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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

1,1,1-Trifluoroethane

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Acting Director
Chemicals Notification and Assessment

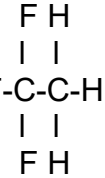
FULL PUBLIC REPORT

1,1,1-Trifluoroethane

1. APPLICANT

A-GAS (Australia) Pty Ltd of Level 3 Como Centre 299 Toorak Road SOUTH YARRA VICTORIA 3141 has submitted a standard notification statement for an assessment certificate for 1,1,1-Trifluoroethane.

2. IDENTITY OF THE CHEMICAL

Chemical name:	1,1,1-Trifluoroethane
Chemical Abstracts Service (CAS) Registry No.:	420-46-2
Other names:	HFC-143a FC-143a Forane 143a
Trade name:	Solkane 507 (R507), mixture with pentafluoroethane; Solkane 404a (R404a), mixture with pentafluoroethane and 1,1,1,2-tetrafluoroethane
Molecular formula:	CF_3CH_3
Structural formula:	
Molecular weight:	84.044
Method of detection and determination:	Infrared (IR)
Spectral data:	IR major absorbance peaks at 817, 842, 970, 1085, 1230, 1270, 1410, 1800, 1930, 2060, 2120, 2200, 2370, 2450, 2510, 2680 and 3050 cm^{-1}

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	colourless gas with a slightly ethereal odour
Boiling Point:	-47.3°C (at 101.3 kPa)
Relative Vapour Density:	2.9 (air = 1)
Vapour Pressure:	2307 kPa at 25°C
Water Solubility:	0.05% at 25°C
Partition Co-efficient (n-octanol/water):	not available (calculated log P = 1.16)
Hydrolysis as a function of pH:	contains no hydrolysable functionalities
Adsorption/Desorption:	not available (calculated log K_{oc} = 1.97)
Dissociation Constant:	contains no dissociable groups
Flash Point:	-90°C
Flammability Limits:	U.E.L.= 7.1% L.E.L.= 16.1%
Autoignition Temperature:	750°C
Explosive Properties:	stable but extremely flammable (imported blends are not flammable)
Reactivity/Stability:	stable but flammable, contact with strong bases or alkaline materials may provoke violent reactions or explosions
Atmospheric Lifetime:	64.2 years
Ozone Depleting Potential:	0
Global Warming Potential:	20 years - 4700 100 years - 3800 500 years - 1600

Comments on Physico-Chemical Properties

On decomposition the notified chemical may produce hydrogen fluoride and carbonyl fluoride.

Water solubility was not measured. It has been estimated using Irmann's equation (1). The appropriate parameters tabulated by Irmann can be selected and entered into the equation to yield solubility of the liquefied gas of 0.00609 g/g H_2O. This equates to solubility of the gaseous R143a of 0.000559 g/g H_2O (0.0559%) by dividing by the vapour pressure (atm). This compares with the much higher estimate of 19,300 mg/L on the ASTER database (2)

Hydrolysis is not expected to be a significant degradation pathway as the notified substance is a stable gas and HFC-143a contains no hydrolysable functionalities. It will partition to the atmosphere in open systems. Significant sorption to soils is not expected as the notified substance is a gas. It contains no readily dissociable groups.

Calculated values for the partition coefficient and adsorption/desorption were obtained from the ASTER database(2).

The atmospheric "lifetime" is defined as the time necessary for 63% degradation; it is equal to the "half-life" divided by ln2 (= 0.69) (3). Destruction is mainly in the troposphere by hydroxyl radical attack (see further discussion in Section 8).

HFC-143a has no effect on stratospheric ozone as it contains neither chlorine nor bromine (3) (see further discussion in Section 10).

Global warming potential is also further discussed in Section 10.

