File No EX/53 (NA/920)

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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

HFC-245fa

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

HFC-245fa

The notified chemical has been notified elsewhere including the United States, Canada, Japan, the Republic of Korea, New Zealand and in Europe (Belgium). The information presented in this Full Public Report is compiled from the data submitted to NICNAS by the applicants as required under Section 23 of the Act, which includes the US EPA pre-manufacture notice (PMN) and the EC Summary Notification Interchange Format (SNIF) and Risk Assessment (Belgium).

1. APPLICANTS

Original Holder of Assessment Certificate (First Applicant)

Assessment Certificates for the notified chemical known by the name HFC-245fa were granted to Ariel Industries Pty Ltd of 23 Kembla Street, Cheltenham, Victoria 3192, (ABN 86 004 428 826), Huntsman ICI Polyurethanes (Australia) Pty Ltd of Gate 3, Ballarat Road, Deer Park, Victoria 3023, (ABN 40 090 446 165) and Honeywell Polymers (Australia) Ltd of 3/71 Queens Road, Melbourne, Victoria 3004, (ABN 35 008 423 096).

The Assessment Report for HFC-245fa is identified by the sequence number NA/920.

Second Applicant

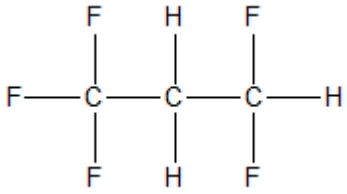
Since granting of the abovementioned Assessment Certificate, A-Gas (Australia) Pty Ltd (ABN 18 066 273 247) of 9-11 Oxford Road, Laverton North, VIC 3026 has submitted a notification statement in support of their application for an extension of the original Assessment Certificate for HFC-245fa. Honeywell Polymers (Australia) Pty Ltd has agreed to this extension.

Information submitted by A-Gas (Australia) Pty Ltd pertains to the introduction of the notified chemical for use in personal hair care products. The end use products will be distributed nation wide. A-Gas (Australia) Pty Ltd will be importing 200 tonnes per year.

Under Section 40G of the Act, the amended Assessment Report for NA/920 will be republished and provided to: the Chief Executive Officer of the National Occupational Health and Safety Commission; the Secretary of the Department of the Environment; and the Secretary of the Department of Health and Ageing.

2. IDENTITY OF THE CHEMICAL

The spectral data, identity and weight percentage of hazardous and non-hazardous impurities and identity and weight percentage of additives/adjuvants have been exempted from publication in the Full Public Report and the Summary Report.

Chemical Name:	1,1,1,3,3-Pentafluoropropane
Chemical Abstracts Service (CAS) Registry No.:	460-73-1
Other Names:	Hydrofluorocarbon 245fa
Marketing Names:	HFC-245fa; R-245fa; Genetron 245fa.
Molecular Formula:	$CHF_2CH_2CF_3$
Structural Formula:	
Molecular Weight:	134
Weight Percentage of Ingredients:	100%
Conversion factors:	1 ppm = 5.48 mg/m^3 = 0.00548 mg/L; 1 mg/m^3 = 0.18 ppm.

3. PHYSICAL AND CHEMICAL PROPERTIES

Unless otherwise specified the physical properties tabulated and discussed below were all determined (HLS, 1996b; HLS, 1997a) using accepted EEC guidelines.

Appearance at 20°C & 101.3 kPa:	Colourless gas at 20ºC with a faint ethereal/sweetish smell. A clear colourless liquid below 15°C.
Freezing Point:	<-25°C (Method A1 of directive 92/69/EEC); <-80ºC (US EPA)
Boiling Point	15.3°C(Method A2 of directive 92/69/EEC)
Liquid Density:	1.32 g/cm^3 at 23°C (Method A3 of directive 92/69/EEC)

Relative Vapour Density (Air = 1):	5.5g/L at 25^0C
Vapour Pressure:	148.5 kPa at 25°C (122.7 kPa at 20°C)
Water Solubility:	7 180 mg/L at ambient room temperature pH 8.11-8.62 – see notes below (water in HFC-245fa 1 600 ppm).
Henry's Law Constant	H = 2 290 Pa.m^3/mole, Log H = 3.36 - see notes below
Particle Size	Not relevant; substance is a gas.
Partition Co-efficient (n-octanol/water):	log P_{ow} = 1.35 at 21.5°C – see notes below.
Hydrolysis as a Function of pH:	Half life estimated between 1 day and 1 year at 25°C at pH values between 4 and 9 – see notes below.
Adsorption/Desorption:	No data provided – see notes below.
Dissociation Constant:	No data provided – see notes below.
Surface Tension:	68.5 mN/m at 6.5°C for a 1 g/L aqueous solution.
Flash Point:	None detected
Flammability Limits:	None
Autoignition Temperature:	412°C
Explosive Properties:	None
Reactivity/Stability:	Generally unreactive. Incompatibilities: avoid contact with strong acids and alkalis, highly reactive metals, molten aluminium, finely powdered or freshly abraded aluminium, sodium, potassium, calcium, magnesium, zinc, barium and lithium shavings under conditions of high temperature and/or high pressure. HFC-245fa exhibits negligible photochemical reactivity. Half life in the troposphere estimated as 6-7.6 years – see environmental fate section 8.2.
Ozone Depleting Potential:	0
Gobal Warming Potential:	790 (100 year time horizon)

3.1 Comments on Physico-Chemical Properties

HCF-245fa, when packaged with a nitrogen pad, is a Class 2.2 dangerous good (Federal Office of Road Safety, 1998). The pressurised product is limited to small cylinders intended for sampling. However, the majority of HFC-245fa imported is packaged as a single material and does not qualify as a Class 2.2 dangerous good.

The relative density of the compound at 10±0.5ºC was determined (HLS, 1997a) from the ratio of the weight to the volume of the compound in a 50 cm^3 pycnometer.

The vapour pressure of the chemical was determined between –5 and 15ºC (the boiling point at atmospheric pressure) using a vapour pressure isoteniscope (HLS, 1997a), and the data extrapolated to provide the result of 122.7 kPa at 20°C.

Due to the volatility of the compound, standard methods for the determination of water solubility could not be employed and a modification of the shake flask method was used (HLS, 1996b). The procedure employed was to shake 10 mL of the test substance with 10 mL of distilled water in a closed separating funnel for one minute with occasional venting of released vapour. Although not indicated in the test report it must be presumed that this mixing was performed below the boiling temperature of 15.3°C. After mixing, the aqueous and non aqueous layers were allowed to separate for 30 minutes, and then samples of the (top) aqueous layer were removed and analysed for HFC-245fa using gas chromatography. The determination was performed in triplicate and provided values of 7.51, 6.96 and 7.08 g/L (average 7.18 g/L).

This is a high water solubility, but not inconsistent with the dipolar nature of the chemical and its relatively small size and molecular weight. A molecular fragmentation procedure for estimating water solubilities (Table 2-16 of (Lyman et al., 1990)) provides an estimate of 1.9 g/L which is of similar magnitude to the experimental value.

The Henry's Law Constant was calculated from the measured vapour pressure (VP), water solubility (S) and molecular weight (MW) through the relation H = VP X MW/S. The relatively high value of H indicates the chemical to be appreciably volatile from water.

The rate of hydrolysis of the chemical was determined (HLS, 1997a) over a 5 day period in buffers of pH 4, 7 and 9 at 50 ^{0}C, with initial concentrations of the test compound in each buffer around 1 g/L. The samples were contained within closed vials (presumably this was deemed sufficient to prevent evaporative losses) and, after 5 days at 50 ^{0}C, the solutions were analysed for the test compound (gas chromatography) and the degrees of degradation were found to be 16.3, 20.4 and 24.2% at pH 4, 7 and 9 respectively. When these data were rationalised to degradation at 25 ^{0}C using the Arrhenius equation the half life at all pH values was found to be between 1 day and 1 year.

The results of this study should be treated with caution since the C-F bond is the strongest single bond commonly encountered in organic compounds (bond strength around 480 kJ/mole) and the stability of fluorocarbons to attack by acids and bases is well known (Greenwood & Earnshaw, 1989). The test temperature (50 ^{0}C) was well in excess of the BP (15.3 ^{0}C) and, since no special precautions to prevent evaporative loss of the compound were apparently implemented, it is possible that the observed losses of the compound were due to evaporation rather than hydrolytic degradation. In respect of this, the chromatograms of the test solutions reproduced in the report showed only a single peak due to the test compound itself and no evidence of other peaks attributable to degradation products were apparent.

The n-octanol/water partition coefficient was determined (HLS, 1996b) from the ratio of the solubility of the compound in n-octanol (water saturated) to that in water (n-octanol saturated), both determined using gas chromatography at 21.5^0C. The procedure employed was to introduce a solution of the test compound in water saturated n-octanol (concentration 186 g/L) into small screw capped vials containing 10 mL of water saturated with n-octanol, and then allowing equilibration and phase separation for two hours. After this time samples of the two phases were removed and analysed for HFC 245fa using gas chromatography. Three different tests were conducted using 5, 10 and 15 mL of the stock HFC-245fa in n-octanol solution respectively, and each aqueous and n-octanol sample from each test vial were analysed in duplicate for dissolved HFC-245fa. The water solubility ranged from 4.16 to 4.73 g/L while the solubility in n-octanol ranged between 82 and 114 g/L. The mean ratio of solubilities (ie. Kow) was found to be 22.63 giving a mean value for Log Kow as 1.35.

No adsorption/desorption data were provided, but the modest value for Log Kow and the appreciable water solubility indicate that the compound would have only small affinity for the organic component of soils and sediments and is also likely to be mobile in these media.

The compound contains no acidic or basic functional groups so dissociation constant data are not relevant.

HFC-245fa is not classified as surface active because the surface tension of the 1 g/L aqueous solution was greater than 60mN/m.

4. PURITY OF THE CHEMICAL

Degree of Purity:	98.5 - 99.9%
Hazardous Impurities	This information is claimed as exempt. All impurities are present at below 0.05 wt%.
Non-Hazardous Impurities (>1%)	None.
Additives/Adjuvants:	None indicated.

5. USE, VOLUME AND FORMULATION

The import volume has been exempted from publication in the Full Public Report and the Summary Report. Altogether, including this extension, the total volume will be less than 500 tonnes per year.

HFC-245fa will not be manufactured in Australia. It will be imported in returnable steel containers (45 kg, 454 kg or 885 kg) or returnable iso-tanks (maximum 18 144 kg) or half and one tonne (nett fill) pressurised cylinders and 20’ iso-tanks, as a volatile liquid.

HFC-245fa will be a replacement for ozone-depleting solvents such as HCFC-141b and HFC-225 ca/cb in polymeric foam systems. It will also be a replacement for HCFC-123 and CFC-11 in centrifugal chillers.

Its primary use will be as a blowing agent in a range of rigid polymeric foam systems at 5 to 15% e.g. polyurethane, polyisocyanurate, polystyrene, polyolefin and other polymeric foams. These foams will be used for thermal insulation, for example in refrigerators and freezers, boardstock foam used in construction (roofing and sheathing), architectural panels, garage doors, water heaters and picnic coolers.

It will also be used as a refrigerant for centrifugal water chillers in commercial air conditioning, where it will be used as the working fluid to produce chilling of water. During this application HFC-245fa will not be part of a formulation.

HFC-245fa will additionally be used in industrial aerosol products as a solvent and propellant for active ingredients, flammability suppressants and/or vapour pressure suppressants. The amount of HFC-245fa in the final aerosol products could range from 5-90%.

The volume of HFC-245fa used in refrigerant and industrial aerosol solvent uses will be small, at approximately 5-10% of the total volume imported.

Overseas, HFC-245fa is also used as a replacement for chlorinated solvents during cleaning (degreasing or flushing) or during deposition of lubricants or anti-coagulants on medical devices. This use was withdrawn in the United States, as exposures in open industrial cleaning equipment are difficult to control consistently. This use has not been notified in Australia.

HFC-245fa was in use in Australia during 1997 under a Commercial Evaluation permit.

6. OCCUPATIONAL EXPOSURE

Occupational exposure is expected to vary according to the use of the notified chemical.

The notifiers' submission contained atmospheric monitoring data from use overseas. The notifiers also indicate that atmospheric monitoring (both personal and grab sampling) is carried out on one site in Australia using a Dräger detection tube. The diffusion technique is used for personal monitoring while the hand and automated pump technique is used for grab sampling monitoring. On another Australian site, a passive dosimeter has been developed for sampling the notified chemical at concentrations of up to 600 ppm.

6.1 Use as Blowing Agent Polymeric Foam Systems

6.1.1 Manufacture of Polyol Blend

Two of the three notifiers have indicated that HFC-245fa is to be used as a blowing agent in polymeric foams. Two methods are used for the formulation of polyol blend.

