European Union Risk Assessment Report

Chlorodifluoromethane

CAS-No. 75-45-6

EINECS No: 200-871-9

Summary Risk Assessment Report

Italy

FINAL APPROVED VERSION

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Final Summary, September 2008

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PREFACE

This report provides a summary, with conclusions, of the risk assessment report of the substance chlorodifluoromethane that has been prepared by Italy in the context of Council Regulation (EEC) No.793/93 on the evaluation and control of existing substances.
For detailed information on the risk assessment principles and procedures followed, the underlying data and the literature references the reader is referred to the original risk assessment report that can be obtained from the European Chemicals Bureau1. The present summary report should preferably not be used for citation purposes.

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EUSES Calculations can be viewed as part of the report at the website of the European Chemicals Bureau: http://ecb.jrc.it

1 GENERAL SUBSTANCE INFORMATION

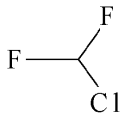
1.1 IDENTIFICATION OF THE SUBSTANCE

CAS Number: 75-45-6

EINECS Number: 200-871-9

IUPAC Name: Chlorodifluoromethane

Molecular formula: $CHClF_2$

Structural formula: 

Molecular weight: 86.47

Synonyms: R-22, HCFC-22

1.2 PHYSICO-CHEMICAL PROPERTIES

Property	Value	REFERENCE
Physical state	gaseous	
Melting point	-160 °C	Kühn-Birett 1994
Boiling point	- 40,8 °C	Hoechst AG 1989
Relative density at 20°C	Gas at 1 atm: 0.0036 Liquid at sat. vap. Press.: 1.210	Calculated Defibaugh and Morrison (1992)
Vapour pressure at 12° C Vapour pressure at 25°C	723 kPa (7.135 atm) 1045 kPa (10.31 atm)	Defibaugh and Morrison (1992) Defibaugh and Morrison (1992)
Water solubility at 25°C and 1 atm at 25° and saturated vapour pressure at 12°C and 1 atm at 12° and saturated vapour pressure	2.93 g/l 2.40 g/l 24.75 g/l 4.22 g/l 30.1 g/l	Hine and Mookerjee (1975) Calculated on the basis of the mean Henry's Law constant Calculated on the basis of the Henry's Law constant Calculated on the basis of Henry's constant Calculated
Partition coefficient n-octanol/water (log value)	log Pow = 1.13	CSCL Japan 1992
Flash point	not applicable	the product is not flammable
Autoflammability	630 °C	Sorbe 1993
Flammability	not flammable	Hoechst AG 1987
Explosive properties	not applicable	the product does not explode

Property	Value	REFERENCE
Oxidizing properties	non oxidizer	Solvay S.A. 1995
Viscosity		
Henry's Law constant	3650 Pa.m^3/mol at 25°C 0.0205 atm.m^3/mole at 12°C	Mean value of the following references: Boggs and Buck (1958) : H = 3058 Pa.m^3/mol Chang and Criddle (1995) : H = 4779 Pa.m^3/mol Zheng *et al.* (1997) : H = 3116 Pa.m^3/mol Mean value of the following references: Boggs and Buck (1958) : H = 0.0179 atm.m^3/mol Chang and Criddle (1995) : H = 0.0241 atm.m^3/mol Zheng *et al.* (1997) : H = 0.0194 atm.m^3/mol

1.3 CLASSIFICATION

1.3.1 Current classification

Not in Annex I to directive 67/548/EEC

1.3.2 Rapporteur proposal

Hazard Symbol: N – Dangerous for the environment

Risk phrase: R 59 - Dangerous for the Ozone layer

Safety phrases: S 59 - Refer to the manufacturer/supplier for information on recovery/recycling.

Repro.Cat.3; R63

2 GENERAL INFORMATION ON EXPOSURE

Chlorodifluoromethane (HCFC-22, $CHClF_2$) does not have significant natural sources. Although concentrations of other fluorocarbons (CFCs 11 and 12) higher than in ambient air have been detected in volcanic vents, chlorodifluoromethane was not found, even when the vent contained a substantial concentration of its chemical precursor, chloroform (Isidorov, 1990).

Industrial production data have been provided by some thirteen companies from throughout the world and, together with their subsidiaries and associates, these constitute a maximum of 37 potential producers of whom seven are in Europe (AFEAS, 2003). The unit processes of these manufacturers are described in Table 3.1, together with the nature and quantity of their emissions to the environment.

Chlorodifluoromethane is generally manufactured by reacting anhydrous hydrogen fluoride with chloroform, mainly in liquid phase reactions employing antimony halide catalysts. The reagent mixtures are toxic and corrosive and the product has a high vapour pressure (911 kPa at 20oC) and so it is manufactured in enclosed equipment and stored as liquefied gas under pressure in closed cylinders prior to use (Hamilton, 1963). Due to the requirement to withstand high pressures safely, the equipment used for the transport and storage of chlorodifluoromethane is subject to European Community directives and local regulations governing design and testing. Consequently, fugitive emissions from the process tend to occur as continuous releases due to venting or short-term, intermittent releases during the cleaning and refilling of cylinders, rather than being infrequent releases that are large relative to the local dispersing power of the atmosphere. The fugitive emissions during the stages of processing, transport, storage and product formulation account for 2.5% of the global production.

Chlorodifluoromethane is used in potentially dispersive applications as an end product, either by itself or in blends with other substances; the other significant use is as feedstock for fluoropolymer manufacture. In the early 1990s, 65% of global production was used as an end product and the remainder was feedstock (Midgley & Fisher, 1993). By the year 2001 in the EU the proportion used as an end product was 40%, reflecting the greater importance of fluoropolymer feedstock in Europe (Cefic, 2003).

HCFC-22 is now a controlled substance under the Montreal Protocol in countries that account for 90% of its dispersive use and will become controlled in the remainder. The scenario for future emissions is therefore relatively robust and was calculated for the 2002 Scientific Assessment of Ozone Depletion (Montzka et al., 2003). It is expected that, globally, production for dispersive uses will gradually reduce to about half of current values by 2015 and subsequently fall to zero by 2040. Under Regulation EU 2037/2000, HCFC production in the EU for dispersive use shall be reduced to 35% of 1997 levels by 2008. However, total production of HCFC-22 will not fall to the same extent because of continuing demand for feedstock material, which is exempted under the Montreal Protocol and EU Regulations and has remained almost constant in the past 6 years in the EU (Cefic, 2003).

