File No: STD/1302

December 2009

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

1,1,1,3,3,3-Hexafluoropropane (HFC-236fa)

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, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

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

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Director
NICNAS

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FULL PUBLIC REPORT

The notifier has submitted with the application an assessment of the chemical by a notification and assessment scheme in an OECD country (Canada). The health and environment hazard assessment of the Canadian reports were provided to NICNAS and where appropriate used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified chemical were carried out by NICNAS.

1,1,1,3,3,3-Hexafluoropropane (HFC-236fa)

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Dupont (Australia) Ltd (ABN 59 000 716 469)
168 Walker Street
North Sydney NSW 2060

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:
Spectral data, Purity, Impurities, Import volume, Use.

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, Adsorption/desorption, Dissociation constant, Particle size, Autoignition temperature, Explosive properties, Acute oral and dermal toxicity, Skin and eye irritation, Skin sensitisation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
No

NOTIFICATION IN OTHER COUNTRIES
USA (1995), Canada (1998), and Korea (2007)

2. IDENTITY OF CHEMICAL

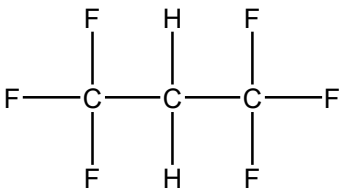
MARKETING NAME(S)
FE-36
HFC-236fa

CAS NUMBER
690-39-1

CHEMICAL NAME
1,1,1,3,3,3-Hexafluoropropane

MOLECULAR FORMULA
$C_3H_2F_6$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
152 Da

ANALYTICAL DATA
Reference IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
>90%

ADDITIVES/ADJUVANTS
NONE

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20ºC AND 101.3 kPa: Colourless gas

Property	Value	Data Source/Justification
Melting Point/Freezing Point	-103ºC	Measured
Boiling Point	-2ºC at 101.3 kPa	Measured
Density (gas)	6.18 kg/m^3 at 22.4ºC	Measured
Vapour Pressure	249 kPa at 25ºC	Measured
Water Solubility	0.724 g/L at 20ºC	Measured
Hydrolysis as a Function of pH	Not determined	Like other hydrofluorocarbons, the notified chemical is expected to be hydrolytically stable.
Partition Coefficient (n-octanol/water)	log P_{ow} = 1.12	Calculated by fragment method. This parameter could not be measured because the notified chemical is a gas that will partition to the atmosphere from water and octanol.
Surface Tension	73.0 mN/m	Measured
Adsorption/Desorption	Not determined	This parameter is not relevant to environmental assessment as the notified chemical is a gas that will partition to the atmosphere.
Dissociation Constant	Not determined	The notified chemical contains no dissociable groups.
Particle Size	Not determined	The notified chemical is a gas at room temperature
Flash Point	Not determined	Does not ignite
Flammability	Non flammable	Measured
Autoignition Temperature	482.85ºC	Estimated by model
Explosive Properties	Not expected to be explosive	The structural formula contains no explosophores.

DISCUSSION OF PROPERTIES
The notified chemical is a gas at 20ºC that is non-flammable, denser than air and has some degree of water solubility. The water solubility measurement is consistent with the mean measured concentrations recorded in stock solutions prepared by bubbling the gas through water and used for aquatic toxicity testing. Available physico-chemical data for the notified chemical indicate that it will partition to the atmosphere. Sufficient information is available for assessment. The key property for evaluating the environmental risk of the notified chemical is the atmospheric lifetime, which is discussed further in section 7.1.2.

For full details of tests on physical and chemical properties, please refer to Appendix A.

Reactivity
The notified chemical is not reactive with water or air under normal conditions (<150ºC), and is predicted to not possess oxidising properties. Hazardous decomposition products of the notified chemical include hydrogen halides, carbon dioxide, carbon monoxide, fluorocarbons, and carbonyl halides.

Dangerous Goods classification
Based on the available data, the notified chemical is classified as follows according to the Australian Dangerous Goods Code (FORS, 1998):

Class 2.2 – Non-flammable, non-toxic gases.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical (at >95%) will be imported by sea in 56, 250 and 700 kg steel US DOT approved cylinders.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<2.4	<2.5	<3.5	<4.0	<4.0

PORT OF ENTRY
Sydney, Melbourne, Brisbane, Adelaide and Perth (Kwinana).