4. PURITY OF THE CHEMICAL

Degree of purity: ≥ 99.7%

Toxic or hazardous impurities: none known

Non-hazardous impurities (> 1% by weight): none known

Additives/Adjuvants: notified chemical will be imported as refrigerant blends of the following composition:

Formulation:	Solkane 507 (R507)
Chemical name:	pentafluoroethane
Synonyms:	R125
CAS No.:	354-33-6
Weight percentage:	50% (50% 1,1,1-Trifluoroethane)

Formulation:	Solkane 404a (R404a)
Chemical names:	pentafluoroethane / 1,1,1,2-tetrafluoroethane
Synonyms:	R125 / R134a
CAS Nos.:	354-33-6 / 811-97-2
Weight percentage:	44% / 4% (52% 1,1,1-Trifluoroethane)

5. USE, VOLUME AND FORMULATION

1,1,1-Trifluoroethane will be imported in refrigerant gas blends to be used in low temperature commercial applications only, such as supermarket, fish market and cold store refrigeration systems. These blends will also replace the current chlorofluorocarbon refrigerants such as R502 in refrigerated transport. The blends will be imported in reusable (720 kg) tanks approved for international shipping.

The notified chemical will be imported in the following volumes over the next five years:

Year 1	10 tonnes
Year 2	15 tonnes
Year 3	25 tonnes
Year 4	25 tonnes
Year 5	40 tonnes

6. OCCUPATIONAL EXPOSURE

1,1,1-Trifluoroethane is a highly flammable gas. It will only be imported in non-flammable blends therefore the risks associated with its importation and use in Australia are reduced. It will be imported in steel tanks 720kg (net weight) approved for international shipping (ISO). Release from the containers during shipping, transport and warehousing would only occur in the unlikely event of the tank or fittings being damaged. As the gas is pressurised any sudden release is potentially dangerous. The imported formulations are classified under the Australian Dangerous Goods Code (4), in the case of Solkane 507, containing 50% of the notified chemical Class 2.2 (no-flammable, non-toxic gas) Hazchem code 2RE. 1,1,1-Trifluoroethane is regulated under the ADG code as Class 2.1, Hazchem 2WE.

The gas will not be decanted to smaller containers at the A-GAS warehouse. The tanks will either be delivered direct to A-GAS's customers or alternatively A-GAS will transport the gas tanks for use at the customer's site. Existing refrigeration systems will be drained and recharged with the blend containing 1,1,1-Trifluoroethane. New systems will simply be charged with the new blend. Systems are charged using a closed pipe transfer system according to the *Australian Refrigeration and Air Conditioning Code of Good Practice* (5). The numbers of workers and likely causes of exposure are tabulated below:

Table 1: Number and category of workers potentially exposed to 1,1,1-Trifluoroethane

Stage of Use	Category of worker	Number exposed	Exposure Source
Import	Dock/Waterside workers	2-5	Cylinder leakage
Transport from dock to A-GAS Warehouse	Transport drivers	2-5	Cylinder leakage
Storage at A-GAS Warehouse	Warehouse workers Repackaging technicians	6-10	Cylinder leakage
Transport from warehouse	Warehouse workers	5	Cylinder leakage
Transport to end users	Transport drivers	5-10	Cylinder leakage
Charging and maintenance of refrigeration systems	Refrigeration technicians Service personnel	50-500 50-1000	Cylinder leakage, emissions from coupling/uncoupling of hoses during charging; leakage from refrigeration plant during operation

The nature of work done by various categories of worker and the likely duration of exposure are as follows:

Table 2: Nature of work done and duration of exposure to 1,1,1-Trifluoroethane

Category of worker	Nature of work done	Maximum duration(hrs/day, days/yr)	Form of chemical during exposure
Waterside/transport and warehouse workers	Unload pressurised tanks and ISO containers and load onto trucks	10 days/yr 2-3 hr/day	Liquefied compressed gas
Warehouse workers	Handling and distribution	10 days/yr 6-8 hr/day	Liquefied compressed gas
Service personnel /refrigeration mechanics	Drain and charge refrigeration systems, connect and disconnect charging hoses to cylinders, service refrigeration plant	Not available	Liquefied compressed gas or vapour.

Exposure to 1,1,1-Trifluoroethane is expected to be minimal in view of the methods employed to minimise release of ozone depleting gases to the atmosphere (5). During charging of refrigeration units a closed refrigerant recovery/recycling system is employed with specialised hoses/vent lines. Release of about 0.1 g of refrigerant can normally occur when the flexible hose connectors between the refrigeration

system and the cylinder are disconnected at the end of charging. The hoses are fitted with automatic shut-off valves which prevent release of the contents of the hose.