HCFC-22 is an ozone depleting substance and, as discussed above, the principal regulation affecting HCFC-22 use is EC 2037/2000[1] which seeks to impose more rigorous constraints

[1] REGULATION (EC) No 2037/2000 OF THE UEROPEAN PARLIAMENT AND OF THE COUNCIL of 29

than the Montreal Protocol. Under the EU Regulation, use of HCFCs is already prohibited in aerosol propellants, most solvent applications, most new refrigeration and air-conditioning equipment and most foams. From 1 January 2004, this ban was extended to all new refrigeration equipment and foam blowing. On 31 December 2008, the remaining solvent applications (precision cleaning in aerospace and aeronautics) will be banned and virgin HCFC-22 will no longer be permitted for maintenance of refrigeration and air-conditioning

In addition to the controls on production and use, EC 2037/2000 also imposes a duty of containment when HCFC-22 is used as a feedstock and during the operating life of equipment, especially at disposal, when recovery of the HCFC for destruction or recycle is mandatory. Recent data show that containment is improving and that the rate of emissions, relative to the quantities produced and in service, is falling (McCulloch et al., 2006).

Chlorodifluoromethane is permitted for use as plastics additive in food contact materials legislation. Commission Directive 2002/72/EC refers and permits use with a specific migration limit of 6 mg/kg food and a content in the substance of no more than 1 mg/kg.

June 2000 on substances that deplete the ozone layer; OJ L244/1; 29. 9. 2000

3 ENVIRONMENT

3.1 ENVIRONMENTAL EXPOSURE

3.1.1 General discussion

An evaluation of environmental exposure coming from significant uses of chloro difluoromethane has been performed in compliance with the Technical Guidance Document for Risk Assessment (TGD), European Chemicals Bureau, 2003.
For that purpose, the electronic prediction model EUSES 2.0 as proposed in the TGD, , was used. Production and use data of fiscal year 2001 have been used.

Chlorodifluoromethane (HCFC-22) is produced by a wet process in closed system on a continuous basis. Emissions to air and waste water may occur during vessel cleaning or coupling and decoupling of pipelines for maintenance purposes or when filling of tanks.
Concentrations of HCFC-22 in surface water are very low and difficult to measure.

3.1.1.1 Calculation of PEClocal for the aquatic compartment

Local PECs are calculated via EUSES 2 for the following scenarios:
- production
- use as a chemical intermediate

3.1.1.1.1 Calculation of PEC_{local} for production

The $PECs_{local}$ calculated for the 10 production sites are reported in table below

Site	PEC_{water} during emission episode (mg/l)	PEC_{water} average (mg/l)	$PEC_{sediment}$ (mg/kg)	Regional PEC in surface water (mg/l)
1	9.42E-2	7.74E-2	0.157	1.05E-5
2	3.17E-3	3.17E-3	5.28E-3	4.72E-6
3	0.145	0.105	0.241	1.68E-4
4	9.8E-12	9.8E-12	1.6E-11	9.28E-6
5	0.0966	0.0794	0.161	9.3E-6
6	0.158	0.151	0.263	1.68E-4
7	27.4E-3	25.9E-3	45.5E-3	3.29E-6
8	0.125	0.103	0.208	9.28E-6
9	1.28E-3	1.21E-3	2.12E-3	6.60E-6
10	4.6E-3	4.3E-3	7.6E-3	4.72E-6

3.1.1.1.2 Calculation of PEC_{local} for industrial/professional use

During the use as a refrigerant
Since the use as a refrigerant is wide and dispersive, no PEC_{local} has been calculated.

During the use as an intermediate in further synthesis
The $PECs_{local}$ calculated for the sites in which HCFC-22 is used as an intermediate are reported in table below.

Site	PEC_{water} during emission episode (mg/l)	PEC_{water} average (mg/l)	$PEC_{sediment}$ (mg/kg)	Regional PEC in surface water (mg/l)
1	2.23E-6	2.23E-6	3.71E-6	6.60E-6
2	0.0164	0.0157	0.0272	1.68E-4
3	0.15	0.124	0.25	1.68E-4

3.1.1.1.3 Calculation of PEC_{local} for disposal

No HCFC-22 is expected to be present in liquid waste

3.1.1.2 Calculation of PEClocal for the terrestrial compartment

3.1.1.2.1 Calculation of PEClocal for production

The calculated PECs for agricultural land, grassland, and porewater for production, storage and transport of HCFC-22 are presented in table below

Site	PEC agricultural soil av. 30 d (mg/kg)	PEC agricultural soil av. 180 d (mg/kg)	PEC grassland	PEC groundwater (mg/l)
1	4.53E-3	7.96E-4	1.98E-4	8.37E-4
2	1.52E-4	2.19E-3	5.13E-4	2.3E-3
3	0.0401	6.87E-3	1.55E-3	7.22E-3
4	8.04E-8	8.04E-8	8.04E-8	8.41E-8
5	4.73E-3	9.01E-4	2.88E-4	9.47E-4
6	7.54E-3	1.28E-3	2.76E-4	1.34E-3
7	1.28E-3	2.3E-04	5.8E-5	2.37E-4
8	5.99E-3	1.02E-3	2.26E-4	1.07E-3
9	2. 1E-4	1.6E-04	1.51E-4	1.68E-4
10	2.45E-4	6.3E-5	3.45E-5	6.7E-5

3.1.1.2.2 Calculation of PEC_{local} for industrial/professional use

During use as a refrigerant
Since the use as a refrigerant is wide and dispersive, no PEC_{local} has been calculated.

During use as intermediate for further synthesis

The calculated PECs for agricultural land, grassland, and porewater for the use of HCFC-22 as a chemical intermediate are presented in table below.

