



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
2-Ethoxyethyl acetate (2-EEA)
Environmental Part

CAS No.: 111-15-09

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Adopted by the SCHER
during the 9th plenary of 27 January 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

On the basis of the available information, the RAR describes a “virtual” assessment, because, at the time being, apparently there is no production or import of 2-Ethoxyethyl acetate (2-EEA) in Europe. This is probably due to substitution of 2-EEA with less hazardous substances.

Thus, the RAR is based on two hypothetical figures of 2-EEA circulation volume (1000 and 5000 t/y), assumed as realistic considering that the volume on the EU market in the year 2000 was 5000 t.

Therefore, assuming that at present there is no production, import and use of 2-EEA, the SCHER agrees with conclusion (ii)¹ proposed in the RAR.

Taking into account that, at least for some specific situations, reasons for concern cannot be excluded, even for the lower value of hypothetical market volume, it is opinion of the SCHER that the assumption of zero use needs to be verified and controlled.

In case of circulation of the chemical in the EU, conclusion (ii) could not be accepted.

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.*

If 2-EEA is used as solvent in the chemical industry, conclusion (i) should be adopted for the aquatic, and the atmospheric environment.

3.2 Specific Comments

3.2.1 Exposure assessment

2-EEA is a readily biodegradable, highly volatile, highly water soluble, poorly lipophilic compound.

Exposure assessment has been performed on the basis of two different default scenarios (1000 and 5000 t/y) of circulation in Europe for different uses.

Using these scenarios, PECs are properly calculated at local and regional level, according with the TGD procedures, for all relevant compartments.

Very few monitoring data are available (all before 1992) indicating sporadic presence of 2-EEA in groundwater in Italy (close to a paint factory) and in surface water in Germany. Quantitative values are not reported in the RAR.

3.2.2 Effect assessment

A $PNEC_{\text{water}}$ was properly calculated by applying a factor of 100 to a set of reliable acute toxicity data for fish, invertebrates and algae, and a long term NOEC value for *Daphnia*.

No data on sediment organisms are available and a PNEC for sediments was not calculated. Due to the low Koc value, accumulation in sediments is unlikely to occur.

A $PNEC_{\text{microorganisms}}$ was properly calculated from a suitable test on *Pseudomonas*.

For the terrestrial environment, no data are available for soil organisms. A PNEC was calculated using the equilibrium partition method.

No ecotoxicological data are available for atmospheric exposure. Taking into account that 2-EEA is a highly volatile chemical, atmospheric exposure should not be neglected, at least at the local scale. Therefore ecotoxicological tests for atmospheric exposure should be performed.

3.2.3 Risk characterisation

In the case of use as solvent in the chemical industry, a PEC/PNEC ratio substantially higher than 1 was calculated for surface water even for the lower hypothetical scenario (1000 t/y). Exposure was calculated by using the default emission values from the TGD. A refinement of the risk characterisation through a better exposure assessment would be required.

Risk characterisation for the atmospheric compartment has not been performed due to the lack of ecotoxicological data. Due to the volatility of the chemical, it is opinion of the SCHER that a risk characterisation should be performed by developing ecotoxicological data from atmospheric exposure, as well as by using inhalation data from the human health assessment.

4. LIST OF ABBREVIATIONS

2-EEA	2-Ethoxyethyl acetate
NOEC	No Observed Effect Concentration
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
RAR	Risk Assessment Report
TGD	Technical Guidance Document

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