



**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-methoxy-1-methylethyl acetate (PGMA)**  
**Environmental Part**

**CAS No.: 108-65-6**

**EINECS No.: 203-603-9**

Adopted by the SCHER  
during the 11<sup>th</sup> plenary of 4 May 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 in general of good quality; the rapporteur has maximized the use of available information and included the information in the RAR; the SCHER welcomes this approach. The report proposes conclusion (ii)<sup>1</sup> for the aquatic and terrestrial compartments and for secondary poisoning. The Committee agrees with the proposals for the terrestrial compartment and for secondary poisoning; however, additional information should be presented to justify the PNEC derivation for the aquatic environment. Regarding the atmospheric compartment, the RAR indicates that this compartment has not been addressed, instead of setting conclusions. The Committee considers that this is a transparent solution for communicating the lack of information on atmospheric effects and suggests the use a similar approach in other RARs.

### 3.2 Specific Comments

#### 3.2.1 Exposure assessment

2-methoxy-1-methylethyl acetate is produced in closed systems in three locations in Europe. The

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<sup>1</sup> 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.*

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RAR is very transparent and includes the location, dilution factors, etc., an approach with is welcomed by the Committee. The chemical is mostly used as a solvent in several industrial categories where paints, lacquers and varnishes represent over 85%. The RAR considers that 10% of these products are use by private consumers and 90% in industrial uses, using information from other glycol ethers.

2-methoxy-1-methylethyl acetate is readily biodegradable, highly water soluble, has a low Log Kow, and low volatility from water.

The RAR includes the exposure assessment in tabular formats, very easy to read and mentions whenever required, the site-specific information. The Committee considers that an annex with the EUSES calculations should be added for increasing the transparency of the report.

The RAR considers that soil exposure is not expected; the rationale supporting this assessment is acceptable.

### *3.2.2 Effect assessment*

A  $PNEC_{\text{aquatic organisms}}$  is calculated by applying a factor of 100 to fish acute data. Valid chronic NOECs covering invertebrates and algae are available, but fish are clearly much more sensitive. In the opinion of the Committee, the rationale for selecting a value of 100 instead of the value of 1000 generally applied to acute toxicity data should be presented. Considering the low toxicity of this chemical the Committee considers that requesting a chronic toxicity test on fish should be avoided if possible. Nevertheless, as the reduction of the assessment factor is critical for the risk assessment results, the SCHER considers that QSAR estimations, comparisons with related substances, ACR estimations for vertebrates, etc. should be presented to demonstrate that the factor of 100 on the acute LC50 is protective enough.

For the marine environment, the use of an additional factor of 10 leading to an assessment factor of 1000, although suggested in the TGD, is not supported by the SCHER as there are no reasons for assuming that marine fish are more sensitive than freshwater fish. The Committee considers that the same PNEC should be use for both compartments.

A  $PNEC_{\text{microorganisms}}$  is calculated from a biodegradability test as no effect assessment tests are available.

No data on sediment or soil dwelling organisms are available. The PNECs are calculated using the equilibrium partitioning methods but these calculations are useless as no PECs have been calculated for these compartments. Data suggest that accumulation in sediments and exposure of soils are unlikely to occur.

### *3.2.3 Risk characterisation*

For the aquatic compartment, the RAR indicates that all PEC/PNEC ratios are below 1 and proposes conclusion (ii). The SCHER considers that the supporting information for the factor used in the PNEC derivation should be presented; without this information, the Committee cannot accept conclusion (ii), as several PEC/PNEC ratios will be above 1 if the default assessment factor of 1000 is used. Nevertheless, QSARs and other alternatives for cross-reading information on related chemicals should be considered before requesting a fish chronic assay.

The SCHER supports the other conclusions and the way in which the lack of assessment for the atmospheric compartment is presented in this particular RAR.

#### **4. LIST OF ABBREVIATIONS**

EUSES	European Union System for the Evaluation of Substances
LC50	median Lethal Concentrations
NOEC	No Observed Effect Concentration
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
QSAR	Quantitative Structure Activity Relationship
RAR	Risk Assessment Report
TGD	Technical Guidance Document

#### **5. ACKNOWLEDGEMENTS**

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