



Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on
TRIS(2-CHLORO-1-METHYLETHYL) PHOSPHATE
(TCPP)
Environmental Part

CAS No: 13674-84-5
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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

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 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 TCPP is in general of good quality. The rapporteurs have done a proper effort for using specific exposure assessment models; covering the essential parts of the life cycle of this flame retardant. Unfortunately, a significant number of PECs are estimated using confidential data; and, therefore, the SCHER cannot comment on the quality and appropriateness of these exposure estimations.

The PNECs are derived using proper methodologies and rationales except for marine organisms and secondary poisoning. For the marine environment, the use of the default TGD approach for increasing the application factor by one order of magnitude is, in the SCHER opinion, in clear disagreement with the rationale for the derivation of PNEC (freshwater) aquatic organisms which assume a similar level of toxicity for all taxonomic groups. Regarding the derivation of the PNEC oral, the RAR does not include enough information on the selected LOAEL for allowing this Committee to establish the adequacy of the employed figure.

Nevertheless, the RAR includes additional information, such as measured environmental data or the experimental confirmation of a very low BCF for fish, for supporting the RAR proposal of conclusion ii) for all environmental compartments.

3.2 Specific Comments

3.2.1 Exposure assessment

TCPP is produced in four sites within the EU. Production volumes are above 30,000 tonnes/year and have increased in recent years due to the substitution of TCEP by TCPP. The RAR includes information from industry indicating that the replacement has been completed for all the applications for which replacement is possible. TCPP is also mentioned as a potential candidate for the substitution of brominated flame retardants. The RAR indicates that no further increases in the production/consumption volumes are expected; but the SCHER has no information for addressing this specific point.

TCPP is an additive (physically combined with the material being treated) flame retardant; mostly (over 98%) used as a flame retardant in the production of PUR for use in construction and furniture.

The RAR includes a summary of life cycle of the substance and additional information in an annex; the Committee acknowledges the relevance of this information. It is noted that the rapporteurs have included specific national issues in several parts of the report. For example section 2.2.2.3.3 *Legislation relating to fire safety* includes specific information on UK, Ireland, and a generic entry "*Mainland Europe*", indicating that there is currently no European legislation concerning the flame retardancy of furniture and similar goods; however, it is not clear from the report if this statement means that there is no EU legislation or that only UK and Ireland have national legislations on these issues. As the report should reflect the EU situation, these specific aspects and their relevance for the risk assessment should be clarified.

The exposure assessment is based on harmonized defaults from the TGD, and the ESD for Additives Used in the Plastics Industry (OECD, 2004); release rates for foam-related stages described in a report (Fisk et al., 2006) included as an Annex to the RAR, and confidential data provided by the industry. Based on a study by Hall, (2005) with pieces of foam spread out on a tray under conditions of controlled air flow, it is assumed that only 40% of TCPP in the matrix is available for release. The Hall (2005) study, as it is described in Annex II (Environmental Agency, 2006) of the RAR, is difficult to interpret. 30 g foam containing 14.3% TCPP was placed in a room of 63 m³ 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 m³ has passed the sample that volume would have contained 34 mg TCPP per m³. This corresponds to a vapour pressure of more than hundred times the saturation pressure for TCPP given in the RAR. 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. 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" for release.

The BAM investigation, also described in Annex II (Environmental Agency, 2006), gives more realistic results were the saturation pressure of TCPP is approached. The high vapour pressure and effective evaporation of TCPP from PUR makes the air exchange rate in sites handling it interesting. If TCPP containing foam would be stored in a site of 10,000 m³, the air is exchanged 10 times per hour and the vapour of TCPP is saturated the loss would correspond to 200 g/h corresponding to almost 2 tons per annum. If the industry handles 1,000 tons TCPP this emission corresponds to 0.2% which is somewhat lower than the fraction suggested by the OECD emission scenario document for open processes, but higher than the 0.025% suggested for closed systems.

The SCHER cannot comment on the proposed PECs as several figures are based on confidential data. The concentrations are highly variable and the range seems to be in agreement with measured data. Nevertheless, there are some measurements indicating very high levels, which are considered in the RAR as errors or outliers. Considering the solubility and volatility of TCPP it should be further investigated if these levels may reflect episodic emissions due to (mis)use of the substance. The preliminary assessment conducted for landfills based on measured data is considered sufficient for assuming low risk from these sources.

The SCHER agrees with the proposed environmental fate, in particular with the low bioaccumulation potential; nevertheless, this assessment should be reviewed with the information related to the mammalian toxicokinetic data once the human health part would be finished.

3.2.2 Effect assessment

The ecotoxicological data on aquatic organisms cover acute toxicity studies on fish, daphnids and algae and chronic figures for *Daphnia magna* and algae. The RAR includes a sound comparison of measures values and QSAR estimations. The final proposal, a factor of 50 on the 21d *Daphnia magna* NOEC is considered a justified decision. Other alternatives for the PNEC derivation (e.g. from the algae data or from the fish QSAR-estimated NOEC) would not modify the conclusions.

The use of the equilibrium partitioning method for the estimation of the PNEC sediment organisms is considered appropriate for TCPP.

The PNEC soil organisms is properly derived by applying a factor of 10 to the lowest NOEC from plants, earthworms and soil micro-organisms. The correction of the earthworm NOEC regarding the organic matter content of the artificial soil is questionable considering the low Koc, but nevertheless this correction is not relevant as the PNEC is based on plant toxicity data.

As expressed in several occasions, the SCHER cannot agree with the current TGD proposal for just increasing the application factor one order of magnitude for the derivation of the PNEC marine organisms from freshwater toxicity data. It should be noted that the RAR assumes equivalent toxicity for all taxonomic groups (based on freshwater data). A justified rationale of expected differences, if any, should be used instead of a default increase in the application factor.

The derivation of the PNEC oral cannot be supported by the SCHER as the magnitude and ecological relevance of the effects observed at the reported figure (effects were observed at the lowest assayed dose) are not mentioned. The figure is in any case of low relevance as it is presented as a "less than" value, and TCPP has a very low potential for bioaccumulation.

3.2.3 Risk characterisation

The Committee has difficulties for accepting that only 40% of the substance is available for release; nevertheless, as all PEC/PNEC ratios are below 0.4 this situation does not affect the conclusions as PEC/PNEC ratios would remain under 1 even for a 100% availability, still leading to conclusion ii) for all environmental compartments for the current production/consumption data. The SCHER must stress that significant parts of the exposure assessment are based on confidential data, and therefore have not been checked by the committee; therefore, the committee will not comment on the acceptability of the conclusions. The low potential for bioaccumulation based on a fish BCF confirms that TCPP cannot be considered as a PBT or vPvB substance.

SCHER has no information for addressing if further increases in the production/consumption volumes should be expected or not.

4. LIST OF ABBREVIATIONS

BCF	Bioconcentration Factor
ESD	Emission Scenario Document
Koc	organic carbon and water partitioning at equilibrium
LOAEL	Low Observed Adverse Effect Level
NOEC	No Observe Effect Concentration
PBT	persistent bioaccumulative toxic
PEC	Predicted environmental concentration
PNEC	Predicted no effect concentration
PUR	polyurethane
QSAR	Quantitative structure-activity relationship
RAR	Risk assessment report
TCEP	Tris(2-chloroethyl) phosphate
TCPP	Tris(1-chloro-2-propyl) phosphate
TGD	Technical Guidance Document
VPvB	very Persistent very Bioaccumulative

References

OECD, 2004: OECD Series on Emission Scenario Documents Number 3, Emission Scenario Document on Plastics Additives ENV/JM/MONO/2004(8), June 2004.

Fisk, P., McLaughlin, L. and Wildey, R. (2006): A new assessment of the release of flame retardants from polyurethane foam, Environment Agency and Peter Fisk Associates, Report version 4, October 2006, Annex II

Hall, 2005: D. Catterall, Hall Analytical Laboratories Ltd, 'Investigation of TCPP loss by volatility at ambient temperature and pressure from small particles of a flexible polyurethane foam by GC-MS', 14th December 2005

Environmental Agency, 2006, A new assessment of the release of flame retardants from polyurethane foam R425_0703_env_ANNEX II / R426_0703_env_ANNEX II/ R428_0703_env_ANNEX II