



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-BUTHOXYETHANOL
(EGBE: Ethylene glycol butyl ether)
Environnemental Part**

CAS No.: 111-76-2

EINECS No.: 203-905-0

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

TABLE OF CONTENTS

1. BACKGROUND..... 3

2. TERMS OF REFERENCE..... 3

3. OPINION 3

 3.1 General Comments 3

 3.2 Specific Comments 3

 3.2.1 Exposure assessment 3

 3.2.2 Effect assessment 4

 3.2.3 Risk characterisation 4

4. LIST OF ABBREVIATIONS 5

5. ACKNOWLEDGEMENTS 6

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

EGBE (as 2-butoxyethanol is called in the RAR) is a relatively high production volume compound. Estimated production volume in the European Union is about 1.5×10^5 tons/y.

The report is of good quality and most conclusions are supported by a sufficient amount of information.

Therefore the SCHER supports conclusion (ii)¹ proposed by the RAR for the aquatic compartment (freshwater, marine and waste water treatment plants), for the soil compartment and for secondary poisoning.

Nevertheless, due to the high volatility of EGBE, it is opinion of the SCHER that toxicity data for atmospheric exposure must be provided.

3.2 Specific Comments

3.2.1 Exposure assessment

EGBE is a readily biodegradable, highly volatile, highly water soluble (miscible), poorly lipophilic compound.

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.*

Kaw (air-water partition coefficient) is relatively low and the main compartment of concern is water. Nevertheless, due to the high vapour pressure (in the order of hPa), atmospheric exposure should not be overlooked if emissions are to the atmosphere.

PECs have been properly calculated at local, regional and continental level, according to the TGD, for all environmental compartments. The possibilities for releases in water, air or soil have been taken into account.

Predicted values have been compared with some experimental data available. For the aquatic compartment, except for some very high concentrations measured in 1981 in a Japanese river, a reasonable agreement was observed. A reasonable agreement was also observed with some data on air concentrations in areas subject to relatively high human pressure. Surprisingly high values are reported as background value from Europe and remote sites (Himalaya, Antarctica). To justify these values, the authors propose natural emissions (vegetation, marine).

3.2.2 *Effect assessment*

Aquatic compartment

Several data on fish and invertebrates are available indicating low toxic effect, with acute EC50 in the order of 10^3 mg/L. A few studies indicating a relatively higher toxicity are classified as unreliable for several methodological reasons. The SCHER supports this position. The most sensitive organisms seem to be algae with a 72h NOEC of 286 mg/L.

Long term NOECs are also available for fish and *Daphnia*. Moreover, a study on fish indicates that EGBE has no potential for endocrine disruption.

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

The proposed PNEC of 10 mg/L, calculated by applying a factor of 10 to the lowest long term NOEC, is appropriate.

PNECs have also been calculated for seawater based on long-term data on freshwater organisms and on some acute data for marine fish and invertebrates. No specific data are available for sediments. Due to the characteristics of the chemical, sediments are a compartment of low concern. PNECs for marine and freshwater sediments have been calculated using the equilibrium partitioning approach.

Soil compartment

No specific data are available for soil. PNEC for soil has been calculated using the equilibrium partitioning approach.

Microorganisms

A PNEC of 463 mg/L has been calculated from data available on bacteria and protozoan.

Atmospheric compartment

No data are available.

Secondary poisoning

No data are available.

3.2.3 Risk characterisation

Aquatic compartment

In all aquatic sites, including seawater and waste water treatment plants, PEC/PNEC ratio was far below 1.

Risk characterization has not been performed for sediments due to the lack of toxicological information. Because of the very low sediment/water partition coefficient, it has been assumed that risk assessment for sediments is covered by that of surface water. This assumption is supported by the SCHER.

Therefore the SCHER supports conclusion (ii) proposed by the RAR for the aquatic compartment.

Soil compartment

All calculated PEC/PNEC ratios are orders of magnitude below 1. Therefore the SCHER supports conclusion (ii) proposed by the RAR for the compartment, even in absence of specific toxicity data on soil dwelling organisms.

Atmospheric compartment

Risk characterization has not been performed for the atmospheric compartment due to the lack of toxicological information. Because of the very high volatility of the chemical and of the possibility of direct atmospheric emissions, it is opinion of the SCHER that toxicity data for atmospheric exposure must be provided. As a minimum requirement, inhalation toxicity data from the human risk assessment must be evaluated.

Secondary poisoning

No data are available for secondary poisoning. Nevertheless, due to the low bioaccumulation potential of the chemical, the SCHER supports conclusion (ii) proposed by the RAR for the aquatic compartment.

4. LIST OF ABBREVIATIONS

EGBE	Ethylene glycol butyl ether
NOEC	No Observed Effect Concentration
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
QSAR	Quantitative Structure Activity Relationships
RAR	Risk Assessment Report
TGD	Technical Guidance Document

5. ACKNOWLEDGEMENTS

Prof. M. Vighi (rapporteur) is acknowledged for his valuable contribution to this opinion.