File No: STD/1019

August 2002

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

3M™ Novec™ Fire Protection Fluid 1230

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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Website:	www.nicnas.gov.au

Director
Chemicals Notification and Assessment

TABLE OF CONTENTS

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3M™ Novec™ Fire Protection Fluid 1230

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
3M Australia Pty Ltd (ACN 000 100 096), 2 – 74 Dunheved Circuit St Marys NSW 1760.

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 Identity, Marketing Name, Composition, Molecular/structural formula, Spectral Data, Specific use of the chemical.

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
No.

NOTIFICATION IN OTHER COUNTRIES
USA, Canada, Europe, Korea.

2. IDENTITY OF CHEMICAL

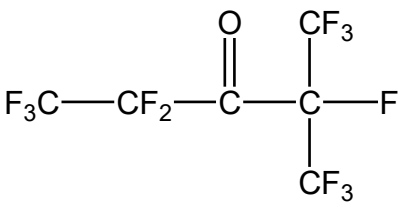
CHEMICAL NAME
1,1,1,2,2,4,5,5,5-nonafluoro-4-(trifluoromethyl)-3-pentanone

OTHER NAME(S)
Perfluoro(ethyl isopropyl ketone)
Perfluoro-2-methyl-3-pentanone
2-Trifluoromethyl-3-nonafluoropentanone
T-7479
L-15566

CAS NUMBER
756-13-8

MOLECULAR FORMULA
$C_6F_{12}O$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
316

SPECTRAL DATA
^{19}F and ^{1}H Nuclear Magnetic Resonance (NMR) spectra were provided.
TEST FACILITY 3M Specialty Materials Manufacturing Analytical Laboratory (2001).

METHODS OF DETECTION AND DETERMINATION
NMR spectroscopy.

3. COMPOSITION

DEGREE OF PURITY
99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None.

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

ADDITIVES/ADJUVANTS
None.

DEGRADATION PRODUCTS
In a fire, maximum HF concentration is approximately 1000 ppm/kW/m^3 given that a circuit board fire is approximately 3 – 5 kW. For a room size of 20' x 20' x 8' and a fire of 3.7 kW the maximum HF concentration is approximately 40 ppm (3M Specialty Materials Division, 2001).

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported ready for use.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 20	≤ 20	≤ 20	≤ 20	≤ 20

USE
The notified chemical will be used as a fire extinguishing fluid to be used in specialised fire situations on high value electronic and telecommunications equipment, which require an extinguishing agent that does not leave residues on the equipment. Some specific uses include: streaming (portable extinguishers); flooding (total and localised, pre-engineered and engineered); explosion suppression; and inerting. The notifier indicates that it will not be commercialised for residential fire protection.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS
Received by notifier.

TRANSPORTATION AND PACKAGING

The notified substance will be imported in 1000 L containers and will subsequently be transferred to pressurised containers of 5-7 L for portable extinguishers and 25-50 L for fixed systems.

5.2. Operation Description

The notified chemical will not be formulated in Australia. The notified substance will be imported as a fire suppression chemical to be used to fill fire extinguishers and flooding fire extinguishing systems. Fire extinguishers and bottles will be filled with the chemical at the manufacturer's facility prior to distribution to customer sites. Containers are 5 – 7L for extinguishers and 25 – 50L for fixed systems.

At customer sites, the notified chemical will be used in contained areas to extinguish fires, which may break out in areas such as computer rooms, and telecommunications and electronics facilities.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Filling storage bottles/fire extinguishers	4 – 6		
- production workers	2 – 4	8 hours/day	6 weeks/year
- forklift driver	1		
- supervisor	1		
System installation			
- system installer	2 – 6	8 hours/day	1 day/week
- electrician	1		
- supervisor	1		

Exposure Details

The liquid fire extinguishant is transferred in a closed system as a liquid from bulk containers to bottles to be used as fire extinguishers or to be connected to fire extinguishing systems. The liquid is then super pressurised. Drips and spills may occur when connecting and disconnecting lines.

Bottles containing the extinguishant will be connected to a fire extinguishing system. Exposure to leaks may occur infrequently.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified chemical will be transferred into portable fire extinguishers (5-7 L) and fixed flooding fire extinguishing systems (25-50 L) prior to distribution to customer sites. Release is expected to be minimal during the filling process as the Fire Protection Association Australia's Code of Good Practice for the Reduction of Emissions of Vaporising Liquid Fire Extinguishing Agents is followed and it is carried out in closed equipment via a direct line from the import drums and under super-pressurised nitrogen gas. Minor amounts may escape during filling and recharging of fire extinguishing systems, but these will be minimised by good industrial hygiene practices.

