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Directorate C - Public Health and Risk Assessment
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**SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE
ENVIRONMENT (CSTEE)**

Opinion on the results of the Risk Assessment of:

**2-ETHYLHEXYL ACRYLATE
ENVIRONMENTAL PART**

CAS No.: 103-11-7

EINECS No.: 203-080-7

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

**Adopted by the CSTEE during the 40th plenary meeting
on 12 November 2003**

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.

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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.

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.*

GENERAL COMMENTS

The environmental part of the document is in general of good quality. Unfortunately, the information is scarce, and the risk assessment is based on a limited amount of data. 2-Ethylhexyl acrylate (2-EHA) is used as monomer for the production of polymers and copolymers used in adhesives and as binders for paints. Specific considerations have been done for diffuse uses including those related to general consumers. The CSTEE has previously recommended 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 presents both generic, and whenever possible site specific information for refining the estimations based on default data, however, the reliability and relevance of the sites for which specific information is available is not presented in a transparent way. Most assumptions seem to be acceptable, although there are some key aspects coming directly from the information provided by the industry and not supported by specific references. 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 cannot verify the suggested conclusion ii) for all environmental compartments. The key point is the local assessment for the aquatic compartment related to production and processing. The generic estimation would give a PEC/PNEC ratio above 1, while the refined site-specific assessment indicate PEC/PNEC ratios below 1 for the two sites for which specific information is available. The refinement of the local risk assessment for the aquatic compartment is based on the assumption that the two sites for which site specific assessments have been conducted cover the overall European production and processing (the RAR indicates that 6 companies produce or import the substance, but no information on the total number of sites for production and processing is reported). The generic value is not longer included in the risk characterisation; however, this assumption is not justified in the RAR.

In addition, the CSTEE recommends checking that the concentration of 2-EHA in aqueous polymer dispersions is lower than 200 mg/kg as indicated by the industry; and that the reported value of 800 mg/kg (which would correspond to PEC/PNEC values above 1) does not represent the European conditions.

SPECIFIC COMMENTS

Exposure assessment

The exposure assessment seems to be well conducted and presents the generic estimation as well as information on two production and processing sites, however, the estimations are based on data not included in the RAR, and the relevance of sites A and B for the overall European production and processing is not established. For example, the justification of site B as a realistic worst case for wet polymerisation of 2-EHA at external processing sites is not presented in the RAR. Therefore, it is not clear if the refined site-specific assessment covers the six companies that produce or import the substance.

The CSTEE agrees with the proposal of ready biodegradation, and the relevance of atmospheric deposition as main source for soil contamination.

Effects assessment

Aquatic organisms

The information covers only acute toxicity data. The RAR has properly considered the solubility and volatility of 2-EHA, and validated only those assays with reported measured concentrations. The PNEC aquatic organisms is derived using a factor of 1000 on the lowest reported EC50. For microorganisms the studies were conducted above the solubility limit and the data on protozoan species are used for the PNEC derivation. 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

No information on the toxicity of 2-EHA to soil organisms is available. The RAR offers a comparison of the PNEC aquatic organisms and soil pore water concentration. However, this information should be considered with care as the physical-chemical properties of 2-EHA indicate that other exposure routes e.g. air, can also be relevant. Mammalian toxicity data (repeated inhalation) presented in the human health part can be used to address this exposure route.

A potential for bioaccumulation is identified but a PNEC for secondary poisoning cannot be proposed as no sufficient data on oral toxicity to mammals is available.

Risk characterisation

The CSTEE supports the risk assessment conclusions for all environmental compartments except for the local aquatic compartment for production and processing. A PEC/PNEC above 1 is obtained if the generic PEC local is used, but this is not even mentioned in the risk characterization. The RAR does not present enough information to verify that the site specific assessments conducted for sites A and B really cover the overall European conditions.

There are other minor aspects in the risk characterisation which, however, do not change the conclusions.

For the atmosphere, a main compartment for environmental exposures, the CSTEE suggest to compare the PEC air with the inhalation toxicity studies. The NOAEC from the inhalation (90 days) study is several orders of magnitude above the PEC air and therefore the CSTEE supports conclusion ii). Regarding the terrestrial (soil) compartment other routes in addition to exposure from pore water should be expected, however, the compartment is not particularly relevant and the estimated PECs are very low, thus, the CSTEE also support conclusion ii).

Finally, as properly mentioned in the report, the lack of information related to mammalian oral toxicity precludes from a quantitative assessment of the risk associated to secondary poisoning. The CSTEE agrees that requesting chronic mammalian toxicity studies exclusively for assessing the risk of secondary poisoning is not a priority, particularly for a chemical which is ready biodegradable, volatile and have a short half life in the atmosphere.