Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on Chlorodifluoromethane

Human Health Part

CAS No.: 75-45-6
EINECS No.: 200-871-9

The SCHER adopted this opinion at its 15th plenary on 30 January 2007

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Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

They are: the Scientific Committee on Consumer Products (SCCP), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR) and are made up of external experts.

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Questions relating to examinations of the toxicity and ecotoxicity of chemicals, biochemicals and biological compound whose use may have harmful consequences for human health and the environment.

In particular, the Committee addresses questions related to new and existing chemicals, the restriction and marketing of dangerous substances, biocides, waste, environmental contaminants, plastic and other materials used for water pipe work (e.g. new organics substances), drinking water, indoor and ambient air quality. It addresses questions relating to human exposure to mixtures of chemicals, sensitisation and identification of endocrine disrupters.

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http://ec.europa.eu/health/ph_risk/risk_en.htm

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TABLE OF CONTENTS

1. BACKGROUND

Council Regulation 793/93 provides the framework for the evaluation and control of the risk of existing substances. Member States prepare Risk Assessment Reports on priority substances. The Reports are then examined by the Technical Committee under the Regulation and, when appropriate, the Commission invites the Scientific Committee on Health and Environmental Risks (SCHER) to give its opinion.

2. TERMS OF REFERENCE

On the basis of the examination of the Risk Assessment Report the SCHER is invited to examine the following issues:

(1) Does the SCHER agree with the conclusions of the Risk Assessment Report?

(2) If the SCHER disagrees with such conclusions, it is invited to elaborate on the reasons.

(3) If the SCHER disagrees with the approaches or methods used to assess the risks, it is invited to suggest possible alternatives.

3. OPINION

3.1. General comments

The health part of the document is of good quality, it is comprehensive, and the exposure and effects assessment follow the Technical Guidance Document.

The RAR covers all studies relevant for exposure and hazard assessment of chlorodifluoromethane.

3.2. Specific comments

3.2.1. Exposure assessment

Due to the high volatility of chlorodifluoromethane, only inhalation exposures are consider relevant. The SCHER supports this approach.

The occupational exposure assessment develops several scenarios. The predicted exposure concentrations are in good agreement with measured data and, for most scenarios, even peak values are below occupational exposure standards for chlorodifluoromethane.

The very high volatility, absence of a bioaccumulation potential, and the use of chlorodifluoromethane in closed systems not directly accessible to consumers suggest that consumer exposures are non-existent or very low. The SCHER agrees with this conclusion.

3.2.2. Effect assessment

Chlorodifluoromethane has a very low potential for toxicity after inhalation, which is the only route of administration considered relevant as a basis for performing a risk assessment. This approach is considered reasonable by SCHER.

SCHER also agrees that chlorodifluoromethane is not irritating, corrosive to skin or a sensitizer. The SCHER concludes that oral studies with a compound with a boiling point of – 40° C do not make sense and should not be addressed in such a document.

In genotoxicity studies in bacteria, chlorodifluoromethane induced a concentration dependent increase in revertant frequencies in some of the experiments in the absence

of metabolic activation. However, results of genotoxicity testing in mammalian cells or in rodents in vivo were negative. No conclusions can be made based on the in vivo bone marrow micronucleus study which used oral gavage. The SCHER agrees that chlorodifluoromethane should not be considered as a genotoxic agent in vivo.

In one of three carcinogenicity studies, inhalation of chlorodifluoromethane at very high concentrations (up to 50,000 ppm for 131 weeks) caused an increased incidence of fibrosarcoma in male rats which appeared late in the study. No increases in tumour incidences were seen in this study in female rats and in two other carcinogenicity studies. The SCHER questions the conclusion that the observation of an increased tumour incidence only in male rats with a NOAEC, which was observed only in one out of three studies available, requires classification in carcinogenicity category 3.

Regarding reproductive and developmental effects, the SCHER agrees with the conclusion of a NOAEC of 1,000 used in the risk characterisation.

3.2.3. Risk characterisation

The risk characterization performed in the RAR uses the margin-of-safety (MOS) approach and is only performed for inhalation exposures.

The SCHER agrees with conclusion ii)[1] for occupational exposures regarding acute and repeated exposures.

Regarding consumer exposure, due to absence of exposure, conclusion ii) is accepted.

While the SCHER accepts conclusion ii) regarding carcinogenicity and reproductive and developmental toxicity, the scientific basis for the selection of a minimal MOS of using a factor of 3 for intraspecies and a factor of 3 for interspecies variability requires explanation and justification.

4. LIST OF ABBREVIATIONS

EASE	Estimation and Assessment of Substance Exposure Physico-chemical properties
LOAEL	Lowest Observed Adverse Effect Levels
MOS	Margin of Safety
NOAEC	No Observed Adverse Effect Concentration
RAR	Risk Assessment Report
TGD	Technical Guidance Document

[1] *According to the Technical Guidance Document on Risk Assessment – European Communities 2003:*
- *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 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.*