TRANSPORTATION AND PACKAGING
The notified chemical as introduced will be transported from the wharves by road to the distributor.

USE
The notified chemical will be used as a heat transfer liquid (refrigerant) for air-conditioning units in industrial settings, and as a fire extinguishing agent.

As a fire extinguishant, the notified chemical will mainly provide fire protection for high value assets or irreplaceable objects that could be damaged or destroyed by conventional fire suppression agents. It may also be used with electronic equipment and circuits and is a point and shoot streaming agent to put out electrical fires in areas such as computer rooms, telephone exchanges and electrical switch gear.

OPERATION DESCRIPTION
Use as a Refrigerant
The notified chemical (at >95%) will be transferred from the import cylinders into 5-20 kg cylinders via hoses and interlock valves for filling air conditioners. The transfer will take place in an open shed with good ventilation.

Refrigeration technicians will top-up or fill air-conditioning units with the notified chemical (at >95%) by transfer from the 5-20 kg cylinders using interlock valves and hoses. Refrigeration technicians will also empty the air-conditioning units during maintenance and end-of-service life of the units. In these instances, the notified chemical will be transferred to a holding tank before being disposed to Refrigerant Reclaim Australia.

Use as a Fire Extinguishing Medium
The notified chemical can be used as a total flooding agent (the fire extinguishing concentration is distributed throughout the enclosure) or local application such as a handheld portable fire extinguisher where the extinguishing concentration is established in a localized area. The notified chemical is maintained in the storage container until release for the purpose of extinguishing a fire.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS (FOR USE AS A REFRIGERANT)

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport workers	5	4	2
Storemen	10	0.2	50
Repackaging (decanting) workers	5	0.2	50
Refrigeration technicians	10	0.2	10

NUMBER AND CATEGORY OF WORKERS (FOR USE AS A FIRE EXTINGUISHING MEDIUM)
It is expected that the number of workers involved in the transportation, storage and repackaging of the notified chemical would be same as is for use as a refrigerant. However exposure would be significantly increased if release of the notified chemical occurs in firefighting. In addition, fire officers will also be using the fire extinguishing medium.

EXPOSURE DETAILS
Potential routes of occupational exposure are dermal, ocular and inhalation. However as the notified chemical is a gas at room temperature, inhalation is the main route of exposure expected. Dermal and ocular exposure to liquid material may occur during transfer operations or accidental leakage.

Occupational exposure is possible during import, transport, repackaging (decanting), filling, topping-up and emptying air-conditioning units, particularly when connecting and disconnecting transfer hoses, and during the release to extinguish a fire.

Transport workers and storemen are not expected to be exposed to the notified chemical except in the unlikely event of an accident.

For use as a refrigerant, the main occupational exposure is expected during air-conditioning installation, filling, topping-up and emptying air-conditioning units, particularly when connecting and disconnecting transfer hoses. However, the potential for exposure will be small during filling as the hose used for the transfer processes being short and smaller diameter.

For use as a fire extinguishing medium, the main occupational exposure is expected during filling, maintenance of the system, an accident discharge, and during the release into a workspace to extinguish a fire. Exposure during manual firefighting may occur. When fixed flooding systems are discharged, this may be done automatically and exposure may not occur.

Awareness of exposure to leakage of the notified chemical may not occur, because as a gas it is odourless and colourless.

Exposure to the combustion products of the notified chemical may occur during fire-fighting, and after re-entry to an area in which the notified chemical has been used as a fire extinguishant.

6.1.2. Public exposure
For use as a refrigerant, the general public will not be exposed to the notified chemical, as it will only be used in air-conditioning units in industrial settings. Similarly, for use as a fire-extinguishing medium, the general public will not be exposed to the notified chemical, as it will only be used by trained personnel. However, the general public can be exposed as a bystander during release into a workspace to extinguish a fire.