RELEASE OF CHEMICAL FROM USE

Release of the notified chemical to the environment could occur during usage of the fire extinguisher to put out fires, while a portion of the chemical may consumed by the fire. The amount of chemical released during use would depend on whether portable or flooding systems are used to extinguish the fire. In most cases, release is expected to be relatively localised and isolated in occurrence. Aquatic exposure is possible where the notified chemical is used in military application on ships.

5.5. Disposal

The notifier recommends disposal by incineration, in the presence of combustible material, in an industrial or commercial facility. Combustion products will include hydrogen fluoride, and thus the incinerator should be suitably equipped for the combustion of halocarbons.

5.6. Public exposure

It is expected that during transport, storage, and the filling of fire extinguishing systems, exposure of the general public to the notified chemical will be low, except in the event of an accidental spill.

The notified chemical will not be sold for residential fire protection. Consequently public exposure will occur in the event of an accidental spill or following the discharge of the fire extinguishing fluid. As this vapourises on discharge, there may be inhalation, dermal and ocular exposure.

6. PHYSICAL AND CHEMICAL PROPERTIES

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

Boiling Point 48°C at 101.3 kPa

METHOD OECD TG 103 Boiling Point.
TEST FACILITY NOTOX (2001a)

Density 1610 kg/m^3

METHOD OECD TG 109 Density of Liquids and Solids.
TEST FACILITY NOTOX (2001b)

Vapour Pressure 31.6 ±0.6 kPa at 20°C.

METHOD OECD TG 104 Vapour Pressure, Static Technique.
Remarks Approximately 15.6 g of test substance was placed in a clean, dry vessel, which was evacuated for 5 seconds. A total of 29 measurements were performed starting at 9 measurements at 36.09°C, and then subsequent measurements at 30.51°C, and 22.97°C. The test substance was considered to show ideal behaviour that hence the vapour pressure curve was derived using a least squares method to calculate line of best fit. The results indicate the notified chemical is highly volatile (Mensink *et al*. 1995).
TEST FACILITY Notox (2001c).

Water Solubility <10 mg/L (estimated).
Remarks The notifier estimated the water solubility of the notified chemical to be < 10 g/L. However, the notified chemical is expected to hydrolyse to form an organic acid which is soluble at all environmentally relevant concentrations, and hence water solubility measurements for the notified chemical's fate.

Hydrolysis as a Function of pH <2.5 minutes at pH 1.2-9.0 and 25°C or 37°C.

METHOD US EPA: Fate, Transport and Transformation Test Guidelines OPPTS 835.2110.

Remarks Approximately 100 mg/L samples of test substance were incubated in buffers of pH 5, 7, and 9 and a temperature of 25°C, and in buffers of pH 1.2, 5, 7, and 9 and a temperature of 37°C (a co-solvent, acetone, was used to generate a high concentration in water). The samples were then analysed at 0 minutes and after 30 and 60 minutes for the test substance or its degradation products. The test substance was not detected in any fortified sample using liquid chromatography/mass spectrometry, where LOQ = 30 mg/L, whereas the notified chemical's hydrolysis product, pentafluoropropionic acid, was detected in all samples. However, recovery of the product decreased at increased pH to 50% at pH 9. Because no test substance could be detected, its half-life could not be explicitly determined. Using the limits of detection and the initial concentrations, the half-life of the test substance was determined to be shorter than 2.5 minutes under all temperature and pH conditions tested.
TEST FACILITY Centre Analytical Laboratories (2001).

Partition Coefficient (n-octanol/water) log Pow at 20ºC = 0.77 (estimated by QSAR for the notified chemical's hydrolysis product).

METHOD QSAR Estimation.
Remarks The partition coefficient was not performed due to the expected rapid hydrolysis of the notified chemical. However, the hydrolysis product, is highly water soluble and is therefore expected to have a low affinity to lipids. Using the log P of a related compound, trifluoroacetic acid (TFA) as a reference, which is -0.2, the notifier estimated a log P of 0.77 for the hydrolysis product using the KOWWIN QSAR system. However, as this is an acid rather than a neutral molecule, the relevance of the result to the notified substance is unclear.

Adsorption/Desorption log K_{oc} = 1.1 (estimated).

METHOD Estimation by PCKOCWIN QSAR
Remarks The notifier estimated a log Koc of 1.1 corrected for organic acids. It was indicated that the Koc value may vary significantly with pH. However, the notified chemical is highly water soluble and therefore is expected to be mobile in soils, and not adsorb to organic matter. However, again, this is for the acidic rather than the neutral molecule, which may be expected to have a greater affinity for soils.

