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SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS

SCHER

Opinion on

"Risk Assessment Report on Tertiary Butyl Hydroxiperoxide (TBHP) Environmental Part"

CAS No.: 75-91-2

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Adopted by the SCHER
during the 2nd plenary meeting of 14 December 2004

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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. GENERAL COMMENTS

The environmental part of the RAR is of good scientific quality and follows the principles recommended by the TGD. The amount of information is very limited, particularly on the effect site, and only allows a preliminary assessment. Conclusion iii[1]) is presented as a regulatory decision (based on the reluctance of industry for conducting additional testing) and therefore the SCHER cannot comment on that, but supports the suggestion from the rapporteur that the logic would recommended conclusion i[1]), requiring a refinement of PECs and PNECs before moving to risk reduction.

The SCHER welcomes the approach for including metabolites in the risk characterization.

4. SPECIFIC COMMENTS

4.1. Exposure assessment

TBHP is relatively stable to abiotic degradation in aqueous solutions. The initial ready biodegradation studies showed no degradation due to the inhibitory effects on microbial activity

[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.

at the high tested concentrations, but new studies confirmed a rapid biodegradation to tertiary butyl alcohol (TBA) and other unknown metabolites and a further mineralization. The SCHER agrees with the explanations given in the RAR and supports the suggested degradation/distribution factors (but only for concentrations below those inhibiting microbial processes).

The PECs have been calculated following the TGD. As part of the information is considered confidential and not included in the report, the SCHER cannot comment on the figures.

As a risk for microbial populations in the WWTP has been identified and biotic degradation is the main dissipation route, it is not clear if this effect has been included or not in the PEC water estimations.

4.2. Effect assessment

4.2.1. Aquatic organisms

The information covers only acute toxicity data, and a chronic NOEC on algae. Therefore, according to the TGD, the PNEC is derived by applying a factor of 1000 to the lowest acute LC50. The SCHER agrees with the proposal and also with the assessment that no PNEC for sediment dwelling organisms is required.

The PNEC micro-organisms is derived following the TGD and the SCHER agrees with the proposed value.

4.2.2. Terrestrial organisms

No information on the toxicity of TBHP to soil organisms is available. The RAR proposes the use of the equilibrium partitioning method. The SCHER, considering the ecotoxicological profile and the physical-chemical properties of TBHP, agrees with this proposal. Nevertheless, the Committee suggests a further consideration of the information provided by Koch et al., 1995. Although the data are not suitable for a PNEC derivation they could be valuable for comparing the sensitivity of plants versus unicellular algae. Therefore, the SCHER would prefer a description of the experimental approach and the results observed by these authors. The SCHER notes the lack of information on soil microbial functional parameters (e.g. soil respiration and soil nitrification), which become particularly relevant for a chemical with identified effects on microorganisms.

A low potential for bioaccumulation is expected.

4.3. Risk characterisation

Several PEC/PNEC ratios are well above 1 suggesting a potential risk. The RAR indicates conclusion iii) as industry has not supported conducting additional studies. The SCHER must stress that from a scientific perspective, the logic indicates conclusion i) as the PNEC is based on a very limited set of data.

The risk characterization includes the assessment of the risk of the TBA metabolite. The SCHER welcomes this approach for including relevant metabolites in the assessment.

5. LIST OF ACRONYMS AND ABBREVIATIONS

LC50	median Lethal Concentration
NOEC	No Observed Effect Concentration
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
RAR	Risk Assessment Report
TBA	Tertiary Butyl Alcohol
TBHP	Tertiary Butyl Hydroxiperoxide
TGD	Technical Guidance Document
WWTP	Waste Water Treatment Plant

6. ACKNOWLEDGEMENTS

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