6.2. Human health effects assessment

6.2.1. Toxicology studies on the notified chemical

The results from toxicological investigations conducted on the notified chemical are summarised in the table below.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	Not submitted. Inhalation would be the primary route of exposure.
Rat, acute dermal toxicity	
Rat, acute inhalation toxicity (4 hr)	LC_{50} > 189,000 ppm (1,175mg/L) LC_{50} > 457,000 ppm (2,841mg/L) low toxicity
Rabbit, skin irritation	Not submitted.
Rabbit, eye irritation	Not submitted
Guinea pig, skin sensitisation – adjuvant test	Not submitted.
Rat, repeat dose inhalation toxicity - 14 days	NOAEL 5,000 ppm
Rat, repeat dose inhalation toxicity - 90 days	NOAEL 20,000 ppm
Mutagenicity – bacterial reverse mutation test	non mutagenic
Genotoxicity–in vitro chromosomal aberration in human lymphocytes test	non genotoxic
Genotoxicity– in vivo mouse bone marrow micronucleus test	non genotoxic
Dogs, cardiac sensitisation	Cardiac sensitization at 150,000 ppm and above
Rat & rabbit, developmental effects	No significant treatment-related

6.2.2. Summaries of the toxicology studies

Systemic Toxicology

The notified substance was found to have low toxicity through inhalation (rat LC_{50} > 457,000 ppm, rat LC_{50} > 189,000 ppm)

Published information indicated that the notified substance caused cardiac sensitization in beagle dogs at 150,000 ppm and above, while no such effect was observed at 100,000 ppm. The relevance of this effect to humans, particularly at such a high concentration, is not clear.

In the 14-day inhalation study, rats were exposed (whole body) to the notified substance 6 hrs/day, 5 days/week, for two weeks at concentrations of 5,000, 20,000 or 50,000 ppm. No mortalities were observed in any of the groups. Mild anesthetic effects in the form of diminished response to an alerting stimulus at 20,000 ppm and lack of response to an alerting stimulus at 50,000 ppm, was observed during the first week of exposure; however, rats showed normal alerting response in the second week of exposure, indicating ability to develop tolerance with time. No other clinical signs of toxicity were reported. Some changes were observed in hematology and clinical chemistry parameters; however, they were not considered to be of toxicological significance. Gross and microscopic examination at necropsy revealed no treatment related changes. The NOAEL was reported as 5,000 ppm. The effects on response to alerting stimulus, observed at 20,000 and 50,000 ppm was considered adverse.

In the 90-day inhalation study, rats were exposed (whole body) to the notified substance 6 hrs/day, 5 days/week, for 14 weeks at concentrations of 5,000, 20,000 or 50,000 ppm. One female in the 5,000 ppm died due to eye injury. No other mortalities were observed in any of the groups. Mild anesthetic effects in the form of diminished response to an alerting stimulus at 50,000 ppm was observed during the first week of exposure; however, the number of rats affected generally decreased with successive exposures and by day 18 all rats from this group had normal alerting responses, indicating ability to develop tolerance. No other clinical signs of toxicity were reported. No changes were observed in food consumption or food efficiency. Some transient body weight increases were observed in treated animals compared to controls; however, by the end of the study the overall body weight gains were not statistically different than controls. Opthalmological evaluation revealed no treatment related ocular abnormalities. Some changes were observed in hematology and clinical chemistry parameters, however, they were not considered to be of toxicological significance. Urinalysis revealed no abnormalities.

Gross and microscopic examination at necropsy revealed no treatment related changes. A statistically significant increase in relative kidney/body weight ratio was observed in males in the 50,000 ppm group when compared to controls, and statistically significant decrease in relative kidney/brain weight ratio was observed in females in the 50,000 ppm group when compared to controls. In absence of microscopic finding, these changes were considered incidental. Gross and microscopic examination at necropsy revealed no compound related changes. Some sporadic changes occurred in control and treatment groups and were not treatment related. The NOAEL was reported as 20,000 ppm. The effects on response to alerting stimulus, observed at 50,000 ppm, was considered adverse.

