EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on 2,3-Epoxipropyltrimethylammonium chloride (EPTAC)

Environmental Part

CAS No.: 3033-77-0
EINECS No.: 221-221-0

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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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

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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 EPTAC is of good quality and offers the information in a transparent manner. The exposure assessment is conducted using the available information and comparing the site-specific information provided by industry with the TDG default values. The SCHER welcomes this approach, which increases the transparency of the process and facilitates the comparison among substances.

The risk assessment covers the emissions of EPTAC from the use of this substance and from the use of the related chemical CHPTAC, the further transformations in the environment are also included in the assessment.

The effect assessment deviates from the default values assuming that the available chronic NOEC for Daphnids covers the most sensitive taxonomic group. The SCHER considers 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.

Considering the overall evidence, the SCHER agrees with the proposed conclusions of potential risks for aquatic organisms in some local scenarios which could be refined in some cases by lowering the limit of detection of the in situ monitoring programs. The committee also agrees with conclusion ii)[1] for the other environmental assessments, with the exception of the marine environment.

[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.

In addition, as new production facilities may appear in the future, it should be mentioned that the absence of emissions from the production activity is related to the specific management of the current production facilities, and does not necessarily means that this condition could be directly attributed to other production sites

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

EPTAC is mostly used as a starch cationization agent in the production of paper, some additional minor uses have been identify and covered in the RAR.

Due to the specific production conditions no emissions from the current production facilities have been considered, as formulation is not an issue for this substance, the emission scenarios are based on the different use patterns and are properly described in the RAR.

Whenever possible, site specific measurements have been incorporated and comparisons between the site-specific and TGD default values are presented. It should be noticed that emissions to water from some facilities are clearly higher than TGD predictions and a reasonable worst case has been used for the assessment. It should be also considered that in a significant number of cases the concentrations are described as below relatively high detection limits, increasing the uncertainty in the assessment and obliging the rapporteur to base the assessment on worst case conditions. Site-specific conditions, such as the specific dilution factors are also included in the RAR.

EPTAC is a highly water soluble chemical with low potential for volatilization, not ready biodegradable and that suffers pH dependent hydrolysis to the diol transformation product with DT50s of weeks-months under environmentally relevant conditions. Its potential for bioaccumulation is assumed to be very low based on the Kow and the absorption to sludge, sediment and soil is not related to lipophilicity but to ionic binding. The rapporteurs have properly assessed the available information for estimating adsorption coefficients and used the information in the PEC estimations.

3.2.2 Effect assessment

The ecotoxicological data on aquatic organisms cover acute assays on the three taxonomic groups and chronic NOECs on *Daphnia magna* and algae. The results indicates that daphnids are much more sensitive than the other groups and based on this difference the PNEC aquatic organisms is derived by applying a factor of 10, instead of the default TGD value of 50, to the chronic *D. magna* NOEC.

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.

No information is available on the toxicity of EPTAC to sediment and soil dwelling organisms and the toxicity is estimated using the equilibrium partitioning method. As the adsorption is not related to lipophilicy there is some uncertainty on bioavailabilty of the adsorbed chemical.

A low potential for bioaccumulation is in principle assumed based on the low Kow.

3.2.3 Risk characterisation

The Committee agrees with the proposal for conclusion iii) for the aquatic compartment associated to some local scenarios as well as with the additional comments from the rapporteur indicating that in some cases the PECs are estimated from limits of detection which are too high for determining if the PEC/PNEC ratio is or is not above 1.

The SCHER also supports the decision of conclusion ii) for the sediment, WWTP, the terrestrial compartment, atmosphere and secondary poisoning.

However, the committee 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. Nevertheless, the RAR explicitly indicated that "EPTAC is a dissociating, cationic substance and there may be changes of the chemical structure in salty marine -water at rather high pH (ca. 8) compared to fresh water environment". However, the consequences of this fact on the toxicity of EPTAC for marine organisms have not 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 under scientific grounds; therefore, in absence of marine data, the extrapolation should be base on a case-by-case assessment of the ecotoxicological profile of the molecule and its physical-chemical interactions in salt water.

Thus, the SCHER considering the special characteristics of EPTAC, would prefer conclusion i) for the marine environment, requesting some toxicity tests on marine invertebrates. It should be noted that direct marine emissions are reported for several uses and that if the default generic TGD application factor of 500 is employed, PEC/PNEC above 1 would be identified for some marine local scenarios.

4. LIST OF ABBREVIATIONS

CHPTAC	3-chloro-2-hydroxypropyl)trimethylammonium chloride
DT50	Degradation half Life
NOEC	No Observed Effects Concentration
PEC	Predicted environmental concentration
PNEC	Predicted no effect concentration
RAR	Risk assessment report
TGD	Technical Guidance Document
WWTP	Waste Water Treatment Plant