EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on chlorodifluoromethane
Environmental Part

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

Scientific Committees
on consumer products
on emerging and newly identified health risks
on health and environmental risk

Opinion adopted by the SCHER during the 16th plenary of 23 April 2007

About the Scientific Committees

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.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Evaluation Agency (EMEA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCHER

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.

Scientific Committee members

Contact:

European Commission
Health & Consumer Protection DG
Directorate C: Public Health and Risk Assessment
Unit C7 - Risk Assessment
Office: B232 B-1049 Brussels

Sanco-Sc8-Secretariat@ec.europa.eu

The opinions of the Scientific Committees reflect the views of the independent scientists who are members of the committees. They do not necessarily reflect the views of the European Commission. The opinions are published by the European Commission in their original language only.

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

ACKNOWLEDGEMENTS

The rapporteur Prof. Bo Jansson, Stockholm University, Sweden, is acknowledged for his valuable contribution to this opinion.

Keywords: SCHER, scientific opinion, Risk Assessment, Regulation 793/93, chlorodifluoromethane, $CHClF_2$, CAS 75-45-6, environment

Opinion to be cited as:

SCHER Opinion on the risk assessment report on chlorodifluoromethane (CAS N° 75-45-6), environmental part, 23 April 2007

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

The SCHER on the basis of the examination of the Targeted Risk Assessment Report is invited to examine the following issues:

1. Does the SCHER find the conclusions of the targeted risk assessment appropriate?

2. If the SCHER finds any conclusion not appropriate, the SCHER is invited to elaborate on the reasons for this divergence of opinion.

3. If the SCHER finds any specific approaches or methods used to assess the risks inappropriate, the SCHER is invited to suggest possible alternative approaches or methods meeting the same objectives.

3. OPINION

3.1 General Comments

The environmental part of the risk assessment of chlorodifluoromethane follows the methodology proposed in the Technical Guidance Document. It has, however, to be kept in mind that the TGD was mainly developed for compounds less volatile than this. The assessors concentrate the assessment on the direct toxic effects based on a limited number of studies, and refer to international assessments of the indirect effects due to ozone depletion, and this is supported by SCHER.

The exposure assessment is partly based on industry data regarding emissions from production and use of the substance, but the major source is the use of chlorodifluoromethane in refrigeration systems, and the disposal of such systems. It is not clear to SCHER if the latter part is included in the calculation of PECs.

There is no information on possible effects on plants, and SCHER had preferred to see a conclusion (i)[1] to improve the basis for the risk characterisation regarding the atmosphere. The conclusions (ii) for the other media are supported by SCHER.

[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.*

3.2 Specific Comments

3.2.1 Exposure assessment

Chlorodifluoromethane is a high volume chemical used mainly as intermediate in the production of fluoropolymers and as refrigerant. There are only a limited number of producers and users of chlorodifluoromethane in the EU and emission data seem to be available for most of them. For some of them, however, default values had to be used and it is difficult to understand how the data for site 6 (0 tons to air and 22 tons to waste water per annum) have been estimated.

The use of chlorodifluoromethane as a refrigerant constitutes the major source of emissions to the environment, and in the calculation of regional and continental PECs it is assumed that the emitted volume equals the amount of the compound being produced for replacement purpose. It is also mentioned that at the end of the service life some of the material can be recovered and recycled. If that is the case the emissions may be larger than that estimated in the RAR. SCHER has also difficulties to see how the emissions from disposal have been included in this calculation. The predicted values, however, agree well with the concentrations measured in the atmosphere.

The distribution of chlorodifluoromethane in the environment is almost exclusively to the atmosphere, where it has a long lifetime and is effectively mixed over at least the hemispheres. The emissions are still exceeding the disappearance of the compound and atmospheric concentrations are expected to increase for another couple of years.

3.2.2 Effect assessment

There are very few studies on direct toxicity of chlorodifluoromethane published. There are single data on acute toxicity in fish and invertebrates (none from algae), but no long-term studies are available. The use of 1000 as assessment factor is supported by SCHER, but the relatively high PEC/PNEC values for the local aquatic environment call for effect data for algae. There is no toxicity data available for the sediment compartment, and the use of equilibrium portioning is used, and accepted by SCHER. There is no assessment of the marine environment which can be accepted as the risk ratio for regional surface water is very low.

There are no data on toxicological effects on plants or soil dwelling organisms. For the latter, PNEC has been calculated with the equilibrium portioning method, which is not appropriate as the organisms is exposed mainly via the vapour phase. This exposure is, however, expected to be very low. The lack of information on toxicological effect on plants is not discussed. SCHER finds this surprising as the atmosphere is the compartment holding almost all the emitted chlorodifluoromethane and that the already now relatively high concentrations are bound to increase further in the near future. A request for further information would therefore be appropriate.

Due to the low bioconcentration potential of chlorodifluoromethane there is no reason to do an assessment of the secondary poisoning.

The major environmental (and human health) effects of chlorodifluoromethane are due to the ozone depletion and greenhouse effects of the compound. SCHER finds the reference to international assessments regarding these effects appropriate.

3.2.3 Risk characterisation

The PEC/PNEC ratios for both aquatic and terrestrial environments are below 1 and SCHER supports the conclusion (ii) drawn in the RAR, as well as the same conclusion for secondary poisoning but recommends conclusion (i) for effects on algae. Based on inhalation studies in mammals the assessors also suggest this conclusion for the atmosphere. There is, however, no knowledge of effects in plants and SCHER would have preferred a conclusion (i) to get at least basic knowledge in this field to support the assessment.

4. LIST OF ABBREVIATIONS

PEC	Predicted environmental concentration
PNEC	Predicted no effect concentration
RAR	Risk assessment report
TGD	Technical Guidance Document