EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on (3-chloro-2-hydroxypropyl)trimethylammonium chloride (CHPTAC) Environmental Part

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

Opinion adopted by the SCHER during the 18th plenary of 19 July 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.

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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 (RAR) 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 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 RAR on CHPTAC is well written and transparent. The assessment is thorough and executed according to the methodology proposed in the TGD.

The RAR assesses the potential local risks of CHPTAC during the production process and five use scenarios. Due to the relatively rapid conversion of CHPTAC into EPTAC the regional risk assessment is discussed in the RAR on the latter compound. The SCHER supports this approach, the methods used and the scenarios examined.

The local exposure assessment of CHPTAC is mainly based on emission measurements (to the aquatic environments) from production and use of the substance provided by industry. Exposure in the other environmental compartment is calculated using TGD procedures.

The effects assessment is based on chronic toxicity data obtained with a daphnid and algal species. The PNEC derived using the chronic daphnid NOEC and an assessment factor which is lower than (10 instead of 100) that recommended by the TGD. The justification for this approach given in the RAR is that the daphnids covers the most sensitive taxonomic group.

The SCHER considers – based on the available information – that this assumption is likely correct, however additional information should be included for substantiating this assessment, such as a cross-reading with other related substances. In addition the RAR indicates that no further refinement of the PNEC is possible; the committee must express that there are additional methods such as the statistical extrapolation based on SSD or the use of high tier ecotoxicity assays such as micro- and mesocosms allowing a further refinement of the PNEC for aquatic organisms.

The conclusions (iii)[1] for the aquatic environment proposed for some of he local use scenarios and the conclusions (ii) for all other scenario's and all other compartments 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;

The committee suggests conclusion i) for the marine environment based on the uncertainties for the extrapolation from freshwater conditions.

3.2 Specific Comments

3.2.1 Exposure assessment

Of the 23695 tons of CHPTAC produced in the EU (2001), 95% is used for cationisation of starch and the remaining 5% for other uses such as synthesis of carnitinesalts, quarternisation of protein and cellulose. There are currently four producers of CHPTAC in the EU. In the exposure assessment one production scenario and five industrial use scenarios were examined. For most of the production and use sites, measured emission/release data were available. For the sites where no monitoring data were available, realistic emission and production or use assumptions were used.

The SCHER supports the methods used to calculate the local PNECs in the various environmental compartments.

The RAR suggests that due to the relatively rapid conversion (T1/2 of 21 days) of CHPTAC to EPTAC, adverse effects to the aquatic environment at the regional (and continental) scale will be caused by the latter compound. As such, no regional aquatic exposure assessment of CHPTAC was performed in the RAR. As adsorption of CHPTAC to sludge is low and there are no direct releases, no regional exposure assessment was conducted for the terrestrial compartment. Considering the low vapour pressure of CHPTAC and the reported absence of emissions to air, no regional estimation of the PEC for the atmosphere was performed.

The SCHER supports (1) the methods used and the results obtained in the local exposure assessments and (2) the proposed procedures to assess (indirectly) the regional exposure.

3.2.2 Effect assessment

Results from short-term toxicity studies are available for bacteria, algae, *Daphnia* and fish. These data are expressed as nominal concentrations. L(E)C50s for these species range from 164 to > 10000 mg/l with aquatic invertebrates being the most sensitive and fish and algae the least sensitive taxa.

Results from a chronic reproduction tests with Daphnia are also presented. This assay, in which CHPTAC and its conversion products were measured, yielded a 21d NOEC of 0.51 mg/l. The RAR presents an in-depth discussion on the validity of all available ecotoxicity data. Based on the argument that this aquatic invertebrate group was by far the most sensitive taxon, the RAR proposes to apply an assessment factor of 10 on the chronic NOEC obtained for *Daphnia*. According to the TGD, a factor of 50 should be used on this dataset.

The SCHER considers that the assumption of aquatic invertebrates as the most sensitive taxa is likely correct; nevertheless, as the acute to chronic ratio is also high (a factor of 100 for *D. magna*), the committee considers that additional information such as a cross-reading with related substances should be incorporated for supporting the use of a factor of 10.

As there is no toxicity data available for the sediment and terrestrial organisms, the use of equilibrium partitioning for both compartments (as proposed in the RAR) is accepted by SCHER.

There are no data on toxicological effects on plants or soil dwelling organisms. Considering the low volatility of CHPTAC, no effect assessment for the atmospheric compartment is presented. SCHER supports this decision.

- conclusion iii): There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

The low Kow indicates a low potential of bioaccumulation.

3.2.3 Risk characterisation

For some sites and use scenarios the (local) PEC/PNEC ratios for the aquatic (water and sediment) environments exceed 1 and conclusion (iii) is proposed in the RAR. For all other scenarios/sites and for all other compartments conclusion (ii) is suggested.

The SCHER supports all conclusions proposed in the RAR on CHPTAC.

However, the SCHER considers that the risk estimation for the marine environment requires further considerations. The RAR suggests conclusion ii) based on the default dilution factor of 100 and an application factor of 100 on the Daphnia NOEC for the PNEC derivation.

SCHER is of the opinion that given (1) the relatively rapid conversion of CHPTAC into EPTAC and (2) that the latter is a dissociating, cationic substance that may experience chemical structural changes in marine water (high pH 8), the ecotoxicity of CHPTAC (and EPTAC) to marine organisms has not been sufficiently been addressed.

The Committee has expressed in several cases that the automatic use of an additional factor of 10 for the derivation of the PNEC for marine organism cannot be supported on scientific grounds; therefore, in absence of marine data, the extrapolation should be based on a case-by-case assessment of the ecotoxicological profile of the molecule and its physical-chemical interactions in salt water.

Considering the characteristics of CHPPTAC (and EPTAC), the SCHER would prefer conclusion i) for the marine environment, requesting toxicity testing with marine invertebrates.

4. LIST OF ABBREVIATIONS

EPTAC 2,3-Epoxipropyltrimethylammonium chloride
LC50 median Lethal Concentration
NOEC No Observed Effects Concentration
PEC Predicted environmental concentration
PNEC Predicted no effect concentration
RAR Risk assessment report
TGD Technical Guidance Document