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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Heptafluoropropane (HFC-227ea)

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Heptafluoropropane (HFC-227ea)

1. APPLICANT

First Applicant

An Assessment Certificate for the chemical Heptafluoropropane was granted to Biolab Australia Pty Ltd of Factory 3, 61 – 63 Canterbury Road, MONTROSE VIC 3765.

The Assessment Report for Heptafluoropropane is identified by the sequence number NA/164.

Second applicant

Since the granting of the original Assessment Certificate, Kidde-Graviner (Australia) Pty Ltd of 328 Boundary Road DINGLEY VIC 3172 has submitted a notification statement in support of their application for an extension of the original assessment certificate for heptafluoropropane.

Biolab Australia Pty Ltd has agreed to this extension.

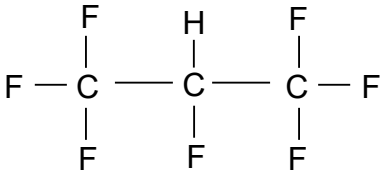
Additional information has been submitted on behalf of Kidde-Graviner (Australia) Pty Ltd, on maternal and developmental toxicity and 90-day repeated dose inhalation toxicity of the notified chemical.

The only important difference in matters affecting occupational, environmental or public exposure as set out in the notification statement that accompanied the application for extension of the original certificate, is the significant increase in the import volume of the notified chemical.

2. IDENTITY OF THE CHEMICAL

Notifer has not requested any information to be considered confidential.

Chemical Name:	1,1,1,2,3,3,3-Heptafluoropropane
Chemical Abstracts Service (CAS) Registry No.:	431-89-0

Other Names:	HFC-227ea 2H-Heptafluoropropane
Marketing Name:	FM-200
Molecular Formula:	C_3F_7H
Structural Formula:	
Molecular Weight:	170.03
Method of Detection and Determination:	infrared spectroscopy or mass spectrometry
Spectral Data:	An infrared spectrum was provided with major peaks at approximately 1125, 1220, 1240, 1305 and 1390 cm^{-1}. A mass spectrum was also provided

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	colourless gas
Odour:	odourless
Boiling Point:	-16.4°C
Specific Gravity:	1.46 (air = 1)
Vapour Pressure:	84 kPa at -18°C 195 kPa at 0°C 404 kPa at 21°C 1046 kPa at 55°C

Water Solubility:	no data were submitted, but reference is made in the biodegradation test to a solubility of 0.26 g/L; estimated using Irmann's equation (1), water solubility is approximately 0.23g/L
Hydrolysis as a Function of pH:	the chemical contains no hydrolysable functionalities
Dissociation Constant:	the chemical contains no readily dissociable groups
Reactivity/Stability:	reacts with strong oxidising agents
Ozone Depleting Potential:	negligible
Atmospheric Lifetime:	42 years

Comments on Physico-Chemical Properties

Data on partition co-efficient and adsorption/desorption were not provided. This is acceptable given the low water solubility and the gaseous state of the notified chemical.

Data for flash point, flammability limits, explosive properties and autoignition temperature were not provided. These data were not required for the notified chemical as it possesses fire-extinguishing properties. Upon exposure to a flame or a hot surface >700°C, the notified chemical will decompose to hydrogen fluoride and other toxic or irritating vapours (2).

4. PURITY OF THE CHEMICAL

Degree of Purity:	approximately 99.6%
Hazardous Impurities:	none known
Non-hazardous Impurities (> 1% by weight):	none
Additives/Adjuvants:	nitrogen gas (CAS No 7727-37-9); weight percentage will vary with pressure requirements of firefighting system

5. USE, VOLUME AND FORMULATION

HFC-227ea will not be manufactured in Australia. The chemical will be imported in pressurised, ready to use containers or tanks and used as a replacement gas for Halon 1301 in total flooding fire-extinguishing systems. The notified chemical extinguishes fires by physically cooling the fuel and by the production of free radicals during decomposition which interfere with the combustion process.

