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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

HFE-7100

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

HFE-7100

1. APPLICANT

3M Australia Pty Ltd of 2-74 Dunheved Circuit ST MARYS NSW 2760 has submitted a standard notification statement in support of their application for an assessment certificate for 'HFE-7100'.

2. IDENTITY OF THE CHEMICAL

HFE-7100 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the spectral data, purity, impurities, use, manufacture and details of exact import volume have been exempted from publication in the Full Public Report and the Summary Report.

Chemical Name: methoxy nano fluoro butanes

Other Names (s): mixture of 1-methoxy 1,1,2,3,3,3-hexafluoromethyl

propane and 1-methoxy 1,1,2,2,3,3,4,4,4-

nonafluorobutane

mixture of methoxynonafluoroisobutane and

methoxynonafluorobutane

Chemical Abstracts Service

(CAS) Registry No.: not assigned

Molecular Formula: $(C_5H_3F_9O)(C_5H_3F_9O)$

Structural Formula:

a)
$$CF_3 - CHF - CF_2 - O - CH_3$$

b)
$$CF_3 - CF_2 - CF_2 - CF_2 - O - CH_3$$

Molecular Weight: 250.1

Method of Detectionand Determination:
Ultra violet (UV)/visible spectroscopy; infrared spectroscopy; nuclear magnetic resonance

spectroscopy

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C

and 101.3 kPa: clear colourless liquid

Freezing Point: < -25°C

Boilinging Point: 60.5-62.0°C

Specific Gravity: 1.5305 at 20°C (pycnometer)

Vapour Pressure: 27.736 kPa at 25°C (isoteniscope technique))

Water Solubility: 8.47 mg/L at 20°C (flask method)

Fat Solubility: not determined

Partition Co-efficient

(n-octanol/water): log P_{ow} 3.54 at 20°C (HPLC method)

Hydrolysis as a Function

of pH: T_{1/2} 1 day to 1 year, at pH 4.0, 7.9, 9.9 (see

comments below)

Adsorption/Desorption: log Koc 2.56 at 20°C (HPLC analysis)

Dissociation Constant: not provided

Particle size: not applicable

Surface Tension: 72.6 mN/m (ring method)

Flash Point: $> 60^{\circ}$ C

Flammability Limits: not flammable

Autoignition Temperature: 397°C

Explosive Properties: not explosive

Reactivity/Stability: not reactive

Atmospheric Lifetime: 4.1 years

Global Warming Potential: 150 (500-year time horizon)

Tests were performed according to EEC/OECD test guidelines at facilities complying with OECD Principles of Good Laboratory Practice.

The notified chemical can be described as slightly soluble, and highly volatile.

Hydrolysis results are questionable. The method used may have resulted in loss of substance through volatilisation, leading to an erroneous conclusion that the notified substance was hydrolysed. No hydrolysis was observed during biodegradation testing, and laboratory experiments conducted by the notifier have shown that the substance is stable under highly acidic conditions.

While the high partition coefficient, and relatively high adsorption/desorption coefficient indicate the notified chemical will associate with sediments or organic carbon, its volatility suggests that it will all volatilise to the atmosphere.

No dissociation constant was provided for the chemical. It does not contain any readily dissociable moieties.

4. PURITY OF THE CHEMICAL

Degree of Purity: nearly 100%

Classification of Impurities: no health hazard classification of the impurities

was provided by the notifier

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured or reformulated in Australia. It will be imported in a ready to use form, as a component of a liquid finished product. The liquid form of the end use product will contain approximately 50% of the notified chemical. These end use product will be used as a cleaning and a heat transfer agent.

The notifier states that the notified chemical is expected to replace older reactive chemicals which are on the market, which in general is considered detrimental to the environment.

Import volumes are expected to increase to up to 20 tonnes of the notified chemical per year by the fifth year.

6. OCCUPATIONAL EXPOSURE

The product containing the notified chemical will be imported in 30 or 55 gallon

metal drums in shipping containers. These will be transported by road to a warehouse and from there to various customer sites. 2 to 5 dockside workers, 2 to 10 transport workers and 2 to 3 storepersons are involved in handling the containers. Exposure of transport and storage workers would occur only in the event of accidental spillage.