Site	PEC agricoltural soil 30 d (mg/kg)	PEC agricoltural soil 180 d (mg/kg)	PEC grassland	PEC groundwater (mg/l)
1	8.2E-8	8.2E-8	8.2E-8	8.63E-8
2	7.86E-4	1.37E-4	3.31E-5	1.44E-4
3	7.17E-3	1.06E-3	2.82E-4	1.12E-3

3.1.1.2.3 Calculation of PEC_{local} for disposal

No HCFC-22 is expected to be present in solid waste.

3.1.1.3 Calculation of PEClocal for the atmosphere

3.1.1.3.1 Calculation of PEC_{local} for production

The calculated PECs for the atmospheric compartment for production, storage and transport of HCFC-22 are presented in table below.

Site	PEC atmosphere (mg/m^3)
1	0.0167
2	0.0228
3	0.0561
4	3.95E-5
5	0.0571
6	0.0122
7	5.7E-3
8	8.29E-3
9	0.0702
10	0.0125

3.1.1.3.2 Calculation of PEC_{local} for industrial/professional use

During the use as a refrigerant
Since the use as a refrigerant is wide and dispersive, non PEC_{local} has been calculated.

During the use as an intermediate in further synthesis
The calculated PECs for the atmospheric compartment for the use of HCFC-22 as a chemical intermediate are presented in table below.

Site	PEC atmosphere (mg/m^3)
1	3.85E-5
2	2.1E-3
3	0.0305

3.1.1.3.3 Calculation of PEC_{local} for disposal

Since no HCFC-22 is expected to be present in liquid or solid waste, no atmospheric releases of HCFC-22 will take place from landfills or incineration plants.

3.1.2 Calculation of PECregional and PECcontinental

3.1.2.1 Aquatic compartment

PEC regional

$PEC_{regional}$ in surface water (total): 8.88E -6 mg/l
$PEC_{regional}$ in sediment (total): 1.41E-5 mg/kg ww

PEC continental

PEC in surface water (total): 5.16E-6 mg/liter
PEC in sediment (total): 8.18E-6 mg/kg ww

3.1.2.2 Terrestrial compartment

PEC regional

$PEC_{regional}$ in agricultural soil (total): 6.39 E-6 mg/kg ww

PEC continental

PEC in agricultural soil (total): 5.41E-6 mg/kg ww

3.1.2.3 Atmospheric compartment

PEC regional

$PEC_{regional}$ in air (total): 2.12E-3 mg/m^3

PEC continental

PEC in air : 1.72E-3 mg/m3

Measured background atmospheric concentrations of HCFC-22

Location	Year of measurement	Mean concentration ng/m^3 (pmol/mol)	Reference
Global troposphere, 7 sites (between 82°N and 90°S)	2000	507(143)	CMDL (2001)
Global troposphere, 5 sites	2000	502(142)	AGAGE (2001)
Global troposphere, 7 sites (between 82°N and 90°S)	mid 1995	414 (117)	Montzka et al. (1996)
Global troposphere, 5 sites	mid 1995	407 (115)	Prinn et al. (1995)
Global troposphere, 7 sites (between 82°N and 90°S)	1992	361 (101.8)	Montzka et al. (1993)

Location	Year of measurement	Mean concentration ng/m³ (pmol/mol)	Reference
Global atmosphere	1987	372 (105)	WMO (1991)
Global : - Northern hemisphere – Southern hemisphere	mid 1979	159 (45) * 177 (50) * 149 (42) *	Rasmussen et al. (1980)
Kitt Peak (32°N)	mid 1992	389-414 (110-117)	Zander et al. (1994)
Jungfraujoch (46.5°N)	mid 1992	395-449 (111.5-126.8)	Zander et al. (1994)
Arctic (68 to 80°N)	1988-1989	304 (85.9)	Pollock et al. (1992)
Kitt Peak (32°N)	1988 1980	241 (68) 35.4 (10)	Rinsland et al. (1989)
Point Barrow, Alaska (72°N)	1986	326 (92) *	NASA (1988)
Point Barrow, Alaska (72°N) -winter –summer	1980-1981	 217 (61.2) * 198 (56) *	Khalil et al. (1983)
Arctic lower atmosphere (70°N) 0 to 4 km	May 1982	259 (73.2) *	Rasmussen et al. (1983)
North west Pacific (45°N) (100 air samples)	Apr 1978 - Jan 1981 Jan 1981	11.7 % per year increase * 230 (65) *	Khalil et al. (1981)
North west Pacific	Jan 1980	223 (63) *	Rasmussen et al. (1981)
Washington (State), USA	1980	110-190 (31-54)	Leifer et al. (1981)
Cape Grim (41°S)	mid 1992	333 (94.2)	Fraser et al. (1995b)
Cape Grim (41°S)	1987	322 (91)	WMO (1991)
South Pole	Jan 1980	159 (45) *	Rasmussen et al. (1981)

Total atmospheric PEC

Since the emission sources (production sites, processing sites as an intermediate, and locations where the substance is used as a refrigerant) are considered to be geographically separated from each other (and more or less evenly spread over the EU area), the total HCFC-22 concentration on a continental scale only is relevant for risk assessment of exposure of environment and man.

Soil, sediment and surface water concentrations are so low for each emission source (nano-to picogram/kg range) that addition of emissions to those compartments will not significantly influence the risk characterisation on total HCFC-22 concentrations in those compartments.
Therefore only atmospheric total concentrations will be evaluated.
It should be noted that EUSES does not take existing background atmospheric levels of HCFC-22 into account (model assumption: HCFC-22-free air flowing into EU).

The resulting continental concentrations calculated by the EUSES model are considered to be at steady state (fraction of steady state =1)
Sum of total emitted HCFC-22 to atmosphere in EU is 82066 kg/d, yielding a continental atmospheric concentration of +/- 166 ng/m^3 (without existing background).
The background concentrations of HCFC-22 in 2001 are not available, but the observed background level was 502 ng/m^3 in 2000.
Assuming that the 2001 background level was comparable to that of 2000, the total atmospheric concentration in the EU would be 668 ng/m^3.