Total flooding fire extinguishing systems are used in contained areas to protect such equipment as computer rooms and telecommunications switching facilities, oil production facilities, records storage facilities, aircraft cargo bays, flammable liquid storage facilities and laboratories, and public areas such as libraries, museums, shopping malls and tourist facilities. HFC-227ea is proposed to be used in industrial applications only, with typical firefighting applications involving dry electrical hazards, such as switching equipment, computer hardware and electrical circuits. It is estimated that 50 tonnes will be imported in the first year increasing to 150 tonnes by the fifth year.

In the application for extension, the import volume for the notified chemical is estimated to be in the range of 10 – 100 tonnes per annum in the first 5 years.

6. OCCUPATIONAL EXPOSURE

Exposure to HFC-227ea may result during transportation, servicing or use.

As the notified chemical will be imported and distributed in pressurised containers or tanks (0.5 to 10 tonnes), exposure during transport should result only in the event of handling accidents. The types of workers likely to be exposed in these situations include dock workers, warehouse workers, transport drivers, police and rescue personnel as well as firefighters.

During servicing and recharging of fire systems, installation fitters and maintenance personnel may be exposed to the chemical in the event of leakages of compressed gas from the tanks. The notifier has indicated, however, that leakages should be minor, and workers will wear appropriate gloves and goggles during servicing of the equipment to avoid cold burns.

The greatest potential for exposure will be during firefighting procedures. The notified chemical will be used in total flooding systems installed in fixed enclosures. The extent of exposure during firefighting will be entirely dependent on the number of fire emergencies and the materials fuelling the fires.

In order for the gas to be effective as a fire extinguisher, it will be used and maintained at a concentration of at least 5.8% (3). Concentrations will generally be between 7 and 9% but may reach levels greater than 14%.

There is a potential for workers to be exposed during evacuation. A draft Australian Standard (2) describes maximum permissible flooding concentrations based on expected evacuation times. Generally speaking, workers should not be exposed for greater than 60 seconds to

concentrations over 9.7% but no greater than 10.5%. A maximum of 30 seconds is recommended for concentrations greater than 10% but less than 14%.

In most cases, with the use of warning devices and time delay mechanisms, personnel will be evacuated before the extinguishant is released. Appropriate personal protective devices, such as self contained breathing apparatus, will be required when worker exposure is anticipated.

7. PUBLIC EXPOSURE

Some leakage of the chemical is expected during extinguisher system servicing and recharging, however the notifier has indicated that this should be minor, and consequently there should be low potential for public exposure during these procedures. The notifier has indicated that any discharge testing of extinguisher systems would be performed with other AICS-listed gases, due to the expense of HFC-227ea.

8. ENVIRONMENTAL EXPOSURE

Release

Use of HFC-227ea will entail inevitable atmospheric release in the case of fire. Minor amounts may escape during recharging of fire extinguishing systems, but economic considerations would be expected to minimise such losses.

State legislation prohibits discharge of halons during testing and training. A draft Standard (revised December1993) (2) for HFC-227ea (FM-200) systems contains details of discharge testing, in which it is specified that "the test medium shall be FM 200". However, a consultant for the applicant has disclosed that other propellants would be used should any discharge testing be required, because of the high cost of HFC-227ea. The draft Standard should be updated accordingly.

High temperature incineration is recommended for any HFC-227ea that requires disposal. This would need to be preceded by export as such facilities do not exist currently in Australia. However, such situations are not expected to arise under normal use conditions, as economic considerations will favour recovery.

Fate

Given its high volatility, any HFC-227ea released to the environment will partition almost entirely to the atmosphere. Any traces entering water would not be expected to undergo biodegradation at significant rates as degradation by activated sludge in a closed bottle test, OECD Test Guideline 301D (4), was minimal (28day biological oxygen demand 1% of theoretical). The main degradation pathway in the environment is reaction with tropospheric hydroxyl radicals, which abstract hydrogen. The estimated atmospheric lifetime is 42years (5).