Dissociation Constant Not determined

METHOD OECD TG 112 Dissociation Constants in Water.
Remarks The notified chemical does not contain any dissociable groups. The substance contains groups expected to have normal acidity.

Particle Size Not applicable.

Henry's Law Constant 1.02 X 10^6 $Pa.M^3/mol$

METHOD The Henry's Law Constant above was calculated by the notifier, using the vapour pressure, a water solubility of 10 ppm, and assuming relative stability in water.
Remarks The results indicate the notified chemical will rapidly partition from water into air.

Flash Point Not detected.

METHOD EC Directive 92/69/EEC A.9 Flash Point.
TEST FACILITY Notox (2001d).

Flammability Limits Not flammable.

Remarks Inspection of structure.
Notox (2001e).

Autoignition Temperature 590ºC

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
TEST FACILITY Notox (2001f).

Explosive Properties Not explosive.

Remarks Inspection of structure.
Notox (2001g).

Reactivity May be reactive to strong bases, amines, alcohols and ultraviolet light.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 > 2000 mg/kg bw	low toxicity
Rat, acute inhalation LC50 > 98658 ppm/4 hour	low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - non-adjuvant test.	no evidence evidence of sensitisation.
Rat, inhalation repeat dose toxicity - 28 days.	LOAEL = 997 ppm
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberrations	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE — Notified chemical.

METHOD — OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.

Species/Strain — Rat/Wistar.
Vehicle — None.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3/sex	2000	0/6

LD50 — > 2000 mg/kg bw
Signs of Toxicity — Lethargy, hunched posture and/or piloerection in all animals between days 1 and 7.
Effects in Organs — No abnormalities.

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

TEST FACILITY — Notox (2001h).

7.2. Acute toxicity - dermal

TEST SUBSTANCE — Notified chemical.

METHOD — OECD TG 402 Acute Dermal Toxicity – Limit Test.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.

Species/Strain — Rat/Wistar.
Vehicle — None.
Type of dressing — Occlusive.

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 - Local — Severe erythema and/or scales was noted in the majority of animals. Effects were reversible in all but one animal on day 4.

Signs of Toxicity - Systemic	Lethargy, hunched posture, piloerection, chromodacryorrhoea were noted in the majority of animals.
Effects in Organs	No abnormalities.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	Notox (2001i).

7.3. Acute toxicity - inhalation

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 403 Acute Inhalation Toxicity – Limit Test. EC Directive 92/69/EEC, 93/21/EEC B.2 Acute Toxicity (Inhalation) – Limit Test.
Species/Strain	Rat/Sprague-Dawley.
Method of Exposure	Oro-nasal exposure.
Exposure Period	4 hours.
Physical Form	Vapour.

RESULTS

Group	*Number and Sex of Animals*	*Concentration <ppm>*		*Mortality*
		Nominal	*Actual*	
1	5/sex	0		0/10
2	5/sex	100000	98658	0/10

LC50	> 98658 ppm/ 4 hours
Signs of Toxicity	Exaggerated breathing was evident in test rats 30 minutes into the exposure and persisted for at least 2 hours post exposure.
Effects in Organs	No treatment-related findings.
CONCLUSION	The notified chemical is of low toxicity via inhalation.
TEST FACILITY	Huntingdon (2000).

7.4. Irritation – skin

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None.
Observation Period	72 hours.
Type of Dressing	Semi-occlusive.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	0	-	0
Oedema	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 non-irritating to skin.

TEST FACILITY Notox (2001j).

7.5. Irritation - eye

TEST SUBSTANCE Notified chemical.

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

Species/Strain Rabbit/New Zealand White
Number of Animals 3
Observation Period 72 hours.

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	0	0	1	1 hour	0
Conjunctiva: chemosis	0	0	0	0	-	0
Conjunctiva: discharge	0	0	0	0	-	0
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.

Remarks - Results Animal number 2 exhibited slight conjunctival redness at 1 hour post-instillation.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Notox (2001k).

7.6. Skin sensitisation

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 406 Skin Sensitisation – Buehler test.
EC Directive 96/54/EC B.6 Skin Sensitisation - Buehler test.

Species/Strain Guinea pig/Dunkin Hartley.

MAIN STUDY

Number of Animals Test Group: 20 Control Group: 10

INDUCTION PHASE Induction Concentration:
topical application, undiluted

Signs of Irritation None.

CHALLENGE PHASE

topical application: undiluted

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after Challenge*	
		24 h	*48 h*
Test Group	undiluted	0/20	0/20
Control Group	undiluted	0/10	0/10

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

TEST FACILITY — Notox (2001m).

7.7. Repeat dose toxicity

TEST SUBSTANCE — Notified chemical.