Genotoxicity

An Ames test (plate incorporation, gas 99.7% pure, proportions of 0 to 100% of notified substance in atmosphere were used, 7 groups, Salmonella typhimurium TA 100/1535/97/98 and E. coli WP2uvrA, 3 plates per concentration, two trials each with and without S9 was conducted. Toxicity was seen in the 100% group possibly attributable to anoxia. Leakage of notified gas was observed over 48 h of the exposure period to the extent of ending up with 10-40% lower concentrations than initial levels, after 48h. Adequate response was seen in the positive control group. No evidence of significant mutagenicity was observed.

Chromosomal aberrations (human lymphocyte culture, gas 99.7% pure, 0 to 100% proportion of notified substance in initial atmosphere with no significant leakage observed, 5 groups, 100 cells scored per dose, 2 trials, each with and without S9 were examined. Adequate response was seen in the positive control group. No toxicity or evidence of significant clastogenicity were observed in this *in vitro* assay.

An *in vivo* mouse bone marrow micronucleus test was conducted (5 mice per sex per dose, 0 to 50000 ppm, 4 groups, whole body exposure, inhalation, 6h per day for 2 days, 2000 cells per animal, acridine orange staining. Reversible gastrointestinal and central nervous system effects were observed indicating adequate target tissue delivery. No significant micronucleus formation was observed.

Overall, no significant evidence of genotoxicity was observed in the tests conducted with the notified substance.

Developmental Toxicity

Two studies were submitted. In rabbits (20 per dose, 0, 5000, 20000, or 50000 ppm of 99.7% pure gas, 6 h per day from day 7 to 19 of gestation, no mortalities or significant treatment-related changes in standard maternal parameters were observed. The highest concentration used was sub-anesthetic. A dose-related negative trend was observed in the litter size (range of 9%). Subsequently, historical control values from the laboratory were sought and the observed variation was well-within the range of historical control values for litter size and was not considered as toxicologically significant. Some degree of growth retardation and delayed ossification was seen in the groups, but without any treatment-related pattern. One dam out of 20 in each of the dose groups had notably small litter sizes (3 to 4 pups). The three pups from the 5000 ppm dam were heavier than usual, 3/3 had retarded ossification, while 2/3 had some signs of edema and haemorrhage. At the next higher concentration (20000 ppm) 3/4 pups were normal while the remaining showed signs of haemorrhage. Finally, the dam from the 50000 ppm group had 2/3 normal pups while the third one had retarded ossification. None of these findings were considered as indicative of a significant treatment-related developmental deficit. The maternal and foetal NOAELs were 50,000 ppm

In rats (25 rats per dose, 0, 5000, 20000, or 50000 ppm of 99.7% pure gas, 6 h per day from day 7 to 16 of gestation, diminished alerting response was seen at the highest concentration, but the animals developed tolerance to the mild anesthetic effect over 4 days. A statistically significant reduction (< 10% of control values) in food consumption was seen at 50000 ppm at certain intervals during the study while significant reduction in body weight gain (> 10% of control values at the highest dose) was seen in the 20000 and 50000 ppm groups at day 7-9 interval but not at other sampling intervals. These individual animals that showed a slight reduction in b.wt and food consumption during the first few days of dosing resumed and maintained their feeding and growth later on and the transient effect does not represent significant toxicity. A greater magnitude of these effects and a more consistent pattern at other sampling intervals would have caused greater toxicological concern. No significant adverse effect was seen in the foetal parameters. Based on the above findings, the maternal NOAEL and the foetal NOAEL were considered to be 50,000 ppm.

No significant treatment-related changes indicative of developmental toxicity were observed in rabbits and rats.

6.2.3. Summary of Human Health Effects

Toxicokinetics, metabolism and distribution.
The notifier has not submitted any information on toxicokinetics, metabolism and distribution of the notified chemical. Partition coefficient determinations showed limited solubility of the notified chemical in blood and tissues. The blood:air partition coefficient is approximately 0.7. This means that residence time of the notified chemical in the body is short; it will be breathed out relatively fast after exposure is stopped.

Acute toxicity
Acute oral and dermal toxicity studies were not submitted, as the notified chemical is a gas and administration of the notified chemical orally or dermally would have been technically difficult.

