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Scientific Committee on Toxicity, Ecotoxicity and the Environment

Brussels,
C2/JCD/csteep/**ButadieneENV07122001/D(01)**

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

Opinion on the results of the Risk Assessment of:

BUTADIENE

CAS No.: 106-99-0

EINECS No.: 203-450-8

**REPORT VERSION (Environment)
June 2001**

**Carried out in the framework of Council Regulation (EEC) 793/93 on
the evaluation and control of the risks of existing substances¹**

Opinion expressed at the 28th CSTEE plenary meeting

Brussels, 07 December 2001

¹ 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.

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 good quality. It also considers emissions other than those related to the life cycle of the substance, such as vehicle exhaust emissions or cigarette smoke. The main problem observed by the CSTEE is the estimation of the PEC surface water. The PEC surface water for production and use are initially estimated using the TGD approach with emission rates corrected from measured data in the US. However, these values are not later used in the assessment. Instead, a non-justified value of 2 µg/l is used in the assessment (but keeping the TGD approach for uses providing estimations below this figure). The CSTEE considers that a much more clear and justified rationale must be presented before accepting this dramatic reduction. Therefore, RAR conclusion ii) for the aquatic compartment is not justified.

Conclusion ii for the atmosphere, soil and secondary poisoning are supported by the CSTEE. In particular the CSTEE recognises the efforts to derive PNEC values for the atmospheric compartment.

SPECIFIC COMMENTS

Exposure assessment

The RAR presents a good and comprehensive overview of the available information on potential emissions of butadiene. It considers emissions other than those related to the life-cycle of the substance, such as vehicle exhaust emissions or cigarette smoke, which are quite useful for setting comparisons, and potential risk reduction measures.

In the absence of enough European information, the RAR compares the default emission factors proposed by the TGD with measured factors reported in other industrialised countries. It was decided to use the US measured values, decision fully supported by the CSTEE.

The main controversy appears for the releases to the aquatic environment. The RAR starts with the PEC estimation using the TGD approach with emission rates corrected from measured data in the US. Values of 0.85 mg/l for production and between 0.22 and 0.0017 mg/l for the different uses are calculated.

Measured data are scarce. In reality there is a single case, a production plant in Canada where they found 2 positive samples out of 2103 samples analysed. However, in the RAR no information is available on release reduction methods in this particular plant. Thus, it is not possible to make direct comparisons with European conditions.

The site-specific release information for the EU plants are summarised in point 3.1.1.1.8. However, this information has not been presented clearly in the RAR. A table with the production/use volumes, release estimations, size of the wwtp, conditions of the receiving waters, and expected dilution is not included. This table is considered essential by the CSTEE. Instead, the RAR only indicates the number of sites for which information has been submitted (about 50% of those in Europe, but without indication of the percentage of EU production/use represented by these sites). Six sites reported zero or negligible releases but the RAR does not mention if these assessments are supported by realistic information. In five sites butadiene was not detected, but the limit of detection is not included in the RAR. Six sites reported emissions up to 60 tonnes/year, but the conditions for these emissions (production/use volumes, release estimations, size of the wwtp, conditions of the receiving waters, and expected dilution) are not reported.

Using this figure of 60 tonnes/year and a river flow of 60 m³/s (which as stated in the report is about 300 times higher than the flow estimated for the default dilution factor of 10 recommended by the TGD) a broad PEC surface water of 2 µg/l (425 times lower than the initial estimation for production) is proposed.

The CSTEE considers that there is not enough information to justify this value. The highest reported emission figure in the EU, 60 tonnes/year, is quite close to the release estimated according to the TGD approach using US emission factors of 93.6 tonnes/year. Therefore, the reduction in the PEC surface water must be attributed, mostly, to the use of a higher dilution factor (300 times higher than the recommended by the TGD). The location of the 22 EU producers and 18 EU main users must be available to Member States, and therefore, the emission conditions (size of the wwtp, effluent flow and flow of the receiving water) must be available. This information must be incorporated in the risk assessment before accepting the proposed generic value of 2 µg/l.

Emission estimations and PEC calculations to atmosphere (the most relevant compartment) and soil are acceptable.