Method 1:
HC-245fa is pumped (using a Lutz electronic pump or a diffusion wand with positive back pressure) from the manufacturer's original closed top container into a closed vessel. The vessel will be fitted with a suitable pressure release valve and have localised high volume extraction at the discharging point, the catalyst station and the minor additions station

(tundish). HFC-245fa will be introduced with stirring under the surface of the polyol blend in the vessel. The polyol blend in the vessel will have been was selected to have maximum solubility and compatibility with HFC-245fa. The polyol blend containing HFC-245fa will then be repacked. This process is designed to ensure minimal loss of HFC-245fa to atmosphere. The blended product will be pumped into closed containers (either steel drums or 1 000 L intermediate bulk containers (IBC)) in a well-ventilated packing area.

Method 2:
This method was implemented as a result of concern about the potential for losses of HFC-245fa in hot summer months during the blending and handling processes of Method 1. A calculated amount of HFC-245fa is pumped into a pressure container, into which a pre-blend of polyols, catalysts, cell stabilisers, fire retardant and non-volatile Zero OCP blowing agent has already been introduced. The container is rolled for a set time in order to ensure complete mixing of the pre-blend and HFC-245fa. These pressure containers will be supplied to customers ready for use.

The following table details the number of workers and the nature of work done, the duration and frequency of exposure and the personal protective equipment used by workers involved in the formulation of polyol blend. It is based on data submitted by Huntsman, Deer Park and Ariel Industries Pty Ltd.

Work Category (number of workers)	*Nature of work*	*Exposure*	*Physical form of chemical*	*Personal Protective Equipment used*
Transport (1)	Transportation of imported drums to the plant.	4 hours/day, 12 days/year	Cool liquid	Safety glasses, neoprene or nitrile gloves, safety boots
Storage (2)	Forklift removal of drums from transport vehicle to storage site and from storage to processing areas.	1 hour/day, 36 days/year	Cool liquid	Safety eyewear, neoprene or nitrile gloves, safety boots, cotton overalls
Process workers (3 - 5)	Pumping chemical into blending vessel, monitoring & adjusting blending conditions and component quantity, discharging blend to packaging.	From 2 hours/day, 36 days/year[a] to 4 hours/day, 210 days/year[b]	Cool liquid/gas	Safety eyewear, neoprene or nitrile gloves, safety boots, cotton overalls, goggles, hard hats, organic vapour mask (where necessary)
Maintenance (2)	Routine maintenance of blending vessel, including opening charging lines and pumps, washing of blending vessel.	From 4 hours per month[c] over a 10 month period[b] to 2 hours/day 3 days/year[a]	Cool liquid/gas	Safety eyewear, neoprene or nitrile gloves, safety boots, cotton overalls, goggles, hard hats, organic vapour mask (where necessary)
Quality assurance laboratory testing (3)	Chemical and physical testing of plant sample, directing plant operators in component addition adjustments	2 hours/day, 36 days/year	Liquid	Safety eyewear, latex gloves, safety boots, cotton lab coat

[a]Huntsman ICI Polyurethanes (Australia) Pty Ltd

[b]Ariel Industries Pty Ltd

[c]Maximum exposure

Loss of HFC-245fa to the atmosphere during the manufacturing process is not anticipated, however dermal and inhalation exposure to HFC-245fa is possible using both methods of formulation when connecting and disconnecting pump lines and during maintenance. Exposure for process workers is limited by pumping from closed containers and by operating at ambient (not elevated) temperatures. The frequency and duration of exposure of process workers is also minimised by running large production batches.

Laboratory quality assurance staff could be exposed to the notified chemical when taking samples. Exposure of these staff is limited by having small sample sizes. Quality assurance staff will handle not more than 500 g of the blended system during the testing of blends, polyol and HFC-245fa, and tests will be conducted on 50 – 80 g samples. Exposure will also be limited by maintaining temperature control of the materials and the environment, and by using laboratory fume hood extraction.

Vessel washings and minor drips and spills which occur during the manufacturing process will be washed into floor drains to an effluent pit. Spill buckets and trays are placed under points of charge and discharge on the blending vessel. These will be collected into drums before being disposed of by a disposal company. Exposure to vapours and drips and spills may be possible during this collection process.

Atmospheric Monitoring during Manufacture of Polyol Blend

The measurements listed in the table below are from area monitoring with readings obtained from grab samples. Readings were taken in a cold room (approximately 3.7 x 4.6 m) with no air exchange. HFC-245fa was added above the surface to a 208 L drum containing the polyol blend. An agitator was then inserted through the bung hole of the drum and used to mix the polyol blend with HFC-245fa. The bung hole of the drum was open during mixing. After mixing, the blend was pumped to a holding tank. It was observed that HFC-245fa was dripping from the connection of the drum to the holding tank. This implies that the notified chemical had not mixed well, instead forming a layer on the surface of the polyol blend. These factors may have led to evaporative losses of HFC-245fa and the high levels of HFC-245fa seen in the cold room.

Vapour concentrations during polyol blend manufacture (Allied Signal, July 1997)

Sample Description	*Vapour Concentration (ppm)*[a]	*Vapour Concentration (ppm, v/v)*[b]
Cold room at 10ºC, adding HFC-245fa to polyol	750	-
Cold room, adding HFC-245fa to polyol	2 400	-
Cold room, addition complete of HFC-245fa, start of mixing	2 430	788
Cold room, after mixing	>2 985	1 255
Cold room, rolling drum of polyol blend	120	-

[a]Gas Tech detector tube.

[b]Analytical data – air can sampling.

6.1.2 Foam Manufacture and Use

In foam applications HFC-245fa is blended along with various other components (typically a polyol blend mixed with MDI) in a blend tank or foam machine and then poured or sprayed into a mould, free-rise conveyor system or cavity and allowed to cure. HFC-245fa becomes trapped in the cells of the foam as it cures. Engineering controls in place during foam manufacture will be similar to those in place for polyol blend manufacture i.e. localised high volume extraction at potential points of emission.

Exposure to HFC-245fa vapour is possible during the foam manufacturing process. During the foaming process approximately 2% - 3% of the blowing agent is lost. Once manufactured, losses of HFC-245fa from the foam matrix will be minimal as long as the foam remains uncut due to the closed cell nature of the foam and the compatibility of HFC-245fa with the foam matrix.

Modelling data using EASE[1] has predicted a concentration range during foam production of 100 – 200 ppm, assuming a processing temperature of 60ºC, a non-dispersive use and local exhaust ventilation. Data for a similar compound, HCFC-141b, which is used for the same applications, indicate that exposure levels during foam production may be between 0.005 and 488 ppm for 8 hours/day for up to 250 days/year.

European exposure monitoring has indicated that typical personnel exposures to HFC-245fa during foam applications are in the range of 3 – 10 ppm with maximum short-term peak exposures of less than 100 ppm.

Workers potentially exposed to foam containing HFC-245fa are advised to wear overalls, gloves, safety eyewear and safety shoes.

6.1.2.1 Appliance Product

In a typical appliance production area, HFC-245fa will be blended with the polyol blend in a blend tank, and then transferred through metering pumps or piping to the foam pour area. A foam fixture will be used to transfer the foam to the appliance, usually a cabinet or door. The finished cabinet or door will then progress to further assembly operations.

Atmospheric Monitoring during Appliance Production and Appliance Filling

Atmospheric monitoring data were provided for foam filling of appliances. Instantaneous (grab) air samples were taken either with evacuated air cans, for subsequent analytical measurement, or direct indication using Gas Tech detector tubes. The HFC-245fa vapour concentrations obtained in the monitoring are tabulated below.

The vapour concentrations during foam filling of refrigerator cabinets, during foam filling of refrigerator/freezer doors and during foam filling of freezer cabinets were obtained using methods that are not typical of commercial production as there was, in these trials, only one gas vent hole for air to escape from as the foam filled the void between the walls of the cabinet. Vapour concentrations during foam filling of freezer cabinets were obtained using only one out of eight fixtures for foaming the cabinets.

Vapour Concentrations during Appliance Production and Appliance Filling

[1] The EASE model is the knowledge based system developed by the UK Health and Safety Executive (HSE).

Sample Location/Description	Vapour concentration (ppm) Detector tube	Air Can sampling
Vapour concentrations during foam appliance production (typical values) (Allied Signal, undated)		
Blend tank(s)	-	6
Directly over vent hole of foam fixture (pouring position)	-	<3[c] – 70
Directly over vent hole of foam fixture (de-mould position)	-	<3[c]
Vapour concentrations during foam filling of refrigerator cabinets (research and development facility) (Allied Signal, July 1997)		
Background	-	<3[a]
2 ft from base of cabinet, 30s after foam shot	-	937
Immediately after vent hole, 30s after foam shot	-	6 234
Near operator at vent hole during plugging of pour hole, 30s after foam shot	-	288
At operator station near fixture, 30s after foam shot	-	86
Range of vapour concentrations during foam filling and after demould of cabinets (Allied Signal, July 1997)		
During foaming[b]	-	<3[a] – 6.0
After demould[c]	-	<3[a]
Vapour concentrations during foam filling of refrigerator/freezer doors (Allied Signal, July 1997)		
Foaming laboratory (background)	Not detected	<3[a]
At vents during foam rise, several seconds after foam shot	30, 30, 30, 150	<3[a], 4.2
Blend tank area	Not detected	<3[a]
During demoulding operation	Not detected	<3[a]
Vapour concentrations during foam filling of freezer cabinets *(Allied Signal, July 1997)*		
Foaming laboratory (background)	Not detected	<3[a], <3[a], 3.6
Foamed door, vented end	Not detected	<3[a]
Above foam fixture during foam rise	180, 210, 270, 360, 360	5.6, 6.6, 70.7
Upon removing breakers from compact chest freezer	Not detected	-
Blend tank area	Not detected	6.0
Above door during demoulding operation	-	<3[a]
At vent holes during foam rise	-	10.4

[a]Less than detection limit of 3 ppm.

[b]Samples taken above fixture during foaming, except in one instance when sample was taken at the base of the fixture during foaming, during which the reading was below the detection limit.

[c]Samples taken after demould (location unspecified), except in two instances when sample was taken inside the cabinet and inside the freezer after demould. In both instances, the reading was below the detection limit.

Atmospheric Monitoring Conducted at Roofing Trial of Insulation Foam

The notifiers' submission contains the following atmospheric monitoring data obtained during a roofing trial of insulating foam. The procedures taken to obtain the vapour concentrations during the trial were not specified. From photographs contained within the notifiers' submission it appears that during this trial the gun operator sprayed the foam onto the roof surface to form an insulating layer, and that after spraying the panels of the roof were replaced.

Personnel monitoring conducted at roofing trial of insulating foam (Honeywell, January 2000)

Personnel	*Vapour Concentration (ppm)*[a]
Gun operator[b]	19
Hoseman[c]	15
Cleaner of spray nozzle	43

[a]8-hour TWA.
[b]The gun operator sprays foam on the roof surface
[c]The hoseman supports the hose through which foam flows. In this trial, he was located approximately 2m behind gun operator.

Area monitoring conducted at roofing trial of insulating foam (details not available) (Honeywell, January 2000)

Sample Location	*Vapour Concentration (ppm)*
Upwind	21
Downwind operator (head level)	63
Downwind hoseman (head level)	27
Spray plumb	39

6.1.2.2 Boardstock Product

On a typical boardstock production line, HFC-245fa will be blended with the polyol blend in a blend tank, and then transferred through metering pumps or piping to the foam pour area. This progresses to a vented oven, and along an open conveyor to a cut-off saw. Another open conveyor then transports the foam portions to the stacking or packaging area.

One notifier states that at the customer's site, small 50 g to 3 kg mixes of polyol blend are used to manufacture rigid foam systems. The foam is contained within a mould in order to minimise loss of the blowing agent. A maximum of 3% of the shot weight is lost during foaming, and thus the maximum exposure to HFC-245fa will be 90 g in a well-ventilated area.

Atmospheric Monitoring during Boardstock Production

Vapour concentrations along the foam boardstock/bunstock production line were obtained from area monitoring. Grab samples were obtained using evacuated air cans, except for the reading obtained in the Stacking/Packaging area, which was obtained using a Gas Tech detector tube. 3 – 5 workers are employed along the boardstock/bunstock production line as follows: the same 1 – 2 operators work on the blend tanks and at the foam pour area, 1 operator works on the conveyor and 1 – 2 operators work at the cut-off saw.

Vapour concentrations along foam boardstock/bunstock production line (Allied Signal, January 1998)

Sample location	*Vapour Concentration (ppm)*
Blend tank(s)	<3[a]
Blend tank(s) (during preparation of batch)	100
Foam pour area (directly above liquid)	<3[a] – 795[b]
Conveyor	<3[a] – 10[c]
Cut off saw	<3[a] – 3[d]
Stacking/Packaging	<3[a]

[a]Less than detection limit of 3 ppm.

