



Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on sodium hypochlorite
Human Health Part

CAS No.: 7681-52-9
EINECS No. 231-668-3

The SCHER adopted this opinion at its 21st plenary on 15 January 2008

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 (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

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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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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 sodium hypochlorite and also includes information on the toxicology of chlorine when considered necessary.

In aqueous solution, which is the major form of application for hypochlorite, a pH-dependent equilibrium between chlorine, hypochloric acid and hypochlorite is present. At the pH (9 – 13) of commercial solutions of hypochlorite, the predominant species is hypochloric acid.

Chlorine can only be released when hypochlorite solutions are mixed with strong acids.

3.2 Specific comments

3.2.1 Exposure assessment

The RAR contains a number of detailed exposure assessments for the known uses of sodium hypochlorite solutions. The assessments performed and the parameters used are well justified.

The occupational exposure assessments conclude that dermal contact with sodium hypochlorite solutions used for disinfection/cleaning purposes are the major routes of exposure.

Regarding consumers, dermal contact during use of sodium hypochlorite solutions for cleaning and dermal contact and oral ingestion of diluted sodium hypochlorite from swimming pools after water chlorination may occur. In addition, chlorinated drinking water is a source for sodium hypochlorite exposures of the general population.

SCHER agrees that indirect exposure via the environment and combined exposure scenarios are not of concern regarding sodium hypochlorite.

3.2.2 Effect assessment

The irritation and corrosive properties of concentrated sodium hypochlorite solutions is well described, a number of studies also support the conclusion that sodium hypochlorite is not a sensitizer. SCHER also considers the assumption of a 10 % dermal bioavailability as reasonable due to the low lipid solubility of sodium hypochlorite.

Regarding repeated-dose toxicity, a number of studies are available for evaluation and SCHER agrees with NOAELs and NOAECs derived from the evaluation of these studies.

Regarding mutagenicity and carcinogenicity, SCHER agrees that additional testing for mutagenicity is not required despite an inconclusive database for mutagenicity since negative carcinogenicity studies for oral consumption of sodium hypochlorite solutions are available. SCHER also agrees that carcinogenicity is not a relevant endpoint regarding oral exposures to sodium hypochlorite due to the availability of negative carcinogenicity studies in animals and inconclusive epidemiology studies on consumption of chlorinated drinking water and cancer incidence in humans.

SCHER also supports the conclusion that there is no evidence for developmental or reproductive toxicity of sodium hypochlorite based on the available database on hypochlorite and chlorine.

3.2.3 Risk characterisation

The risk characterization performed in the RAR uses the margin-of-safety (MOS) approach and is performed for oral, inhalation and dermal exposures of consumers and dermal and inhalation exposures of workers.

SCHER agrees with conclusions ii)¹ for all exposure scenarios due to high MOS.

4. LIST OF ABBREVIATIONS

MOS	Margin of Safety
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
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.*