Detailed atmospheric degradation pathways for HFC-227ea do not appear to have been elucidated. However, after the initial radical abstraction, further transformation and breakdown would be expected to lead to hydrophilic products that would be removed from the troposphere by dissolution in rain.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1.1 Acute Toxicity

Data on oral and dermal toxicity, as well as eye irritation, skin irritation and skin sensitisation, were not submitted for the notified chemical. This is acceptable, as these tests are inappropriate for gases.

However, a literature review (6) on related chemicals (1,1-dichloro-1-fluoroethane, 1-chloro-2,2,2-trifluoroethane and 1,1-dichloro-2,2,2-trifluoroethane) described these chemicals as being non to mild irritants when applied to the skin of rabbits or guinea pigs. They were reported to produce mild ocular irritation, mild to moderate conjuctival irritation and slight corneal opacity in the rabbit eye, but no skin sensitisation reactions when tested in guinea pigs.

9.1.2 Inhalation Toxicity I (7)

The acute whole body inhalation toxicity of HFC-227ea was assessed in 12 Crl:CD/BR rats (3/sex/dose) at static exposure levels of 121,267 ppm for 4 hours or 241 188 ppm for 4.5 hours. The high dose treatment was divided into two parts (with a 19 minute break between the two parts) to minimise any effects from oxygen depletion and/or carbon dioxide accumulation. Control animals received air for 4 hours in a sealed chamber. Animals were monitored for a 14 day period post exposure and terminally necropsied.

No deaths occurred during the study. There were no significant body weight changes, test material-related necropsy findings or lung weight differences in any of the animals during the course of the study. All animals receiving HFC-227ea exhibited anaesthesia, hypoactivity, bradypnea and/or ataxia during treatment. Signs of anaesthesia diminished after the animals received fresh air. Two test animals showed signs of salivation for one day.

The results of this study indicate HFC-227ea to have an acute inhalation LC50 of >241 188 ppm (24%) in rats.

9.1.3 Inhalation Toxicity II (8)

This study was conducted in accordance with OECD guideline No: 403 (9).

The acute whole body inhalation toxicity of HFC-227ea was assessed in 10 Crl:CD/BR rats (5/sex/dose) at an exposure level of 788 696 ppm. The test material was administered continuously in oxygen to the test chamber for 4 hours. Animals were monitored for a 14 day period post exposure and terminally necropsied.

No deaths occurred during the study and there were no significant lung weight differences in any of the animals during the course of the study. During the observation period, a decrease in mean body weight (1.4%) was observed in female animals, while males exhibited a reduction in mean body weight gain. All animals showed signs of anaesthesia during the study (including decreased motor activity, decreased respiration, ataxia and prostration). Lacrimation was observed in one animal and tail chewing in another. Necropsy revealed red foci in the lung of one animal, and a mottled lung in another.

The results of this study indicate HFC-227ea to have an acute inhalation LC_{50} of >788,696 ppm (79%) in rats.

9.1.4 Cardiac Sensitisation (10)

The potential of HFC-227ea to sensitise the heart to the effects of adrenalin was studied in 10 beagle dogs. Each dog was exposed to atmospheres of 0, 3.5, 7, 9, 10.5 and 14% HFC-227ea for a minimum of 30 minutes with at least 36 hours between each exposure. The animals were challenged with sequential doses of adrenalin (1.2, 2.4, 4.8 and 6 μg/kg intravenous bolus injections ~90 seconds apart) both before and immediately after each induction. Blood samples were collected for estimation of HFC-227ea after 25 minutes exposure. ECG data were recorded continuously during both adrenalin challenges.

After exposure to 9%, 10.5% and 14% HFC-227ea, evidence of cardiac sensitisation (specifically the occurrence of one or more premature ventricular contractions) was observed in 1/10, 5/10 and 6/10 animals respectively, after adrenalin challenge doses of 4.8 and/or 6 μg/kg. The severity of the cardiac responses increased dose-dependently. There were no treatment-related clinical findings.

