EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on Tris[2-chloro-1-(chloromethyl)ethyl]phosphate (TDCP) Environmental Part

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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 20th plenary on 29 November 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.

Scientific Committee members

Herman Autrup, Peter Calow, Wolfgang Dekant, Helmut Greim, Wojciech Hanke, Colin Janssen, Bo Jansson, Hannu Komulainen, Ole Ladefoged, Jan Linders, Inge Mangelsdorf, Marco Nuti, Anne Steenhout, Jose Tarazona, Emanuela Testai, Marco Vighi, Matti Viluksela

Contact:

European Commission
Health & Consumer Protection DG
Directorate C: Public Health and Risk Assessment
Unit C7 - Risk Assessment
Office: B232 B-1049 Brussels

Sanco-Sc8-Secretariat@ec.europa.eu

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Prof. M. Vighi University of Milano Bicocca, Italy

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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 RAR is of good quality and is based on a sufficient amount of data. In particular, the effect assessment is based on reliable data on organisms representative of all relevant compartments (water, sediment, soil). These data are not very frequently available.

However, the exposure assessment is mainly based on site specific data that are not reported for reason of confidentiality. In most cases also the type of use likely to produce significant emissions is confidential and, therefore, emission patterns are totally unknown. This make impossible for the SCHER to express an opinion on the reliability of exposure assessment.

It follows that most of the conclusions of the RAR are biased by the impossibility of a sound evaluation.

SCHER suggests that more information would be provided for supporting the validity of exposure assessment for all environmental compartments relevant for this chemical (water, sediment, soil).

3.2 Specific comments

3.2.1 Exposure assessment

TDCP is produced only in two sites within the EU (total production about 10,000 tons/y). It is a flame retardant, potential substitute of brominated compounds, such as the parent compounds TCPP and V6.

Physical-chemical properties of TDCP indicate negligible volatility, relatively low water solubility, relatively high affinity for soil, moderate bioaccumulation potential.

TDCP is not readily biodegradable, not inherently biodegradable; the potential for abiotic degradation in soil and water (e.g. hydrolysis) is poor.

There are no measurements of TDCP emissions from flame retarded foam, but another flame retardant (TCPP) with similar structure has been studied (Hall, 2005). The Hall study, as it is described in Annex II of the RAR, is difficult to interpret. 30 g foam containing 14.3% TCPP was placed in a room of 63 m^3 with an estimated air exchange of one time per day. After one day the mean concentration in the foam was 10% and as maximum 126 m^3 has passed the sample that volume would have contained 34 mg TCPP

per m^3. This corresponds to a vapor pressure of more than hundred times the saturation pressure for TCPP. There may be adsorption of the compound on other surfaces of the room, a process which is rather slow and hardly of a major importance over one day. The SCHER does not believe the results from that study can be used to assume that only 40% of the TCPP in the foam is "available". The TCPP results are then used to derive corresponding data for TDCP and with the argument that TDCP "has a lower level of volatility than TCPP, expressed as rates of loss" and thus must be less available. The result is that the assessor regard the available fraction of TDCP is 10% at most. SCHER regards this process very uncertain. There is no solid base for the transformation of the TCPP results to TDCP. A ten times higher availability would have given substantially different results.

The calculation of PECs was performed by applying TGD procedures to production and to some life cycle stages, by using site specific data. However, most of these data are confidential and this makes impossible a precise evaluation of the reliability of exposure assessment. It is worth to note that, for some uses indicated as "confidential", the PECwater is up to two orders of magnitude higher than for production. The same occurs for PECsoil, where the difference is up to three orders of magnitude.

This makes also the comparison with the available monitoring data difficult, in particular on WWTP effluents, where relatively high concentrations cannot be related to particular emissions from given life cycle stages. However, some data from German rivers shows concentrations of the same order of magnitude as the regional PECwater. No experimental data are available for soil and the atmosphere.

PECs are also calculated for the marine environment. The same comments as for the freshwater compartment can be made. In particular, being production sites only two in the EU, the real relevance of the calculation of PEC for production, using site specific data, is unclear. The information on the location of production sites (on the sea or on internal water bodies) is not provided in the RAR.

PECs for secondary poisoning are calculated according to the TGD.

3.2.2 Effect assessment

For the aquatic compartment, reliable acute toxicity data are available for the three representative trophic levels, and chronic NOECs are available for *Daphnia* and algae. An acceptable agreement exists between experimental and QSAR data. A PNEC of 0.01 mg/L is calculated by applying a factor of 50 to the 21d NOEC on *Daphnia*.