7. PUBLIC EXPOSURE

The gas blends containing 1,1,1-Trifluoroethane will be contained in reusable 720 kg tanks approved for international shipping, and will not be repacked in Australia. Following transport to end users such as supermarkets, cold stores, refrigerated transport and fish markets, gas blends containing the notified chemical will then be loaded into low temperature refrigeration units via closed piping.

Under normal conditions, there is negligible potential for public exposure to 1,1,1-Trifluoroethane, which will spend its working life enclosed in refrigeration systems. Release of refrigerant during charging operations is limited by a closed refrigerant recovery/recycling system employing specialised hoses and vent lines. Release is limited to the loss of refrigerant occupying the small dead space between couplings and cylinders and is estimated to be only 0.1g. Refrigerant gases containing the notified chemical will be reclaimed and recycled, and not disposed of by discharging to the atmosphere.

8. ENVIRONMENTAL EXPOSURE

Formulation, Handling and Disposal

No reformulation using 1,1,1-Trifluoroethane occurs in Australia. 1,1,1-Trifluoroethane is imported in pre-formulated gas blends.

The 720 kg pressurised tanks holding the refrigeration blends will be unloaded at the wharf and transported by road to the warehouse facility in Melbourne, from where they will be stored or transported directly to the customer site. There will be no decanting of liquid 1,1,1-Trifluoroethane from the pressurised tanks to smaller cylinders.

Tanks will be transported by service personnel to the site of use. Existing refrigeration systems will be drained and recharged with the new blend. Charging will be done using a closed piping system as recommended in the *Australian Refrigeration and Air Conditioning Code of Practice* (5), so as to minimise refrigerant release. Systems are charged by connecting the tank to the refrigeration unit via a flexible hose. The gas is allowed to flow into the unit until the desired pressure is achieved. The hose has an automatic shut off valve that minimises gas release following charging.

The *Australian Refrigeration and Air Conditioning Code of Good Practice* (5) requires that release of ozone depleting refrigerants to the atmosphere during manufacturing, installation or servicing operations be reduced to the minimum level by re-use of refrigerant recovered. Recovery of refrigerant is required from performance testing during development and production. Refrigerant must be recovered in dedicated

cylinders, identified by valving, labelling and colour coding. Where contaminated refrigerants are stored, they must be labelled to indicate the contents.

Release

The notified substance will not enter the environment intentionally when used in refrigeration systems, but any releases during filling or use of cooling systems, or following disposal of obsolete equipment or recovery of refrigerants therefrom, will rapidly volatilise to the atmosphere. Once in the atmosphere, 1,1,1-Trifluoroethane diffuses from the troposphere into the stratosphere.

Releases can be expected through charging and servicing of refrigeration units when hoses are disconnected. Estimates quote losses at approximately 0.1 g per charge/recharge.

Total losses through fugitive emissions have been predicted by the Industry to be between 5-8% of working charge per annum. Therefore, in a worst case scenario, assuming a total import of 40 tonnes of the notified gas was imported and all put into service in one year, losses through fugitive emissions would be expected to be approximately 3.2 tonnes/year. However, under normal working practices release will be reduced to minimum levels by re-use of recovered refrigerant.

Disposal of 1,1,1-Trifluoroethane will not occur in Australia. Refrigerant gases containing 1,1,1-Trifluoroethane will be reclaimed and recycled according to the *Australian Refrigeration and Air Conditioning Code of Good Practice* (5). Surplus or unusable refrigerant will not be discharged to the atmosphere but returned to the supplier ie the notifier.

Fate

Given its high volatility, any 1,1,1-Trifluoroethane released to the environment will partition almost entirely to the atmosphere. The main degradation pathway in the environment is reaction with tropospheric hydroxyl radicals, which abstract hydrogen. Atmospheric lifetimes of refrigerant gases have been compiled under the Alternative Fluorocarbons Environmental Acceptability Study (AFEAS). Recent AFEAS data sheets indicate an atmospheric lifetime of 64.2 years for the notified substance. A lifetime of about 40 years has been reported elsewhere (6).