3.2 EFFECTS ASSESSMENT: HAZARD IDENTIFICATION AND DOSE (CONCENTRATION) - RESPONSE (EFFECT ASSESSMENT)

3.2.1 Aquatic compartment (incl. sediment)

Very few experimental aquatic toxicity tests have been carried out using chlorodifluoromethane. This is probably because of the physical nature of the substance. Due to its high vapour pressure, it is very difficult to test chlorodifluoromethane meaningfully.
Its Henry's law constant (H = 0.0205 atm.m^3/mol or 2077 pa m^3/mol at 12°C) indicates that the preferred environmental compartment of chlorodifluoromethane is the atmosphere.
Any chlorodifluoromethane released will partition rapidly into the air even if the primary vehicle for the release was an aqueous solution (Ballschmiter, 1992; Mackay, 1985). Chlorodifluoromethane has been shown to accumulate in the atmosphere where it is dispersed rapidly and oxidised slowly (WMO, 1994).

3.2.1.1 Calculation of Predicted No Effect Concentration (PNEC)

Determination of the PNEC for water compartment
There are only two reliable experimental results from tests on fish and daphnia for chlorodifluoromethane, giving a 96h LC50 and a 48h EC50 of 777 mg/l and 433 mg/l respectively. As described above, QSAR methods can be used to calculate accurately the aquatic toxicity of chlorodifluoromethane. Data from the QSAR methods suggest a similar sensitivity to fish, daphnia and algae for chlorodifluoromethane.

It is proposed to base the PNEC on the lowest EC50 obtained from the QSAR, which is 250 mg/l for a 96 hour exposure to algae.

An assessment factor of 1000 is applied.

Therefore: **PNEC aqua = 250 mg/l / 1000 = 250 µg/l**

Determination of the PNEC for the sediments

In the absence of any toxicological data for the sediment dwelling organisms, the PNEC is calculated using the equilibrium partitioning method (TGD, part ii, paragraph 3.6.2.1, page. 117).

$$PNEC_{sediment} = (K_{susp\text{-}water} / RHO_{susp}) \times PNEC_{water} \times 1000 \quad (1)$$

where:
- $K_{susp\text{-}water}$ is the partition coefficient suspended matter-water;
- RHO_{susp} is the bulk density of suspended matter;

$K_{susp\text{-}water}$ can be calculated from the equation:

$$K_{susp\text{-}water} = Fair_{susp} \times K_{air\text{-}water} + Fwater_{susp} + Fsolid_{susp} \times (Kp / 1000) \times RHO_{solid} \quad (2)$$

Where:

Fx_{susp} is the fraction of phase x in the sediment compartment;
$K_{air-water}$ is the air water partitioning coefficient ($K_{air-water}$ = HLC /RT); R = 8.31 J/mol/K; T = 298 °K; HLC + 2496 Pa m3/mol (calculated at 25 °C, by EUSES 2).
K_p is the solids-water partition coefficient in the compartment. $K_p = K_{oc} \times$ fraction of organic carbon.
.

Parameters used:

- K_{oc}: a value of 40.5 l/kg was considered for K_{oc}. The estimation is derived from EUSES 2, considering HCFC-22 as a non-hydrophobic substance. The low K_{ow} of HCFC-22 justifies this assumption.
- Fraction of organic carbon: 0.1 (*)
- $K_p = K_{oc}$ x fraction of organic carbon = 4.05 l/kg
- RHO_{solid}: 2500 kg/m^3
- $Fair_{susp}$: 0 (*)
- $Fwater_{susp}$: 0.9(*)
- $Fsolid_{susp}$: 0.1 (*)
- RHO_{susp}: 1150 kg/m^3 (*)

*default values, taken from TGD, part II, paragraph 2.3.4, table 5, page. 43.

The PNEC value for sediment dwelling organisms is calculated to be **416 µg/kg** wet weight (1910 µg/kg dry weight).

3.2.1.2 Determination of Predicted No Effect Concentration (PNEC) for terrestrial compartment

In the absence of any toxicological data for the terrestrial organisms, the PNEC is calculated using the equilibrium partitioning method (TGD, part ii, paragraph 3.6.2.1, page. 117).
The equations used are the same of the PNEC calculation for sediments (3.2.1.2).

$$PNEC_{soil} = (K_{soil-water} / RHO_{soil}) \times PNEC_{water} \times 1000$$

where:

- $K_{soil-water}$ is the partition coefficient soil-water;
- RHO_{soil} is the bulk density of wet soil;

$K_{soil-water}$ can be calculated from the equation:

$$K_{soil-water} = Fair_{soil} \times K_{air-water} + Fwater_{soil} + Fsolid_{soil} \times (Kp / 1000) \times RHO_{solid}$$

The input parameters specific for the terrestrial compartment are the following:

- Fraction of organic carbon: 0.02 (*)
- $K_p = K_{oc}$ x fraction of organic carbon = 0.81 l/kg
- $Fair_{soil}$: 0.2 (*)
- $Fwater_{soil}$: 0.2(*)
- $Fsolid_{soil}$: 0.6 (*)
- RHO_{soil}: 1700 kg/m^3 (*)

*default values, taken from TGD, part II, paragraph 2.3.4, table 5, page. 43.

The PNEC value for terrestrial dwelling organisms is calculated to be **239 µg/kg** wet sediment (271 µg/kg dry weight).

3.2.2 Atmosphere

No test results are available. For possible abiotic effects of HCFC-22 due to ozone depletion and global warming potential.

3.2.3 Secondary poisoning

As chlorodifluoromethane does not present indications of a bioaccumulation potential, a risk assessment for secondary poisoning is not necessary.