[b]Appears to be formulation dependent. Readings were <3, 8, 11, 38, 304, 320, 340, 565 and 795 ppm. The readings of 565 and 795 ppm were obtained from one manufacturing facility. Commercially acceptable product was not produced.

[c]Readings were <3, <3, <3, 9 and 10 ppm.

[d]Readings were <3, <3, <3, <3, <3 and 3 ppm.

6.2 Working Fluid in Centrifugal Water Chillers

As a refrigerant for centrifugal water chillers, HFC-245fa will be used in closed systems in which the refrigerant and water circuits are isolated from one another. Initial charging of the chiller with HFC-245fa and subsequent maintenance and repair present the major sources of occupational exposure, and service technicians are the main population at risk of occupational exposure to HFC-245fa.

The degree of exposure to HFC-245fa depends on the number of hours spent at chiller installations using HFC-245fa as a refrigerant and the type of maintenance or repair work carried out. The NICNAS PEC Report on HCFC-123 (NICNAS, 1996) describes refrigerant applications and identifies refrigerant transfer, leak testing and chiller stripdown as procedures likely to give rise to significant exposure for chiller service technicians. Other sources of exposure include accidental spillage from refrigerant drums and leaks caused by chiller malfunction.

Refrigerant Transfer

Refrigerant transfer is performed during the initial start up of newly installed equipment and during repair jobs. During refrigerant transfer the refrigerant from the chiller system is removed, transferred to recovery/storage vessels, and then replaced. This involves placing a vacuum on the recovery/storage vessel, so that when the pressure in the recovery/storage is

lower than in the chiller, the refrigerant flows from the chiller to the storage/recovery vessel.

Most low-pressure chillers are field charged with the refrigerant at the job site. Maintenance personnel may be exposed to HFC-245fa if there is spillage of the refrigerant or vapour escape, which may occur during connection and disconnection of transfer lines/hoses from the recovery/storage vessels and chiller. Refrigerant vapour may also be vented into the workroom air during operation of the vacuum pump.

Leak Testing

Under normal operating circumstances, leakage is not a source of refrigerant exposure. However, the process of testing for leaks may result in the release of refrigerant. Leaks are detected either by increasing the chiller pressure to induce refrigerant emission or by purging the empty chiller with nitrogen (or a mixture of nitrogen and an inert refrigerant) under atmospheric pressure. Should leaks be present, both these procedures are potential sources of HFC-245fa vapour emissions and exposure to service technicians may occur.

Chiller Stripdown

Depending on the work being done, many chiller repairs require that the chiller be opened or dismantled. This is referred to as stripdown. Stripdown represents the largest potential source of release of residual refrigerant vapour from maintenance activities, and usually requires the prior removal (transfer) of refrigerant charge. The amount of refrigerant vapour released during stripdown depends on the efficiency of the refrigerant transfer procedure, the degree of chiller opening or dismantling and the amount of residual refrigerant in the chiller.

Purge

In low-pressure chillers air, will leak into the chiller system rather than refrigerant leaking out. This air must be purged from the system in order for the chiller to function efficiently. Purging represents a source of occupational exposure to HFC-245fa as refrigerant contained in the purged air will be released to the atmosphere.

Oil Change

Chiller oil becomes contaminated with refrigerant during normal operation. Oil drainage and the removal and changing of the chiller filters and the refrigerant core drier are sources of occupational exposure to HFC-245fa.

The notifier states that monitoring of job sites has demonstrated that exposure levels of service technicians to HFC-245fa rarely exceed 0.5 ppm. Even at jobsites with marginal industrial hygiene, exposure levels rarely exceeded 2 ppm for an 8 hour day. Current emission rates, including those due to leakage, purge losses and service losses are < 0.5% of the refrigerant charge per year for low pressure chillers, and approximately 5% of the refrigerant charge per year for high pressure chillers.

6.3 Use as a Solvent in Aerosols

As it is used in industrial aerosol products, HFC-245fa will be blended with other components and packaged in conventional aerosol cans. Occupational exposure will arise on

sites at which aerosol filling occurs and on sites at which the aerosols are used (mainly for contact cleaning, for example, of printed wiring boards, and as mould release agents).

6.3.1 Manufacture of Aerosol Products

Aerosol filling lines are designed to minimise emissions for both safety and economic reasons. Exposure is expected to be minimal, as aerosol filling operations are highly automated, involving little or no direct contact with the components being charged to the aerosol cans. HFC-245fa can be introduced into aerosol cans by either metering into open cans, which are then sealed (or capped), or through the aerosol valve of a capped can, the latter being conducted in an isolated gassing room. The notifier states that no emission data are available as there have been no line trials to date, however, based on the physical properties of HFC-245fa, it is not expected that emissions will differ significantly from those obtained with other solvents.

Assuming a vapour and process temperature of 25ºC, a non-dispersive use and local exhaust ventilation, the EASE model predicted a concentration range of 100 – 200 ppm during aerosol production. Due to the process being largely enclosed, it can be assumed that exposures would not be expected to exceed 100 ppm.

6.3.2 Use of Aerosol Products

Contact cleaners

To remove any contamination introduced during soldering technicians will spray the aerosol cleaner onto the printed wiring board and leave the solvent to evaporate. According to a manufacturer of aerosol contact cleaners, a typical use rate of aerosol contact cleaners is one can per week per technician. During testing to characterise the emissions from an aerosol contact cleaner containing a mixture of CFC-113 and alcohols, the concentrations of CFC-113 in air samples[2] ranged from <3 ppm to 27 ppm (70 mg/m^3 to 210 mg/m^3), TWA. The notifier states that there is no reason to expect significantly higher emissions for contact cleaners formulated with HFC-245fa, as the products will be used in the same manner and have similar delivery rates. A typical delivery rate is approximately 1 g/sec, and is independent of the solvent used in the formulation.

Mould release agents

Aerosols containing HFC-245fa will typically be used in plastics moulding operations. The product is sprayed onto moulds to enable easier removal of finished parts. According to two manufacturers of aerosol mould release products, a typical use rate ranges from one to three cans per day. Emissions data are not available, but a worst-case scenario assuming a 454 g net-weight product (half of which is HFC-245fa), a use of three cans per day sprayed into a 565 m^3 room with no ventilation (that is, a high use rate in a relatively small facility with no air changes) gives the concentration of HFC-245fa as 216 ppm (1205 mg/m^3). If constant use throughout an 8-hour shift and normal ventilation (one air change per hour) is assumed, the level of HFC-245fa would be below 36 ppm (200 mg/m^3).

[2] Collected on charcoal tubes attached to low-flow air pumps over a 5-hour period at 5 workstations where the product was being used

Modelling data during aerosol applications

Assuming a vapour and process temperature of 25ºC, a non-dispersive use and direct handling with dilution ventilation, the EASE model predicted a concentration range of 500 – 1000 ppm during aerosol and solvent applications. Assuming a worst-case scenario (exposure to 1 000 ppm HFC-245fa for 8 hours/day, 250 days/year), at 25ºC this corresponds to inhalation of 540 mg/kg bw/day for a 70 kg worker.

6.4 Transport and Storage

Drums of the notified chemical will be delivered to the notifiers' sites without being opened. On site, drums of the notified chemical will be transported on pallets using a forklift or the appropriate lifting attachment on the tines. Except in the case of accidental spillage or leakage, exposure to the notified chemical during transport or storage is therefore unlikely.

6.5 Disposal

Inhalation exposure to the notified chemical may occur during the disposal of appliances containing foam and aerosol cans containing HFC-245fa.

6.6 Education and Training

All production staff will receive training in the handling of low boiling materials such as HFC-245fa, with particular attention to be paid to the handling of HFC-245fa containers to minimise product loss. In addition, the handling of all polyurethane system components will be reviewed. This will include reference to industrial hygiene, minimisation of exposure, the correct use of protective equipment and its maintenance, spill guides and MSDS. Instruction on the use of protective clothing will be given annually. Written work instructions, competency-based training manuals and process and system operation manuals are used to manage correct use of plant and equipment. Emergency simulation training will take place every six months, and written procedures are available for dealing with foreseeable emergency situations. MSDS will also be available around the plant.

Upon receipt of commercial quantities of HFC-245fa and packaging details, specific training with regard to HFC-245fa will be undertaken. Core health and safety training on the hazards of HFC-245fa and the routes of entry of HFC-245fa into the body will be given to new employees during safety induction training and during the introduction of the notified chemical on site.

Customers will be given guidance and advice on the preparation of suitable MSDS.

7. PUBLIC EXPOSURE

Public exposure may occur in the event of spillage or leakage on the occasion of a serious transport or industrial accident. Public exposure by both dermal contact and inhalation or both is possible in these instances. Spillage of liquid will be mopped up with absorbent material and disposed of according to regulatory guidelines. A high rate of evaporative loss from a street spillage or disposal site is likely.

The notified chemical is intended only for industrial use. There is potential for public contact with residual amounts of the chemical in various items which have been constructed with boardstock foam. These amounts will be minimal and in most instances the foam will be inaccessible in such items. The public are not likely to have contact with HFC-245fa in industrial aerosol, refrigerant or solvent applications. Thus, public contact with this chemical is unlikely as a result of the industrial uses of products containing the notified chemical.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

When used as a blowing agent for production of polymer foam the notified chemical will be released into the environment in two ways: (1) into the atmosphere by diffusion, and (2) minor releases into water through equipment cleaning, housekeeping and vessel maintenance.

Use of the chemical as a refrigerant and in aerosols is expected to be a minor use pattern in Australia, but again the chemical will be released primarily to air when employed in these roles. In the case of its use in aerosol cans, the release would be immediate.

Release into the Atmosphere

Almost all of the notified chemical will eventually be released into the atmosphere. Most of the imported HFC 245fa will be used as a blowing agent for the production of polyurethane foam, and the notifiers indicated that up to 1% of the compound is expected to be lost (released) during formulation of the polyol blends which would amount to a maximum release of 2.5 tonnes per annum. One of the applicants also indicated that around 3% of the blowing agent is lost directly to the atmosphere during production of the polymer foams, and so a further (maximum) 7.5 tonnes would be released each year during these activities. The remainder of the chemical is encapsulated within the bubbles of the polymer foam and it was indicated that while the foam remains intact, diffusion of the HFC-245fa from the foam cells is a slow process. Nevertheless, loss via diffusion over the service lifetime of the foam products is expected.

A test conducted (Covance, undated) to ascertain the extent to which the blowing agent escaped from the foam in refrigerators and freezers (to be replaced by air) through diffusion showed that the blowing agent slowly escapes from the foam. This test was conducted using four appliances over a 168 day period, and showed that initially the gas could be detected in the air inside some operating freezers at a concentration of between 10 and 36 ppm, although the concentrations fell steadily to levels below detection (1 ppm). The extent to which the agent was released appeared to depend on the appliance type (presumably different standards of construction), but in one case the gas was still detectable (1 ppm) after 168 days. Although the details in this report are insufficient to allow for estimation of definitive rates of diffusion, it appears clear that over time the gas is released from the foam and will enter the atmosphere.

Advice solicited and obtained from the Australian Greenhouse Office indicated that most of the blowing agent is expected to escape from the foam over 20 years, which is roughly equivalent to the service life of most domestic appliances.

Regardless of losses from the foam to the atmosphere during product lifetime, after product retirement most foam products will be either sent to land fill or will be incinerated. In the case of incineration, the notifier claims that the blowing agent is destroyed prior to atmospheric release, although the high thermodynamic stability of hydrofluorocarbons indicates that this may not be the case[3] and most would be liberated to the atmosphere. However, if the end product is crushed upon disposal and sent to land fill, the foam cells are destroyed during crushing or during subsequent biodegradation of the polymer matrix, and all of the notified chemical will be released into the atmosphere from the cells.

Although it may take some time for full emissions to be realised, as a worst case scenario it must be assumed that 100% of the imported chemical will be released into the atmosphere.

Any chemical used as a refrigerant would be released slowly through leaks and diffusion during the refrigerator's service life, while any used as a solvent would be released to the air almost immediately after use of the solvent.

Release into Water

The notified chemical may be released into water during minor drips and spills and vessel washing during production of the polyol blends. The spills are washed into floor drains to an effluent pit and then be sent to on site effluent treatment treated plants or containment facilities prior to being released to metropolitan sewer systems or storm water drains. However, despite the appreciable water solubility (7.18 g/L), due to the high value for Henry's Law constant, it is probable that most of the spilt compound would vaporise before being discharged, and little would remain in the water.

At the Huntsman plant the containment pit is intended to prevent escape of the chemical to the local Creek (Kororoit Creek) via stormwater drains. According to the notifier, the pit is currently monitored by the Victorian EPA and the local water authority, City West Water.