A generic scheme has been developed for predicting the fate of HFCs and HCFCs (6). According to this scheme, hydrogen abstraction from 1,1,1-Trifluoroethane would generate the trifluoroethyl radical, which would react rapidly with oxygen to form the trifluoroperoxyethyl radical. Such radicals decay by various mechanisms with estimated lifetimes less than 10 minutes to generate trifluoroethoxy radicals or carbonyl products (in this case, trifluoroacetaldehyde). Further breakdown of these products leads via trifluoromethoxy radical to carbonyl fluoride, which is thought to be removed from the atmosphere by dry or wet deposition.

Possible alternative breakdown pathways for trifluoroacetaldehyde include photolysis to fluoroform or oxidation to trifluoroacetic acid (TFA). Fluoroform would degrade via reaction with hydroxyl radicals to carbonyl fluoride, but is more persistent in the

atmosphere than the original 1,1,1-Trifluoroethane. TFA would precipitate in rain. Recent studies (7) indicate that trifluoroacetate is biodegradable in aerobic and anaerobic sediments. However, the rate and significance of these processes remain uncertain.

The persistence of the degradation product trifluoroacetic acid (TFA) raises concerns for its accumulation in the environment, possibly within a few decades in certain wetlands where evaporation is high and water seepage limited. The recent discovery of aerobic and anaerobic sinks for TFA is promising, but further research in this area will need to be monitored. (8, 9)

It has been estimated recently that by 2010 the global average TFA concentration in rainwater will be 0.016 mg/L, mainly due to atmospheric degradation of HCFC-123, HCFC-124 and 1,1,1-Trifluoroethane, with the notified chemical, 1,1,1-Trifluoroethane, not a major source. This level of TFA is three orders of magnitude below toxic thresholds of the most sensitive species yet addressed. However, under high evaporation conditions TFA levels in some wetlands could reach 100 mg/L^{-1} within a few decades, assuming no loss by degradation or water seepage (8, 9). The effects of TFA at such levels are unknown. While there is no immediate prospect of such levels being reached in Australia, further research in this area should be monitored.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Studies on acute oral toxicity, acute dermal toxicity, skin irritation, eye irritation and skin sensitisation were not conducted. This is acceptable since 1,1,1-Trifluoroethane is a gas.

9.1.1 Acute Inhalation Toxicity (10,11)

Groups of 6 male Crl:CD BR rats were exposed nose-only for a single 4 hour period to 97,000 or 540,000 ppm 1,1,1-Trifluoroethane. Following termination of treatment, the rats were observed for 14 days.

Rats exposed to 1,1,1-Trifluoroethane exhibited dry, red ocular and nasal discharges but this was said to be the result of being held in restrainers.
Three rats exposed to 97,000 ppm 1,1,1-Trifluoroethane showed slight weight loss on the day following exposure and 4 rats in the high dose group showed moderate to severe weight loss on the same day.

No mortality was observed during the observation period and no clinical signs of toxicity were observed in either of the exposure groups.

It can be concluded that the 4 hour acute inhalation LC_{50} is greater than 540,000 ppm.

A second inhalation study was conducted using CD rats. The mode of exposure was similar but with a control and two dose groups of 305000 and 591000 ppm. Each test group consisted of 5 male and 5 female animals. No adverse effects were noted. The 4 hour acute inhalation LC_{50} was greater than 591,000 ppm.

9.2 Repeated Dose Inhalation Toxicity

9.2.1 Four-Week Repeated Dose Inhalation Study (12)

Charles River rats (10/sex/dose) were exposed nose-only by inhalation to 1,1,1-Trifluoroethane at concentrations of 0, 2000, 10000 or 39000 ppm for 6 hours per day for 20 days over a 31 day period. There was no recovery period.

All treated males had statistically significant decreased body weight and body weight gain compared to controls at various intervals during the exposure period but the decreases were not dose-dependent.

A number of functional observations were made to determine an effect on the nervous system. No compound-related neurotoxic effects were observed. No compound-related effects on haematology or clinical chemistry were observed. One male animal in each of the 2000 or 10000 ppm dose groups and one female animal in the 39,000 ppm dose group were found dead on test days 8, 9 and 15 respectively. The cause of death was not determined.