The results of this study indicate that HFC-227ea sensitises canine heart to the effects of adrenalin only at atmospheric concentrations of ≥9% under the conditions of this study.

9.1.5 Other Toxicity Studies

In the application for extension, the following developmental toxicity studies were provided.

a) An Inhalation Developmental Toxicity Study in Rabbits (29)

The potential for maternal and developmental toxicity of the notified chemical was evaluated using two replicates of artificially inseminated New Zealand White rabbits (12/group/replicate, ie 24 rabbits/dose). The pregnant rabbits were exposed daily to the notified chemical from gestation days 6-18 (13 consecutive days) by whole body inhalation for 6 hours/day, at doses of 137.37 (low dose), 348.42 (mid dose) and 731.69 (high dose) mg/L (20 000, 50 000 and 105 000 parts per million, ppm). Oxygen was provided to the high exposure group to ensure an oxygen level of 19%. Laparohysterectomy was performed on all surviving animals on gestation day 29. One high dose animal was euthanised in error on day 28. The control group was exposed to clean, filtered air only.

The study was conducted in accordance with the US-EPA Toxic Substances Control (TSCA) Act Health Effects Test Guidelines (33), the OECD Guidelines for Testing of Chemicals (30) and the Japanese Ministry of International Trade and Industry Guidelines (25). The protocol was modified in order to document the study schedule data and the selection of exposure levels, and to clarify the storage conditions.

One animal treated with 731.69 mg/L died of a pre-existing pathological condition on gestation day 10. Since there were no other mortalities observed during the study and no deaths recorded in animals treated with 1 393.67 mg/L during the range finding experiment, this death was not considered to be treatment-related. Also, the historical control data show that spontaneous mortalities (26%) over 35 day observation period are occasionally observed in this species and strain of rabbit. Two other high dose animals aborted on gestation days 20 and 28. The abortions were not considered to be treatment related since the spontaneous abortion rate late in gestation is 12% in this species and strain of rabbit, based on the historical control data. In addition, there were no clinical signs observed on both animals prior to abortion.

At termination, no treatment related internal findings on decedents were observed at any dose level. One high dose female which aborted had an early resorption *in utero* but was internally normal. The other female aborted one fetus and had two late resorptions with no apparent malformations.

Mean body weight gain was significantly reduced in mid dose animals during pre-exposure period (gestation days 0 to 6) and in the overall study period (gestation days 0 – 29) compared to the control group. The reduced mean body weight gain was attributed to biological variation during the pre-exposure period and was not considered to be treatment-related since the mean body weight data in high and low dose groups was not statistically different from the control group.

Food consumption in the mid dose group was reduced compared to the control group. Although, the reduction in food consumption was statistically significant, it was not considered to be treatment-related since a similar reduction was not observed in the high dose group.

The mid dose mean kidney and lung weights were significantly reduced compared to the control group. Mean liver weight was also reduced (but not significantly) compared to the control group. The reductions in organ weights observed in the mid dose group were not considered to be treatment-related since similar effects were not observed in the high dose group and such decreases in organ weights could be related to the reduced mean body weight of animals in this group.

Intrauterine growth and foetal survival were not affected at any dose. Reproductive parameters evaluated included pre-and post-implantation loss, live litter size, foetal sex ratios, foetal body weights and mean numbers of *corpora lutea* and impantation sites.

External malformations such as acephaly, carpal flexure (bilateral) and gastroschisis were observed in one foetus in each of the mid dose and control groups. The percentages of litters with omphalocele in the mid dose group was lower (5.0%) than the maximum values observed in historical control data (7.1%). Also, this effect was not observed in the high dose group, so not considered to be treatment-related.