During manufacturing of the blends spill trays and buckets are placed under points of charge and discharge on the blending vessel and collected into drums. The drums will be disposed of via a disposal company via incineration. However, some resin containing HFC-245fa may be disposed of to approved land waste sites.

Release to Soil

Except in the case of a transport or materials handling accident very little of the compound will be released to the soil compartment. However, the low expected affinity of the compound for the organic component of soils and sediments together with its volatile nature indicate that the compound would move from the soil to the atmospheric compartment.

8.2 Fate

Atmosphere

[3] HFCs can be destroyed under the very high temperature conditions in an electric arc furnace, but such facilities would not be used for routine industrial incineration.

The notified chemical is a highly fluorinated low molecular weight alkane most of which is expected to enter the atmosphere and is also expected to persist in this environment. The predominant mechanism for initial degradation of HFC-245fa in the atmosphere is expected to be through hydrogen abstraction by hydroxy radicals with production of the $CF_3CH_2CF_2\bullet$ radical (Chen et al., 1997), and in a document supplied in the notification (Ko et al., undated), the atmospheric half life of the chemical in the troposphere was estimated as 7.6 years.

The rate constant for degradation through hydrogen abstraction may also be estimated using published data from an OECD monograph (OECD, 1992), and using the appropriate procedures described in this document, the rate constant for hydrogen abstraction from HFC-245fa is estimated as $k_{abs} = 0.077 \text{ X } 10^{-13}$ cm^3 molecule/sec. The atmospheric half life may then be estimated through the relation $t_{1/2} = \text{Log}(2)/ ([OH\bullet] \text{ X } k_{abs})$ where $[OH\bullet]$ is the average concentration of atmospheric hydroxy radicals which is given as $5 \text{ X } 10^5$ radicals/cm^3 by (Calamari, 1993). Using these data and relationships, the value of $t_{1/2}$ is estimated as $1.8 \text{ x } 10^8$ seconds, or approximately 6.3 years.

In a second paper included in the notification, Chen and co-workers (Chen et al., 1997) concluded that following production of the $CF_3CH_2CF_2\bullet$ radical after hydrogen abstraction, this species subsequently reacted with oxygen to produce primarily CF_3CHO and CF_2O, and that these would in turn eventually decompose to HF and CO_2 through further reactions with oxygen and water vapour. The authors of this study indicated that no other long-lived organic
intermediates were detected during the degradation process. The HF would eventually be precipitated to the surface in rainwater.

Water and biodegradation

Only small quantities of the compound are expected to enter the water compartment, and due to the high value of Henry's Law constant, most of this would volatilise to the atmosphere. The notifier provided a test report on the biodegradation of HFC-245fa by microorganisms in aqueous media (KRL, 1996). The test was carried out in accordance with OECD guidelines for testing the biodegradability of substances (ie. TG 301D, Closed Bottle Test).

The test used inoculum separated from sewage sludge collected from Tsubuku city sewage plant. The test gas, HFC-245fa, was introduced into purified water and inoculum, in 100 mL vacuum vessels. The concentration of the test gas in solution was determined at 4585 mg/L. The test substance was left to cultivate (degrade) in a closed vessel for a period of 5, 15 and 28 days, at a temperature of 20 °C. The test substance was found not to be degraded by microorganisms under these test conditions. The IR spectra of the test substance before the start of cultivation and after termination of the cultivation were identical.

The biodegradation tests suggest that microorganisms will not degrade the notified chemical once it is released into the manufacturer's effluent treatment pits. However, given the low boiling point, and high values of vapour pressure and log H, the notified chemical is expected to be very volatile from water. Hence under normal atmospheric pressures and temperatures, the notified chemical is not expected to remain dissolved either in the effluent water, or in natural water bodies, and hence is not expected to pose a threat to aquatic organisms once released into the environment via stormwater drains.

Bioaccumulation

Little of the chemical will reach the water compartment and so exposure to aquatic organisms will be low. Nevertheless, due to the relatively high water solubility and modest value for Log Kow, the potential for bioaccumulation is considered to be low (Connell, 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

9.1.1 Oral Toxicity

In view of the volatile nature of the test substance (gaseous at room temperature) it is not considered technically feasible and not scientifically relevant to conduct this study.

9.1.2 Dermal Toxicity (Pharmaco LSR Ltd, 1994b)

Species/strain: Rabbit / New Zealand White

Observation period: 14 days

Method of administration: Occlusive, 24-hour application.
Because of the volatile nature of the test substance (b.p. 14.7°C), the regulatory limit test dosage is expressed volumetrically (2 mL/kg) rather than the gravimetrically (2 g/kg).

Group	*Number of animals/sex*	*Dose (mL/kg bw)*	*Mortality*
I	5/sex	2	0

Test method: OECD TG 402

Clinical observations: There were no systemic or local signs of reaction to treatment.

Morphological findings: No significant macroscopic findings were observed.

LD50: The study report quotes an LD50 of > 2mL/kg (2.64 g/kg).
Because of volatility it cannot be excluded that most if not all of the test substance probably evaporated through the occlusive dressing prior to the end of the 24-hour contact period.
Test substance loss from evaporation prevents the establishment of a valid LD50 for this study.

Result: A valid LD50 cannot be established.

9.1.3 Inhalation Toxicity in Rats (HLS, 1996a)

Species/strain: Rat / Sprague-Dawley

Observation period: 14 days

Method of administration: Inhalation: whole body exposure for 4 hours.

Group	*Number of animals/sex*	*Nominal concentration % v/v*	*Achieved concentration % v/v (mg/L)*	*Mortality*
I	5/sex	0	0	0
II	5/sex	15	14.3 (790)	0
III	5/sex	20	20.3 (1110)	0

Test method: OECD TG 403

Clinical observations: During exposure exaggerated respiratory movements, abnormal body posture and reduced response to external stimuli were noted in all treated animals at both exposure concentrations. Occasional clonic convulsions were also seen in three low concentration females. Rats recovered from effects within 10 minutes of exposure cessation and remained normal throughout the observation period.

Morphological findings: No macroscopic findings were observed.

LC50: >1110 mg/L/4-hour

Result: The notified chemical was of very low acute inhalation toxicity in rats.

9.1.4 Inhalation Toxicity in Mice (Pharmaco LSR Ltd, 1994a)

Species/strain: Mouse / CD-1

Observation period: 14 days

Method of administration: Inhalation: snout only exposure for 4 hours.

Group	*Number of animals/sex*	*Nominal concentration*		*Achieved concentration*		*Mortality*
		ppm	*mg/L*	*ppm*	*mg/L*	
I	5/sex	0	0			0
II	5/sex	100 000	548	101 300	555	0

Test method:	OECD TG 403
Clinical observations:	Treated animals were observed to be less active than controls from 30 minutes into the exposure period. All animals appeared normal on cessation of the exposure and throughout the observation period.
Morphological findings:	No macroscopic findings were observed.
LC50:	> 555 mg/L/4-hour
Result:	The notified chemical was of very low acute inhalation toxicity in mice.

9.1.5 Cardiac sensitisation

Study 1 (Interfauna UK, Ltd, cited in (Rusch et al., 1999))

The original study report was not submitted. The following is taken from the published report by Rusch et al, 1999.

Species/Strain:	Dog / Beagle
Test method:	In house method; Reinhardt et al 1971
Study design:	Six male dogs were included in the study. Each individual animal's sensitivity to adrenaline (doses of 4-12 μg/kg were used) was determined independently following the Reinhardt procedure described for cardiac sensitisation in Study 2 below. Exposure to the test substance was varied until a cardiac response was achieved.

Exposure[a] *ppm v/v (mg/L)*	*Dog number*[b]				*Number responding/ total exposed*	*Dogs showing clinical signs*		
						None/minimal	*Slight*	*Moderate /severe*
73 000 (400)	1351 [c]				1/1			
44 000 (241)	1371	1373	1375	1379	1/4	1371, 1373, 1379	1375	
54 100 (296)	1373	1375	1379		0/3		1373, 1379	1375
34 100 (187)	1371	1373	1379	1375	0/4	1371, 1373, 1379, 1375		

[a] Exposure levels are presented in the order they were run.
[b] One additional animal (1347) could not be trained to accept the procedure and was excluded from the study.
[c] Animal died during exposure.

Observations	73 000 ppm: exposure resulted in an almost immediate fatal ventricular fibrillation to dog 1351. Due to the rapidity and severity of the response, no additional animals were exposed at this level. 54 100 ppm: no animals showed any indication of developing an arrhythmia. However, all showed a clinical response, typically restlessness and muscle rigidity with a loss of ability to support their own weight. Dog 1371 was not exposed at this level as it had given a positive response at 44 000 ppm. 44 000 ppm: dog 1371 developed a transient ventricular fibrillation. Dog 1375 although not showing a cardiac response, showed signs of muscle rigidity and restlessness. 34 100 ppm: no cardiac arrhythmias or clinical responses were observed at this exposure level.
Comment:	No cardiac arrhythmias or clinical responses were observed at 34 100 ppm. At 44 000 ppm a positive cardiac response occurred in one dog and this is considered the threshold concentration for cardiac sensitisation.
Result:	In this study, the NOEL for cardiac sensitisation was 187 mg/L (34 100 ppm).

<u>Study 2</u> 2-week dose range finding inhalation toxicity study in dogs (HLS, 1998)

Species/Strain:	Dog / Beagle
Test method:	In house method; Reinhardt et al 1971.
Study design:	Three groups (one control, two test) of two male dogs each received inhalation exposure, via a face mask, for 6 hours per day, 5 days per week for two consecutive weeks. One control animal was treated in a similar manner to the treated animals but was exposed to air only. The second control animal was a kennel control, ie no exposure. On the day after the last day of exposure all dogs were subjected to testing for cardiac sensitisation as follows:

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

ECG recording.

The nominal exposure concentration of 35 000 ppm was selected as it was the highest NOEC in the cardiac study described by Rusch et al 1999.

Group	*Two-week exposure*				*Cardiac sensitisation*			
	Nominal		*Actual ppm*		*Nominal ppm*		*Actual ppm*	
	ppm	*mg/L*	*ppm*	*mg/L*	*ppm*	*mg/L*	*ppm*	*mg/L*
I (air only)	0	0	0	0	35 000	192	35 500	195
II	1000	5.48	1010	5.53	35 000	192	35 500	195
III	10 000	54.8	9790	53.6	35 000	192	35 500	195

Summary of Cardiac Response

Dog Number (Group Number)	*Adrenaline Dose (mg/kg)*	*Number of Ectopic Beats*:*		*Cardiac Response**
		1st Adrenaline Challenge	*2nd Adrenaline Challenge*	
1001 (II)	8	1	4	Negative
1003 (III)	4	3	1[1]	Negative
1005 (I)	NA			NA
1007 (II)	4	0	0	Negative
1009 (I)	12	1	1	Negative
1011 (III)	2	2	2	Negative

* Mention is made only of ectopic beats or unexpected responses. The expected response to intravenous injection of adrenaline (initial tachycardia followed by bradycardia and increase in height of T-wave) is not mentioned.

[ ] Values in parenthesis indicate abnormal beats of uncertain origin – typically escape beats.

NA animal not exposed due to failure to accept restraint procedure.

Observations – general: Clinical observations, haematology, blood biochemistry and post-mortem investigations revealed no treatment-related findings.

Observations - myocardial A single focus of minimal myocardial degeneration was seen in one dog at 53.6 mg/L (9790 ppm). There were no treatment related differences in serum cardiac markers (CPK, AST and alpha-hydroxybutyrate dehydrogenase) between control and treated animals. In the absence of any findings in the other dog at 53.6 mg/L (9790 ppm) and changes in enzymes, the finding of myocardial degeneration is considered incidental and unlikely to be associated with exposure to the test substance.

There was no evidence of cardiac sensitisation in any animal.

Result: In the absence of any treatment related findings, the NOAEL for this study is 53.6 mg/L (9790 ppm).
The NOEL for cardiac sensitisation was 195 mg/L (35 500 ppm).

9.1.6 Skin Irritation

Due to the volatile nature of the test substance it is not considered technically feasible to conduct these studies.

9.1.7 Eye Irritation

Due to the volatile nature of the test substance it is not considered technically feasible to conduct these studies.

9.1.8 Skin Sensitisation

Due to the volatile nature of the test substance it is not considered technically feasible to conduct these studies.

9.2 Repeated Dose Toxicity

9.2.1 14 Day Range Finding Repeated Dose Inhalation Toxicity (HLS, 1997d)

Species/strain: Rat / Sprague-Dawley

Method of administration: Inhalation: snout only exposure to vapour for 6 hours/day for 14 consecutive days.