Overall there were no statistically significant changes in final body or organ weights in treated groups relative to controls although a trend of diminishing testes weight was evident. Regarding gross organ changes, small testes were noted in 1/10 and 2/10 male rats in the 10,000 and 39,000 ppm dose groups respectively.

Significant pathological changes were noted in the testes of exposed male rats. Degenerative changes were present at all exposure concentrations. Microscopically, these changes were characterised by minimal to mild accumulation of eosinophilic debris within the lumen of seminiferous tubules. Tubular architecture was generally intact and germ cell necrosis was not prominent. In the epididymes of affected animals, decreased sperm density and increased exfoliated germ cell debris were correlated to the testicular changes. The changes were minimal to mild in all animals in both the 39000 and 10000 ppm dose groups and less severe in the 2,000 ppm dose group where testicular changes were generally very slight and epididymal sperm density was affected in only 3/10 animals.

All other microscopic findings noted were considered incidental occurrences of spontaneous lesions common to rats of this strain and age.

A possible explanation of the testicular changes advanced was that the rats were inadvertently exposed to excessive heat leading to increased body temperatures during the nose-only exposures.

9.2.2 28-Day Repeated Dose Inhalation Study (13)

A second four-week repeated dose study was conducted to discover if the testicular changes observed in a previous study (see section 9.2.1 above) could be confirmed. Toxicity evaluations were limited to body weights, clinical signs and anatomic and/or histopathological evaluations of the testes and epididymes.

Charles River rats (10 males/dose) were exposed whole-body to 1,1,1-Trifluoroethane at concentrations of 0, 2,000, 10,000 or 40,000 ppm for 6 hours per day, for 20 days over a 28-day period. On day 21 all rats were killed for pathological examination.

Exposed rats did not exhibit any statistically significant changes in body weight or body weight gain compared to controls. All rats survived to scheduled termination and no compound-related clinical signs were observed in any of the exposed groups. No effect of exposure to 1,1,1-Trifluoroethane was observed on testes weights and there were no compound-related changes in gross or microscopic findings.

9.2.3 90-Day Repeated Dose Study (14)

Charles River rats (20/sex/dose) were exposed whole-body to 0, 2020, 10141 or 40072 ppm 1,1,1-Trifluoroethane, 6 hours per day, 5 days per week for 90 days. At the conclusion of the 90 day exposure approximately 10 rats per dose group were allowed to recover for approximately one month.

There were no compound-related effects on body weight or body weight gain or food consumption at any exposure concentration during either the exposure period or the recovery period. During the exposure and recovery periods there were no compound-related effects or clinical signs. No compound-related deaths were observed. Three rats died or were killed *in extremis*. No compound-related effects on ocular tissue were observed.

Isolated statistically significant differences in haematology and clinical chemistry values were within normal ranges and were not considered to be biologically significant.

There were no statistically significant or biologically significant differences in organ weights at any exposure concentration at either 90 days or at the end of the one month recovery period. There were no compound-related gross or microscopic morphological changes in any organ at any exposure concentration after 90 days. In particular, there was no evidence of pathological changes in the testes.

9.3 Developmental Toxicity

9.3.1 Inhalation Developmental Toxicity Study in Rabbits (15)

Artificially inseminated New Zealand White rabbits were exposed to 0, 2,000, 10,000 or 40,000 ppm 1,1,1-Trifluoroethane by inhalation for 6 hours (24/dose) on each of 13 consecutive days (gestational days 6-18). The control group was exposed to air. All surviving females were killed on day 29 of gestation for a scheduled laparohysterectomy.

One animal in the 2,000 ppm dose group spontaneously aborted on day 17 but was not considered compound-related in view of the fact that spontaneous abortions are not uncommon in this species.

No compound-related clinical signs were noted during the study. No compound-related changes in mean body weight, body weight gain, gravid uterine weight, net body weight or net body weight change were observed. No compound-related changes in food consumption were observed.

At the scheduled necropsy on day 29, a number of gross organ changes including a white precipitate in the amniotic fluid at one implantation site for one 2000 ppm animal were noted but these were not attributable to 1,1,1-Trifluoroethane. Organ weights (kidney, liver and lung) were comparable in the control and exposed groups.