METHOD — OECD TG 412 Repeated Dose Inhalation Toxicity: 28-day or 14-day Study.
EC Directive 92/69/EEC B.8 Repeated Dose (28 Days) Toxicity (Inhalation).

Species/Strain	Rat/Wistar.
Route of Administration	Inhalation – oro-nasal exposure.
Exposure Information	Total exposure days: 28 days; Dose regimen: 5 days per week; Duration of exposure (inhalation/dermal): 6 hours/day; Post-exposure observation period: 14 days.
Vehicle	None.
Physical Form	Vapour.

RESULTS

Group	*Number and Sex of Animals*	*Dose/Concentration ppm*		*Mortality*
		Nominal	*Actual*	
I (control)	5/sex	0	0	0/10
II (low dose)	"	1000	997	"
III (lower-mid dose)	"	4000	3984	"
IV (upper-mid dose)	"	10000	10018	"
V (high dose)	"	20000	19644	"
VI (control recovery)	"	0	0	"
VII (high dose recovery)	"	20000	19644	"

Clinical Observations

A trend to reduction in bodyweight was noted in high dose males; this was statistically significant by day 21 and also in the recovery group but not observed in females. A slightly lower overall food intake in high dose males accompanied by a lower food conversion efficiency.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis, Peroxisome Proliferation

Clinical Chemistry:

	Dose group				
	High		Low	Lower-Mid	Upper-Mid
		Recovery			
glucose		♂↑(17%)	♂↑(14%) ♀↑(21%)	♂↑(18%) ♀↑(23%)	♂↑(17%)
albumin		♂↑(11%)	♂↑(10%)	♂↑(11%)	♂↑(5%)
albumin/globulin ratio	♂↑(38%)	♂↑(43%)	♂↑(42%)	♂↑(56%)	♂↑(19%) ♀↓ (9%)
γ-glutamyl transferase				♀↑(0.3 U/l; control = 0 U/l)	♀↓ (0 U/l but control = 0.5 U/l)
cholesterol	♂↓(22%)	♂↓(19%)		♂↓(32%)	♀↑(20%)
triglycerides		♂↑(61%)	♂↑(61%) ♀↑(95%)	♀↑(95%)	
creatinine				♀↓(23%)	♂↓(16%)
phospholipids					♂↑(19%) ♀↓ (9%)

Haematology: No significant findings.

Urinalysis: Urinary fluoride concentration, total fluoride excretion in urine and the urinary fluoride/creatinine ratio were increased in a concentration-related fashion in males of the lower-mid, upper-mid and high dose groups and in females of the upper-mid and high dose groups. At the end of the recovery period, urinary fluoride concentration, total fluoride excretion, total fluoride excretion in urine and the urinary fluoride/creatinine ratio in females of the high dose group were still significantly higher when compared to controls.

Peroxisome Proliferation: Increased acyl-CoA oxidase (up to nearly 8 times the control value) and lauric acid hydroxylase (up to 10 times the control value) were observed in the liver of all male exposure groups. Maximum induction was observed at 4000 ppm for both activities. In female animals the increases were smaller (up to 4 times and 2 times the control value, respectively). Statistical significance was not reached in females of the lower mid exposure group for acyl-CoA oxidase but was reached for lauric acid hydroxylase.

In male high dose recovery animals some elevation of the above activities were still present but this was not the case in females.

Effects in Organs

A concentration-related statistically significant increase in relative liver weights was observed in males of all exposure groups and in females of the upper mid and high dose groups. Absolute liver weights were elevated in males of the lower mid, upper mid and high dose groups and in females of the high dose group. Relative lung weights were elevated in upper mid and high dose animals and absolute lung weights were elevated in high dose animals.

At the end of the recovery period relative liver weights of exposed males were still elevated as were the relative lung weights of both sexes.

There were no macroscopic anomalies in exposed animals. However, nucleolar enlargement in liver cells indicative of elevated activity was observed in exposed animals but was not concentration dependent. This was no longer apparent at the end of the recovery period. The lungs of the upper mid and high dose animals exhibited an accumulation of alveolar macrophages. In high dose recovery animals the effects were milder.

CONCLUSION
The Lowest Observed Adverse Effect Level (LOAEL) was established as 997 ppm in this study, based on changes associated with increased peroxisome proliferation.

TEST FACILITY TNO (2001).

7.8. Genotoxicity - bacteria

TEST SUBSTANCE NOTIFIED CHEMICAL.

