

EUROPEAN COMMISSION HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment C7 - Risk assessment

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# SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)

Opinion on the results of the Risk Assessment of:

BUT-2-YNE-1,4 DIOL ENVIRONMENTAL PART

CAS No.: 110-65-6

EINECS No.: 203-788-6

Carried out in the framework of Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances<sup>1</sup>

# Adopted by the CSTEE during the 39<sup>th</sup> plenary meeting of 10 September 2003

<sup>&</sup>lt;sup>1</sup> Regulation 793/93 provides a systematic framework for the evaluation of the risks to human health and the environment of those substances if they are produced or imported into the Community in volumes above 10 tonnes per year. The methods for carrying out an in-depth Risk Assessment at Community level are laid down in Commission Regulation (EC)1488/94, which is supported by a technical guidance document.

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#### Terms of Reference

In the context of Regulation 793/93 (Existing Substances Regulation), and on the basis of the examination of the Risk Assessment Report the CSTEE is invited to examine the following issues:

- (1) Does the CSTEE agree with the conclusions of the Risk Assessment Report?
- (2) If the CSTEE disagrees with such conclusions, the CSTEE is invited to elaborate on the reasons for this divergence of opinion.

#### **GENERAL COMMENTS**

The environmental part of the document is in general of very good quality. The RAR has considered not only the major uses as chemical intermediate but also minor uses. Specific considerations have been made for diffuse uses including those related to general consumers even if these uses represent only a very small percentage of the total production. The CSTEE has previously recommend specific evaluations for chemicals present in consumers' products, which represent a diffuse and widespread potential release into the environment; thus, this approach is welcomed.

The exposure assessment considers site-specific information for refining the estimations based on default data. The assumptions are supported by the CSTEE. Unfortunately, no information on monitoring data is available to check the predicted estimations.

The effect assessment is based on a very limited data set and follows the TGD approaches.

The CSTEE supports the suggested conclusion (ii) for all environmental compartments.

### SPECIFIC COMMENTS

#### Exposure assessment

The exposure assessment is well conducted and presents information on the two production and main processing sites as well as specific assessments for minor uses including diffuse uses. The CSTEE agrees with the proposal of ready biodegradation.

Effluent measurements indicate much lower concentrations than those estimated from default values. As the data include all (two) production and major processing sites, the CSTEE supports the use of this information for the assessment.

### Effects assessment

#### Aquatic organisms

The information covers only acute toxicity data. The PNEC for aquatic organisms is derived using a factor of 1000 on the lowest reported LC50. For microorganisms the available data cover bacteria and protozoan and both taxa are used. The CSTEE agrees with the proposed values.

No PNEC for sediment dwelling organisms is proposed, assuming that this compartment is not relevant for this chemical. This proposal is also supported by the CSTEE.

#### Terrestrial organisms

The PNEC is derived from the equilibrium partitioning method and from data on microorganisms nitrification. Both PNECs are used in the risk characterisation.

Low risk for secondary poisoning is assumed.

#### **Risk characterisation**

The CSTEE supports the risk assessment conclusions for all environmental compartments.