No adverse effects on intrauterine growth or survival were observed at any exposure level. An increased mean number of implantation sites in the 10,000 ppm dose group was statistically significant compared to the control, but within historical control values. One animal in the 2,000 ppm dose group had a completely resorbed litter.

Regarding the foetal morphology, external, soft tissue and skeletal malformations were observed in 4, 14, 5 and 5 foetuses in the control, 2,000, 10,000 and 40,000 ppm dose groups, respectively. The total malformation rate (expressed as per cent per litter) was 3.1%, 8.2%, 3.4% and 7.1% for these same groups, respectively, which is within the historical control range for total malformations (0.0 - 12.9%).

9.3.2 Inhalation Developmental Toxicity Study in Rats (16)

1,1,1-Trifluoroethane was administered by inhalation to groups of 25 female Crl:CD BR rats 6hrs/day for 10 consecutive days on days 7-16 of gestation. The target dose levels chosen were 0, 2,000, 10,000 and 40,000 ppm.

All animals survived to scheduled termination on day 22 of gestation. No adverse effects on body weight or body weight gain were observed. No clinical signs were noted and no compound-related effects were observed during gross postmortem examinations.

No significant dose-related effects on reproductive parameters (early deliveries, incidence of dams with total resorptions, litter means for live, dead or resorbed foetuses or mean corpora lutea) were detected.

Regarding effects on the foetus, no significant effects on mean foetal weights were observed. No compound-related effects on the incidence of foetal malformations were detected.

The mean percent of affected foetuses examined for variations due to retarded development during the visceral examination was significantly increased for all test groups. The incidences were 1.6%, 10.5%, 8.7% and 10.0 % for the 0, 2,000, 10,000 and 40,000 ppm dose groups, respectively. Retarded renal papillary development was the primary and most frequently recorded observation for this category. However, it was concluded that these effects were not biologically

significant because the control value was abnormally low, the increases were not dose-dependent and there was no other evidence of developmental toxicity.

9.4 Genotoxicity

9.4.1 Bacterial Reverse Mutation Assay (17,18)

The effect of the notified chemical on back mutation to prototrophy was tested in two studies. In the first study the tests used *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537 and TA 1538 and in *Escherichia coli* strain WP2 *uvrA* both in the presence and the absence of metabolic activation provided by rat liver S9. In the second study the tests used *S. typhimurium* strains TA 97, TA 98, TA 100 and TA 1535 and in *E. coli* strain WP2 *uvrA* both in the presence and the absence of metabolic activation provided by rat liver S9.

Agar plates seeded with the test strains were exposed to the notified chemical in the vapour phase at nominal concentrations up to 100% v/v in the first study and 3.5% v/v in the second study.

Negative controls were within acceptable limits for both studies. Positive controls of dichloromethane (in vapour phase), benzo[a]pyrene (BaP), 2-nitrofluorene, 2-aminoanthracene (2AA), 9-aminoacridine (9AA), N-ethyl-N'-nitro-N-nitrosoguanidine (ENNG) and sodium azide gave the expected increases in mutant yields in the first study. In the first study in the absence of S9, dichloromethane was tested on all strains, sodium azide on TA 1535 and TA 100, 9AA on TA 1537, 2-nitrofluorene on TA 1538 and TA 98 and ENNG on WP2 *uvrA*. In the presence and absence of S9, 2AA was tested on TA 1535 and WP2 *uvrA* and BaP on TA 1537, TA 1538 and TA 100.

1,1,1-Trifluoroethane did not increase the level of back mutation in any strain at any dose level.

It can be concluded that 1,1,1-Trifluoroethane is not genotoxic in these assays.

9.4.2 *In vitro* Chromosome Aberration Assay in Human Lymphocytes (19)

Potential clastogenic activity in cultured human lymphocytes was assessed both in the presence (S9 mix) or absence of metabolic activation. The test atmospheres contained 0, 0.5, 1.5, 2.5 or 3.5 % of 1,1,1-Trifluoroethane. Cells were harvested at 18-20 hours post treatment. A second trial at 0. 2.5 or 3.5% 1,1,1-Trifluoroethane and a harvest time of 43 hours was also conducted. Harvested cells were stained with Giemsa and 100 metaphase cells were scored for chromosome aberrations.