Dermal, inhalational and ocular exposure may occur during cleaning industrial parts typically inolving dipping into solvent containing the notified chemical. It is estimated that approximately 200 workers will be exposed 2 to 8 hours/day for 100 to 200 times/year. These workers may be exposed to significant levels of the notified chemical as a result of evaporative loss through the top of the cleaning tank or from vapours resulting from excess solvent in contact with cleaned parts following removal from the cleaning tank. The protective measures used at cleaning sites include local exhaust ventilation. The notifier states that under the conditions employed, workplace air monitoring studies have shown that levels of the notified chemical in the breathing zone to be 10 to 44 ppm and increasing up to 360 ppm during cleaning up a spill of 100 to 200 ml.

The notified chemical will also be used in secondary loop heat transfer applications. It is estimated that approximately 400 workers will be exposed 2 to 5 hours/day for 100 to 200 times/year. The notifier states that no worker exposure to the notified chemical will be anticipated during normal use, since, these systems typically circulate fluid in low-pressure closed systems. However, there could be exposure to service or maintenance personnel during filling of the coolant systems.

7. PUBLIC EXPOSURE

8. ENVIRONMENTAL EXPOSURE

Release

The notifier provides sealed returnable delivery systems, thereby eliminating disposal problems of used containers.

• Cleaning solvent use:

The notified substance will be used in a cleaning system to clean industrial parts such as electronic circuit boards, medical devices and aerospace and automotive parts. The cleaning solution will remove grease, solder flux, fine particles and other material from these parts. The process typically involves dipping the part into a solvent solution, then rinsing with the same or another solvent. The system is closed during cleaning operations, only being opened to add or remove articles.

Release during degreasing operations will be a result of volatilisation either through the top of the cleaning tank when opened at the start or end of cleaning operations, or from excess solvent on cleaned parts after their removal from the cleaning tank.

The notifier estimates losses as a result of vaporisation (both from opening the tank lid, and from chemical evaporating off cleaned parts) at 1%. With an estimated use of 10 tonnes per annum as a cleaning solvent, this equates to 100 kg per annum.

Once contaminated the solvent is transferred back to the notifiers sealed returnable delivery systems, and returned to the notifier. This is then reclaimed by a solvent reclamation company in Australia, and re-used.

• Heat Transfer Agent:

The notified substance will be imported as part of an azeotrope blend for use in secondary loop heat transfer systems. These are low pressurised, and the mixture would be in the form of a low viscosity liquid. Normally, such coolant systems are only filled once, and the coolant is not replaced or purged during the life of the equipment. Losses to the environment as a result of this use is likely to be minimal, only occurring in the case of system leakage, or accidental spillage.

A further 10 tonnes per annum may be used for this use. The notifier claims that, unlike gas based systems, fluid based systems such as these have no leakage through seals. Decommissioned units have refrigerant reclaimed and recycled.

Currently, there is no code of practice governing the solvent reclaiming and recycling industry. The notifier will be overseeing the process of reclamation with regard to the notified product, due to difficulties in separating this solvent from others. In the absence of data, it will be assumed that 10% of the chemical is lost through volatilisation during reclamation processes for both end uses. Based on the maximum import volume of 20 tonnes, this is an annual release of 2000 kg to the atmosphere. In reality, the cost of this material (approximately \$50.00 per kilogram) provides a strong incentive to minimise losses, and 10% is likely to be a considerable overestimation.

Fate

The Level 1 Fugacity Model predicts that, at equilibrium, 99.999% of the notified chemical will partition to the atmosphere, with the remainder found in soil air. This is expected due to the high vapour pressure and low water solubility of the chemical. As such, no chemical released would be expected to remain in the aquatic system.

While no information on the breakdown of the notified chemical in the atmosphere has been provided, it is likely the main reaction would be with hydroxyl radicals at the methyl groups on both isomers. This would form hydrophilic products which would precipitate in rain. Their further fate is unclear.

Ozone depletion potential

The USEPA has assessed this chemical as one which does not deplete the ozone layer since it does not contain chlorine or bromine (1).

Global warming potential (GWP)

The notified chemical has been estimated to have a relatively short atmospheric lifetime of around 4.1 years (1). This compares with CFC's which can have an atmospheric lifetime of 15 to 400 years, and carbon dioxide with approximate lifetimes of 50-200 years (2).

The notifier has provided a GWP of 150 on a 500 year time horizon, and 480 on a 100 year time horizon. Because of the short atmospheric lifetime of this chemical, the GWP on a 20 year time horizon would be preferable, but for the purpose of this assessment, the 100 year value will be used. This is discussed in the Environmental Hazard section below.

Biodegradation

Testing to OECD TG 301D (closed bottle test) concluded that the notified substance was not readily biodegradable, with 22% degradation (based on BOD) after 28 days.