Effects assessment

Aquatic organisms

No information on the toxicity of butadiene to aquatic organisms is available. Therefore, the RAR includes two different options for presenting a preliminary assessment, the use of QSARs and the use of the available information on related compounds: isoprene (methylbutadiene) and pentadiene. The assessment also considers the comparison of QSAR predicted and measured data for both related compounds.

Getting real information on the toxicity of the substance to aquatic organisms is considered a basic requisite for a proper risk assessment. However, for butadiene, the RAR considers the special properties of this gas and the difficulties for getting valid figures on its toxicity to

aquatic organisms. This proposal is considered scientifically sound by the CSTEE. The rationale for the PNEC derivation is acceptable, and the use of the most conservative approach offers a preliminary assessment.

Direct toxicity assessment of industrial effluents containing butadiene is proposed by the CSTEE for refining the PNEC value if required.

PNEC_{sediment} is estimated using the equilibrium partitioning method. Water exposure is expected to be the main exposure route for sediment dwelling organisms and therefore, this approach is also acceptable.

Terrestrial organisms

Atmosphere: The RAR considers the available information on plants and mammals (inhalation) and propose the derivation of a PNEC. No recommendations on PNEC derivation for this compartment are available in the TGD. The RAR considers separate PNECs for plants and mammals, but both are in the same range. The rationales for deriving the PNEC values are supported by the CSTEE. No data on ground or foliar invertebrates are available.

Soil: No data on the toxicity of butadiene to soil organisms are available. The RAR proposes to use the equilibrium partitioning method. However, no information on aquatic organisms is available, and the proposed PNEC comes from QSAR estimations and a few data on related compounds. In addition, soil organisms are expected to be exposed to butadiene mostly for the air phase, not from the water phase. The CSTEE considers that a PNEC_{soil} organisms cannot be derived.

The potential for bioaccumulation is low, and this data is supported not only by the low K_{ow} , but also by toxicokinetic data on mammals exposed by inhalation.

Risk characterisation

Aquatic compartment: The reduction of the PEC_{surface water} on the basis of a higher dilution factor is not justified. A significant risk, PEC/PNEC ratio of 26, should be obtained using the PEC values calculated according to the TGD and using measured US release factors. Conclusion ii) is not acceptable and a clear justification for the proposed value is required.

Atmosphere: There is a lack of information on the toxicity to invertebrates. However, the PNEC_{plants} and PNEC_{inhalation mammals} are similar, and there are no indications of a specific mechanism of action. In addition most PEC/PNEC values are below 0.1 giving an additional margin of safety. Therefore conclusion ii) can be accepted.

Soil: The PNEC value can not be accepted but due to the low relevance of this compartment the CSTEE agrees with conclusion ii).

Secondary poisoning: The CSTEE agrees with conclusion ii).

ANNEX

The ECB has presented the M. State *rapporteur's* comments on a draft opinion distributed for the discussions at a previous CSTEE Plenary. This document addresses specifically the CSTEE's comments on the derivation of PECwater and particularly the CSTEE's recommendation for including a table with information related to local emissions (production/use volumes, release estimations, size of the wwtp, conditions of the receiving waters, and expected dilution).

These ECB's comments point out that the M. State *rapporteur* tried to make as much use of what information was available to it and that they agreed not to include such data in the risk assessment report.

The data, which are essential for supporting the conclusion of low risk, have not been included in the ECB's comments, and therefore, are not available to the CSTEE. Obviously, the CSTEE cannot support a conclusion based on data that have not been presented to the committee. In addition, the transparency of the whole process is severely affected by excluding the data which support the final conclusion. Similar data have been included in the RAR of other chemicals, and therefore the exclusion cannot be justified in terms of confidentiality. The same comments indicate that two production sites will have PEC/PNEC ratios above 1 if the proposal for large chemicals plants (dilution of 200 rather than 10 as now) included in the revised TGD is accepted. Again, the CSTEE cannot validate this information, but if confirmed, a risk refinement or risk reduction measures for at least these sites should be implemented, while the conclusion of the RAR is that no further measures are required.