In summary, similar types of soft tissue developmental variations and skeletal malformations were observed in the control and treated groups. External malformations, soft tissue and skeletal malformations were observed in 1(1), 4(3), 1(1) and 2(2) foetuses (litters) in the control, low dose, mid dose and high dose groups, respectively. The malformations were considered to be of spontaneous origin. None of the malformation differences or developmental variations was statistically significant between the treated and control groups on either an incidence or proportional basis. There were no treatment-related trends in comparisons of numbers of malformations or specific types of anomalies. Non dose-related foetal developmental variations were observed in treated group, and any foetal developmental variations were within the range of the historical control data.

Based on the results of the study, the no observable adverse effect level (NOAEL) for both maternal and developmental toxicity in rabbit was 731.69 mg/L, 6 hours/day.

b) Inhalation Developmental Toxicity Study in Rats (28)

The potential for maternal and developmental toxicity of the notified chemical was evaluated using of 3 groups of inbred Sprague Dawley rats (24/group). The pregnant rats were exposed daily to the notified chemical from gestation days 6-15 (10 consecutive days) by whole body inhalation for 6 hours/day, at dose levels 139.37 (low dose), 348.42 (mid dose) and 731.69 (high dose) mg/L (20 000, 50 000 and 105 000 ppm). Oxygen was supplemented to the high exposure group to ensure an oxygen level of 19%. Laparohysterectomy was performed on all surviving animals on gestation day 20. A concurrent control group was exposed to clean, filtered air only.

The study was conducted in accordance with the US - EPA Toxic Substances Control Act (TSCA) Health Effects Test Guidelines (33), OECD Guidelines for Testing of Chemicals (30) and the Japanese Ministry of International Trade and Industry Guidelines (25).

All animals survived up until the scheduled necropsy on gestation day 20. In treated animals, salivation or red material around the nose occurred at similar incidence when compared with the control group.

There were no changes observed in the mean body weights, mean gravid uterine weights or net body weights in any treated groups. A non-treatment related increase in mean body weight gain in the high dose group was observed during gestation days 13-14. All other values were comparable between the treated and control groups. Food consumption in the treated and control groups was comparable.

At scheduled necropsy, there was no treatment related internal findings at any dose. Nematodes were observed in both treated and control groups. Mottled lungs were observed in the control and high dose groups. No treatment related organ weight differences were observed between the treated and controls animals.

Intrauterine growth and survival of foetuses were unaffected by treatment at any concentration tested. Parameters evaluated included pre- and post-implantation loss, live litter size, foetal sex ratios, foetal body weights and numbers of *corpora lutea* and implantation sites. There were no statistically significant differences observed between the treated and control groups.

External malformations, soft tissue and skeletal malformations were observed in 1(1), 1(1), 6(4) and 2(2) foetuses (litters) in the control, low dose, mid dose and high dose groups, respectively. The malformations were considered to be of spontaneous origin. None of the malformation differences or developmental variations was statistically significant between the treated and control groups on either an incidence or proportional basis. There were no treatment-related trends in comparisons of numbers of malformations or specific types of anomalies.

Based on the results of the study, the no observable adverse effect level (NOAEL) for both maternal and developmental toxicity in rat was 731.69 mg/L, 6 hours/day.

9.2 Repeated Dose Toxicity (27)

A 90-day inhalation study was conducted on 72 Sprague Dawley Crl:CD BR rats (three groups of 12/sex) in order to evaluate the potential subchronic toxicity of the notified chemical. The notified chemical was administered via whole body inhalation at dose levels of 139.37, 348.42 and 731.69 mg/L (20 000, 50 000 and 105 000 ppm) for six hours/day, 5 days/week, for 13 weeks (minimum of 65 exposures). Additional 24 rats (12/sex) were used as a control group under conditions identical to the exposed groups except that the animals were exposed to clean, filtered air only.