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Species/Strain *S. typhimurium*:
TA1535, TA1537, TA98, TA100.
E. coli: WP2 uvrA.
Metabolic Activation System S9 microsomal fraction from rat liver (5% (v/v) in experiment 1 and 10% (v/v) in experiment 2).
Concentration Range in Main Test a) With metabolic activation: 10 - 5000 µg/plate.
b) Without metabolic activation: 10 - 5000 µg/plate.
Vehicle ethanol

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1		none observed	none observed	none observed
Test 2		"	"	"
Present				
Test 1		"	"	"
Test 2		"	"	"

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

TEST FACILITY Notox (2001n).

7.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.

Cell Type/Cell Line Chinese Hamster Ovary (CHO) cells.

Metabolic Activation System Arolclor 1254-induced rat liver S9 microsomal fraction.

Vehicle ethanol

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	840, 1200, 2450, 5000	6 hours	20.7 hours
Test 2	2000, 2500, 3750, 5000	17.5 hours	20 hours
Test 3	2000, 2500, 3750, 5000	41.6 hours	44 hours
Present			
Test 1	840, 1200, 2450, 5000	6 hours	20.7 hours
Test 2	1250, 2500, 3750, 5000	6 hours	20 hours

All cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1		-	1720 (slight)	-
Test 2		2000	1500 (slight)	-
Test 3		1500	1500 (slight)	-
Present				
Test 1		2450	1720 (slight)	-
Test 2		2500	1250 (slight)	-

CONCLUSION The notified chemical was not clastogenic to CHO cells treated in vitro under the conditions of the test.

TEST FACILITY Covance (2001).

ADDITIONAL INVESTIGATIONS

7.10. Cardiac sensitisation to adrenaline

TEST SUBSTANCE Notified chemical.

METHOD Reinhardt (1971).

STUDY DESIGN

Species/Strain Dog/Beagle

Study Design Six dogs were used and had all been used previously for studies of the same type. During challenge, each dog received snout only exposure to the test substance.

Challenge Procedure

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

Summary of Cardiac Response					
			Number of Ectopic Beats:		
Dog Number	*Adrenaline Dose (µg/kg)*	*Test Substance Concentration (%)*	*1st Adrenaline Challenge*	*2nd Adrenaline Challenge*	*Cardiac Response*
1373	1	0	0	0	
	2	0	0	1	
1375	8	0	2	3	
1379	1	0	0	0	
	2	0	1	6	
1381	8	0	1	1	
1383	8	0	12	not performed	
1385	2	0	0	dog moved	
1387	2	0	2	0	
1389	2	0	10	dog moved	
1391	1	0	0	0	
	2	0	3	11	
1373		air only	0	8	Negative response
1375		"	0	0	Negative response
1379		"	15	Infection failure	-
1381		"	30 – 35 beats of uncertain origin	30 – 35 beats of uncertain origin	All ectopic complexes separated and unifocal
1387		"	8		Negative response
1391		"	39		All ectopic complexes separated, unifocal and from left ventricle
1373	2	1.02	10	16	Negative response
1375	8	0.97	1	1	Negative response
1379	2	1.04	10	19	Negative response
1381	8	1.03	26	19	Negative response
1387	2	1.00	1	1	Negative response
1391	2	1.00	2	2	Negative response
1373	2	2.00	0	0	Negative response
1375	8	1.98	1	2	Negative response
1379	2	1.98	22	33	Negative response
1387	2	1.98	2	0	Negative response
1391	1	1.98	2	1	Negative response
1373	2	5.00	0	5	Negative response
1375	8	4.99	0	1	Negative response
1379	2	5.10	17	24	Negative response
1387	2	5.09	0	0	Negative response
1391	1	5.01	0	0	Negative response
1373	2	10.00	5	18	Negative response
1375	8	9.98	0	0	Negative response
1379	2	10.02	28	27	Negative response
1387	2	10.00	10 beats of uncertain origin	19 beats of uncertain origin	Negative response
1391	1	9.87	0	0	Negative response
1373	2	15.51	0	Adrenaline not given	Unable to assess
1375	8	15.42	1	0	Negative response

1379	2	15.52	18	Adrenaline not given	Unable to assess
1381	8	15.46	4	"	"
1387	2	15.50	1	"	"
1391	2	15.47	0	"	"

Signs of Toxicity	Anaesthetic properties of the vapour were seen. The severity of the signs: agitation, abnormal breathing pattern, limb rigidity, violent struggling and partial loss of consciousness, was dose-related. The clinical response to exposure included a degree of struggling against restraints which at the highest concentration necessitated premature termination of exposure.
CONCLUSION	There was no evidence of cardiac sensitisation under the conditions of the test. The NOAEL for cardiac sensitisation is judged to be 9.97%.
TEST FACILITY	Huntingdon (2001).