Inhalation would be the primary route of exposure and acute and repeated dose inhalation studies have been performed on the notified chemical. The notified substance was found to have low acute toxicity through inhalation (rat LC_{50} > 457,000 ppm; rat LC_{50} > 189,000 ppm).

A brochure of the notified chemical states that inhaling high concentrations of the notified chemical may cause temporary nervous system depression with anaesthetic effects such as dizziness, headache, confusion, loss of coordination, and even loss of consciousness. Inhalation exposure to high levels of the notified chemical may lead to cardiac sensitisation or adverse long-term effects.

Irritation and Sensitisation
Skin irritation, eye irritation and skin sensitisation studies were not submitted. As the notified chemical is a gas, it was technically difficult to conduct these studies. However, no irritation was reported in the acute and repeated dose inhalation studies conducted using whole animal exposure, as exposure to skin and mucous membranes would have occurred in these studies.

Repeated Dose Toxicity
In the 14-day and 90-day inhalation studies in rats, no mortalities were observed in any of the groups. Mild anaesthetic effects in the form of diminished response to an alerting stimulus was observed during the first week of exposure in both studies; however, rats showed normal alerting response in the second week of exposure in the 14-day study and by day 18 in the 90-day study, indicating ability to develop tolerance with time. No other clinical signs of toxicity were reported. Gross and microscopic examination at necropsy revealed no treatment related changes. In the 14-day study, the NOAEL was 5,000 ppm, based on the adverse effects on response to alerting stimulus observed at 20,000 and 50,000 ppm. In the 90-day study, the NOAEL was 20,000 ppm, based on the adverse effects on response to alerting stimulus observed at 50,000 ppm.

The notified chemical caused cardiac sensitization in beagle dogs at 150,000 ppm and above, while no such effect was observed at 100,000 ppm.

Mutagenicity
The notified chemical was found to be non-mutagenic in a bacterial reverse mutation test and also showed no evidence of clastogenicity to human lymphocytes *in vitro* and in mouse bone marrow micronucleus test *in vivo*. Based on these results, the notified chemical is not suspected to be genotoxic.
Carcinogenicity
Information is not available for the carcinogenic potentials of the notified chemical.

Toxicity for reproduction/development
No significant treatment-related changes indicative of developmental toxicity were observed in rabbits and rats.

Physico-chemical hazard
Release of the material may cause frostbite burns to skin or eyes.

Health hazard classification
Based on the available data the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Acute oral and dermal toxicity studies were not available. The notified chemical was found to have low acute toxicity through inhalation (rat LC_{50} > 457,000 ppm; rat LC_{50} > 189,000 ppm). Skin irritation, eye irritation and skin sensitisation studies were also not available, however, no irritation was reported in the acute and repeated dose inhalation studies conducted using whole animal exposure, where exposure to skin and mucous membranes would have occurred. The notified chemical was not mutagenic in *in vivo* or *in vitro* assays. No significant treatment-related changes indicative of developmental toxicity were observed in rabbits or rats.

In the 14-day inhalation study, the NOAEL was 5,000 ppm, and in the 90-day inhalation study, the NOAEL was 20,000 ppm. These studies also indicated the ability to develop tolerance with time and that the mild anaesthetic effects were reversible even during the treatment. The cardiac sensitization effect was observed in beagle dogs at 150,000 ppm and above, while no such effect was observed at 100,000 ppm (NOEL= 100,000)

For use as a refrigerant, the main occupational exposure risk is expected during air-conditioning installation, filling, topping-up and emptying air-conditioning units, particularly when connecting and disconnecting transfer hoses. Engineering controls and personal protective equipment (PPE) are expected to be used during these procedures to minimise exposure. Decanting will be performed in an open shed with good ventilation and while wearing PPE. Scenarios with high exposure include those with poor ventilation or confined spaces, those where aerosols are generated, and those including filling, topping-up and emptying air-conditioning units.

