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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 2-methoxy-2-methylbutane (TAME: *tert*-amyl-methyl ether) Environmental Part

CAS No.: 994-05-8

EINECS No.: 213-611-4

Adopted by the SCHER
during the 4th plenary of 18 March 2005

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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 draft RAR is of good quality. The risk assessment procedures proposed by the TGD are applied and are generally based on a suitable amount of information on the most relevant issues. However, some specificities of this chemical have not been properly considered.

The only information lacking refers to toxicity data on terrestrial organisms through air exposure. It is the opinion of the SCHER that for such a chemical, highly volatile and subject to relevant emissions in the atmospheric compartment, this kind of information should be provided. In addition, the mammalian inhalation studies should be summarised and used for the environmental risk assessment.

Therefore the SCHER agrees with most of the conclusions of the report. In particular:

Conclusion ii)[1] and Conclusion iii) for different scenarios of the aquatic compartment respectively;

Conclusion ii) for microorganisms in WWTP;

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[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.*

Conclusion ii) for soil;

Conclusion ii) for secondary poisoning;

Conclusion ii) and Conclusion iii) for different scenarios of the marine environment respectively.

For the reasons previously mentioned, the SCHER doesn't agree with conclusion ii) for the atmospheric environment. Conclusion i) is more suitable.

Moreover, conclusion iii) is proposed for groundwater; it is the opinion of the SCHER that there are reasons for supporting a concern for groundwater. Nevertheless, not enough elements are provided for endorsing this conclusion in the environmental part of the RAR. The risk for groundwater has not been considered for other substances comparable to TAME.

The proposal is based on the evidence of measured concentrations above those producing taste problems for drinking water. However, a comparison of measured concentrations and the PNEC for aquatic organisms is not included.

Finally, the SCHER agrees with the suggestion of not classifying TAME as a PBT substance, due to relatively high persistence, but relatively low toxicity and no bioaccumulation potential.

4. SPECIFIC COMMENTS

4.1 Exposure assessment

TAME is a relatively persistent, highly volatile, highly water soluble, poorly lipophylic compound.

PECs are properly calculated at local and regional level, according with the TGD procedures, for all relevant compartments. Local values for production, formulation and industrial uses are assessed according to EUSES, by applying, where possible, site-specific data.

Experimental monitoring data in surface water are too scattered for a proper comparison, but a rough agreement with calculated data can be observed. Very high concentrations, up to some mg/l, have been measured in some groundwater sites. Considering the persistence of TAME, this is reason for concern.

Taking into account that some production sites discharge waste into the sea through WWTP, PECs for the marine environment have been calculated for water and sediments according to the TGD.

4.2 Effect assessment

TAME is a problematic compound for aquatic toxicity testing, due to its volatility. Nevertheless, reliable data, obtained with suitable procedures (flow trough tests, measured concentrations, closed vessels, etc.) are available for all levels of aquatic organisms. A $PNEC_{water}$ is properly calculated by applying a factor of 50 to a set of data including two long term NOECs. A $PNEC_{water, intermittent}$ is also proposed.

No data are available for sediment dwelling organisms. Taking into account the high water solubility, the SCHER considers that the risk for sediment dwelling organisms can be covered by those on aquatic organisms.

A PNEC$_{microorganisms}$ is properly calculated from a suitable test on *Pseudomonas*.

For the terrestrial environment, no data are available for soil. A PNEC is calculated using the equilibrium partition method. The principle of the equilibrium partitioning method assumes that the only exposure route is from pore-water. Nevertheless the volatility of TAME creates some concern, for additional exposure routes at least for plants.

No data are available on the effects on biota through atmospheric exposure. Considering the high volatility of the chemical, these data for animals and, in particular, for plants, should be provided, taking also into account the possible exposure due to volatilisation from soil.

For the derivation of a PNEC for the marine environment, data on the marine crustacean *Americamysis bahia* have been included in the data set. This invertebrate is the most sensitive among all tested aquatic organisms. The PNEC has been calculated according with the TGD by applying a factor of 500 to the long term NOEC, being available two long term NOECs on freshwater and saltwater species representing the two trophic levels of algae and crustaceans, but not on additional marine taxonomic groups (e.g.: echinoderms, molluscs).

Even if this is the procedure proposed by the TGD, the SCHER agrees with the previous CSTEE opinion, and does not consider that an additional factor of 10 in the derivation of the PNEC marine organisms is scientifically justified. Instead, a proper assessment should be conducted (see CSTEE opinion on the TGD-Marine risk assessment at: http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out152_en.pdf).

4.3 Risk characterisation

In some industrial sites a PEC/PNEC ratio higher than 1 has been calculated for the freshwater environment. It has been evaluated that even a refinement of the information will not remove the concern, therefore conclusion iii) is proposed. Same comments can be made for some emission sites in the marine environment, even increasing the PNEC by a factor of 10.

Conclusion iii) is also applied to groundwater. This conclusion is not based on ecotoxicological endpoints. Nevertheless, due to the properties of TAME (high persistency, low odour and taste threshold in water) and to the very high concentrations measured in groundwater, the conclusion is proposed due to the needs for general groundwater protection. The SCHER recognizes the concern for the groundwater compartment, but the conclusion is not based on a risk characterisation approach suitable for an environmental risk assessment., The issue should also be reconsidered in the human health risk assessment.

 The reasons for not calculating a PEC/PNEC ratio for the atmospheric exposure of plants and animals are not sufficiently supported. Therefore the SCHER cannot accept conclusion ii).

5. LIST OF ABBREVIATIONS

CSTEE	Scientific Committee on Toxicity, Ecotoxicity and the Environment
EUSES	European Union System for the Evaluation of Substances

NOEC	No Observed Effect Concentration
PBT	Persistent Bioaccumulative Toxic
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
RAR	Risk Assessment Report
TAME	*tert*-amyl-methyl ether
TGD	Technical Guidance Document
WWTP	Wastewater Treatment Plant

6. ACKNOWLEDGEMENTS