8. ENVIRONMENT

8.1. Environmental fate

The environmental fate and aquatic toxicity tests were performed on the hydrolysis product of the notified chemical owing to the expected volatility and rapid hydrolysis in water.

8.1.1. Ready biodegradability

TEST SUBSTANCE	Hydrolysis product (4.8% active ingredient).
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Activated sludge from municipal waste treatment.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	CO_2 evolution by titration.
Remarks - Method	Microorganisms in sewage sludge were exposed to nominal concentrations of 1,940 mg/L of the test substance, equivalent to 93 mg PFPA/L and 21 mg/L theoretical dissolved organic carbon (DOC). A single positive control containing 34.3 mg/L sodium benzoate, equivalent to 20 mg/L DOC, was also established, as was a toxicity control containing 34.3 mg/L sodium benzoate and 1940 mg/L of whole test substance with a combined DOC of 41 mg/L.
RESULTS	
Remarks - Results	Only 3% of the notified chemical was degraded over 28 days, while 88% of sodium benzoate, and 43% of the toxicity control were degraded at the end of the 28-day test period, indicating the test system was viable.
CONCLUSION	The test substance is not readily biodegradable under the conditions tested.
TEST FACILITY	Wilbury (2001a).

8.1.2. Bioaccumulation

No bioaccumulation data were available. The notified chemical is unstable and breaks down in water to an acid with a high water solubility and estimated low partition co-efficient indicating a low affinity to lipids. As such, the chemical should not bioaccumulate. In any case aquatic exposure is not anticipated under normal usage of the chemical.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Hydrolysis product (4.7% active ingredient).
METHOD	OECD TG 203 Fish, Acute Toxicity Test –static conditions.
Species	*Pimephales promelas*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	40-48 mg $CaCO_3$/L
Analytical Monitoring	Dissolved oxygen, pH, conductivity, temperature were recorded daily.
Remarks – Method	Following a range finding test using 0.1, 1.0, 10, 100 and 1000 mg/L test substance, a definitive test was performed in which 30 fish (3 replicates per treatment) were randomly assigned to test vessels containing, nominal concentrations of 1000 mg/L PFPA, an acetone control containing 3.6 mg/L acetone, or a blank control. The acetone control was included

because the test solution, supplied by the sponsor, contained acetone. The test report, however, indicates the test substance was added directly to water. Test concentrations in each tank were verified chromatographically at 0 and 96 hours. The mean measured concentration of PFPA was 1070 mg/L. No insoluble material was observed in the test vessels during the test. The endpoints were calculated using mean measured concentrations.

RESULTS

LC50	>1070 mg/L at 96 hours (as PFPA)
NOEC (or LOEC)	1070 mg/L at 96 hours.
Remarks – Results	No mortalities or sublethal effects were observed in fish exposed to the test substance or controls during the test.

CONCLUSION The test product is practically non toxic to fish.

TEST FACILITY Wilbury (2001b).

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Hydrolysis product (4.7% active ingredient).

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test – static conditions.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	160-180 mg $CaCO_3$/L
Analytical Monitoring	Dissolved oxygen, pH, conductivity, and temperature.
Remarks - Method	Following a range finding test using 0.1, 1.0, 10, 100 and 1000 mg/L test substance, a definitive test was performed in which 20 fish (2 replicates per treatment) were randomly assigned to test vessels containing, either 150, 250, 400, 600 and 1000 mg/L test substance, an acetone control containing 3.6 mg/L acetone, or a blank control. The acetone control was included because the test substance contains acetone. Test concentrations in each tank were verified chromatographically at 0 and 48 hours. No insoluble material was observed in the test vessels during the test. The endpoints were calculated using mean measured concentrations.

RESULTS

Concentration mg/L Measured	*Number of D. magna*	*Dead*	*Immobilised*	
		48 h	*24 h*	*48 h*
Control	20	0	0	0
Acetone control	20	0	0	0
178	20	1	0	0
285	20	1	1	2
430	20	2	5	1
619	20	2	1	6
1080	20	2	2	2

LC50	>1080 mg/L at 48 hours (hydrolysis product)
NOEC (or LOEC)	178 mg/L (hydrolysis product)
Remarks - Results	In addition to death and immobilisation, 2 daphnid exposed to 619 mg/L and 5 daphnids exposed to 1080 mg/L were lethargic.

CONCLUSION The test substance is practically non toxic to daphnia.

TEST FACILITY Wilbury (2001c).