For use as a fire-extinguishing medium, the main occupational exposure risk is expected during filling, maintenance of the system, and during the release into a workspace to extinguish a fire or an accidental discharge. The notified chemical has a high vapour pressure and as a result, it will volatilise rapidly on release. Therefore, the most likely route of exposure to any released gas will be through inhalation. Furthermore, vapours of the notified chemicals are heavier than air and can cause suffocation by reducing oxygen available for breathing. However, because the notified chemical will rapidly dissipate, exposure to elevated levels of the gas for any extended period of time will be unlikely, except in very confined spaces. Inhaling high concentrations of the notified chemical may cause temporary nervous system depression with anaesthetic effects such as dizziness, headache, confusion, loss of coordination, and even loss of consciousness. Inhalation exposure to high levels of the notified chemical may lead to cardiac sensitisation or adverse long-term effects.

Considering the health effects of the notified chemical, the restriction of airborne concentrations to low levels in the workplace situation is important to minimise the risk of adverse health effects from inhalation exposure to the notified chemical. Scenarios with high exposure include those with poor ventilation or confined spaces, those where aerosols are generated, and those where there is accidental discharge of the notified chemical. Inhalation exposure to airborne concentrations of the notified chemical can also be minimised by the use of the notified chemical in well-ventilated areas. However, if significant inhalation exposure is expected, respiratory protection is warranted.

There is at present no Australian occupational exposure limit for the notified chemical. However, the notifier has set an acceptable exposure limit (AEL) for 8- or 12 hour time-weighted average (TWA) inhalation exposure of 1000 ppm.

The notified chemical is imported as 99% pure gas in pressurised containers. At room temperature, vapours have little or no effect on the skin or on eyes. However, in the liquid form, the notified chemical can freeze skin or eyes on contact, causing frostbite. Therefore, the use of protective clothing and eye protection is recommended when using the notified chemical.

There is risk of exposure to hazardous decomposition products of the notified chemical during and after the use of the notified chemical in firefighting. Precaution should be taken to avoid inhalation of hazardous decomposition products during and after the use of the notified chemical in firefighting.

For use as a fire-extinguishing medium, the main occupational exposure risk is expected during filling, maintenance of the system, and during the release into a workspace to extinguish a fire or an accidental discharge. Because this is a life safety devise, the notifier has advised NICNAS that there are significant required procedures in standards and regulations to assure human exposure to the agent is minimized and that the concentration must be below the 5-minute safe human exposure limit. These standards and regulations also require the owner to maintain the equipment and monitor for any leakage and immediate corrective action is also required if any leakage is detected. These standards and regulations also contain the required maintenance and inspection procedures to assure the unit is operational. The notifier has also advised that there are separate standards and regulations concerning the use of portable fire extinguisher.

As the notified chemical will be sold as a specialized product, the notifier has advised NICNAS that it should only be used by trained personal. The notifier has also advised NICNAS that air conditioning and refrigeration is a recognised trade and is supported by the TAFE education system with a 3 years certificate course. In addition, the notifier also offers targeted training for its distributors and their maintenance staff upon request and product stewardship reviews of distributors are conducted once every three years.

Therefore, considering the use, controls in place, education and training, and the health effects of the notified chemical, the risk to workers is expected to be low.

6.3.2. Public health

The application as a refrigerant for use in air-conditioning units is directly related to a low volume industrial setting that does not have the public in close proximity. The application as a fire extinguishing medium will be used in industrial or commercial environment and public will not have direct access to the notified chemical or involved in its application. However, public may be exposed as a bystander for a brief period of time in the event of a fire.

Therefore, based on the above, public exposure to the notified chemical is expected to be low and the risk to public health is also considered to be low.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical is imported as 99% pure gas in pressurised containers. There will be no reformulation in Australia, but minor releases (0.6%) may occur at distributor storage sites from connector hoses used to transfer the notified chemical to smaller containers and natural leakage from cylinders.

RELEASE OF CHEMICAL FROM USE

The deliberate venting to the atmosphere of hydrofluorocarbons such as the notified chemical is prohibited under federal and state legislation. Technicians must be trained and accredited, and owners are required to maintain equipment and monitor for leakage, with immediate corrective action where leaks are detected. Use for fire protection is considered non-emissive, as the gas is required to be contained within equipment unless needed for fire suppression, but release of the notified chemical from testing of fire protection systems is prohibited.