Bioaccumulation

A bioconcentration study was performed on carp (*Cyprinus carpio*). The high exposure level of 0.5 μ g/mL gave a top bioconcentration factor (BCF) of 118, while the low exposure level (0.05 μ g/mL) gave a top bioconcentration factor (BCF) of 71 after an exposure period of 8 weeks. On the basis of these results, it was concluded that the test substance was not bioaccumulative. Testing was carried out in a closed system due to the volatility of the test substance.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

All studies were conducted using the noitified chemical except where indicated

Summary of the acute toxicity of Reactive Black 2506-MS

Test	Species	Outcome	Reference
acute oral toxicity	rat	LD ₅₀ > 5 000 mg/kg	(8)
acute inhalation toxicity	rat	$LC_{50} > 123.9 \text{ mg/L}$	()
skin irritation	rabbit	non-irritant	(10)
eye irritation	rabbit	non-irritant	(11)
skin sensitisation	guinea pig	non-sensitising	(12)

9.1.1 Oral Toxicity (8)

Species/strain: rat/CD(SD)BR

Number/sex of animals: 5/sex

Observation period: 14 days

Method of administration: gavage; test substance administered

undiluted

Clinical observations: one female had a soft stool on day 1

Mortality: none

Morphological findings: none

Test method: according to OECD guidelines (13)

 LD_{50} : > 5 000 mg/kg

Result: the notified chemical was of low acute oral

toxicity in a limit test in rats

9.1.2 Dermal Toxicity:

no acute dermal toxicity study was provided. The notifier has argued that the inhalation route to be the more appropriate route of exposure in the occupational setting.

9.1.3 Acute Inhalation Toxicity ()

Species/strain: rat/Crl:CD BR VAF/Plus

Chemical Type: normal perfluorobutyl methyl ether

Physical Form of Substance

Administered: liquid at room temperature; vapour at

exposure

Number/sex of animals: 10/sex in 4 groups of 5

Exposure period: 4 hours

Method of Exposure: nose only

Post Exposure Period: 14 days

Dose: 30.2 mg/L (2 959 ppm) and 123.9 mg/L

(12 122 ppm)

Clinical observations: rapid respiration was observed in all animals

immediatly following 4-hour exposure; increased salivation noted in 3 animals immediatly following exposure: all

immediatly following exposure; all

pharmacotoxic signs returned during the 14-

day post exposure period

Mortality: none

Morphological findings: none

Test method: according to OECD guidelines (13)

 LC_{50} : > 123.9 mg/L (12 122 ppm)

Result: normal perfluorobutyl methyl ether was of low

acute oral toxicity in a standard test in rats¹

9.1.4 Skin Irritation (10)

Species/strain: rabbit (New Zealand White)

Number/sex of animals: 3 males

Observation period: 72 hours

Method of administration: 0.5 ml (756 mg) of test substance was

applied to a 6 cm² area of intact dorsal skin; test site was covered with semi-occlusive

dressing for

4 hours; site was irrigated with lukewarm water once dressing removed; skin reactions were assessed at 1, 24, 48 and 72 hours after removal of the dressing and scored according to the method of Draize (14)

Draize scores: no erythema or oedema were observed at the

1 and 24 hour time points;

Test method: according to OECD guidelines (13)

Result: the notified chemical was a non-irritant to

rabbit skin

9.1.5 Eye Irritation (11)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3 males

Observation period: 72 hours

Method of administration: 0.1 ml (153 mg) of test substance was

instilled into the conjunctival sac of one eye;

untreated eye served as a control

 $^{^1}$ The notifier has argued that it is not necessary to carry out an acute inhalation test with the notified chemical because the 28-day inhalation study with the notified chemical demonstrated that the 4-hour LC_{50} in rats was greater than 295 mg/L and is not classified "hazardous" by the inhalation route in accordance with *Approved Criteria for Classifying Hazardous Substances*.