3.3 RISK CHARACTERISATION [2]

3.3.1 Aquatic compartment (incl. sediment)

Surface water

Estimated PEC/PNEC ratios for the surface water at local scale

Scenario		PEC emission period (mg/l)	PNEC (mg/l)	PEC/PNEC	Conclusion
Production	1	0.0942	0.250	0.377	ii
	2	3.17E-3	0.250	0.0127	ii
	3	0.145	0.250	0.578	ii
	4	9.81E-12	0.250	3.92E-11	ii
	5	0.0966	0.250	0.386	ii
	6	0.158	0.250	0.632	ii
	7	0.0274	0.250	0.109	ii
	8	0.125	0.250	0.5	ii
	9	1.28E-3	0.250	5.12E-3	ii
	10	4.58E-3	0.250	0.0183	ii
Use as an intermediate	1	2.23E-6	0.250	8.93E-6	ii
	2	0.0164	0.250	0.0655	ii

[2] Conclusion (i) There is a need for further information and/or testing.
Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.
Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

	3	0.15	0.250	0.601	ii
Combined production + use as an intermediate	Site 9 + 1	1.28E-3	0.250	5.12E-3	ii
	Site 6 + 2	0.174	0.250	0.70	ii

Estimated PEC/PNEC ratios for the surface water at regional and continental level

Scenario	PEC (mg/l)	PNEC (mg/l)	PEC/PNEC	Conclusion
Regional scenario	8.88E-6	0.250	3.56E-5	ii
Continental scenario	5.16E-6	0.250	2.06E-5	ii

Sediment

Estimated PEC/PNEC ratios for the sediment water at local scale

Scenario		PEC (mg/kg)	PNEC (mg/kg)	PEC/PNEC	Conclusion
Production	1	0.157	0.416	0.377	ii
	2	5.28E-3	0.416	0.0127	ii
	3	0.241	0.416	0.578	ii
	4	1.63E-11	0.416	3.74E-11	ii
	5	0.161	0.416	0.386	ii
	6	0.263	0.416	0.632	ii
	7	0.0455	0.416	0.109	ii
	8	0.208	0.416	0.5	ii
	9	2.12E-3	0.416	5.09E-3	ii
	10	7.62E-3	0.416	0.0183	ii
Use as an intermediate	1	3.71E-6	0.416	8.93E-6	ii
	2	0.0272	0.416	0.0655	ii
	3	0.25	0.416	0.601	ii
Combined production + use as an intermediate	Site 9 + 1	2.12E-3	0.416	5.09E-3	ii
	Site 6 + 2	0.290	0.416	0.697	ii

Estimated PEC/PNEC ratios for the sediment water at regional and continental scale

Scenario	PEC (mg/kg)	PNEC (mg/kg)	PEC/PNEC	Conclusion
Regional scenario	1.41E-5	0.416	3.4E-5	ii

Continental scenario	8.18E-6	0.416	1.9E-5	ii

Conclusions to the risk assessment for the aquatic compartment:

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to the scenarios production, use as a chemical intermediate and use as a refrigerant.

3.3.2 Terrestrial compartment

Estimated PEC/PNEC ratios for the terrestrial compartment at local scale

Scenario		**PEC agr soil 30 d (mg/kg)**	**PNEC (mg/kg)**	**PEC/PNEC**	**Conclusion**
Production	1	4.53E-3	0.239	0.0190	ii
	2	1.52E-4	0.239	6.39E-4	ii
	3	0.0401	0.239	0.169	ii
	4	8.04E-8	0.239	3.36E-7	ii
	5	4.73E-3	0.239	0.0199	ii
	6	7.54E-3	0.239	0.0315	ii
	7	1.28E-3	0.239	5.36E-3	ii
	8	5.99E-3	0.239	0.0251	ii
	9	2.10E-4	0.239	8.8E-4	ii
	10	2.45E-4	0.239	1.03E-3	ii
Use as an intermediate	1	8.2E-8	0.239	3.45E-7	ii
	2	7.86E-4	0.239	3.31E-3	ii
	3	7.17E-3	0.239	0.0301	ii
Combined production + use as an intermediate	Site 9 + 1	2.10E-4	0.239	8.8E-4	ii
	Site 6 + 2	8.33E-3	0.239	0.0348	ii

Estimated PEC/PNEC ratios for the terrestrial compartment at regional and continental scale

Scenario	PEC (mg/kg)	PNEC (mg/kg)	PEC/PNEC	Conclusion
Regional scenario	6.39E-6	0.239	2.7E-5	ii
Continental scenario	5.41E-6	0.239	2.26E-5	ii

Conclusions to the risk assessment for the terrestrial compartment:

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to production, use as a chemical intermediate and use as a refrigerant scenarios.

3.3.3 Atmosphere

Based on its physical-chemical properties, the air compartment is the preferred target for chlorodifluoromethane. As no experimental data on environment organisms exposed through the gas phase are available, no biotic assessment is possible for the atmosphere. In view of the very low atmospheric concentration calculated with EUSES and the very high NOECs found in experimental testing (inhalation toxicity studies in mammals), we can conclude that there is no risk for the atmospheric environment.
For the evaluation of an atmospheric risk, abiotic effects can be considered. The atmospheric lifetime of chlorodifluoromethane is 12.1 years. It has a very low ozone depletion potential (ODP); the value adopted for the purpose of the Montreal Protocol is 0.055. Its Global Warming potential (GWP) is 1700 on a unit-mass basis relative to a reference value of 1 for CO_2 at an Integration Time Horizon of 100 years (Ramaswamy *et al.*, 2001). WMO (2001) predicts for 2010 a maximum tropospheric concentration of 183 pptv (only 29 % above the 2000 level). However, as a Montreal Protocol substance, chlorodifluoromethane is not included in the Kyoto Protocol on greenhouse gas emissions. The EU Regulation 2037/2000 bans all dispersive uses of HCFC-22 (see paragraph 2.4).

Conclusions to the risk assessment for the atmosphere:

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to production, use as a chemical intermediate and use as a refrigerant scenarios.

3.3.4 Secondary poisoning

The low octanol-water partition coefficient indicated that chlorodifluoromethane is not likely to bioaccumulate. Therefore non-compartment specific effects relevant to the food chain have not to be considered.

Conclusions to the risk assessment for secondary poisoning:

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to applies to production, use as a chemical intermediate and use as a refrigerant scenarios.