Estimated annual releases from transfer operations at user sites are 4% of the imported quantity. Releases for fire suppression are impossible to predict, but expected to be low. Use for fire suppression is expected to be restricted to high value applications. A hypothetical worst case of 100% will be assumed for this assessment.

RELEASE OF CHEMICAL FROM DISPOSAL

Used gas must be collected and returned to Refrigerants Reclaim Australia for recycling. Economic considerations are expected to favour reuse. In the unlikely event that disposal is required, this will entail destruction at a licensed destruction facility by plasma arc. A further 0.5% of the imported quantity may be released annually during reclamation and destruction.

7.1.2 Environmental fate

The notified chemical is a stable gas that is expected to partition almost entirely to the atmosphere. Spills to water will rapidly volatilise, while releases to soil are expected to partition to soil pore space. The water solubility and rapid volatilisation from water will preclude any significant bioaccumulation in aquatic biota.

The substance was subjected to a biodegradation study using the Closed Bottle Test (OECD 301D). Biodegradation was measured using BOD and actual concentration by GC. Using BOD, degradation of the substance was measured at 16% over the 28 day test period while the residue of test substance was 100%, indicating the substance was not biodegradable. Similar results were obtained for analogue substances in three other biodegradability tests.

Expectations that the notified chemical will persist in the atmosphere are confirmed in the published scientific literature. The atmospheric lifetime is prolonged, with a value of 240 years reported in IPCC/TEAP (2005). This compares with lifetimes of 7.6 years for the lower homologue 1,1,1,3,3-pentafluoroethane (STD/920) and 34.2 years for the higher homologue 1,1,1,2,3,3,3-heptafluoropropane (STD/164). The main route for removal from the atmosphere is expected to be reaction with hydroxyl radicals.

7.1.3 Predicted Environmental Concentration (PEC)

A predicted environmental concentration for aquatic exposures cannot be calculated because the notified chemical is a volatile gas and no aquatic exposure is anticipated.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	EC50 = 292 (220-544) mg/L	Not harmful
Daphnia Toxicity	EC50 = 299 (190-354) mg/L	Not harmful
Algal Toxicity	EC50 > 186 mg/L	Not harmful

A 96 hour static test was conducted to assess the acute effects of the substance on Zebra fish (*Brachydanio rerio*). The fish were exposed to solutions with mean measured concentrations of 84, 140, 240, 390 and 660 mg/L in containers with minimal headspace. Sublethal effects were observed at concentrations of 220 mg/L and greater.

An acute toxicity study has been performed on *Daphnia magna* in containers without headspace to avoid loss due to volatilization. Nominal concentrations ranged from 94 to 730 mg/L. Mean recoveries ranged from 73 to 83%. Measured concentrations were used for the calculations.

A 96 hour static toxicity limit test was conducted on *Selenastrum capricornutum*. A nominal test concentration of 720 mg/L was used (75% stock, 25% medium dilution) which contained an appropriate level of dissolved oxygen. The initial measured concentration was 663 mg/L while the final concentration was 52.1 mg/L, with the loss being attributed to volatilization. The geometric mean of the concentrations at the beginning and end of the study is 186 mg/L. Neither the mean cell density nor the growth rate was affected in the study.

7.2.1 Predicted No-Effect Concentration

It is neither necessary nor meaningful to determine a predicted no-effect concentration as no aquatic exposure is expected.

7.3. Environmental risk assessment

The proposed uses of the notified chemical may present a risk to the environment because of its contribution to global warming. This contribution arises from its atmospheric persistence and ability to absorb infrared radiation. Global warming potentials are determined relative to carbon dioxide over various time horizons (typically 20, 100 and 500 years). The most recent values reported in IPCC/TEAP (2005) are 7620, 9500 and 7700, respectively.

The hypothetical worst case upper limit for annual atmospheric releases of the notified chemical is 2.2 tonnes. This compares with Australia's estimated anthropogenic emissions of gases not controlled by the Montreal Protocol for the base year (1990) of more than 500 x 10^6 tonnes carbon dioxide (DECC, 2008). The worst case upper limit for releases of the notified chemical represents a very small increment (< 0.005%) to total anthropogenic greenhouse gas emissions. The net contribution of the notified chemical to global warming will be further reduced as it will replace other gases with similar properties.