There was no increase in the frequency of cells with chromosome aberrations and hence1,1,1-Trifluoroethane was not clastogenic under the test conditions.

9.5 Cardiac Sensitisation in Dogs (20)

The effect of intravenous injection of beagle dogs with adrenaline before and during inhalation of 1,1,1-Trifluoroethane on the electrocardiogram was studied.
Optimal doses of adrenaline were chosen on the basis of the number of ectopic beats and ranged from 2 - 12µg/kg.

The exposure concentration of 1,1,1-Trifluoroethane ranged from 5 - 30% (v/v). Positive responses (presence of multiple multifocal ectopic beats following adrenalin administration) were observed only at 30% 1,1,1-Trifluoroethane in 2/5 dogs.

9.6 Overall Assessment of Toxicological Data

1,1,1-Trifluoroethane exhibits low acute inhalation toxicity in rats. Repeated dose studies indicate that 1,1,1-Trifluoroethane does not exhibit toxic effects in rats exposed by inhalation for up to 90 days at doses up to 40000 ppm.

Developmental toxicological studies did not reveal any effects on foetal development in either rats or rabbits.

1,1,1-Trifluoroethane was found not to be genotoxic in bacterial reverse mutation and *in vitro* human lymphocyte tests.

1,1,1-Trifluoroethane was found to induce cardiac sensitisation in dogs at a dose of 30% v/v. Therefore, it can be concluded that 1,1,1-Trifluoroethane is a cardiac sensitiser at high concentrations.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No data were provided. Effects on organisms are not expected as 1,1,1-Trifluoroethane, like other hydrofluorocarbons, has negligible biological activity. Its expected low partition coefficient suggests a low potential for bioaccumulation and a low risk to the aquatic environment. Furthermore, significant exposure of aquatic organisms to this gaseous substance is not expected as it will not remain in solution for any significant length of time.

However, the data in the following table have been obtained from ASTER (2).

Test	*Species*	*Results*
acute toxicity	rainbow trout	4 Day LC50=184.0 mg/L
acute toxicity	channel catfish	4 Day LC50=164.8 mg/L
acute toxicity	fathead minnow	4 day LC50=383.3 mg/L
acute toxicity	bluegill	4 day LC50=282.1 mg/L
chronic toxicity	*Daphnia magna*	32 Day MATC=50.5 mg/L
acute toxicity	*Daphnia magna*	2 Day LC50=176.2 mg/L

* NOEC - no observable effect concentration

These results indicate that 1,1,1-Trifluoroethane is likely to be practically non-toxic to aquatic invertebrates and fish under acute and slightly toxic to aquatic invertebrates under chronic conditions.

1,1,1-Trifluoroethane contains neither chlorine nor bromine, and thus will not act as a source of ozone depleting halogen radicals in the stratosphere (3). Scientists from the US National Oceanic and Atmospheric Administration concluded that hydrofluorocarbons have negligible potential to destroy ozone (21).

Like other halocarbons, 1,1,1-Trifluoroethane adds to the global warming potential of the atmosphere. AFEAS data provided in the submission indicate that the global warming potential of the notified substance is smaller than those for the CFC refrigerants that it will replace.

The extent to which a greenhouse gas contributes to global warming depends on the volume emitted, the time that elapses before it is purged from the atmosphere and the infra-red energy absorption properties of the gas. An index termed the Global Warming Potential (GWP) has been developed which provides a simplified means of describing the relative ability of each greenhouse gas emission to affect global climate change. It is the ratio of the warming caused by a substance to the warming caused by CO_2 (on a molecule per molecule basis) to allow a common basis for comparing impacts (22). Thus, with the GWP of CO_2 defined as one, 1,1,1-Trifluoroethane has 1600 times the GWP of CO_2 over a 500 year time horizon.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

1,1,1-Trifluoroethane is not expected to exert a direct effect on living organisms. 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 1,1,1-Trifluoroethane replaces current chlorofluorocarbon refrigerants, as the replacement refrigerant will not carry chlorine or bromine to the stratosphere. 1,1,1-Trifluoroethane retains a significant global warming potential, but less than those of the ozone depleting CFC refrigerants that are currently used.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Animal tests suggest that 1,1,1-Trifluoroethane is unlikely to exhibit toxic effects to individuals exposed by inhalation either acutely or to repeated doses.