Test method: OECD TG 412

Group	*Number of animals/sex*	*Nominal concentration*		*Achieved concentration*		*Mortality*
		ppm	*mg/L*	*ppm*	*mg/L*	
I	5/sex	0	0	0	0	0
II	5/sex	5000	27.4	5052	27.7	0
III	5/sex	15 000	82.2	15 231	83.5	0
IV	5/sex	50 000	274	50 432	276.4	0

Clinical observations:
No deaths occurred. Clinical observations could not be made during exposure due to the confines of the exposure chambers. No signs of toxicity were observed in any animals when not being exposed. Bodyweights were unaffected.

Clinical chemistry/Haematology:
Statistically significant increases were noted in blood urea nitrogen (BUN) (44% increases

and greater compared to controls) and in serum aspartate aminotransferase (AST) (54% and greater compared to controls) in males and females in all treatment groups. Males and females in Group III and IV showed statistically significant increases (15% and greater compared to controls) in alanine aminotransferase (ALT). Females in all treatment groups showed statistically significant decreases (38% and greater compared to controls) in cholesterol. Females also showed smaller statistically significant increases (13-16%) in potassium (Group IV) and inorganic phosphatase (Groups III and IV). A dose-response relationship was only evident for the increase in AST.

Histopathology:
No treatment-related macro or microscopic findings were observed. No treatment related differences were seen in liver peroxisome.

Comment:
The changes noted in several blood chemistry parameters are likely to be indicative of altered metabolism. Achieved vapour concentrations were close to nominal concentrations. Based on findings from this study, concentrations of 500, 2000, 10 000 and 50 000 ppm were selected for the 28-day, 90-day and developmental toxicity studies.

Result:
A no observed adverse effect level (NOAEL) of 276.4 mg/L (50 432 ppm) is indicated.

9.2.2 28 Day Repeated Dose Inhalation Toxicity (HLS, 1997b)

Species/strain: Rat / Sprague-Dawley

Method of administration: Inhalation: whole body exposure for 6 hours/day on 28 consecutive days followed by a 14 day recovery period.

Test method: OECD TG 412

Group	*Number of animals/sex*	*Nominal concentration*		*Achieved concentration*		*Mortality*
		ppm	*mg/L*	*ppm*	*mg/L*	
I	5/sex	0	0	0	0	0
I - recovery	5/sex	0	0	0	0	0
II	5/sex	500	2.74	516	2.83	0
III	5/sex	2000	10.96	1998	10.9	0
IV	5/sex	10 000	54.8	10 102	55.4	0
V	5/sex	50 000	274	49 600	271.8	2 females
V - recovery	5/sex	50 000	274	49 600	271.8	0

Clinical observations:
Two Group V females died in week four. Four Group V females exhibited lethargy and unsteady gait following overnight collection of urine samples in week 4. The rats recovered when given water. Bodyweight changes were unremarkable.

Clinical chemistry/Haematology
Findings at the end of treatment (week 4):
Males from Groups IV and V showed statistically significant increases (10% compared to

controls) in mean packed cell volume (PCV), haemoglobin and red blood cell count.

Group IV and V animals also showed statistically significant increases (34% and greater compared to controls) in BUN, alkaline phosphatase (AP) (females only), ALT and AST. Females in all treatment groups also showed statistically significant increases (17% and greater compared to controls) in BUN and decreases (14% and greater compared to controls) in cholesterol. A dose-response relationship was only evident for the increase in ALT in males.

Group V males and females and Group IV males showed statistically significant increases (46% and greater) in urine volume, which was not evident in the Group V-recovery animals. Urine specific gravity and urinary protein was decreased in Group IV and V animals.

There were statistically significant and dose-related increases in urinary fluoride in males and females in Groups III, IV and V.

Findings at the end of recovery (week 6):
No statistically significant changes were seen after the 2-week recovery period.

Effects on the organs:
Lung congestion was noted in the two females that died in week four. There was evidence of peroxisome proliferation in Group V animals ($p<0.003$). No other macro- or microscopic findings were observed. Speen weight was increased in females of Group IV and V.

Comment:
It is not clear whether the deaths in two Group V animals were related to treatment but the possibility cannot be excluded. The increases in haematological parameters and increased urine volume may be indicative of a diuretic effect. Rusch, 1999 suggests the diuresis may be fluoride ion induced or due to some other subtoxic response to the fluoride ion. The changes in clinical chemistry parameters are likely to be indicative of metabolic changes. Achieved vapour concentrations were close to nominal concentrations.

Result:
From this study the NOAEL is considered to be > 271.8 mg/L (> 49 600 ppm), based upon the lack of histopathological effects together with the significant recovery from biochemical effects considered associated with the metabolism of the test substance evident following the 2-week withdrawal period. The NOEL is 2.83 mg/L (516 ppm) based on clinical chemistry (urinary fluoride ion) changes at >500 ppm in males and females.

9.2.3 13-week Repeated Dose Inhalation Toxicity (HLS, 1997c)

Species/strain:	Rat / Sprague-Dawley
Method of administration:	Inhalation: whole body exposure for 6 hours/day, 5 days/week for 13 consecutive weeks.
Test method:	OECD TG 413

Group	*Number of animals/sex*	*Nominal concentration*		*Achieved concentration*		*Mortality*
		ppm	*mg/L*	*ppm*	*mg/L*	
I	10/sex	0	0	0	0	0
II	10/sex	500	2.74	508	2.78	0
III	10/sex	2000	10.96	2038	11.2	0
IV	10/sex	10 000	54.8	10 152	55.6	0
V	10/sex	50 000	274	50 555	277	1 male

Clinical Observations:
One Group V male died under anaesthesia during blood removal in week 13. The death was not considered to be treatment-related. No treatment-related signs of toxicity were observed throughout the study duration. There were no effects on bodyweight gain, or food consumption.

Clinical Chemistry/Haematology
Group IV and V males and females showed small but statistically significant increases (up to 10% compared to controls) in PCV, haemoglobin and red blood cell count. Mean corpuscular haemoglobin concentration increases were observed in males only of Groups IV and V. Group IV and V males and females showed approximately two-fold increases in the numbers of neutrophils, monocytes and large unstained cells (generally regarded as reactive lymphocytes). Only the increase in neutrophils in females did not reach statistical significance.

Statistically significant and dose-related increases in ALT (50 to 68% compared to controls), AST (two to three fold) and creatinine phosphokinase (CPK) (74 to 98%) were seen in Group IV and V animals. Statistically significant increases were also seen in potassium (8 to 14% in all treated males and 9 to 12% in group III and IV females) and in inorganic phosphorous (22 to 41% in Group III and IV animals).

Females in all treatment groups and males in Groups IV and V showed up to two-fold increases in urinary volume. Corresponding decreases in specific gravity (1 to 2%) and protein levels (20 to 52%) were also seen.

Statistically significant and dose-related increases in urinary free fluoride were seen in all treated groups. Serum fluoride levels were below the level of detection in all groups.

Effects on the organs:
Group V males showed statistically significant increases in lung (15% compared to controls) and spleen (20% compared to controls) weight. No other macroscopic findings were observed.

Myocardial lesions were reported in treated animals. In the study report prepared by the testing facility the finding of myocarditis was described as either ‘myocarditis, diffuse’ or ‘myocarditis focal’. Myocarditis was increased in incidence and severity in Group IV and V males and Group V females. Group IV females showed an increase in myocarditis incidence, but not severity. Myocarditis was also observed in Group III animals but the change was not statistically significant. No increases in incidence or severity of myocarditis were seen in Group I or II animals. Diffuse myocarditis was more commonly seen in Group IV and V animals.

External Peer Review of Hearts (Alison, 1999)
The slides were subjected to an external peer review. Alison RH, 1999 considered findings recorded as 'myocarditis, focal' were consistent with spontaneous cardiomyopathy and those recorded as 'myocarditis, diffuse' were different in distribution and appearance and were consistent with treatment related changes. Alison RH, 1999 described the diffuse myocarditis as being primarily present in the ventricular muscle, but with no apparent predilection for areas susceptible to anoxic damage (i.e. the papillary muscles). It was characterised by separation of muscle fibres, with infiltration by mononuclear cells, principally macrophages. Myocyte vacuolation, hyalin degeneration, and fibrosis were also present to a varying degree. The consensus opinion between Alison RH, 1999 and the testing facility on the incidence and severity of diffuse myocarditis is tabulated below. Alison RH, 1999 concluded that there was a treatment-related 'diffuse myocarditis' in males and females of Group IV and V, which was consistent with the elevated CPK and AST activity observed in these treatment groups.

Incidence and Severity of Diffuse Myocarditis

	Male					*Female*				
ppm	*0*	*500*	*2000*	*10 000*	*50 000*	*0*	*500*	*2000*	*10 000*	*50 000*
Grade 1	0	0	0	1	0	0	0	1	8	5
Grade 2	0	0	0	7	6	0	0	0	1	4
Grade 3	0	0	0	1	3	0	0	0	0	1
Total	0	0	0	9	9	0	0	1	9	10

Grade 1 = trace; Grade 2 = minimal; Grade 3 = mild; Grade 4 = moderate; Grade 5 = most severe.

Comment:
In this study, diffuse myocarditis and urinary diuresis were observed as adverse effects. The increases in haematological parameters and increased urine volume may be indicative of a diuretic effect possibly fluoride ion induced. Treatment related diffuse myocarditis occurred with increased incidence in all animals at 277 mg/L (50 555 ppm) and in the majority exposed at 55.6 mg/L (10 152 ppm). At 11.2 mg/L (2038 ppm) one female presented with trace diffuse myocarditis - this would be considered a threshold effect at this exposure level. There were no treatment related findings at 2.78 mg/L (508 ppm). Achieved vapour concentrations were close to nominal concentrations.

Result:
The NOAEL indicated for this study is 2.78 mg/L/ (508 ppm).

9.2.4 Developmental Toxicity – Inhalation (HLS, 1997e)

Species/strain:	Rat / Crl:CD
Test method:	OECD TG 414
Study design:	Whole body inhalation exposure for 6 hours per day from days 6 to 19 post coitum, inclusive. All animals were sacrificed on day 20. The concentrations selected for this investigation were

determined from a pilot study (cited in Rusch 1999).

Group	*Number of females*	*Nominal concentration*		*Achieved concentration*		*Mortality*
		ppm	*mg/L*	*ppm*	*mg/L*	
I	25	0	0	0	0	0
II	25	500	2.74	503	2.76	0
III	25	2000	10.96	2069	11.3	1
IV	25	10 000	54.8	10 347	56.7	0
V	25	50 000	274	51 933	284.6	0

Pilot Study – Results, cited in Rusch et al, 1999
Study design and exposure concentrations were identical to that described above. At 50 000 ppm there was a reduction in bodyweight gain in the dams between days 9 and 13. There were no obvious effects on dams, litter parameters, or macroscopic external foetal structure at the lower levels.

Main Study
Clinical observations:
No treatment related clinical signs were observed at any exposure concentration. The one death was recorded on day 14. Clinical signs reported prior to death were: lethargy, hunched posture and piloerection on days 13 and 14.

In Group V animals there was a reduction in mean bodyweight gain between days 6 to 20 ($p<=0.01$) compared with controls (86% of control value), with the reduction more obvious during days 6 to 12 ($p<=0.01$), 71% of control values. In Group IV animals there was a reduction in mean bodyweight gain between days 6 and 12 compared with controls ($p<=0.05$). From day 12 mean weight gain was similar to controls.

Food consumption in Group V animals was lower during days 6 to 19 compared with controls ($p<=0.05$). This effect was more marked during days 6 to 11 ($p<=0.01$) than during days 12 to 19 ($p<=0.05$). Food consumption in Group IV was lower during days 12 to 19 compared with controls ($p<=0.05$).

Reproduction findings:
There were no abortions. Three females of Group IV and one female of Group V were non gravid. There were no treatment related effects on the pregnancy rate, number of corpora lutea, number of implantations, preimplantation loss, resorptions, litter size, number of dead foetuses, or foetal sex ratio at any exposure concentration. In Group V gravid uterine weight was slightly lower compared with controls ($p<=0.05$). The lower gravid uterine weights were due in part to a slightly lower mean litter size than controls.

Macroscopy of dams:
The findings at post mortem were not considered test substance related.

Post mortem examination of the animal that died in-study revealed red staining of the fur of the perinasal region, watery contents of the stomach, severe increased pelvic dilatation of the kidneys and distension of the ureters with cloudy urine. The uterus was noted to have one implantation site in the left horn and two implantation sites in the right horn. The death was not considered treatment related.

Foetal examination
The incidence and distribution of malformations was comparable in all groups. The incidence and distribution of skeletal variants was comparable for all groups. The incidence of incomplete ossification (cranial centres, veterbrae, pelvic) was slightly higher in Groups III and V. In the absence of any other findings this was considered incidental and not treatment related. Mean foetal weight and litter weight were slightly lower in Group V ($p<=0.05$, $p<=0.01$ respectively). The lower litter weights were due in part to a slightly lower mean litter size than controls.