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Hydrolysis product (4.75 % active ingredient)

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species	*Selenastrum capricornutum*
Exposure Period	96 hours
Concentration Range Nominal	1.3, 2.5, 5.0, 10 and 20 mg/L of hydrolysis product.
Concentration Range Measured	1.59, 3.71, 6.03, 10.2 and 23.1 mg/L of hydrolysis product.
Auxiliary Solvent	None
Water Hardness	Not reported
Remarks - Method	Green algae were exposed to five nominal concentrations of the test substance, a control, and an acetone control containing 0.071 mg/L acetone, which is the same amount of acetone in 20 mg/L hydrolysis product. Test concentrations were verified at 0 and 96 hours using chromatographic techniques. Endpoints were calculated by weighted least squares non-linear regression technique.

RESULTS

Biomass		*Growth*	
Endpoint	*mg/L*	*Endpoint*	*mg/L*
EC50	5.37 (CI = 4.81-5.99)	EC50	10.6 (CI = 9.63-11.6)
NOEC	1.59	NOEC	3.71

Remarks - Results No size differences, unusual cell shapes, colours, flocculation, adherence of cells to containers, or aggregation of cells were noted during the test. To determine whether the test substance was algistatic or algicidal, a 0.5 mL aliquot of test media was taken from each vessel containing the highest test concentration and transferred to flasks containing 100 mL of fresh media for incubation. Algae increased from approximately 180 cells/mL to 190,000 cells/mL, indicating the effects were algistatic rather than algicidal.

CONCLUSION The test substance is moderately toxic to freshwater green algae according to the criteria of Mensink *et al* (1995).

TEST FACILITY Wilbury (2001d).

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE

The notifier has indicated that while release to sanitary sewers is highly unlikely, a test conducted on isoperfluorobutyric acid indicates that the hydrolysis product would likely have insignificant toxicity to activated sludge organisms. The EC_{10} for 3 hours of exposure to iso-PFBA was >1000 mg/L.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

No environmental exposure estimates were provided for the notified chemical. The notifier indicated that direct release of the chemical into the aquatic environment will be very limited and is only likely to occur at end use in military applications where the fire extinguishers are used on ships. Should the notified chemical enter the aquatic environment, very little is expected to partition into the water compartment, and that which does will hydrolyse fairly rapidly to 50% of a hydrolysis product and 50 % of 1,1,1,2,3,3,3,-heptafluoropropane (HFC-227), both of which are expected to be highly water soluble and resistant to biodegradation. In addition, as a gas, HFC-227 would partition to the atmosphere where biodegradation would not occur.

The Henry's Law Constant (H) and vapour pressure indicate that most of the chemical will rapidly volatilise from surfaces, water or moist soil, and partition into the atmosphere. Once in the vapour phase the material does not go back into the liquid phase. In the atmosphere, photolysis is expected to be the predominant pathway for degradation, rather than hydrolysis. A study by Guschin *et al*. (1999), which examined atmospheric loss mechanisms of the notified chemical, found that while the chemical did not react with hydroxyl radical (•OH), substantial decay (12%) occurred when the substance was exposed to UV radiation for 10 minutes. The chemical showed significant absorbance at wavelengths above 300 nm, indicating that photolysis in the lower atmosphere will be a significant sink for the compound. The expected atmospheric lifetime of the notified chemical against solar photodissociation is expected to be from 3 to 5 days.

In the atmosphere, the notified chemical is expected to degrade to fluorinated alkyl radicals such as CF_3CF_2• and $(CF_3)_2CF$•. The atmospheric chemistry of fluorochemicals producing similar radicals (eg. HFC-125 and HFC-227ea) demonstrates that these radicals and their degradation products have no impact on stratospheric ozone. For example, the ECETOC (1994) report on HFC-125 indicates the products formed from atmospheric degradation of CHF_2CF_3 will occur through attack by naturally occurring hydroxyl radicals in the troposphere, which results in the formation of intermediate products with varying atmospheric lifetimes. However, the final products formed from atmospheric degradation (COF_2 and CF_3O) are expected to be removed from the atmosphere within a few days to a few months by uptake into clouds followed by rapid hydrolysis to CO_2 and HF. It is likely that HF will be washed out in rain, but it is not expected to contribute significantly to acid rain.

Because the chemical does not contain chlorine or bromine, it is not expected to affect stratospheric ozone.

The notifier has indicated a low Global Warming Potential (GWP) calculated to be 1 for (Integration Time Horizon) ITH = 100 years using the Intergovernmental Panel on Climate Change method as updated in WMO (1999) for notified chemical, and based on measured IR cross-section and a 5 day half-life in air. Hence, the chemical is not expected to impact atmospheric radiative balance or influence climate change.