Draize scores: no erythema or oedema were observed at the

1 and 24 hour time points;

Test method: according to OECD guidelines (13)

Result: the notified chemical was a non-irritant to

rabbit eye

9.1.6 Skin Sensitisation (12)

Species/strain: guinea pig/albino

Number of animals: 20 males; 10 control, 10 test

Induction procedure: occluded application 0.4 mL of test material

on the dorsal anterior left quadrant for a period of 6 hours and patche removed and site washed with warm water (test group only); above precedure repeated on days 8

and 16

Challenge procedure: Day 30: occluded application of 0.4 mL of

test material for a period of 6 hours on the dorsal anterior right quadrant and site washed with warm water (test and control

groups)

Challenge outcome:

01	Test a	nimals	Control	animals
Challenge concentratio n	24 hours*	48 hours*	24 hours	48 hours
100%	0/10**	0/10	0/10	0/10

^{*} time after patch removal

Test method: according to OECD guidelines (13)

Comments: The Buehler method was chosen over the

Guinea-pig Maximisation test because of the insolubility of the test substance in water and Freunds Complete Adjuvant (FCA) and the inability to mix/disperse the test substance in

FCA

number of animals exhibiting positive response (one of the animals in the test group was found dead on test day 24 - at necropsy reddish discolouration of the lungs and abdominal cavity containing blood and blood clots were observed)

Result: the notified chemical was not a skin

sensitiser in guinea pigs

9.2 Repeated Dose Toxicity (15)

Species/strain: rat/Crl:CD(R)BR Sprague-Dawley

Number/sex of animals: 5/sex per control/dose groups

Method of administration: inhalation

Dose/Study duration: vapour of the test administered for 6 hour per

day, 5 days per week for a total of 28 days

control: 0 mg/L

low dose: 15.3 mg/L or 1489 ppm

low intermediate

 dose
 30.0 mg/L or 2935 ppm

 mid dose:
 94.9 mg/L or 9238 ppm

 high dose:
 95.3 mg/L or 28881 ppm

all animals were sacrificed 72 hours after the

treatment period,

Clinical observations: isolated incidence of piloerection, increased

foot splay and hair loss were observed but these effects were not considered to be

treatment related

Clinical Haematology:

chemistry/Haematology increased neutrophils and basophils levels

in females of the high dose group but not

observed in males

Clinical biochemistry:

increased serum glucose and cholesterol

levels in males of high dose group

Urinalysis:

elevated pH and protein levels in males of the two higher dose groups and increase in fluoride output in both males and females of

the three higher dose groups

Peroximal Proliferation Assay (palmitoyl CoA

Assay (pairiiloyi Co

oxidase)

a statistically significant increase in total protein in all males and increased in palmitoyl CoA oxidase activity in 3 males of

the high dose group and few of the mid dose

group

Macroscopic findings and

Histopathology:

no treatment-related effects were observed except increased liver weights in males of the high dose group; centrilobular hepatocyte enlargement of the liver in 4 males and females of the high dose group and in few animals in the mid dose group

Test method: according to OECD guidelines (13)

Result: the findings of this 28 day subacute toxicity

study indicate that treatment with the notified chemical at high doses induces increase in haematopoietic activity; as 60% of males showed increased proxisome proliferation (PP) activity and zero percent in females hypato histopathological effects observed in the liver at the high dose level would not appear to be associated with increase in PP

activity.

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (16)

Strains: Salmonella typhimurium TA 1535, TA 1537,

TA 98, TA 100 and Escherichia coli strain

WP2uvrA

Concentration range: 1250, 2500, 5000, 10 000 and 20 000

μg/plate

Test method: according to OECD guidelines (13)

Result: the notified chemical was not mutagenic in

the bacterial strains tested in the presence or absence of metabolic activation provided by

rat liver S9 fraction

9.3.2 Chromosome Aberration Assay in chinese hamster lung cells (17)

Dosing schedule: without S9 mix:

 $0.63 - 10 \mu g/mL$ - treatment time 24 hours

and 48 hours with S9 mix:

0.63 - 10 μg/mL - treatment time 6 hours

for all treatment groups, cells were prepared 24 hours and 48 hours after the start of treatment and scored for structural

chromosomal aberrations

Test method: according to OECD guidelines (13)

Result: the notified chemical did not induce structural

chromosomal aberrations in chinese

hamster V79 cells, in either the presence or

absence of metabolic activation

9.3.3 Micronucleus Assay in the Bone Marrow Cells of the Mouse (17)

Species/strain: bone marrow polychromatic erthrocytes of

CD-1 outbred swiss mice

Dose levels: 1 250, 2 500 and 5 000 mg/kg

Sacrifice time: 24, 48 and 72 hours

Number of animals at each dose level for each sacrifice

time: ten(5/sex)

Vehicle: aqueous 1% methylcellulose

Test method: according to OECD guidelines (13)

Result: the notified chemical did not show

statistically or biologically significant increase

in the incidence of micronucleated

plychromatic erythrocytes, compared to the

vehicle control values.