Comments:
Treatment-related maternal toxicity (decreased bodyweights and feed consumption) were observed at 56.7 mg/L (10 347 ppm) (Group IV) and 284.6 mg/L (51 933 ppm) (Group V). No maternal toxicity was observed at 2.76 or 11.3 mg/L (503 or 2069 ppm). Developmental toxicity, evidenced as lower mean foetal weights, occurred at 284.6 mg/L (51 933 ppm). No effects considered related to treatment were observed in foetuses at 2.76, 11.3, or 56.7 mg/L (503, 2069 or 10 347 ppm). Achieved vapour concentrations were close to nominal concentrations.

Results:
The NOAEL determined for maternal toxicity is 11.3 mg/L/6-hour (2069 ppm). The NOAEL for developmental toxicity is 56.7 mg/L/6-hour (10 347 ppm).

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *E. coli* Reverse Mutation Assay (Pharmaco LSR Ltd, 1995)

Strains:	*Salmonella typhimurium*: TA1535, TA1537, TA1538, TA98, TA100; *Escherichia coli:* WP2*uvr*A**.**
Metabolic activation:	S9 fraction from Aroclor 1254 induced rat liver.
Concentration range:	2.5% - 40% v/v (2.22 g/L) (nominal)
Test method:	OECD TG 471 & 472 – plate incorporation. Gaseous exposure. Appropriate strain specific positive controls were employed.
Comment:	No toxicity was observed. There were no significant increases in revertant colony numbers at any concentration, in the presence or absence of metabolic activation. Concurrent positive controls used in the test induced marked increases in the frequency of revertant colonies and the activity of the S9 fraction was found to be

satisfactory.

Result: The notified chemical at up to 40% v/v (2.22 g/L) in gaseous phase was non mutagenic under the conditions of the test.

9.3.2 Chromosomal Aberration Assay (Pharmaco LSR Ltd, 1994c)

Cells: Human peripheral lymphocytes.

Metabolic activation system: S9 fraction from Aroclor 1254 induced rat liver.

Dosing schedule: Each concentration was tested in duplicate, with or without metabolic activation, in two independent experiments.

Experiment 1 (preliminary toxicity test):
without metabolic activation,
0, 10, 25, 40, 55, 70% v/v;
treatment/harvest time = 24/21 hours;

with metabolic activation,
0, 10, 25, 40, 55, 70% v/v;
treatment/harvest time = 3/21 hours,

Experiment 2:
without metabolic activation,
0, 10, 20, 30% v/v;
treatment/harvest time = 24/21 hours;
positive control: 2 µg/mL C;

with metabolic activation,
0, 30, 50, 70% v/v;
treatment/harvest time: 3/21 hours,
positive control: 6 µg/mL CP.

CP – cyclophosphamide. C – chlorambucil.

Test method: OECD TG 473

Comment: In experiment 1, no toxicity was observed in cultures without metabolic activation exposed to HFC-245fa at 10% v/v. Reductions in mitotic activity of 46, 87, 93 and 96% were seen at 25, 40, 55 and 70% v/v respectively. In experiment 2, no toxicity was observed in cultures without metabolic activation exposed to HFC-245fa at 10 or 20% v/v, while at 30% v/v, there was a 25% reduction in mitotic activity. With metabolic activation, no toxicity was observed at any test concentration in both experiments 1 and 2.

One hundred metaphases were scored from all cultures.

In experiment 2, in the absence of metabolic activation, no significant increases in aberrant cell frequency were seen in cultures exposed to HFC-245fa at 10 or 20% v/v. At 30% v/v, statistically significant increases were seen when gaps were included, however these were not considered to be biologically significant.

Additional chromosomal analysis of the cultures used in experiment 1 without metabolic activation revealed that at a concentration of 25% v/v, there were statistically significant increases in the frequency of aberrant cells when gaps were included. At 40% v/v, statistically significant increases in aberrant cell frequencies were seen both including and excluding gaps. However the increase in aberrant cell frequencies at this concentration may have been caused by the toxicity of the test material rather than true mutagenic events.

Positive controls used in the test caused marked increases in the incidence of aberrant cells and the activity of the S9 fraction was found to be satisfactory.

Result: The notified chemical was weakly clastogenic in the absence of metabolic activation under the conditions of the test

9.3.3 Chromosomal Aberration Assay (HLS, 1996)

Cells: Human peripheral lymphocytes.

Metabolic activation system: Tests were conducted without metabolic activation.

Dosing schedule: Each concentration was tested in duplicate.

0, 20, 30, 40*, 50*, 70*% (3.9 g/L)v/v;
treatment/harvest time = 6/24 hours;
positive control: 2 µg/mL chlorambucil;

0, 10, 20*, 25, 30*, 35, 40*% (2.2 g/L) v/v;
treatment/harvest time = 24/24 hours;
positive control: 2 µg/mL chlorambucil;

*cultures selected for metaphase analysis.

Test method: OECD TG 473

Comment: No cytotoxicity was observed in cultures exposed to the test substance for 6 hours. Reductions in mean mitotic index of 24, 51, 49 and 68% v/v were seen in cultures exposed to

HFC-245fa for 24 hours at 25, 30, 35 and 40% v/v respectively.

One hundred metaphases were scored from each selected culture.

No significant increases in the frequency of cells with aberrant chromosomes were seen in cultures exposed to the test substance for 6 hours. Exposure to the test substance at 30 and 40% v/v for 24 hours produced increases in the frequency of aberrant cells both including and excluding gaps. When gaps were excluded, these increases were not reproducible between the replicate cultures at 30% v/v. The increases were replicable at 40% v/v, and exceeded the historical negative control range.

There were no cells with endoreduplication, and the number of cells with polyploidy was within the normal range.

Positive controls used in the test caused marked increases in the incidence of aberrant cells.

Result: The notified chemical was weakly clastogenic under the conditions of the test.

9.3.4 Micronucleus Assay in the Bone Marrow Cells of the Mouse (Pharmaco LSR Ltd, 1994d)

Species/strain: Mouse / CD-1

Method of administration: Whole body inhalation exposure to the test substance (vapour phase) for 4 hours. The positive control, chlorambucil was administered by oral gavage.

Substance	*Number/sex of animals*	*Nominal concentration ppm (mg/L/4-hour)*	*Achieved concentration ppm (mg/L/4-hour)*	*Sacrifice time hours*
Air	5 males	0 ppm	0	24
Air	5 males	0 ppm	0	48
Test substance	5 males	100 000 (548)	101 300 (555)	24
Test substance	5 males	100 000	101 300	48
Positive control	5 males	30 mg/kg	-	24

Test method: OECD TG 474

Comment: No mortalities were observed. Animals exposed to the test substance were underactive during the exposure period.

	At least 2000 erythrocytes were counted per animal. Bone marrow toxicity, as evidenced by depression of bone marrow proliferation, was not observed. Frequencies of micronucleated polychromatic erythrocytes (PCE) in animals killed 24 or 48 hours after exposure were similar to those in the concurrent vehicle control group. The positive control caused a significant increase in micronucleated PCE ($p<0.01$).
Result:	The notified chemical did not show evidence of causing chromosome damage or bone marrow cell toxicity when administered by inhalation in this in vivo test procedure.

9.4 Toxicokinetic assessment (Anonymous, dated 25 June 1997)

The assessment of absorption, distribution, metabolism and excretion of the notified chemical is a notification requirement of Annex VIIA of EEC Directive 92/32/EEC. Relevant notes from the document prepared for the toxicokinetic assessment under this Directive are reproduced here.

The results of the toxicity studies conducted on the notified chemical show that it is absorbed via the inhalation route and is systemically distributed. The biochemical changes may indicate that the substance is metabolised, this suggestion is supported by the findings seen in the one month and 90 day rat study regarding increased urine output and increased urinary fluoride which indicates metabolism of the test substance and possible excretion via the kidneys. In addition, the effects of metabolic activation seen in the in vitro cytogenetics study support the theory that the substance is metabolised. However, there was no substantive evidence of an effect on the kidney. The significant degree of reversal of all changes seen after the 2-week recovery period following one month of exposure indicate that the substance and/or its metabolites had been cleared.

9.5 Overall Assessment of Toxicological Data

Toxicokinetics
A toxicokinetic assessment of the notified chemical concluded that the notified chemical is absorbed via the inhalation route and systemically distributed, from where it may be metabolised and excreted, possibly via the kidneys.

Acute Toxicity
In acute inhalation toxicity tests with rats and mice, signs of central nervous system depression were observed during exposure. However, there was no mortality and animals recovered within 30 minutes upon cessation of exposure. The notified chemical is considered to be of very low inhalation toxicity. Although there were no systemic or local signs of reaction to treatment in an acute dermal toxicity study, a valid LD50 was unable to be determined due to the possibility of evaporation of the notified chemical during the 24-hour contact period. It was not considered technically feasible to conduct tests for acute oral

toxicity, skin irritation, eye irritation and skin sensitisation due to the volatility of HFC-245fa.

Cardiac Sensitisation
Two studies on cardiac sensitisation to adrenaline have been conducted in dogs. In the first study (published report only available), the NOAEL was established at 187 mg/L (34 100 ppm) based on the absence of cardiac arrhythmias or clinical responses at this dose. In a 2-week dose range finding inhalation toxicity study that included a cardiac sensitisation component, a single focus of minimal myocardial degeneration was observed only in one high dose animal. All other findings for this and other animals were negative. Although cardiac lesions were observed in rats of the 90-day inhalation study, they occurred with higher incidence and were associated with changes in serum CPK and AST. The finding of myocardial degeneration in this one dog is considered incidental and not likely associated with exposure. A NOAEL of 53.6 mg/L (9790 ppm) is determined, based on the absence of any treatment related findings. No cardiac sensitisation was observed and the NOEL for this effect is established at 195 mg/L (35 500 ppm). This value is in agreement with the NOAEL of the first study.

Repeat Dose Toxicity
Consistent findings from the 14-day, 28-day and 90-day inhalation studies in rats, include increased liver enzyme activity, BUN and increased urine volume and urinary fluoride ion levels. The fluoride ion is thought to induce the observed diuresis. These clinical chemistry findings were not accompanied by histopathological changes in the liver or kidney and appear reversible following cessation of exposure. In the 90-day study treatment related diffuse myocarditis was observed. A NOAEL of 2.78 mg/L (508 ppm) is established for the 90-day study, based on diffuse myocarditis in higher dose groups.

Developmental Toxicity
A developmental inhalation study in rats established the NOAEL for maternal toxicity at 11.3 mg/L (2069 ppm), and the NOAEL for developmental toxicity at 56.7 mg/L (10 347 ppm) based on decreased bodyweight and food consumption in dams and decreased mean foetal weights. No skeletal abnormalities were observed in foetuses.

Genotoxicity
HFC-245fa was not mutagenic in a bacterial reverse mutation assay. In vitro, the notified chemical was weakly clastogenic to human peripheral lymphocytes in the absence of metabolic activation only. In vivo, the notified chemical did not show evidence of causing chromosome damage or bone marrow cell toxicity in a mouse micronucleus assay.

Classification
Based on the toxicological data provided, the notified chemical is not classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10 ASSESSMENT OF ENVIRONMENTAL EFFECTS

10.1Toxic Effects on Aquatic Organisms

Although very little of the compound will be released to water the notifier provided test

reports on the toxicity of the chemical HFC-245fa to fish and *Daphnia* (HLS, 1997f; HLS, 1997g).

Because of the low boiling point of the notified chemical (15.3°C), the test medium used in both the fish and *Daphnia* tests were prepared by adding the notified chemical directly to the dilution medium, which had been cooled to <13°C. To prevent the gas from escaping, each test vessel was sealed following introduction of the test species, leaving no headspace.

Test	Species	Results
Acute Toxicity to fish (limit test)	Rainbow Trout *Oncorhynchus mykiss*	96 h LC_{50} (not computed, no mortalities)
		96 h EC_{50} >81.8 mg/L
OECD TG 203		96 h NOEC see below
Acute Toxicity to *Daphnia* (limit test)	*Daphnia magna*	48 h EC_{50} and 48 h NOEC could not be identified, but both >97.9 mg/L.
OECD TG 202		

* NOEC - no observable effect concentration

Fish

An initial range-finding test performed under semi-static conditions at 0 (control), 10 and 100 mg/L nominal concentrations of the test material was conducted against Rainbow Trout using 10 fish at each concentration. No mortalities were observed, although two of the fish exposed to the nominal 100 mg/L test media exhibited darkened pigmentation.