Reliable long term data are also available on three sediment dwelling organisms. A PNEC of 0.18 mg/kg ww has been calculated by applying a factor of 10 to the NOEC on the most sensitive organisms (*Chironomus riparius*). This value is in good agreement with those calculated using the equilibrium partitioning approach. It must be noted that the used NOEC was calculated as the geometric mean of the measured concentrations of the first three days of experiment. A lower PNEC (0.08 mg/kg ww) can be derived using a NOEC calculated as the time weighted average over the 28 days of experiment. This problem is discussed in the RAR. However, using this lower PNEC does not affect risk characterisation.

Data are also available on soil invertebrates and terrestrial plants (short and long term) as well as on terrestrial micro-organisms. A PNEC of 0.29 mg/kg ww has been calculated by applying a factor of 10 to the lowest long term NOEC.

As data on marine organisms were not available, the PNEC for the marine environment was calculated according to the TGD by applying an additional factor of 10 to the freshwater PNEC. However, the SCHER disagrees with the TGD procedure in absence of enough justification for supporting the application of the additional factor. In particular, for TDCP, toxicity data for the different aquatic organisms are comparable, within the

same order of magnitude, indicating a non specific effect. This is an additional reason for not supporting the need for a higher factor.

For secondary poisoning a PNEC <3.3 mg/kg food has been calculated from a two-year carcinogenicity study on mammals. The value is controversial as a NOAEL was not available (PNEC has been calculated from the LOAEL as "less than") and as the details of the test results are not clearly reported.

3.2.3 Risk characterisation

For the freshwater compartment, PEC/PNEC values for production and uses are below 1, except for uses indicated as C2 and D1. It is not clear what this really means, because these uses are indicated as "Confidential".

For sediments PEC/PNEC values higher than 1 were calculated for uses C1b, C2 and D1. All other values are far below 1, so using a PNEC of 0.08 mg/kg ww the risk characterisation does not change.

The RAR proposes conclusion ii)[1] for all production and use patterns, except for C1b (only for sediments), C2 and D1, for which conclusion iii) is proposed.

Considering that most information on exposure has not been made available for confidentiality reasons, a precise judgement is impossible.

Even if a relatively large amount of monitoring data is available, no information was provided to assess the relationship of these data with emission sources therefore the meaning of these data (continental background or peak values) is difficult to interpret.

Therefore the SCHER cannot support the proposed conclusions. In particular, for the uses C1b, C2 and D1, there is insufficient information available for deciding if conclusion iii) is adequate or if a more precise exposure assessment is needed.

The same conclusions as those made for sediments are proposed for the soil compartment. For the same reasons, the SCHER cannot endorse the proposed conclusions.

Considering the negligible volatility, the SCHER agrees with conclusion ii) for the atmospheric compartment.

For the marine environment, a PEC/PNEC higher than 1 was calculated for use C2, for both water and sediments. By using a higher PNEC, as suggested above, these values too will be reduced. However, the same comments on confidentiality apply also to marine conclusions.

For secondary poisoning, the RAR proposes conclusion ii) for all production and use patterns. It is opinion of the SCHER that the PNEC for secondary poisoning is not adequately supported. Moreover TDCP has a potential for bioaccumulation (although moderate) and, at least in one case, PEC/PNEC is indicated as >0.83 (this means likely higher than 1). Therefore, the SCHER cannot support this conclusion.

As mentioned before, physical-chemical properties, as well as experimental evidence, indicate a moderate potential for bioaccumulation. However, measured BCF values in fish are far below the bioaccumulation criterion proposed in the TGD. Therefore, the 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;*
- *conclusion iii): There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.*

agrees with the conclusion that the "B" criterion for the PBT assessment is not met for TDCP.

Even if precise half-life values were not determined, the experimental evidence indicates that, at the persistence criteria laid down in the TGD for water sediments and soil, no substantial degradation was observed. Therefore, the SCHER agrees with the conclusion that the "P" criterion for the PBT assessment is met for TDCP.

4. LIST OF ABBREVIATIONS

LOAEL	Lowest Observed Adverse Effect Level
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
PBT	Persistent, Bioaccumulable, Toxic
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
RAR	Risk Assessment Report
TCPP	tris (2-chloro-1-methylethyl) phosphate
TDCP	tris [2-chloro-1-(chloromethyl) ethyl] phosphate
TGD	Technical Guidance Document
V6	2,2-bis(chloromethyl)trimethylene bis[bis(2-chloroethyl)phosphate]
ww	wet weight
WWTP	Waste Water Treatment Plants