4 HUMAN HEALTH

4.1 HUMAN HEALTH (TOXICITY)

4.1.1 Exposure assessment

At all ambient temperatures at which exposure can be predicted chlorodifluoromethane is a gas. Thus exposures will predominately be by inhalation. Dermal contact with the liquefied gas escaping from cylinders can occur, but such exposures will only occur rarely in the occupational setting. The limited water solubility presents a theoretical possibility of ingestion in drinks.

The main uses of chlorodifluoromethane are:
1. Refrigerant fluid
2. Chemical intermediate

The main categories of persons likely to be exposed the chlorodifluoromethane are workers involved in its production and use. Exposure of consumers and general public to HCFC-22 is not expected, except in accidental case. Some cases of acute intoxication from intentional inhalation abuse have been reported (Garriot and Petty, 1980; Kamm, 1975; Kurbat et al., 1998).
The human health section covers the health related effect from direct and indirect exposure to chlorodifluoromethane. As regulation concerning the ozone depleting potential of the substance is in place, it is not the intention of this risk assessment report to cover the indirect human health effects from increased UV-radiation caused by the stratospheric ozone layer depleting potential of the substance

Available data on occupational exposure are summarized in table below. Frequency and duration have been estimated by making an average of the information provided by some plants. It has to be stressed that, for some activities such as maintenance, operational practices can be very different from one site to the other. In each scenario, short term exposure data refer to specific cases in which an exposure is possible because of system breaching (filling, sampling, decoupling, etc.). For normal operation work during production, no short term exposure value is reported, because the exposure can only take place in case of accidental leaks. As HCFC-22 is a gas under normal conditions of production and use, only inhalation exposure is possible.

Conclusions of the occupational exposure assessment

Scenario	Activity [1]	Frequence	Duration	Inhalation worst case	Reasonable
		Days/year	Hours/day	mg/m3	Method [2]
Production					
Subscenario 1	Full shift	160	10	3.8	Measured
Normal activity					
Subscenario 2	Full shift	46	7	3.8	Measured
Maintenance	Short term			126.7	Measured
Subscenario 3	Full shift	160	10	30.5	Measured
Packaging/filling	Short term	160	1.5	126.7	Measured
Subscenario 4	Full shift	3	10	3	Measured
Sampling/lab	Short term	50	0.1	49.7	Measured
Uses					
Subscenario 1	Full shift		7	235	Measured
Use as a refrigerant	Short term		0.2	2027	Measured
Subscenario 2	Full shift			3.8	Measured
Use as an intermediate					

1: Full shift, short term, etc.
2: Measured, EASE, Expert judgment, Calculated, etc.
NR: not relevant

4.1.1.1 Consumer exposure

HCFC-22 was used in the past in domestic refrigeration and air conditioning equipments. In these applications, refrigeration units are hermetically sealed and maintenance is carried out only by professionals. Therefore, there is no direct consumer exposure to HCFC-22.

4.1.1.2 Humans exposed via the environment

HCFC-22 does not bioaccumulate, therefore no significant human exposure via the environment is expected.

4.1.2 Effects assessment: Hazard identification and dose (concentration)-response (effect) assessment

4.1.2.1 Toxicokinetics, metabolism and distribution

The studies in animals show that chlorodifluoromethane is rapidly absorbed into the blood stream by the inhalation route, since 75-80% of the inhaled concentration equilibrated with the blood. It is not metabolised to any significant extent and is very rapidly (half-life $\leq$ 1 minute) and extensively eliminated unchanged in the exhaled air, indicating very limited period of retention within the body.
The inhalation absorption figure will therefore depend on the exposure duration within each day with high absorption during the beginning of exposure and lower absorption when the equilibrium is reached. It is recognised that route specific NOAELs are available from studies of sufficiently long daily exposure. Thus this phenomenon of reaching equilibrium is included in these NOAELs and does not have to be taken into account in the risk characterisation.
Only a very small amount of radiolabelled material (<<0.1 % of administered dose) has been detected in urine. A similar profile is seen in humans, where, after rapid equilibration with the blood (blood/expired air partition ratio 0.77), chlorodifluoromethane is rapidly eliminated in the breath; the compound metabolism is minimal and excretion into the urine extremely limited. Thus it can be reasonably assumed that animal studies suitably model toxicokinetics of chlorodifluoromethane in man.

4.1.2.2 Acute toxicity

Chlorodifluoromethane has an extremely low order of acute toxicity by the inhalation route. Despite the variety of conditions used and the different laboratories involved, there is a consistency between the effects seen in the different animal species. The primary toxic effect following acute inhalation of chlorodifluoromethane was central nervous system depression, which occurred only at extremely high concentrations.

The oral and dermal routes of exposure are not significant for chlorodifluoromethane. No informative studies of its acute toxicity by these routes have been reported.

As with many other fluorocarbons chlorodifluoromethane causes cardiac sensitisation in animal testings, but only at extremely high acute exposure concentration. The threshold concentration for inducing cardiac sensitisation to adrenaline in dogs is 50,000 ppm (175,000 mg/m^3) and the NOAEC is 25,000 ppm (87,500 mg/m^3). At very high concentrations, respiratory effects have also been noted in animal testing.

The available data on acute toxicity can be summarized as follows:

Mortality: LC50/4h/rat = 219,000 ppm (766,500 mg/m^3); LOAEC/2h/rat = 297,000 ppm (1050,000 mg/m^3).
Cardiac sensitisation in dog: LOAEC in dog = 50,000 ppm (175,000 mg/m^3) and NOAEC = 25,000 ppm (87,500 mg/m^3).
The overall **NOAEC** for acute toxicity is 25,000 ppm (**87,500 mg/m^3**) and the overall LOAEC is 50,000 ppm (**175,000 mg/m^3**).

4.1.2.3 Irritation

As chlorodifluoromethane is a gas at room temperature, it has not been tested as such in rabbit skin and eye irritation tests. However, the clinical observations during acute and/or repeated inhalation toxicity studies did not show any indication of skin irritation nor any evidence of eye damage. Only lacrymation was reported but at very high concentrations.

Chlorodifluoromethane, when applied as a liquefied gas, is very slightly irritant to eyes and slightly irritant to skin in rabbit assays. These irritant effects are mainly due to its liquefied form under pressure, causing tissue freezing. Such effects have been observed in accidental conditions in human.

