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Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on Sodium Hypochlorite

Environmental Part

CAS No.: 7681-52-9
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Scientific Committees
on consumer products
on emerging and newly identified health risks
on health and environmental risks

The SCHER adopted this opinion at its 22nd plenary on 12 March 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 (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.

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

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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

Due to its characteristics of reactivity and instability, sodium hypochlorite is a very particular chemical. Thus environmental risk assessment cannot be performed by simply applying the usual and standardised TGD procedures.

The RAR is of good quality and takes into account this complexity. Different chemical species and by-products produced in the environment as a consequence of emissions of sodium hypochlorite are taken into account.

However, it is opinion of SCHER that conclusion ii)[1], proposed by the RAR for all scenarios, needs to be better supported, at least in some specific use scenarios. In particular, some more information and details of the procedures applied for reaching this conclusion must be provided. Therefore, in these cases, which are better detailed in the specific comments, conclusion i) would be more appropriate.

3.2 Specific comments

3.2.1 Exposure assessment

Sodium hypochlorite is a high production volume chemical. Production data reported in the RAR are quite old (1994) and are estimated as about 288,000 tons (as Cl_2 equivalents).

Major uses are household, several applications for disinfection (municipal water, sewage, swimming pools, food industry), chemical synthesis, textile and pulp & paper industry.

[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.

Due to its high reactivity and instability it rapidly disappears in the environment. Therefore, in the RAR, a regional scenario is considered as unrealistic and only local assessment is performed. SCHER agrees with this assumption.

Sodium hypochlorite undergoes several transformations in the environment, so in the different local emission scenarios the main by-products, such as adsorbable organic halogens (AOX) haloacetic acids (HAA) and trihalomethanes (THM) are evaluated in the assessment. However, it is practically impossible to identify all possible products of the reactions of sodium hypochlorite in different environmental conditions. Therefore, exposure calculation is quite complex and several scenarios must be considered.

The decay of hypochlorite in the environment has been studied with a kinetic model described in detail in an Appendix. According to this model, disappearance of hypochlorite is practically immediate in the natural aquatic environment, reaching in a short time concentration as low as 10^{-22} μg/L or less in all emission scenarios. However, all the Appendices mentioned have not been provided together with the RAR. It is opinion of SCHER that, for a complete opinion on the RAR, all the information and model description must be provided.

The RAR calculates PECs for the major by-products for production and for most major uses. In some cases, such as the use for production of other chemicals, by-products are related to the different chemical processes involved and a specific assessment is impossible. In these cases, the RAR suggests that risk should be assessed in connection with these specific processes and products.

In other cases, PEC calculations are performed for freshwater and, if applicable, for marine emissions. The result is a complex summary table of PECs for AOX, HAA and THM. The variability of value for different scenarios is very high. Maximum values correspond to pulp & paper (3100 μg/L for AOX and 14 μg/L for THM) and to swimming pools (6.22 μg/L HAA).

It is opinion of SCHER that the procedures for calculating PECs are appropriate.

For the atmosphere PECs have not been calculated. As a general rule, it is assumed that volatile chlorine species may be relevant in some indoor scenarios, but have negligible impact in open environmental conditions.

Also for the soil compartment, the role of hypochlorite pollution is assumed as negligible.

Finally, no secondary poisoning has been considered, being hypochlorite not transferred in the trophic chain.

It is opinion of SCHER that all these assumptions can be endorsed.

3.2.2 Effect assessment

Several data are available for the aquatic environment; however their reliability is often questionable, due to the instability of hypochlorite.

Moreover, the particular behaviour of the chemical makes difficult the derivation of a PNEC by applying usual procedures, based on well established ecotoxicological endpoints, such as EC/LC50 on well defined chemical species.

For freshwater, only two data (one short term LC50 on crustaceans and one long term NOEC on algae) can be assumed as valid without restrictions and representative of traditional endpoints. Other data derive from experimental approaches that are scientifically sound but not based on standardised procedures (e.g.: intermittent exposure, field studies, etc.). Therefore they are proposed as "supportive information". From all the available data, a PNEC = 0.04 μg/L is proposed by applying a factor of 50 to the long term NOEC on algae, expressed as free available chlorine (FAC).

A PNEC of 0.04 μgFAC/L is proposed also for saltwater. SCHER agrees with the proposed PNECs.

PNEC values are also proposed for the main by-products, such as THM, HAA and AOX.

The main THM produced during hypochlorite use is chloroform. In condition of high bromide (seawater) bromoform can also be relevant. Literature data indicate comparable toxicity of chloroform and bromoform (data for the same organism within a factor lower than 3). Therefore, the PNEC calculated in a RAR (quoted in the references) for chloroform (PNEC=146 μg/L) is proposed.

For HAA, the PNEC for TCA estimated in an OECD SIDS risk assessment document is proposed (PNEC= 0.85 μg/L). A PNEC for intermittent emissions (PNEC = 2.58 μg/L) is also proposed. The OECD SIDIS document is not quoted in the references.

It is opinion of SCHER that PNECs for by-products need to be better supported.

No toxicity data are available for the atmospheric and the terrestrial compartment as well as for secondary poisoning. Being exposure in these compartments negligible and being transfer in the trophic chain not applicable, the RAR assumes that effect assessment is not relevant in these cases. SCHER agrees with these assumptions.

3.2.3 Risk characterisation

For sodium hypochlorite, in fresh and seawater, being calculated PECs negligible (10^{-22} μg/L or less) in all scenarios, conclusion ii) is proposed. As previously mentioned, it is opinion of the SCHER that, in order to endorse this conclusion, details of the kinetic model applied to calculate PECs should be provided.

Conclusion ii) is also proposed for risk characterisation of by-products, in particular for THM and HAA. As previously mentioned, PNECs for by-products need to be better supported. However, for THM, PEC/PNEC ratios are always very low (maximum value around 0.1). A revision of the PNEC is not likely to produce PEC/PNEC ratios of concern.

On the contrary, for HAA, in many cases (swimming pools, sewage treatments, drinking water treatment, pulp & paper) PEC/PNEC ratios are higher than 1, sometimes even using the PNEC for intermittent emissions. The RAR supports this conclusion with hardly acceptable sentences. For example "the uncertainty about the TCA PNEC" is not a reason for excluding risk; on the contrary, it is a reason for supporting the need for more precise information. Also "the lack of toxicity in the whole effluent test" is referred to a specific condition and cannot be generalised.

Therefore it is opinion of the SCHER that for HAA by-products, conclusion ii) cannot be accepted. Sounder element should be provided for supporting this conclusion. At the time being, conclusion i) seems more appropriate.

4. LIST OF ABBREVIATIONS

AOX	Adsorbable organic halogens
FAC	Free available chlorine
HAA	Haloacetic acids
NOEC	No Observed Effect Concentration
OECD	Organisation for Economic Cooperation and Development
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
TCA	Trichloroacetic acid
RAR	Risk Assessment Report
SIDS	Screening Information Data Sets
TGD	Technical Guidance Document
THM	Trihalomethanes

WWTP	Waste Water Treatment Plants