The notified chemical is not expected to contribute to stratospheric ozone depletion because it does not contain chlorine or bromine. It will replace halon and hydrochlorofluorocarbon compounds that do have ozone depletion potential.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Human health risk assessment

Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified chemical is not considered to pose an unacceptable risk to public health.

Environmental risk assessment

On the basis of the global warming potential and the notified use pattern, the notified chemical may pose a risk to the environment. While the contribution to global warming is expected to be very small relative to current anthropogenic emissions, every precaution must be taken to avoid releases to the atmosphere, as required under federal and state legislation.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- The notified chemical should be classified as follows under the ADG Code:
  - Class 2.2 – Non-flammable, non-toxic gases.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - Ensure that workers are not exposed to the notified chemical in high concentrations e.g., in confined spaces.
  - Workers should be trained in the safe handling of the notified chemical, and where appropriate, should be accredited for handling hydrofluorocarbons.
  - The notified chemical has virtually no odour. Therefore, equipment should be maintained and monitored for leaks, with immediate corrective action where leaks are detected.
  - Ensure that worker exposure to the notified chemical and its decomposition products during and after fire-fighting is minimised.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Safety glasses, gloves, and coveralls are recommended to avoid frost burns.
  - Respiratory protection is warranted if significant inhalation exposure is expected, such as in scenarios with poor ventilation or confined spaces, those where aerosols are generated.

  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 *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Public Health

- The following measures should be taken by distributors and equipment owners to minimise public exposure to the notified chemical when used in commercial settings:
  - Equipment must be maintained and monitored for leaks, with immediate corrective action where leaks are detected.

Environment

- The following control measures should be implemented by distributors and equipment owners to minimise environmental exposure during storage and use of the notified chemical:
  - Technicians must be trained and accredited for handling hydrofluorocarbons.
  - Equipment must be maintained and monitored for leaks, with immediate corrective action where leaks are detected.
  - The notified chemical must not be vented to the atmosphere, except when used for *fire suppression.*

Disposal

- The notified chemical must be disposed of at a licensed extinguishing agent or refrigerant destruction facility.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by ventilating enclosed areas until safe for re-entry.

Transport and Packaging

- As the notified chemical has been classified under the ADG Code, proper transportation and packing requirements should be followed.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from use as a refrigerant or fire extinguishing medium, or is likely to change significantly;
- the amount of chemical being introduced has increased from 4 tonnes, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet
The MSDS of the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point -103ºC

Method	Equivalent to OECD TG 102 Melting Point/Melting Range.
Remarks	DSC method
Test Facility	TNO PML (1997a)

Boiling Point -2ºC at 101.3 kPa

Method	Equivalent to OECD TG 103 Boiling Point.
Remarks	DSC method
Test Facility	TNO PML (1997a)

Density 6.18 ± 0.06 kg/m^3 at 22.4ºC

Method	EC Directive 92/69/EEC A.3 Relative Density.
Test Facility	TNO PML (1997a)

Vapour Pressure 249 kPa at 25ºC

Method	EC Directive 92/69/EEC A.4 Vapour Pressure.
Test Facility	TNO PML (1997a)

Water Solubility 0.724 ± 0.042 g/L at 20ºC

Method	EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Flask Method. Measured by gas chromatographic analysis of a saturated solution prepared by bubbling the gas through water.
Test Facility	TNO PML (1997a)

Partition Coefficient (n-octanol/water) log P_{ow} at 20ºC = 1.12

Method	EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks	Calculation method
Test Facility	TNO PML (1997b)

Surface Tension 73 mN/m at 20ºC

Method	EC Directive 92/69/EEC A.5 Surface Tension.
Remarks	Concentration: 638 mg/L
Test Facility	TNO PML (1997b)

Flammability Non flammable

Method	EC Directive 92/69/EEC A.11 Flammability (Gases).
Remarks	Tests were performed at concentrations ranging from 1.4 to 28.0% at 20ºC and 101.4 kPa.
Test Facility	TNO PML (1997a)

Autoignition Temperature 482.85ºC

Method	Estimated using model
Test Facility	MTU (1996)

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