However, as reported above, frostbite has to be considered as a physical hazard and not as toxicological response.

4.1.2.4 Corrosivity

Chlorodifluoromethane has no corrosive properties.

4.1.2.5 Sensitisation

Chlorodifluoromethane has no skin sensitising potential in experimental testing. There is no skin or respiratory sensitisation case reported in human.

4.1.2.6 Repeated dose toxicity

Two oral exposure studies have been conducted with chlorodifluoromethane, however since the potential risk for exposure to chlorodifluoromethane is by inhalation, oral exposure studies are considered of limited value for a risk assessment. Furthermore, these studies were poorly reported.

Several repeat-dose inhalation toxicity studies on chlorodifluoromethane have been conducted in a range of species, with durations ranging from 4 to 131 weeks. Rabbits, rats, guinea-pigs, dogs, cats and mice all reflected the generally low level of target organ toxicity shown by chlorodifluoromethane.

The most robust studies were conducted according to GLP standard in mice and rats, which were exposed to chlorodifluoromethane at concentrations up to 50,000 ppm until 80% mortality occurred for male and female mice and rats respectively. No organ-specific toxicity was identified in these studies at any exposure concentration. The overall No Observed Adverse-Effect Concentration (NOAEC) for repeated inhalation exposure of chlorodifluoromethane in long-term inhalation studies with rats and mice was 10,000 ppm (35,000 mg/m3) based on clinical signs of hyperactivity in mice and body weight changes in rats exposed, respectively, to 50,000 ppm.

4.1.2.7 Mutagenicity

Chlorodifluoromethane exerts some mutagenic activity in some bacterial strains.

HCFC 22 was not active in the three studies using yeast (Schizosaccharomyces Pombe and Saccharomyces Cerevisiae). It was not active in the three studies conducted using mammalian cell cultures (CHO cell HGPRT, V-79 HGPRT and unscheduled DNA synthesis). It was also not active in two in vivo studies (rat dominant lethal and mouse cytogenetics). It only showed limited activity in TA 1535 and TA 100 in 3 of 5 Ames assays. This activity was independent of the S-9. It did not show any activity with TA 1538 and TA 98. Taking all of this data into account, there is strong support for the conclusion of Litchfield and Longstaff (1984), that this activity appears to be the result of a bacterial specific metabolism.

The in vivo cytogenetic and dominant lethal studies in the rat and mouse provide no evidence of consistent or dose-related genotoxic activity. Taken with the negative result of the inhalation micronucleus test, the findings indicate that chlorodifluoromethane does not possess genotoxic activity in vivo.

4.1.2.8 Carcinogenicity

The animal studies provide limited evidence for the carcinogenicity of chlorodifluoromethane in rats only. In one rat inhalation study, increases in the incidence of fibrosarcomas at different sites and squamous cell carcinomas of the skin were noted in male animals at the highest doses. A significant incidence of Zymbal gland squamous cell carcinomas was also observed in male rats at 50,000 ppm, even though they could not be distinguished with certainty from squamous cell carcinomas of the ear canal. In the latter case, however, they would further increase the number and significance of total squamous cell carcinomas. These observations are somewhat mitigated by the occurrence of significant tumor increases in male rats only. In addition, most tumors appeared beyond week 105 of the study.
A clear **NOAEC** of **1000 ppm** (**3500 mg/m^3**) was demonstrated in the male rats. No increased tumor incidence attributable to chlorodifluoromethane exposure was diagnosed in female rats or in mice of either sex.

4.1.2.9 Toxicity for reproduction

Fertility was not affected by chlorodifluoromethane in male rats and mice. Developmental toxicity was not demonstrated in rabbits. The chlorodifluoromethane showed a significantly increased incidence of anophthalmia (1.6% in litters of treated group vs 0.16% in controls) and combined anophthalmia+microphthalmia (2.6% in litters treated group vs 0.5% in controls) in the offsprings of dams exposed to 50,000 ppm. The historical controls showed from 0 to 0.8% of incidence of anophthalmia and from 0 to 2.6% of incidence of anophthalmia+microphthalmia per litters. Therefore the incidence of anophthalmia in the large study is higher than in the historical controls and the incidence of anophthalmia+microphthalmia is comparable to the upper limit of historical controls. Maternal toxicity at 50,000 ppm is related only to slight reduction of body weight gain, in fact no other adverse effect was recorded. Due to the high specificity of this kind of malformations (anophthalmia and anophthalmia+microphthalmia) in laboratory animals, it is unlikely that they are related to maternal toxicity.

Therefore the NOAEC for developmental toxicity in the rat is considered 1000 ppm (3500 mg/m3).
Moreover, since a low rate of specific malformations was evident in presence of slight maternal toxicity, this could justify a classification of chlorodifluoromethane in cat 3 (harmful for reproduction) with the risk phrase R63.

The use of the NOAEC of 1000 ppm from the Palmer study (Palmer, 1978b) has been considered as a very conservative approach. Indeed no adverse effects were observed in the study of Culik and Crowe (1978) up to 20,000 ppm. This will be taken into account in the risk characterisation section.

4.1.3 Risk characterisation

4.1.3.1 General aspects

Because chlorodifluoromethane is a gas (boiling point -40.8ºC) and is only moderately soluble in water and has a high Henry's constant, its potential effects on mammalian health have been almost exclusively studied using the inhalation route. Although dermal penetration and oral ingestion cannot be totally excluded, they appear as minor routes of entry in the organism.
Exposure has been evaluated only for workers, since HCFC 22 is used only as a chemical intermediate and as a refrigerant mainly in large refrigeration units. Therefore, consumers' exposure is possible only in accidental cases.
The studies in animals show that chlorodifluoromethane is rapidly absorbed into the blood stream by the inhalation route of administration. It is not metabolised to any significant extent and is eliminated unchanged in the exhaled air. A similar profile is seen in humans.

