevertheless be used to gain some insight into the effects of using the chemical in Australia. In the worst case, assuming that 30 tonnes of the notified chemical is released to the atmosphere each year in Australia, when averaged over a 100 year period this is roughly equivalent to releasing $30 \times 55 = 1650$ tonnes of $CO_2$. This calculation could obviously be refined, but this $CO_2$ emission equivalents is relatively small compared with Australia's overall annual greenhouse gas emissions which were estimated as approximately 460 million tonnes of $CO_2$ equivalent in 1999 (Australian Greenhouse Office, 2001). So the release of 30 tonnes per annum of the notified chemical would represent an annual increase of approximately 0.0004%.

Incineration of the notified chemical will destroy the compound with the generation of water vapour, oxides of carbon and fluorine salts.

### 9.1.2. Environment – effects assessment

The results of the ecotoxicological testing indicate the notified substance is non-toxic to fish, Daphnia and algae up to the limit of its solubility. The most sensitive species are algae, where the 96 h $E_rC50$ is greater than 2.32 mg/L and a NOEC less than 2.33 mg/L.

Acute results are available for three trophic levels. Applying an assessment factor of 100 to the most sensitive species (algae), the predicted no effects concentration (PNEC) is greater than 23.3 μg/L.

### 9.1.3. Environment – risk characterisation

The new compound is a volatile liquid and its use pattern as a movie film cleaner, vapour degreaser and as a heat transfer agent indicates that it will eventually be released mainly to the atmosphere.

Only minor releases to the water and soil compartments are expected, and due to the high values of vapour pressure and Henry's Law constant ($H = 1.738 \times 10^6$ Pa $m^3$/mole) any compound released to water or soil is expected to quickly evaporate to the atmosphere. Consequently exposure to aquatic organisms will be low, but in any case the available test data indicates that the compound is of low toxicity to aquatic species up to the limit of its solubility and as a consequence would have little potential for bioaccumulation.

The compound will be degraded in the atmosphere through reaction with hydroxy radicals, and will eventually degrade to HF and $CO_2$. Due to the absence of chlorine and bromine in the chemical, it is not expected to have potential for removing ozone from the stratosphere. Furthermore, it release into the atmosphere would represent an annual increase of approximately 0.0004%.

When used in the indicated manner the new compound is not expected to be a hazard to the atmospheric, aquatic or terrestrial compartments.

## 9.2. Human health

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

The notified chemical is used in movie film cleaning, solvent cleaning and as a heat transfer agent. In each case the notified chemical must be pumped from the drum to either a film cleaning machine, solvent degreaser or refrigeration apparatus. There will be specific couplings and transfer lines for each scenario but typically they are designed to avoid spillage if good work practices are followed. As the notified chemical is high value and designed to be recycled, the likelihood of spillage should be considered to be low. Once the chemical is introduced into the system, means are provided to avoid losses. The cleaning apparatus are provided with chiller coils and the refrigeration systems are normally tested for leaks on a regular basis. Inhalation exposure is possible with the notified chemical particularly as it is used at temperatures of 35ºC (film cleaning) or 43ºC (solvent cleaning). Atmospheric measurements conducted for solvent cleaning indicate a concentration of less than 44 ppm and this may be considered the upper limit for film cleaning given the controls used on the machines.

### 9.2.2. Public health – exposure assessment

The public is unlikely to be exposed to the notified chemical except if there is a transport accident. In this case cleanup with an inorganic absorbent material is recommended.

### 9.2.3. Human health - effects assessment

The notified chemical was demonstrated to be of low acute oral and inhalation toxicity in rats, was not a skin irritant in rabbits and was a slight eye irritant in rabbits. It was not a skin sensitiser in guinea pigs and was neither mutagenic in bacteria nor clastogenic in CHL cells *in vitro*.

Twenty-eight day repeated dose inhalation and oral toxicity studies were conducted in rats. An adaptive liver response was observed together with increased kidney weight. As there were no histopathological correlates of the kidney effects, the notified chemical could not be classified as hazardous on repeated or prolonged exposure on this basis. The same could be said of the repeated dose inhalation study where an adaptive liver response was seem with minor effects in the larynx and kidney.

Cardiac sensitisation was observed at 4.9% notified chemical in air.

The notified chemical would not be classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

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

Any exposure from spillage during any of the transfer operations is not likely to cause any adverse health outcomes given the toxicological profile indicated above and the fact that exposure is likely to be short term and intermittent. The level of exposure via inhalation indicated by monitoring studies is 44 ppm. The acute and repeated dose inhalation toxicity studies indicate no adverse health effects at levels far above this. Cardiac sensitisation was detected in dogs but only at a level of 4.9% in air, which is several orders of magnitude greater than the likely maximum atmospheric concentration in the workplace. In addition, the manufacturer recommends an exposure standard of 200 ppm on the MSDS.

In summary the fact that a range of toxicological studies do not indicate the notified chemical is a hazardous substance together with likely low and/or intermittent worker exposure suggests a low probability of adverse health outcomes to workers.

### 9.2.5. Public health – risk characterisation

The public are unlikely to be exposed to the notified chemical except in the event of a transport accident or, perhaps, leakage from refrigeration equipment to which the public could have access.

## 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.*

### 10.2. Environmental risk assessment

While the PEC/PNEC ratio indicates the chemical is not considered to pose a risk to the environment based on its reported use pattern, there are significant uncertainties surrounding the behaviour of fluorocarbon compounds in general in the environment in areas of partitioning behaviour, degradation, chronic toxicity and bioaccumulation. While the notified chemical degrades quickly in the atmosphere, this leads to species which are likely to be more persistent.

There is insufficient information to classify the notified substance according to the Globally Harmonised System of Classification and Labelling of Chemicals.

### 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 Negligible Concern to public health when used as indicated.

## 11. MATERIAL SAFETY DATA SHEET

### 11.1. Material Safety Data Sheet

The MSDS of the notified chemical and products containing the chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). They are published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

### 11.2. Label

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

## 12. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:
  - Good general and local exhaust ventilation at points of vapour release

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Neoprene or nitrile gloves, safety glasses with side shields, protective clothing and footwear

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

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

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

Environment

- The following control measures should be implemented by end users to minimise environmental exposure during of the notified chemical:
  - waste should be collected for disposal by incineration.

Disposal

- Material should not be discharged to the open environment. Where possible, it is recommended that disposal be through incineration at a facility permitted for halogenated wastes.
- The decommissioning of refrigeration units should be completed in accordance with the Australian Refrigeration and Airconditioning Code of Good Practice.

Emergency procedures

- In the event of spillage, cover with absorbent material. Place in a metal container and seal the container. Incinerate in an industrial or commercial facility in the presence of a combustible material. Combustion products will contain hydrogen fluoride. The incinerator should be equipped with suitable controls for combustion of halogenated materials.

### 12.1. Secondary notification

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

(1) Under Section 64(2) of the Act:
- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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