Based on developmental toxicity studies, 1,1,1-Trifluoroethane is not expected to have effects on the developing foetus.

The data on genotoxicity suggest that 1,1,1-Trifluoroethane is not genotoxic. However, there is evidence in the literature that 1,1,1-Trifluoroethane may be mutagenic in *Salmonella typhimurium* strains TA 1535 and TA 100 (23). In the same paper 1,1,1-Trifluoroethane was reported to be negative for transformation of hamster kidney cells and was not carcinogenic in Wistar rats dosed at 300 mg/kg for 52 weeks.

1,1,1-Trifluoroethane induces cardiac sensitisation in dogs though at higher doses than refrigerants it is designed to replace. For example, the lowest dose at which 1,1,1-Trifluoroethane induces cardiac sensitisation is 60 times higher than for CFC-11 (trichlorofluoromethane).

Exposure to 1,1,1-Trifluoroethane during charging or recharging refrigeration equipment is expected to be minimal in view of the well established procedures to minimise release of ozone-depleting gases to the atmosphere (2).

Negligible public exposure to 1,1,1-Trifluoroethane is anticipated, since the notified chemical is transported and used within sealed equipment, and is recycled at the end of its operational life.

From the above considerations, the risk of adverse health effects resulting from the use of 1,1,1-Trifluoroethane as a refrigerant is low.

Although pure 1,1,1-Trifluoroethane is highly flammable, the mixtures (Solkane 507 and Solkane 404a) are not. Nevertheless, contact of the refrigerant with hot surfaces or open flames should be avoided because of the potential for release of hydrogen fluoride and carbonyl fluoride.

A possible hazard from releases of Solkane 507 and Solkane 404a from pressurised gas cylinders is their potential to cause frostbite.

The notified chemical, 1,1,1-Trifluoroethane, on the basis of the submitted toxicity data would not be classified as hazardous according to the Worksafe Australia *Approved Criteria for Classifying Hazardous Substances* (15). The imported formulations are classified under the Australian Dangerous Goods Code (1); in the case of Solkane 507, containing 50% of the notified chemical, as Class 2.2 Hazchem code 2RE.

13. RECOMMENDATIONS

To minimise the occupational health risk of and environmental exposure to 1,1,1-Trifluoroethane the following guidelines and precautions should be observed:

- Those taking sympathomimetics, bronchodilators or cough and cold medications should have their medication evaluated by their medical adviser, if exposure to the notified chemical is likely.
- Physicians treating a patient after exposure to high concentrations of notified chemical should not administer adrenalin or other sympathomimetic amine stimulants.
- Manufacturers, distributors and users should minimise atmospheric emissions of 1,1,1-Trifluoroethane by adhering to the Australia Refrigeration and Air Conditioning Code of Good Practice.
- Charging and recharging of refrigeration equipment should be conducted in accordance with Australia Refrigeration and Air Conditioning Code of Good Practice.
- 1,1,1-Trifluoroethane is heavier than air and may displace oxygen. Care should be taken not to allow concentrations to accumulate in confined areas. Floor level ventilation should be used.
- If engineering controls and work practices are insufficient to reduce exposure to 1,1,1-Trifluoroethane to a safe level, then personal protective devices which conform to and are used in accordance with Australian Standards (AS) for eye protection (in this case a face shield) (AS 1336, AS 1337) (25,26), respiratory protection (27), thermal gloves (AS 2161) (28) and protective overalls (AS2919)(29) and shoes (AS2210)(30) should be worn.
- It is recommended that leak testing be conducted quarterly on equipment containing in excess of 50 kg of refrigerant.
- Training of refrigeration maintenance workers should include relevant information from Australian Refrigeration and Air Conditioning Code of Good Practice and Australian Standard 1677 - refrigeration systems, Safety Code for Mechanical Refrigeration (31) and the Material Safety Data Sheet (MSDS).
- A copy of the 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* (32).

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. No other specific conditions are prescribed.

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