The study was conducted in accordance with The Environment Protection Agency (EPA) Proposed Guideline for Registering Pesticides in the US (US-EPA, 1984), the EPA Toxic Substances Control Act (TSCA) Health Effects Test Guidelines (34), the OECD Guidelines for Testing of Chemicals (31) and the Japanese Ministry of International Trade and Industry

Guidelines (26).

All animals survived until the termination of the study. Soft stool and red material around the nose were observed in both treated and control groups. Non-dose related effects such as hair loss and scabbing on the forelimbs, and occasional salivation and dried yellow genital matting were observed in the treated group at a similar incidence to the control group.

There was no difference found in the mean body weight or body weight gains between the control and the treated groups. No treatment-related effects on food consumption were observed in any dose group. There were small differences in food consumption in higher dose females compared with the control group; however, this occurred sporadically and was not considered to be dose or time related.

There were no treatment-related changes in the haematology parameters observed at any dose level.

There were no treatment-related changes in serum chemistry parameters observed at any dose level. Slight differences between the treated and the control groups in mean aspartate aminotransferase, gamma glutamyl transferase, glucose, total bilirubin, calcium and potassium were observed in a non dose-related manner. Some of the differences were also inconsistent between sexes and therefore not considered to be of toxicological importance.

Ophthalmological examinations did not show pathological lesions indicative of toxic effects, in any dose groups.

The organ weight values of the treated groups were comparable with the control group. No treatment-related gross lesions were observed in any dose group. Haemorrhagic thymus gland and clear fluid uterus contents were observed in both treated and control groups; single animals demonstrated small kidneys and mottled lungs.

Histological findings revealed lymphocyte infiltration and splenic hemosiderosis in both treated and control groups. Germinal epithelium degeneration of the testes, a small benign glioma and a splenic cyst was present in one animal in both treated and control groups. Tubular mineralisation of the renal cortico-medullary junctions and alveolar oedema was observed in a non dose-related manner.

Based on the observations above, the NOAEL for systemic toxicity was 731.69 mg/L, 6 hr/day.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assays (11)

This study was conducted largely in accordance with OECD guideline Nos: 471 (12) and 472 (13).

The test substance was tested in the *Salmonella typhimurium* test strains TA 98, TA 100, TA 1535, and TA 1537, as well as *Escherichia coli* strain WP2uvrA, with or without metabolic activation.

One experiment was conducted (2 plates/strain/dose). All strains tested without S9 were exposed for 24 hours at 37øC with 500 ml HFC-227ea gas at concentrations of 0, 1.8, 4.6, 9.4, 17, 46 and 80% in air. Strains tested with S9 were exposed to concentrations of 0, 1.7, 4.6, 9.0, 18, 44 and 88% in air. The reference mutagens sodium azide (TA 1535; - S9), 2-(2-furyl)-3-(5-nitro-2-furyl)-acrylamide (TA 98, TA 100, WP2uvrA; - S9), 9-aminoacridine (TA 1537; - S9) and 2-aminoanthracene (all strains; + S9) were used as positive controls.

All positive controls showed an increase in revertant colonies compared to the negative control. No increase was noted with any concentration of HFC-227ea.

The results of this study indicate that HFC-227ea is not mutagenic against *Salmonella typhimurium* or *Escherichia coli* in this test.

9.3.2 Other Genotoxicity Studies

No other genotoxicity studies were provided for HFC-227ea. Data on the related chemical 1,1,1,2-tetrafluoroethane have been reported (14), and suggest negative results in vitro (Ames assay, human lymphocyte assay) and in vivo (Micronucleus, dominant lethal) for this chemical.

9.4 Overall Assessment of Toxicological Data

Animal tests suggest that HFC-227ea has low acute inhalational toxicity (rat LC_{50} >788,696 ppm (79%)). A genotoxicity study indicates that the chemical does not cause point mutations in *Salmonella typhimurium or Escherichia coli*. Studies involving related chemicals suggest that HFC-227ea may have minimal to moderate skin and eye irritancy potential, however there is no evidence to suggest potential for positive skin sensitisation, or mutagenicity potential in the literature.