A definitive test was conducted over 96 hours using static renewal procedures against 10 fish at a nominal concentration of 100 mg/L. The test medium comprised dechlorinated tap water of hardness between 216-222 mg/L as $CaCO_3$ at pH levels between 7.1 and 7.9. The water temperature was between 12.9 to 14.6 °C, and dissolved oxygen levels were always in excess of 74% solution.

No mortalities were observed over the 96 hour test period although three fish exhibited darkened pigmentation. Measured concentrations of the notified chemical in the test media remained between 48 and 138% of nominal, but averaged 81.8 mg/L. The results of the limit test indicate LC50 >81.8 mg, while those for the range-finding test indicate NOEC > 10 mg/L.

The variability in measured concentrations of HFC-245fa over the test period, suggest it had a slow rate of dissolution in the dilution medium under the conditions of the test, which is consistent with its low boiling point and high vapour pressure.

Daphnia

An initial range-finding test was performed against 10 *Daphnia* using nominal concentrations of 1, 10 and 100 mg/L of the test substance. To prevent evaporation losses, the notified substance was added to the test medium via a tube into the sealed vessels containing the test animals. Within the first hours of exposure, all of the 10 *Daphnia* exposed at 100 mg/L nominal concentration were immobile. After 48 hours, three of the *Daphnia* had recovered. The recovery of the three test animals suggests that the *Daphnia* may have been anaesthetised

during the initial introduction of the chemical. In any case, chemical analysis of the test medium showed that the concentrations of HFC-245fa in all replicate vessels were much higher than intended (ie. >200% of the nominal concentration).

A second range-finding test was conducted in which the *Daphnia* were added to the test media after the notified substance had been added. Following introduction of the chemical to the test media, the vessels were sealed and warmed to 19.5°C. The vessels were then opened to add the *Daphnia*. During the second test, no *Daphnia* were immobilised when exposed to the 100 mg/L nominal concentration. However, the measured concentrations of the chemical in the test media were all below the intended concentrations, being between 43-45% of the intended nominal concentrations. This suggests that some of the gas escaped from the warmed containers when the vessels were opened to add the *Daphnia*.

It was concluded from the range finding test that the 48-hour EC_{50} was >100 mg/L nominal.

A definitive test was conducted against a group of 30 *Daphnia* using static exposure conditions over a period of 48 hours at nominal concentrations of 0 (control) and 100 mg/L of the notified chemical. In the definitive test, the notified chemical was added directly to the test medium which had been cooled to 13°C. The test medium comprised dechlorinated tap water with a total hardness of 202 mg/L, and an alkalinity of 180 mg/L as $CaCO_3$ at pH values in the range of 7.4 to 7.6. During testing, the water temperature was warmed to between 19.5°C and 21.0°C. The dissolved oxygen ranged from 9.35 to 9.37 mg O_2/L.

No *Daphnia* was immobilised during the definitive test. Thus, neither the 48-hour EC_{50} value nor the NOEC could be determined. To verify exposure levels, the concentrations of HFC-245fa were measured using gas chromatography at the beginning and end of the test. The results showed that the intended exposure concentration of the notified chemical was maintained between 92 and 104 % of nominal value, and averaged 97.9 mg/L. It was concluded that the 48-hour EC_{50} and NOEC were $\geq$97.9 mg/L.

No algal test were conducted using HFC-245fa, however, the notified chemical is not expected to be toxic to algae, nor to other aquatic organisms in the natural environment under Australian conditions given its high volatility from water. The chemical's volatility is borne out by the difficulty in determining the water solubility of the notified chemical under normal atmospheric pressures, and also with maintaining nominal concentrations of the notified chemical in the test medium during the toxicity testing. The high volatility suggests that the notified gas will not remain dissolved in water bodies under normal atmospheric pressures and in temperature ranges found in Australian aquatic environments.

10.2Ozone Depletion Potential

The ozone depletion potential (ODP) of a gaseous compound is a measure of its ability to migrate to the stratosphere, together with its ability to degrade (through direct and indirect photolysis) to radical species which are able to react with and destroy ozone molecules. The most damaging chemicals in this regard are compounds which contain chlorine and/or bromine, and this has been a characteristic of various chlorinated hydrocarbons (CFCs) and hydrochlorofluorocarbon (HCFCs) compounds which have been used as foam blowing agents, solvents and refrigerants in the past. The ODP of such compounds is roughly related to the content of chlorine (or bromine) in the compounds together with its atmospheric lifetime (Verschueren, 1996). Although the atmospheric lifetime of HFC-245fa is

appreciable at 6-7.6 years since it contains no chlorine or bromine[4] it is expected to have zero or very low ODP.

The notified chemical is intended as a replacement for blowing agents such as HCFC-141b (CH_3CFCl_2) which contains chlorine and has an ODP of 0.1 compared with the reference compound trichlorofluoromethane (CFC-11, (Verschueren, 1996)). Consequently, the introduction of the new chemical as a replacement blowing agent is expected to be beneficial in respect of stratospheric ozone destruction.

10.3 Global Warming Potential

The Global Warming Potential (GWP) of a gaseous compound is a composite measure of its ability to absorb radiation in the infrared (IR) spectral region (typically 500-1200 cm^{-1}), together with its expected atmospheric lifetime (Verschueren, 1996). Effectively the GWP of a chemical compares the amount of IR radiation absorbed by unit weight (eg 1 tonne) of the chemical over a given time (taking into account its removal through degradation processes) with that absorbed by an equivalent weight of emitted CO_2. Because of atmospheric degradation of compounds (eg through reaction with OH• radicals) the GWP decreases with time, and it is usual to estimate the GWP using 20, 100 and 500 year horizons. By determining the IR absorption cross section from the measured IR spectrum of HFC-245fa between 500 and 1500 cm^{-1} together with an estimation of the atmospheric half life, Ko *et al* (undated report) derived 20 and 100 year global warming potentials for HFC-245fa of 2400 and 760 respectively. However, more recent data (IPCC, 2001) gives the 100 year horizon GWP of the new chemical as 950.

Although these GWP figures are subject to some uncertainty they may nevertheless be used to gain some insight into the effects of using the chemical in Australia. In the worst case, assuming that 500 tonnes of HFC-245fa are used and released to the atmosphere each year in Australia, when averaged over a 100 year period this is roughly equivalent to the effect of releasing 500 x 950 = 475,000 tonnes of CO_2. This calculation could obviously be refined, but this CO_2 emission, equivalents is relatively small compared with Australia's overall annual greenhouse gas emissions which were estimated as approximately 460 million tonnes of CO_2 equivalent in 1999 (Australian Greenhouse Office, 2001). Therefore, HFC-245fa would represent an annual addition of less than 0.1% to consolidated emissions over 100 years.

However, in respect of this it should be noted that as a blowing agent, HFC-245fa will be used as a replacement for other compounds such as hydrochlorofluorocarbons (HCFCs) including HCFC-141b (CH_3CFCl_2) which themselves have significant GWP in addition to ozone depleting potential by virtue of the contained chlorine (see above). If it is assumed that HFC-245fa is to replace HCFC-141b on a mole for mole basis, then 500 tonnes of HFC-245fa (MW = 134 g/mole) would replace approximately 440 tonnes of HCFC 141b (MW = 117 g/mole). The 100 year horizon GWP of HCFC-141b is 700 (WMO, 1999) so replacement by HFC-245fa would effectively reduce greenhouse gas emissions by approximately 310,000 tonnes release of CO_2 equivalent. Consequently, the nett release of additional CO_2 equivalent resulting from introduction of HFC-245fa as a blowing agent is estimated as approximately 165,000 tonnes per annum. This represents only 0.04% increase in Australia's total

[4] Although fluorine is a halogen and is in many ways chemically similar to chlorine and bromine, the ozone depletion potential of fluorine in the stratosphere is accepted as being negligible.

greenhouse gas emissions.

However, it should be noted that HCFC-141b is not currently considered in the Australian Greenhouse Gas Inventory[5], and so the full 475,000 tonnes of CO_2 equivalent originating from release of the HFC-245fa will appear in this document.

The increase in the use volume arising from this extension is not expected to have a major impact on GWP.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The new compound is a volatile gas and its use pattern as a blowing agent for production of polyurethane foams indicates that it will be released mainly to the atmosphere, although diffusion from the polymer foam may be extended over several years. It is possible that HFC-245fa may also be used as a refrigerant and as a specialised solvent. However, these use patterns would involve relatively small quantities of the chemical, but again almost all would be released to the atmosphere with release of solvent being immediate and release from refrigeration equipment due to slow leaks and diffusion occurring over the lifetime of the plant.

Only minor releases to the water and soil compartments are expected, and due to the high values of vapour pressure and Henry's Law constant any compound released to water or soil is expected to quickly evaporate to the atmosphere. Consequently exposure to aquatic organisms will be low, but in any case the available test data indicates that the compound is of low toxicity to aquatic species, and would also have little potential for bioaccumulation.

The notified chemical will be slowly degraded in the atmosphere through reaction with hydroxy radicals, and will eventually degrade to HF and CO_2, However, due to its relatively long anticipated atmospheric half life (estimated as 6-7.6 years) together with its large infrared cross section the most environmentally significant effect resulting from use of the compound will be its contribution to global warming. On a 100 year horizon basis use of the compound as a foam blowing agent at the indicated import quantities are estimated to annually add less than 475,000 tonnes of CO_2 equivalent to Australia's greenhouse gas emission inventory which (based on 1999 data) represents a contribution of less than 0.1% to Australia's total greenhouse gas emissions. However, when it is considered that the new chemical will replace HCFC-141b as a blowing agent, and that this compound also has significant global warming potential, the nett additional annual release of CO_2 equivalents is reduced to around 165,000 tonnes, or an approximate 0.04% increase. However, HCFC-141b is not currently considered in the Australian Greenhouse Gas Inventory, and so the full 475,000 tonnes of CO_2 equivalent will appear in this document.

Due to the absence of chlorine and bromine in the notified chemical, it is not expected to have potential for removing ozone from the stratosphere, and this represents a definite environmental advantage over blowing agents such as HCFC-141b for which the new chemical is intended as a replacement.

[5] Because the hydrochlorofluorocarbons such as HCFC-141b are ozone depleting substances and regulated under the Ozone Protection Act 1989, they are not considered in Australia's greenhouse gas inventory, despite the fact that these compounds have global warming potential in addition to their ozone destroying properties.

When used in the indicated manner in the production of polymer foams the new compound is not expected to be a hazard to the aquatic or soil environmental compartments, but may effectively contribute to Australia's greenhouse gas emissions.

12. HEALTH AND SAFETY RISK ASSESSMENT

12.1 Hazard Assessment

The notified chemical, HFC-245fa, is a liquid or vapour at ambient temperature and pressure so most of the toxicological studies conducted to date have used the inhalation route of exposure. In inhalation studies in rats and mice, HFC-245fa was of very low acute toxicity.

Consistent with findings in structurally similar chemicals, HFC-245fa was shown to induce cardiac sensitisation. In an inhalation study in dogs, a NOAEL of 34 100 ppm (187 mg/L) was established, based on cardiac arrhythmias and clinical responses at the next dose, 44 000 ppm. In a 2-week dog study, cardiac sensitisation was not observed at vapour concentrations up to 35 500 ppm.

Several repeated dose inhalation studies were conducted in rats. In a 2-week range-finding study at concentrations up to 50 433 ppm, findings were limited to clinical chemistry parameters including blood urea nitrogen and liver enzyme changes. In the following 28-day study at concentrations up to 49 600 ppm, similar results were obtained, with a NOEL of 516 ppm (2.83 mg/L) established, based on statistically significant increases in urinary fluoride levels. In the subsequent 13-week study at concentrations up to 50 555 ppm, a dose-related incidence in myocarditis was observed in addition to the clinical chemistry changes noted in the preliminary studies. Focal myocarditis was taken to be spontaneous as it was seen in control and treated rats, however, diffuse myocarditis was observed in animals at the 10 000 and 50 000 nominal doses and in one animal at 2069 ppm, with the NOAEL taken to be 508 ppm (2.78 mg/L).

In an inhalation study in pregnant rats, the NOEL for maternal toxicity and developmental toxicity were determined to be 2069 ppm (11.3 mg/L) and 10 347 ppm (56.7 mg/L) respectively, based on decreased body weight and food consumption in dams and decreased mean weights in foetuses. No skeletal abnormalities were observed in foetuses at any dose.

In bacteria HFC-245fa was not mutagenic. In human peripheral lymphocytes, HFC-245fa was weakly clastogenic without metabolic activation. In vivo, the notified chemical did not show evidence of chromosome damage or bone marrow cell toxicity in a mouse micronucleus assay.

Based on the data provided, the notified chemical is not classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999). However, as a NOHSC exposure standard is recommended (see below), HFC-245fa is a hazardous substance for the purposes of workplace regulations.

