



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 ACETATE
(EGBEA: Ethylene glycol butyl ether acetate)
Environmental Part**

CAS No.: 112-07-2

EINECS No.: 203-933-3

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

EGBEA (as 2-butoxyethanol acetate is called in the RAR) is a relatively high production volume compound. Estimated production volume in the European Union is about 1.2×10^4 tons/y. This value is about 10 times lower than the comparable chemical EGBE.

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 EGBEA, it is opinion of the SCHER that a risk characterisation for atmospheric exposure must be performed, at least on the basis of inhalation data from the Human Health Report.

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.*

3.2 Specific Comments

3.2.1 Exposure assessment

EGBEA is a readily biodegradable, highly volatile, highly water soluble, poorly lipophilic compound.

The main compartment of concern is water. Nevertheless, due to the high vapour pressure (0.56 hPa); atmospheric exposure should not be overlooked if emissions are into 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.

Experimental monitoring data are not reported in the RAR.

3.2.2 Effect assessment

Aquatic compartment

The set of valid toxicity data on aquatic organisms is sufficiently complete, indicating relatively low toxic effect, with acute EC50 in the order of 10^2 mg/L.

PNECs have been calculated for fresh and seawater and for chronic and intermittent exposure. In some cases, the procedures were not based on the most conservative approach. However, even assuming the most conservative PNECs, does not change any of the conclusions of the RAR.

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 722 mg/L has been calculated from data available on bacteria.

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 below 1. As previously mentioned, the result is the same by using more conservative PNECs.

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 far 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 taken into account. Nevertheless, considering the generally low toxicity of the chemical and the moderate release in the atmospheric compartment, the SCHER does not support the need for specific toxicity testing. An evaluation based on inhalation toxicity data from the human risk assessment will be sufficient.

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

EC50	Median Effect Concentration
EGBE	Ethylene glycol butyl ether
EGBEA	Ethylene glycol butyl ether acetate
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
RAR	Risk Assessment Report
TGD	Technical Guidance Document

5. ACKNOWLEDGEMENTS

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