9.1.2. Environment – effects assessment

Owing to the expected volatility and rapid hydrolysis in water, the aquatic toxicity tests were performed on the hydrolysis product of the notified chemical. Toxicity test reports were provided for fish, daphnia and algae. These tests showed the test substance is not toxic toward fish or daphnia, which had LC50 values of 1070 mg/L and 1080 mg/L, respectively. The hydrolysis product is moderately toxic to algae, having an LC50 of 5.37 mg/L. However, exposure to aquatic organisms will be low, and available data indicates that the compound would have little potential for bioaccumulation.

9.1.3. Environment – risk characterisation

Direct release of the chemical into the aquatic and soil environment will be very limited during

use of the substance in specialised fire extinguishers. Owing to its high vapour pressure and Henry's Law constant, any compound released onto surfaces, or into water and soil is expected to quickly evaporate to the atmosphere. In the atmosphere the notified chemical is expected to undergo photolytic degradation and to form fluorinated alkyl radicals. The atmospheric chemistry of fluorochemicals producing similar radicals demonstrates that these radicals and their degradation products have no impact on stratospheric ozone. The notifier has also indicated a low Global Warming Potential (GWP). Given these considerations and the low expected aquatic exposure, the notified chemical is not likely to pose a threat to the environment when used at the volumes and patterns indicated, particularly when the relevant users comply with the Fire Protection Association Australia's Code of Good Practice for the Reduction of Emissions of Vaporising Liquid Fire Extinguishing Agents.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Exposure of workers can potentially occur while transferring the liquid notified chemical to fire extinguishers or bottles to be attached to fire protection systems. Typically engineering controls would be expected to be in place to minimise spills and leaks. The notifier has indicated that releases of extinguishant would be minimised by adherence to the Fire Protection of Australia NSW Committee Code of Good Practice for the Reduction of Emissions of Vaporising Liquid Fire Extinguishing Agents (FPAA, 2000). This code of practice references the relevant Australian Standards. Personal protective equipment required is indicated in the MSDS for the notified chemical. This includes: vented goggles, butyl rubber gloves and a supplied air respirator where necessary. Similar considerations apply to attaching bottles to fire suppressing systems and maintenance and refilling of those systems.

9.2.2. Public health – exposure assessment

Fire extinguishers containing the notified chemical will not be sold to the public. Public exposure is likely to be acute exposure, arising from accidental spills of the notified chemical or from discharge of fire extinguishant due to a fire risk.

9.2.3. Human health - effects assessment

The notified chemical was found to be of low acute oral, dermal and inhalation toxicity in rats and was found not to irritating to skin and slightly irritating to eyes in rabbits. It was not a skin sensitiser in guinea pigs and was neither mutagenic in bacteria nor clastogenic in chinese hamster ovary cells. In a 28-day repeated dose inhalation study in rats, effects on the liver and lungs were observed at high doses. Cardiac sensitisation was not observed in dogs at an atmospheric concentration of approximately 10%.

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

9.2.4. Occupational health and safety – risk characterisation

Exposure of workers during fire extinguisher and bottle filling, fitting bottles to fire suppressant systems, system maintenance, refilling and decommissioning is expected to be infrequent. The risk of adverse health effects is considered to be low given the low hazard of the notified chemical and the low exposure levels. Rare incidents have occurred where workers have been exposed to system discharges but adverse health effects under these conditions would be unlikely. There may be a low risk of burns to skin should there be exposure of skin during a leak of high pressure gas.

9.2.5. Public health – risk characterisation

Although toxicity was evident in rats following repeated inhalation exposure, the acute toxicity of the notified chemical is low. Consequently the risk from public exposure to the notified chemical throughout all phases of its life-cycle is considered to be low.

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

10.1. Hazard classification

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

10.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its proposed use pattern, and limited aquatic exposure and toxicity.

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.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

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

11.2. Label

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

12. RECOMMENDATIONS

REGULATORY CONTROLS

CONTROL MEASURES

Occupational Health and Safety

- Recommendations contained in the Fire Protection Association of Australia NSW Committee Code of Good Practice for the Reduction of Emissions of Vaporising Liquid Fire Extinguishing Agents (FPAA, 2000) should be followed.

- Employers should ensure that the following personal protective equipment is used by workers where necessary to minimise occupational exposure to the notified chemical as introduced:
  - Vented goggles, butyl rubber gloves, a supplied air respirator.

  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

- For information on handling, storage, and disposal refer to the Fire Protection Association Australia NSW Committee, Code of Good Practice for the Reduction of Emissions of vaporising liquid fire extinguishing agents, July 2000.

Disposal

- The notified chemical should be disposed of through an authorised party by incineration. Incinerators used for disposal of the notified chemical should be suitably equipped for the combustion of halocarbons.

- Surplus or contaminated chemical should not be discharged into the atmosphere.

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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