



Scientific Committee on Health and Environmental Risks SCHER

Risk Assessment Report on Chlorine Human Health Part

CAS No.: 7782-50-5 EINECS No. 231-959-5



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 compounds 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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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 chlorine.

3.2 Specific comments

3.2.1 Exposure assessment

Chlorine is used as an intermediate in a large number of synthetic processes in industrial chemistry. It is also used for disinfection of drinking water and swimming pools. Due to its wide-spread use, well justified occupational exposure limits for chlorine are available.

Regarding occupational exposure assessment, the RAR relies on the large number of data available measuring air concentrations of chlorine in occupational settings. Based on these data, representative exposure scenarios can easily be derived. SCHER agrees that dermal exposures under occupational exposure conditions are not relevant and that consumer exposure and indirect exposures should not be considered due to the high reactivity and the short half-life of chlorine.

3.2.2 Effect assessment

The RAR describes in detail all the toxicity studies performed with chlorine and also references to studies performed with hypochloride, which is formed from chlorine in aqueous solutions. Regarding repeated-dose toxicity, a number of studies are available for evaluation and SCHER agrees with NOAECs derived from the evaluation of these studies.

The target organ for chlorine toxicity after inhalation is the respiratory tract in animals. Accidental exposures of humans to chlorine also confirm that the respiratory tract is a target for chlorine toxicity in humans. SCHER agrees that there is no concern regarding carcinogenicity of chlorine since a guideline-conforming inhalation study in rodents without increases in tumour incidences in chlorine exposed groups has been performed.

Regarding reproductive toxicity only studies relating to oral exposures to chlorine with drinking water are available. These studies are negative. Inhalation exposures to chlorine

will unlikely result in reproductive toxicity due to the high reactivity of chlorine in the respiratory tract and its rapid transformation.

3.2.3 Risk characterisation

The risk characterization performed in the RAR uses the MOS approach for inhalation exposures of workers. The SCHER agrees with conclusion ii)¹ for all occupational scenarios as concluded in the RAR. The NOAEC derived in the RAR is identical to the occupational exposure limit in a number of EU-members. Therefore, SCHER is of the opinion that application of a MOS to a health-based occupational exposure limit is not necessary.

4. LIST OF ABBREVIATIONS

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.