9.3.4 Cardiac Sensitisation Study ()

Species/strain: dog Beagle

Number/sex of animal: 6 males

Method of administration: inhalation

Method: adrenalin was administered by intravenous

> injection to the animals before and during inhalation of test substance; positive evidence of cardiac sensitisation would be

observed as the presence of multiple

multifocal ectopic beats or ventricular fibrillation following adrenaline administration during inhalation of the test substance; no such effects should be observed in the absence of test substance

Exposure:

all six animals were separately and sequentially exposed to the test substance at dose levels of 1.0%, 1.88% and 4.89% v/v in air; two of the six animals were also exposed to 8.93% of the test substance

Observations:

Summary of cardiac responses to adrenaline adminstration

Dog	Adrenaline	concer	ntration ir	air (%) v	//v
number	dose	1.00	1.88	4.89	8.93
1153	12	N	N	N	-
1157	04	N	Ν	N	-
1159	01	N	Ν	N	-
1161	02	N	Ν	Ν	N
1163	12	N	Ν	N	S
1119	12	N	Ν	Ν	-
Numbe	er positive	0/6	0/6	0/6	0/6
Cumulative %					
positive	e responses	0	0	0	0

at 1.0%, 1.88%, 4.89% and 8.93% v/v of the test substance in air were no indications of cardiac sensitivity; clinical signs such as restlessness, cold extremites, limb rigidity, head and whole body tremors, arched back, agitation and salivation were observed in two dogs exposed to the high dose; similar clinical signs, but less severe, were observed with all animals exposed to the 4.89% v/v dose

Result:

the notified chemical has no potential to cause cardiac sensitisation in beagle dogs at concentration up to 8.93% v/v

9.4 Overall Assessment of Toxicological Data

The notified chemical exhibited low acute oral toxicity in rats ($LD_{50} > 5\,000\,$ mg/kg). An acute inhalational toxicity study carried out in rats with normal perfluorobutyl methyl ether exibited low acute inhalation toxicity ($LC_{50} > 123.9\,$ mg/L). The notified chemical was not a skin nor eye irritant in rabbits. It

was not a skin sensitiser when tested in guinea pigs.

A repeat dose 28 day inhalation toxicity study indicated that treatment with high doses (94.9 mg/L and 295.3 mg/L at 6 hours/day, 5 days/week for 4 weeks) of the notified chemical induced increase haematopoietic activity in females with increased neutrophils and basophils. Increased peroxisome activity in some males in the two higher dose groups did not correlate to the hypato histopathological effects observed in the liver.

No mutagenicity was observed in bacteria and no clastogenicity was observed in chinese hamster cells *in vitro* and in bone marrow cells of the mouse.

A cardiac sensitisation study done on Beagle dogs showed the notified chemical was not a cardiac sensitiser

Based on the toxicological studies provided by the notifier, HFE-7100 would not be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (18).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies (Table 1) have been supplied by the notifier. The tests were carried out to OECD Test Methods.

Ecotoxicity Test Results

Test	Species	Results (mg/L)
Acute Toxicity (S; N)	Fathead minnow (<i>Pimephales promelas</i>)	96 h LC ₅₀ >7.9
Immobilisation (S; N)	Water Flea (<i>Daphnia</i> <i>magna</i>)	48 h EC ₅₀ >10
Growth Inhibition (S; N)	Algae (Selenastrum capricornutum)	72h ErC ₅₀ >8.9

F=Flow through; S=Static; N=Nominal Concentration.

To avoid volatilisation of the chemical, tests were performed in closed vessels with no head space.

During fish testing, sub lethal effects (abnormal swimming behaviour) was observed. Over the test period, only 1.25% loss in concentration of the test substance occurred. One concentration only was tested, at the limit of solubility.

No sublethal effects were observed with *Daphnia*. An average of 29% loss in concentration of the test media (over three tested concentrations) occurred.

No observations were made during algal testing. Due to the restricted gas exchange situation because of the closed test vessel, the algae media was enriched with sodium bicarbonate to allow for algal growth. A glass marble was placed in each test chamber to aid in algal suspension.

While no sublethal effects were observed with *Daphnia* and no observations were made during algae testing, the notified chemical may exhibit slight toxicity to fish, with a NOEC < 7.9 ppm. The volatility of the chemical suggests any of the notified substance entering waterways will not remain long enough for toxic effects to occur.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

When released, the notified chemical is expected to partition almost entirely to the atmosphere. It has an expected lifetime in the atmosphere of 4.1 years, which is far lower than those for many other solvents and greenhouse gases.