The results of a cardiac sensitisation study in the dog showed the notified chemical to be capable of sensitising the heart to the effects of adrenalin at concentrations ≥9%.

A study on the potential for maternal and developmental toxicity of the notified chemical was conducted using pregnant rabbits and rats.

One high dose rabbit died of a pre-existing pathological condition; there were no similar deaths at a higher dose (1 393.67 mg/L or 200 000 ppm) during the range finding experiment.

Two high dose rabbits aborted during the study. The study authors did not consider the abortions to be treatment-related since spontaneous abortions are commonly observed in this species and strain of rabbit and there were no clinical signs observed prior to abortion. At termination, no treatment-related internal findings or organ weight changes were observed up to 731.69 mg/L, the maximum dose tested.

There were no deaths observed in the rat study. Similarly, no treatment-related internal findings or organ weight differences were observed in rats up to 731.69 mg/L, the maximum dose tested.

In both the rabbit and rat studies, there were no statistically significant differences in the intrauterine growth and survival of foetuses after implantation between the treated and control groups. Parameters evaluated included pre-implantation loss, post-implantation loss, live litter size, foetal sex ratios, foetal body weights and numbers of *corpora lutea* and implantation sites. Some foetal external, soft tissue and skeletal malformations and variations were observed; however, these observations are commonly observed in the historical control data and appeared at a similar incidence in the concurrent control group, or occurred occasionally. Based on the results of the animal studies, the NOAEL for both maternal and developmental toxicity in rabbits and in rats was 731.69 mg/L, 6 hr/day.

Repeated administration of the notified chemical to rats by inhalation over 90 days did not induce treatment-related effects at any dose tested. All treated animals survived until termination. There were no treatment-related changes in the haematology and serum chemistry parameters observed at any dose. The NOAEL for systemic toxicity was 731.69 mg/L, 6 hr/day.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No data were provided, with the omission justified by the lack of significant aquatic exposure to this volatile and sparingly soluble gas. Hydrofluorocarbons are stable substances that do not exhibit significant biological activity.

Volatile halocarbons can affect the atmosphere. The principal concern is ozone depletion. Halonÿ1301 has a particularly high ozone depletion potential of 10 (3). HFC-227ea contains neither chlorine nor bromine, and thus will not act as a source of ozone depleting halogen radicals in the stratosphere. Scientists from the US National Oceanic and Atmospheric Administration concluded recently that hydrofluorocarbons have negligible potential to destroy ozone (15).

Like other halocarbons, HFC-227ea makes a positive contribution to the global warming potential of the atmosphere. However, the atmospheric lifetime of 42 years is significantly shorter than that for Halonÿ1301 (110 years) (16). While this may suggest an easing of global warming hazard, in practice any improvements would be marginal as more of the replacement gas (a ratio of 1.7ÿby weight) will be required for equivalent performance (3).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

HFC-227ea is not expected to exert a direct effect on living organisms by analogy with other

hydrofluorocarbons. The high volatility should ensure minimal exposure of aquatic and terrestrial compartments, and therefore minimal hazard to organisms inhabiting them.

Hazard to the atmosphere will be reduced when HFC-227ea replaces Halon 1301, as the replacement refrigerant has negligible potential to destroy ozone. However, the replacement retains significant global warming potential.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Although dermal or eye contact is likely, given the expected duration of exposure and the physical state of HFC-227ea, skin and eye irritation should not be a significant concern.