Being a liquid with a low boiling point (15°C), HFC-245fa is generally handled as a refrigerated liquid in a pressure vessel. Under these circumstances, the notified chemical does not meet the Class 2.2 dangerous good classification in accordance with the ADG Code (Federal Office of Road Safety, 1998). However, when packaged with a nitrogen pad, HFC-

245fa is a Class 2.2 dangerous good.

At elevated temperatures (250ºC), HFC-245fa decomposes to produce hazardous hydrofluoric acid, which is highly toxic and corrosive and has a NOHSC exposure standard of 3ppm peak limitation (NOHSC, 1995).

12.2 Occupational Health and Safety

The critical health effect for acute exposure is cardiac sensitisation, with the lowest NOAEL being 34 100 ppm, established in a dog inhalation study. For chronic effects, the critical health effect is diffuse myocarditis, observed in a 90-day rat inhalation study. For the purposes of the risk assessment, the NOAEL from this study, 508 ppm, will be used for chronic exposure.

Due to the volatility of HFC-245fa, exposure to the notified chemical is largely by the inhalation route. Dermal exposure may occur when handling the chemical in concentrated form at room temperature or below, however, evaporation would be rapid in these circumstances.

Use as blowing agent rigid polymeric foams

Manufacture of polyol blend
Manufacture of the blend occurs in a closed system, however, dermal and inhalation exposure may occur during addition of HFC-245fa to the mixing vessel and during discharge of the blend to steel drums or IBCs. Exposure may also occur when connecting and disconnecting pump lines, during cleaning and maintenance, and during sampling by laboratory quality control staff.

From limited monitoring data available, the margin of exposure (MOE) for cardiac sensitisation is 34 100/1255 = 27, indicating some cause for concern.

In the absence of time-weighted average (TWA) monitoring data, e.g. for an 8-hour shift, the vapour concentration predicted from EASE, 100 ppm, is used. The resultant MOE for myocarditis is 508/100 = 51, indicating a slight cause for concern.

Foam manufacture and use
Exposure during foam manufacture is likely to be similar to polyol blend manufacture as the process is largely enclosed with opportunities for exposure to HFC-245fa during the charging and discharging operations. Exposure may be higher during discharge as it is estimated that up to 3% of the blowing agent (HFC-245fa) may be lost. Using a worst-case EASE estimate of 200 ppm, the MOE for myocarditis is 508/200 = 25, indicating some cause for concern, particularly when 8-hour exposures of up to 488 ppm have been reported for a similar chemical HCFC-141b.

During foam application, exposure to the notified chemical may be more open, however, HFC-245fa is present at a lower concentration in the matrix (5-15% in foam). The only personal monitoring data available were for roof insulation, where 8-hour TWA results up to 43 ppm were obtained for the spray nozzle cleaner. Lower values were obtained for the gun operator (19 ppm) and hoseman (15 ppm). Taking 50 ppm as a typical atmospheric

concentration during such application, the MOE is 508/50 = 10, indicating some cause for concern. European exposure monitoring data indicated lower personal exposures (3-10 ppm) during foam application.

Several sets of instantaneous atmospheric monitoring (grab sampling) data were provided by the notifier for foam application, primarily for the foam filling of refrigerator cabinets and doors. Vapour concentrations were extremely variable, ranging from not detectable to greater than 6000 ppm, a value obtained immediately after the foam shot. However, an operator would not be expected in the vicinity of this reading, so a concentration of 288 ppm obtained near an operator at the same time is regarded as more suitable for the risk estimate. Taking 300 ppm as a worst-case scenario, the MOE for cardiac sensitisation is 34 100/300 = 114, indicating little cause for concern. One set of data was available for boardstock production, with vapour concentrations ranging from not detectable to 795 ppm, a value obtained directly above the foam pour area. Taking 800 ppm as a worst-case scenario, the MOE for cardiac sensitisation is 34 100/800 = 43, indicating a slight cause for concern.

Once manufactured, losses of HFC-245fa from the foam matrix are expected to be minimal as long as the foam remains uncut due to the closed cell nature of the foam and the compatibility of HFC-245fa with the foam matrix.

Use as working fluid in centrifugal water chillers

As a refrigerant for centrifugal water chillers, HFC-245fa will be used in closed systems. Exposure to the notified chemical is not expected once the chiller has been charged with HFC-245fa, except in the case of a cylinder or chiller leak. In data provided by the notifier, measured service technician exposure levels were rarely found to exceed 0.5 ppm for an 8 hour day, with 2 ppm at jobsites with marginal occupational hygiene. However, monitoring data available for the less volatile chemical which is being replaced (HCFC-123), indicate that higher vapour concentrations, up to several hundred ppm, can be obtained under certain circumstances, for example, chiller repair operations (NICNAS, 1996).

Using the data available for HFC-245fa, the MOE for is 508/2 = 254, indicating that the risk of adverse health effects to service technicians resulting from repeated inhalation exposure during charging and servicing of chillers is low.

Control measures available for reducing the occupational health and safety risks for chiller technicians during refrigerant handling can be found in the following codes and standards:

- Safety Code for Mechanical Refrigeration (ASHRAE, 1994);
- The Australian Refrigeration and Air Conditioning Code of Good Practice (AFCAM, 1997); and
- AS/NZ 1677 (1998) - Refrigeration Systems (Standards Australia, 1998).

Use as solvent in aerosol applications

Manufacture of aerosol products
The manufacture of aerosol products is largely enclosed and highly automated. Exposure to workers may arise if leaks occur during the filling operation or maintenance, however, no

monitoring data were available. Using an EASE estimate of 100 ppm, the MOE for myocarditis is 508/100 = 51, indicating a slight cause for concern. The occupational risk posed to aerosol filling operators from the notified chemical is therefore expected to be low.

Use in contact cleaners
Aerosol contact cleaners are expected to be used at a rate of one can per week. Emissions data for contact cleaners containing HFC-245fa were not available, however, CFC-113 vapour concentrations up to 27 ppm were obtained for an aerosol contact cleaner containing a mixture of CFC-113 and alcohols. The EASE model predicted considerably higher vapour concentrations (500-1000 ppm), assuming direct handling with dilution ventilation. For regular use, this equates to an MOE for myocarditis of 508/1000 = 0.5, which would indicate a high level of concern for workers. However, on the basis that usage will be intermittent only, the risk to workers will be much lower.

Due to the small quantities used during application, the instantaneous vapour concentrations are unlikely to exceed 1000 ppm. For cardiac sensitisation, this corresponds to an MOE of 34 100/1000 = 34, indicating a slight cause for concern.

Use in mould release agents
The use pattern for workers using mould release agents containing HFC-245fa will be similar to workers using contact cleaners except that it is estimated that the frequency of use ill be higher, up to three cans per day. Emissions data were not available, however, a short-term exposure estimate of 216 ppm was provided, assuming a high use rate in a relatively small facility with no air changes. With normal ventilation (one air change per hour) and assuming the aerosol was used constantly throughout an 8 hour shift, the HFC-245fa vapour concentration would be 36 ppm. The EASE model predicted considerably higher vapour concentrations (500-1000 ppm), assuming direct handling with dilution ventilation.

Taking the predicted value of 36 ppm, the MOE for myocarditis is 508/36 = 14, indicating some cause for concern. However, if the EASE estimate is used, the MOE is 508/1000 = 0.5, which would indicate a high level of concern for workers. As for contact cleaners, the level of concern for cardiac sensitisation is lower, due to the smaller volumes being used.

Conclusion
The risk characterisation indicates some cause for concern for workers potentially exposed to HFC-245fa. The risk of cardiac sensitisation is greatest where larger volumes are handled, for example, in manufacture of the polyol blend and foam application. The risk of longer term effects, that is, myocarditis, is greatest in the more open work systems, for example, some foam applications and aerosol can use. The MOEs obtained indicate that risk reduction measures are necessary to minimise occupational exposure to HFC-245fa.

Exposure standard
The American Industrial Hygiene Association (AIHA) has set a workplace environmental exposure level (WEEL) of 300 ppm (1644 mg/m^3) TWA, based on a LOAEL of 2000 ppm in the 13-week rat inhalation study and comparison with the toxicity of similar hydro-fluorocarbons. Documentation is available (American Industrial Hygiene Association, 2001).

Based on the LOAEL of 2000 ppm established in the same study in this evaluation, and taking into account the lack of personal monitoring data available for the notified chemical, a provisional exposure standard of 200 ppm TWA is recommended until a NOHSC standard is

established. The available monitoring data suggest this vapour concentration is achievable.

12.3 Public Health

Public contact with HFC-245fa is unlikely as a result of the industrial uses of products containing the chemical. Exposure of the public will occur only in the event of accidental release of the gaseous form and is not likely to result in the inhalation of any significant amount of the chemical. Therefore, the risk to public health is considered to be minimal due the unlikely exposure and low toxicity of the notified chemical.

13. RECOMMENDATIONS

Regulatory controls

HFC-245fa does not meet the NOHSC Approved Criteria for classification as a hazardous substance. However, since the chemical needs to have an exposure standard, it should be labelled as 'Hazardous', with the safety phrases

S3/9 – Keep in a cool, ventilated place
S23 – Do not breathe vapours
S38 – In case of insufficient ventilation, wear suitable respiratory equipment
S41 – In the case of fire and/or explosion, do not breathe fumes

Products containing the notified chemical, for example, aerosol products, should be similarly labelled.

When stored or transported as a pressurised liquid with a nitrogen pad, HFC-245fa must be labelled as a Class 2.2 dangerous good (UN number 3163).

The NOHSC Chemicals Standards Sub-committee should consider establishing a national exposure standard for HFC-245fa, with this report serving as supporting documentation. Based on the incidence of myocarditis in a 13-week rat inhalation study, a provisional atmospheric concentration of 200 ppm TWA is recommended until a national standard is established.

Control Measures

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - Local exhaust ventilation at potential points of emission during polyol blend manufacture and foam manufacture, including transfer to and discharge from mixing vessels
  - Local exhaust ventilation in foam application areas

- Employers should implement safe work practices in accordance with the NOHSC *Model Regulations to Control Workplace Hazardous Substances* (NOHSC, 1994b). For use of HFC-245fa as a refrigerant, employers should follow the safe work practices outlined in the available codes and standards, that is, the Safety Code for

Mechanical Refrigeration (ASHRAE, 1994), The Australian Refrigeration and Air Conditioning Code of Good Practice (AFCAM, 1997), and AS/NZ 1677 (1998) - Refrigeration Systems (Standards Australia, 1998).

- Employers should ensure that use of aerosol products containing HFC-245fa is conducted in a safe manner. For example, application must be in a well-ventilated work area, application must be away from the breathing zone and respiratory equipment must be available if required.

- Employers should ensure that personal protective equipment is used by workers to minimise occupational exposure to HFC-245fa when engineering controls are insufficient to maintain vapour concentrations below the provisional exposure limit. Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- Personnel atmospheric monitoring should be conducted by employers to measure workplace HFC-245fa vapour concentrations to establish baseline exposure patterns for each use of the notified chemical. If it is established that sites for the same use pattern are equivalent in terms of worker exposure to HFC-245fa, then representative monitoring will be sufficient. The results should be forwarded to NICNAS.

- Employers should ensure that workers potentially exposed to the notified chemical are educated in the hazards of the chemical and trained to use, handle and store the chemical safely. Education should include instruction from the available standards and codes where relevant.

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing HFC-245fa are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

- Due to the global warming potential of HFC-245fa and the expected substantial releases to the atmosphere, annual data on import quantities should be reported to the Australian Greenhouse Office.

- When HFC-245fa is used as a refrigerant, all usage of the chemical and its eventual removal from retired appliances should be performed in compliance with the appropriate Australian standard relating to refrigerating systems, that is, AS/NZ 1677 (1998) - Refrigeration Systems (Standards Australia, 1998).

Storage

- The notified chemical must be stored in a cool, well ventilated place.

Emergency procedures

- An emergency response plan must be available at all sites where large volumes of the notified chemical are to be stored or handled.

Transport and Packaging

- HFC-245fa must be transported in accordance with the provisions of the ADG Code, in particular, its transport as a Class 2.2 pressurised liquid when packaged with a nitrogen pad.

Secondary Notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under subsection 64(1) of the Act; if
  – the notified chemical is to be used as a general cleaning or degreasing solvent in open systems; or

(2) Under subsection 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

14. MATERIAL SAFETY DATA SHEET

MSDS for the notified chemical were provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a).

The MSDS were 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.

A Material Safety Data Sheet for HFC-245fa was provided by A-GAS (Australia) Pty Ltd in a format consistent with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 1994b). The accuracy of this information remains the responsibility of the applicant

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Attachment 1

The Draize Scale (Draize, 1959) 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 (Draize *et al*., 1944) for evaluation of eye reactions is as follows:

CORNEA

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

CONJUNCTIVAE

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