Summary of effects

Substance name	Inhalation (N(L)OAEL)	Dermal (N(L)OAEL)	Oral (N(L)OAEL)
Acute toxicity	NOAEC: 25,000 ppm (87,500 mg/m^3) LOAEC: 50,000 ppm (175,000 mg/m^3)	NR	NR
Irritation / corrosivity	NR	NR	NR
Sensitization	NR	NR	NR
Repeated dose toxicity (local)	NR	NR	NR
Repeated dose toxicity (systemic)	NOAEC: 10,000 ppm (35,000 mg/m^3)	NR	NR
Mutagenicity	NR	NR	NR
Carcinogenicity	NOAEC: 1000 ppm (3500 mg/m^3)	NR	NR
Fertility impairment	NR	NR	NR
Developmental toxicity	NOAEC: 1000 ppm (3500 mg/m^3)	NR	NR

NR: not relevant

4.1.3.2 Workers

It is estimated that a few hundred workers in the EU are potentially exposed to chlorodifluoromethane during its production, storage and transport. Exposure is possible only by the inhalation route.

Overview of the conclusions with respect to occupational risk characterisation

		Acute toxicity (Minimal MOS = 9)		**Local toxicity after single or repeated exposure**			**Sensitisation**	**Repeated dose toxicity Systemic (Minimal MOS = 9)**			**Mutagenicity**	**Carcinogenicity (Minimal MOS = 9)**	**Reproductive toxicity (Minimal MOS = 9)**
		Dermal	Inhalation	Dermal	Inhalation	Eye		Dermal	Inhalation	Combined			
Production													
Subscenario 1	MOS	NR	NR	NR	NR	NR	NR	NR	9210	NR	NR	921	921
Normal activity	Concl.								ii			ii	ii
Subscenario 2	MOS	NR	690	NR	NR	NR	NR	NR	9210	NR	NR	921	921
Maintenance	Concl.		ii						ii			ii	ii
Subscenario 3	MOS	NR	690	NR	NR	NR	NR	NR	1147	NR	NR	114	114
Packaging/filling	Concl.		ii						ii			ii	ii
Subscenario 4	MOS	NR	1760	NR	NR	NR	NR	NR	11666	NR	NR	1166	1166
Sampling/lab	Concl.		ii						ii			ii	ii
Formulation													
Subscenario 1	MOS	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	Concl.												
Uses													
Subscenario 1 Use as a refrigerant	MOS	NR	43.2	NR	NR	NR	NR	NR	150	NR	NR	15	15
	Concl.		ii						ii			ii	ii
Subscenario 2 Use as an intermediate	MOS	NR	NR	NR	NR	NR	NR	NR	9210	NR	NR	921	921
	Concl.		ii						ii			ii	ii

NR: not relevant

4.1.3.3 Summary of risk characterisation:

4.1.3.3.1 Workers

Based on the dataset for the various effect endpoints and on the exposure data for the different scenarios, it can be concluded that there is no concern for occupational exposure to HCFC-22 (conclusion ii for all scenarios).
Conclusion (ii)

4.1.3.3.2 Consumers

Consumers' exposure to HCFC-22 is not expected. Some domestic refrigeration equipment contain HCFC-22 (either in the refrigeration system or in the insulating foams). The maintenance and servicing of the equipment are always made by professionals. In addition, under the provision of EC Regulation 2037/2000, the use of HCFC-22 for new refrigeration systems and foam blowing will be banned from 1st January 2004.
Conclusion (ii)

4.1.3.3.3 Humans exposed via the environment

HCFC-22 does not bioaccumulate, therefore no human exposure via the environment is expected. According to EUSES modelling, indirect exposure of humans to HCFC-22 via food, air and drinking water is negligible (see 4.1.1.4).

Conclusion (ii)

4.1.3.3.4 Combined exposure

There is no concern for consumers combined exposure to HCFC-22.

4.2 HUMAN HEALTH (PHYSICO-CHEMICAL PROPERTIES)

4.2.1 Exposure assessment

4.2.1.1 Workers

HCFC 22 does not present a physico-chemical hazard in the normal conditions of use. Frostbite may occur on skin contact with accidental released liquid or pressurized gas.

4.2.1.2 Consumers

Consumers are normally not exposed to HCFC-22.

4.2.1.3 Humans exposed via the environment

Humans are not exposed to HCFC-22 via the environment.

4.2.2 Effects assessment: Hazard identification

4.2.2.1 Explosivity

HCFC-22 has no explosion potential.

4.2.2.2 Flammability

HCFC-22 is not flammable.

4.2.2.3 Oxidizing potential

HCFC-22 is not an oxidising agent.

4.2.3 Risk characterisation

There is no risk of physico-chemical hazard for the population and workers due to HCFC-22.

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those that are being applied already.

5 RESULTS

5.1 INTRODUCTION

5.2 ENVIRONMENT

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

5.3 HUMAN HEALTH

5.3.1 Human health (toxicity)

5.3.1.1 Workers

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to production, use as a chemical intermediate and use as a refrigerant scenarios.

5.3.1.2 Consumers

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to production, use as a chemical intermediate and use as a refrigerant scenarios.

5.3.1.3 Humans exposed via the environment

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to production, use as a chemical intermediate and use as a refrigerant scenarios.

5.3.1.4 Combined exposure

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to production, use as a chemical intermediate and use as a refrigerant scenarios.

5.3.2 Human health (risks from physico-chemical properties)

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to production, use as a chemical intermediate and use as a refrigerant scenarios.

The report provides the summary of the comprehensive risk assessment of the substance Chlorodifluoromethane It has been prepared by Italy in the frame of Council Regulation (EEC) No. 793/93 on the evaluation and control of the risks of existing substances, following the principles for assessment of the risks to man and the environment, laid down in Commission Regulation (EC) No. 1488/94.

The evaluation considers the emissions and the resulting exposure to the environment and the human populations in all life cycle steps. Following the exposure assessment, the environmental risk characterisation for each protection goal in the aquatic, terrestrial and atmospheric compartment has been determined. The environmental risk assessment concludes that there is no concern for any of the environmental compartments.

For human health the scenarios for occupational exposure, consumer exposure and humans exposed via the environment have been examined and the possible risks have been identified. The human health risk assessment concludes that there is no concern for any of these populations.