Because of the absence of chlorine and bromine groups, the chemical is considered to have zero ozone depleting potential.

Its global warming potential (GWP) is rated as 480 on a 100 year time horizon (ie, a radiative forcing of 480 times that of carbon dioxide). However, put in perspective, the annual release of this chemical in Australia is a maximum of 2 100 kg per annum. In the 1980's, world carbon dioxide emissions from fossil fuels and cement production amounted to over 20x10⁹ tonnes per annum (16).

Release of the solvent is reduced through management practices involving the reclaiming and recycling of solvent, and the use of sealable and returnable delivery systems from the notifier. Additionally, this chemical will be used to replace ozone depleting substances which are likely to exhibit longer atmospheric lifetimes. The environmental hazard resulting from the use of this chemical is rated as low.

The notifier will be involved in the solvent reclaiming process, and due to the inhibitory cost of the chemical, release during reclaiming will be kept to a minimum.

Hydrofluoroethers are approved by the US EPA as they are not ozone-depleting, offer reduced lifetimes compared to perfluorocarbons and are generally minimally toxic (17).

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The occupational health risk posed to waterside, transport and storage workers is negligible, as the exposure to the notified chemical will only occur in the event of an accident or leaking containers.

The notified chemical will be imported as a component of a liquid finished product. During cleaning, industrial parts are dipped into solvent containing the notified chemical. The notifier states release of chemical vapour during cleaning will be reduced by local exhaust ventilation. Should dermal, occular or inhalational exposure occur, animal data indicates that the notified chemical is unlikely to cause skin, eye, respiratory or cardiac effects at the observed levels of exposure. Therefore, there is low occupational health risk posed to those workers involved in

cleaning.

The occupational health risk for workers handling the notified chemical during loop heat transfer applications is also low, as these systems nearly always circulate fluid containing the notified chemical in low-pressure closed systems. The notifier states there could be possible exposure to service or maintenance personnel. However considering the short duration of exposure and the low inherent toxicity of the notified chemical, the occupational health risk to these workers will be low.

A repeat dose 28 day inhalation toxicity study indicated that treatment with high doses of the notified chemical induced increased haematopoietic actiivity, peroxisome proliferation in some male rats and unrelated centrilobular hypertrophy of the liver. It is unlikely that these haematological and histopathological effects will occur as a result of workplace exposure, since, workplace exposures are expected to be low.

The potential for public exposure to the notified chemical resulting from its use as a cleaning solvent is negligible. Air sampling studies have indicated that air concentrations are low in the breathing zone of the workers using the notified chemical in industry and is expected to dissipate further in ambient air. Therefore, public exposure to the notified chemical via inhalation is expected to be negligible. There is possible public exposure from the end-use application of the notified chemical as a coolant in refrigerators, but this exposure is minimised by the use of the notified chemical in a low pressure closed system. In the event of leakage, the potential for adverse acute effects is minimal, considering the low toxicity of the notified chemical.

13. RECOMMENDATIONS

To minimise occupational exposure to HFE-7100 the following guidelines and precautions should be observed:

- It is good work practice to wear industrial clothing which conforms to the specifications detailed in Australian Standard (AS) 2919 (18) and occupational footwear which conforms to Australian and New Zealand Standard (AS/NZS) 2210 (19) to minimise exposure when handling any industrial chemical;
- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly and put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the material safety data sheet (MSDS) should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (21).

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

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

Secondary notification shall be required if import volumes of the notified chemical increase to 10 tonnes per year, or if the notified chemical is to be used under different circumstances which may lead to increased environmental exposure, such as use in country dyehouses, or dyehouses discharging to inland water ways.

16. REFERENCES

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- 4. Hilaski, R. 1995, *Nose Only Acute Inhalation Toxicity Evaluation on T-6101 in Rats*, Project No. 137-177, data on file, IRDC, Mattawan.
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- 7. Glaza, S. 1996, *Dermal Sensitsation Study of T-6334 in Guniea Pigs Closed Patch Technique*, Project No. CHW 50904621, Corning Hazelton Inc., Madison.

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Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	Rating	Oedema Formation	Rating
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well- defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	Rating	Area of Cornea involved	Rating
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	Rating	Chemosis	Rating	Discharge	Rating
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and	3 severe
	30,016	Swelling with lids half-closed to completely closed	4 severe	considerable area around eye	

IRIS

Values	Rating
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe