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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate C - Public Health and Risk Assessment
C7 - Risk assessment

SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS
SCHER

Opinion on

Risk Assessment Report on
Tris (2-chloroethyl) phosphate (TCEP)
Environmental Part

CAS No.: 115-96-8

EINECS No.: 201-029-3

Adopted by the SCHER
during the 11th plenary of 4 July 2006

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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 very good quality, and provides a complete report based on the available information. The inclusion of a generic scenario for production is particularly welcomed, as although TCEP is not longer produced in the EU-15, the production of this chemical in one of the new Member States is at least partially covered by this generic scenario.

The report proposes conclusion (ii)¹ for all compartments; the SCHER agrees with this proposal. Similarly, the lack of bioaccumulation potential characterise TCEP as a non-PBT chemical.

Nevertheless, it should be considered that the PEC/PNEC ratios are below but close to 1. The use of TCEP has exhibited a significant reduction in the last years; however, considering the new restrictions of other flame retardants the Committee recommends to monitor the production/use volume of this chemical for identifying a possible recovery of former production/use volumes that could represent a potential risk.

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.*

3.2 Specific Comments

3.2.1 Exposure assessment

According to the RAR, TCEP is not produced in EU-15 but imported from a new Member State and from abroad. TCEP is a flame-retardant plasticizer. The main use is in the production of unsaturated polyester resins.

TCEP is non-readily degradable and it is stable to hydrolysis. The volatility is low and has a high solubility in water.

The emissions and PEC estimations are appropriate, and additional specific emission scenarios have been considered. There is an acceptable level of agreement between the PEC estimations and the monitoring data.

The potential for bioaccumulation is low and the physical-chemical properties suggest water as the main relevant compartment.

3.2.2 Effect assessment

The effect assessment includes acute toxicity data on fish and acute and chronic data on algae and invertebrates. There are large differences in the toxicity of TCEP to algae, with conflicting information regarding the toxicity to *Scenedesmus subspicatus*. The uncertainty cannot be solved and the RAR properly uses the lowest value for the PNEC derivation.

No toxicity data are available on sediment dwelling organisms. The RAR estimates a PNEC based on the equilibrium partitioning method. Although the approach is acceptable, this estimation is unnecessary as the main exposure route for sediment dwelling organism would be water, not sediment.

There is a significant amount of information on terrestrial (soil) dwelling organisms. The rapporteur includes in the RAR a description of these assays and offers a proper justification for the selection of the value employed for the PNEC derivation.

The PNEC_{wwtp} is also properly developed and a PNEC for secondary poisoning is not presented due to the lack of bioaccumulation potential.

3.2.3 Risk characterisation

The PEC/PNEC ratios are below 1 in all cases, but mostly above 0.1 for both the aquatic and the terrestrial (soil) compartments. Therefore, the SCHER agrees with conclusion (ii) for all compartments. Nevertheless a potential future risk cannot be excluded if the production/use volumes rise in the future as a consequence of actions on other flame retardants. It is recommended to monitor that the current trend, reflecting a reduction in the use of TCEP, is not inverted in the future.

The PBT assessment concludes that TCEP is persistent but not bioaccumulable. The Committee agrees with this proposal.

4. LIST OF ABBREVIATIONS

PBT	Persistent/Bioaccumulative/Toxic
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
RAR	Risk Assessment Report
TCEP	Tris (2-chloroethyl) phosphate

5. ACKNOWLEDGEMENTS

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