SIDS INITIAL ASSESSMENT PROFILE

CAS No.	75-10-5
Chemical Name	Difluoromethane
Structural Formula	CH_2F_2

SUMMARY CONCLUSIONS OF THE SIAR

Human Health

Kinetic and metabolic studies in rats and mice indicate that during inhalation exposure difluoromethane is poorly absorbed (about 1%), eliminated mainly via exhalation as unchanged compound and as carbon dioxide, the major metabolite, the remaining being excreted in urine as formic acid presumably. The equilibrium in blood is reached after 2 hours of exposure.

Acute inhalation toxicity of difluoromethane is very low with no mortality in the rats after 4 hours exposure to 520,000 ppm (1,107 g/m^3). Signs of toxicity were essentially limited to a central nervous system depression at concentrations of 86,000 ppm (183 g/m^3) and above. There was no evidence of cardiac sensitization in dogs.

Repeated inhalation exposure studies have been conducted in rats exposed 6h/d, 5d/wk to difluoromethane for 4 and 13 weeks respectively at concentrations up to 50,000 ppm (1,050 g/m^3). In both studies, even at the highest concentration of 50,000 ppm, no target organ and no significant sign of any toxicity have been identified. The NOAEC was then determined at that level, about 1,050 g/m^3.

Difluoromethane has not shown any genotoxic activity both in *in vitro* and *in vivo* studies. Difluoromethane had no mutagenic effect *in vitro* in the Ames test, no clastogenic activity *in vitro* in two different mammalian cell assays. *In vivo*, difluoromethane was also negative in the mouse micronucleus assay.

In developmental toxicity studies, difluoromethane did not induce teratogenic or significant embryo-foetal toxic effects in rats and rabbits exposed up to 50,000 ppm during gestation days 7 to 16 and 6 to 18 respectively. Based on the results from the 13-wk repeated inhalation exposure study including macroscopic and histopathological examinations of the reproductive organs, the available evidence suggests that difluoromethane is unlikely to have the potential to affect fertility in rats up to 50,000 ppm. Thus, the NOAEC for fertility and developmental endpoints were both established at 50,000 ppm.

Environment

Difluoromethane is a colourless, odourless, flammable gas with a melting point of –136°C, a boiling point of –51.7°C, a vapour pressure of about 17000 hPa (25°C), a water solubility ranging from 1900 mg/l to 4400 mg/l at 20°C and 25°C respectively and a measured log Kow of 0.21 (25°C).
On the basis of its chemical properties, and according to the distribution modeling, when released to the environment the majority of difluoromethane will partition into the air compartment (99.99%). It will then degrade in the lower atmosphere by reaction with hydroxyl radicals to yield $C(=O)F_2$ as an intermediate product which will be further converted to HF and CO_2 by hydrolysis in atmospheric water. The calculated atmospheric lifetime of difluoromethane is 4.9 years corresponding to a 1/2-lifetime of 3.39 years.

Due to its structure without chlorine or bromine, difluoromethane is not expected to have an impact on the

stratospheric ozone layer (ODP = 0). Because of its low reactivity with OH, difluoromethane is not expected to contribute significantly to the formation of ground ozone (POCP = 0,2). Its Global warming potential is 650. Its contribution to the greenhouse effect can be considered as small (9 10^{-5} wm^{-2} from IPCC 2000 data).

In water, difluoromethane is not dissociated and not expected to hydrolyse owing to the lack of hydrolysable functional group in its chemical structure. It is not readily biodegradable under aerobic conditions (about 5 % of biodegradation after 28 days) and is not expected to sorb significantly to sediment based on a calculated logKoc of 1.37. Difluoromethane has a low potential to bioaccumulate in aquatic species based on a measured log Kow of 0.21. No experimental data are available on the effects of difluoromethane on organisms in the environment. Its toxicity to aquatic organisms has been estimated using QSAR method. Results from QSAR models (EPA ECOSAR and TGD) show a low acute toxicity to fish, daphnia and algae, the lowest calculated LC 50 being higher than 100 mg/l. A 16d NOEC to fish of 65.8 mg/l has been calculated using the US EPA ECOSAR program for neutral organics confirming the low toxicity of difluoromethane.

Exposure

The annual worldwide production capacity of difluoromethane is estimated to be approximately 15,000 tones.

Its main uses are in the fields of refrigeration and air conditioning. It is used as a substitute of HCFC 22 in blends with other hydrofluorocarbons in new stationary air conditioning systems (mainly small and medium size systems) and in new domestic and residential air conditioning system. A very minor use is as a refrigerant for industrial equipment (less than 2%).

Difluoromethane is manufactured in closed system. Therefore under normal manufacturing practices, emissions to the atmosphere during production are negligible. Emissions to the atmosphere mainly occur during the use of difluoromethane in stationary air conditioning systems of medium size (5 kW < power < 100 kW).

There are no aqueous streams from the production and the uses of the substance. Emissions to water are possible during handling and storage. No emission data are available but possible releases are considered to be negligible.

There is no direct consumer exposure to difluoromethane due to the fact that domestic air conditioning equipments (<5 kW) are hermetically sealed. Air conditioners of medium size are located in dedicated buildings and only maintained by professionals

RECOMMENDATION

The chemical is currently of low priority for further work.

RATIONALE FOR THE RECOMMENDATION AND NATURE OF FURTHER WORK RECOMMENDED

Human health :

The chemical is currently of low priority for further work because of its low hazard profile.

Environment:

According to values estimated by QSAR models supported by available measured data on other fluorinated compounds of similar structure, the substance has a low hazard profile for the aquatic environment.
The substance predominantly partitions into the air compartment and has an important atmospheric half-life (3.4 years). Its intermediate atmospheric degradation product $C(=O)F_2$ has a lower half-life (48.5 days). No data on

toxicity for the air compartment is available for both substances. One of the final atmospheric degradation product, namely HF, has already been assessed at the OECD and the EU levels and is recommended for further work. Based on emission scenarios used by IPCC and according to the current uses of the substance, its atmospheric concentration is expected to be low. Therefore, the chemical is currently of low priority for further work.
In case of other uses of the substance in the future, e.g. use in automotive air conditioning, or higher exposure than expected, complementary investigation would be necessary, including toxicity of F32 and $C(=O)F_2$ to terrestrial plants, environmental fate and toxicity profile of $C(=O)F_2$ and contribution to the greenhouse effect of F32.