Animal studies indicate that HFC-227ea may potentiate the effects of adrenalin at and above 9%. In an emergency fire situation workers will have elevated blood adrenalin levels, while some workers may also be taking sympathomimetic agents such as bronchodilators or cold medications. As a result, these workers will be at risk of cardiac effects (such as cardiac arrhythmia) if exposed to ≥9% concentration of HFC-227ea. At higher concentrations, there is a risk the notified chemical may displace oxygen in the breathing mixture resulting in oxygen deprivation and possibly death. Workers exposed to the gas during a fire will also be at risk of exposure to corrosive and/or toxic thermal decomposition products, such as hydrogen fluoride. In the application for extension, the potential for maternal and developmental toxicity of the notified chemical was evaluated using pregnant rabbits and rats. There was no maternal or developmental toxicity observed at any dose concentration tested. The no observable adverse effect level (NOAEL) in both studies was determined to be 731.69 mg/L (105 000 ppm), 6 hr/day. In a 90-day inhalation repeat-dose study, NOAEL for systemic toxicity was found to be 731.69 mg/L (105 000 ppm), 6 hr/day.

Under normal use conditions, however, all personnel will be evacuated before the firefighting systems are started, and workers will be required to wear adequate personal protective devices if exposure is anticipated. As a result the risk to workers should be minimal.

During servicing of the fire suppression systems, gas may escape from pressurised tanks. In these situations the expanding gas may cause 'cold burns' if it contacts the skin. With appropriate personal protective equipment, the risk will be minimal.

As the gas is denser than air, it may accumulate in confined or low-lying spaces and displace oxygen. Therefore the enclosures must be ventilated adequately prior to the return of personnel.

Public exposure to the notified chemical is unlikely when it is used in the proposed manner. HFC-227ea will, therefore, not pose a significant risk to public health or safety.

13. RECOMMENDATIONS

To minimise occupational, public and environmental exposure to HFC-227ea the following guidelines and precautions should be observed.

- Areas where HFC-227ea is used should have good general ventilation or local exhaust ventilation.

- Localised sources of high temperature in the region of the notified chemical should be avoided if possible. If welding is necessary, appropriate protective equipment should be worn.

- If engineering controls and work practices are not sufficient to reduce exposure to a safe level and:

    . inhalation of HFC-227ea gas or its decomposition products is possible, respiratory protection conforming to Australian Standard 1715 (17) and AS 1716 (18) should be worn;

    . eye contact with the cold or expanding gas is possible, face shield conforming to Australian Standards 1336 (19) and 1337 (20) should be worn; and

    . skin contact with the cold or expanding gas is possible, impermeable thermal gloves (elbow length) conforming to Australian Standard 2161 (21) and protective clothing conforming to Australian Standards 3765.1 (22) or 3765.2 (23) should be worn.

- HFC-227ea is heavier than air and may displace oxygen. Care should be taken not to allow concentrations to accumulate in confined areas.

- After release of the notified gas, care should be taken when reentering sunken or enclosed areas. Any such areas should be marked and breathing apparatus conforming to Australian Standard 1715 (17) donned before entering.

- Workers who are taking sympathomimetic medication should be warned about potential cardiovascular sensitisation from excessive HFC-227ea exposure.

- Physicians treating a patient after exposure to high concentrations of notified chemical should not administer adrenalin or other sympathomimetic amine stimulants.

- A copy of the MSDS for products containing the notified chemical should be easily accessible to all employees.

- To minimise public exposure to HFC-227ea the following guidelines and precautions should be observed.

- Extinguisher systems containing HFC-227ea should be routinely maintained to prevent gas leakages.

- Precautions should be taken to prevent public access to areas in which an extinguisher system is releasing, or has been released.

- To minimise environmental exposure to HFC-227ea the following guidelines and precautions should be observed.

- Restrictions on discharge of halons, except in the case of fire, should be retained for HFC-227ea as it has significant global warming potential. This should be reflected in the Draft Standard for FM-200 (HFC-227ea) Total Flooding Fire Suppression Systems, which currently (revision of 1 December 1993) specifies that HFC-227ea shall be the test medium for any discharge testing that may occur.

14. MATERIAL SAFETY DATA SHEET

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

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 Industrial Chemicals (Notification and Assessment) Act 1989, secondary notification of HFC-227ea shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise.

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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.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	3 severe	Swelling with lids half-closed to completely closed	4 severe		

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