EUROPEAN COMMISSION
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
1-METHOXYPROPAN-2-OL (PGME)
Environmental Part

CAS No.: 107-98-2

EINECS No.: 203-539-1

Adopted by the SCHER
during the 10 plenary of 17 March 2006

TABLE OF CONTENTS

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 estimated production volume of PGME (as 1-methoxypropan-2-ol is called in the RAR) in the EU is 188.10^3 t/y; 144.10^3 of which is used in the EU.

The report is of good quality and the conclusions are, in general, supported by sufficient information.

The SCHER therefore supports conclusion (ii)[1] for all compartments (including secondary poisoning) as proposed by the RAR.

3.2 Specific Comments

3.2.1 Exposure assessment

PGME is a readily biodegradable substance and has a low volatility, high water solubility (miscible) and a low potential for accumulation in biota (low Kow). Fugacity modelling based on these properties indicates that PGME mainly (96%) partitions to the aquatic compartment.

In general, PEC values have been properly calculated at local, regional and continental level, according to the TGD, for most environmental compartments. Deviations from TGD guidance

[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.

are clearly described and justified. For the local exposure at one production site it is, however, unclear from the RAR how the $PEC_{seawater}$ was derived.

Two types of local releases are considered separately: PGME used in oilfield chemicals and its use in oil spill dispersants. For both uses the RAR concludes that it is not possible to perform an exposure assessment. Consequently, it needs to be recognized that the RAR does not cover potential risks due to these uses.

No comparison of the predicted environmental concentrations with monitoring data is available in the RAR.

3.2.2 Effect assessment

Aquatic compartment

Acute toxicity tests with fish, invertebrates and algae resulted in L(E)C50s ranging 20,800 (*Pimephales promelas*) to 23,300 mg/l (*Daphnia magna*) PGME. A number of other test results reports undefined L(E)C50s ranging from > 500 to > 1000 mg/l with no effects observed at these concentrations. The data seem to have been assessed for their quality and relevance, although no description is given of the procedure used to assign the validity scores. No long-term studies with representatives of these three trophic levels are available.

The few experimental data available are in reasonable agreement with values calculated using the QSAR equation for non-polar narcotics.

The proposed PNEC of 10 mg/L is based on the results of algal test which indicated 21% effect at a nominal concentration of 1000 mg/l. An assessment factor of 100 is used based on the fact that PGME is assumed to be a non-polar narcotic. The SCHER supports the proposed PNEC value.
No specific ecotoxicity data are available for sediments. The PNECs for marine and freshwater sediments were calculated using the equilibrium partitioning approach as proposed in the TGD. The SCHER supports the derived values.

Terrestrial compartment

No specific soil ecotoxicity data are available. The PNEC for soil was calculated using the equilibrium partitioning approach. The SCHER supports the derived value.

Sewage Treatment Plant - Microorganisms

A PNEC of 100 mg/L was derived based on respiration inhibition test with sludge. No details on this study are given in the RAR.

Atmospheric compartment

No data are available and no PNEC was derived.

Secondary poisoning

As PGME has a very low potential for bioaccumulation, the RAR concludes that secondary poisoning can be considered to be negligible. The SCHER supports this view.

3.2.3 Risk characterisation

Aquatic compartment

In the aquatic compartment (including freshwater, STP, sediments and marine environments) the PEC/PNEC ratio is smaller than 1. The SCHER therefore supports conclusion (ii) proposed by the RAR.

Soil compartment

Although a PNEC was derived no PEC/PNEC ratios were calculated. The RAR justifies the proposed conclusion (ii) by indicating that the exposure of the terrestrial compartment will be negligible as there is no direct release of PGME to soil and the substance is very mobile in soils and readily biodegradable. The SCHER shares this view and supports conclusion (ii) proposed by the RAR.

Atmospheric compartment

Risk characterization has not been performed for the atmospheric compartment due to the lack of effect data.

Secondary poisoning

Due to the very low bioaccumulation potential of PGME, the SCHER supports conclusion (ii) proposed by the RAR for secondary poisoning.

4. LIST OF ABBREVIATIONS

L(E)50	Lethal (or effect) Concentration for 50% of the test organisms
PEC	Predicted Environmental Concentration
PGME	1-Methoxypropan-2-ol
PNEC	Predicted No Effect Concentration
QSAR	Quantitative Structure Activity Relationships
RAR	Risk Assessment Report
TGD	Technical Guidance Document

5. ACKNOWLEDGEMENTS

Prof. C. Janssen (rapporteur) is acknowledged for his valuable contribution to this opinion.