

EUROPEAN COMMISSION DIRECTORATE-GENERAL HEALTH AND CONSUMER PROTECTION Directorate C - Scientific Opinions Unit C2 – Management of Scientific Committees; scientific co-operation and networks

Scientific Committee on Toxicity, Ecotoxicity and the Environment

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

Opinion on the results of the Risk Assessment of:

TRICHLOROETHYLENE

CAS NO: 79- 01- 6 EINECS NO: 201-167- 4

REPORT VERSION (Environment) September 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 29th CSTEE plenary meeting

Brussels, 09 January 2002

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, and the assessment includes one of the breakdown products, dichloroacetic acid. The PEC/PNEC ratios for trichloroethene are for several scenarios close to 1, which makes the use of available data critical.

The assumption that all used trichloroethene is released may give an overestimation of the exposure, while no inclusion of imported amounts may underestimate it.

The ecotoxicity data has been thoroughly evaluated. The conclusions presented in the RAR are supported by the CSTEE.

The extrapolation of effects and behaviour of trichloroacetic acid to dichloroacetic acid is not scientifically supported.

SPECIFIC COMMENTS

Exposure assessment

The exposure assessment is done according to the TGD. It is assumed that the majority of trichloroethene used will be released to the environment. The major use is metal degreasing (82%) and it is assumed that 70% of this volume is released. This means that the remaining 30% (25% of the total use volume) must be taken care of in other ways, which may lead to a smaller release than has been assumed in the RAR. Industry has also estimated the release of trichloroethene to air to be 60% of the used amount. On the other hand, no data on imported volumes are available, but it is mentioned that "there are a number of agents acting as distributors for smaller amounts of imported trichloroethene".

The possibility of natural sources of trichloroethene is mentioned in the report and that these need to be up to one order of magnitude greater than the anthropogenic sources to explain concentrations in remote locations. This is, however, not reflected in the data presented in the report.

There are a large number of measured data on trichloroethene in environmental water samples and these cover a wide range of concentrations. The predicted data falls within this range. High concentrations have been found in ground water, but the assessment does not address risks arising from that. The CSTEE would at least have liked to see these levels reflected in the indirect exposure of humans.

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The major part of emitted trichloroethene will be distributed to air, and there are a number of measured concentrations available for this compartment. The predicted data falls generally within the range of measured levels.

Effects assessment

Aquatic organisms

A large number of acute and chronic toxicity data on aquatic organisms behaving to different trophic levels is available, nevertheless, due to the volatility of the substance, their reliability must be evaluated carefully. In the RAR a detailed critical evaluation of available data, with comments on their reliability, is given in an appendix.

On the basis of this evaluation, valid long-term data were selected for two species (fish and algae), while chronic data on daphnia were not considered reliable enough. the PNEC_{water} of 115 μ g/L, calculated by applying an assessment factor of 50 to the long term NOEC on fish, can be accepted. For the derivation of PNECmicroorganisms an EC₅₀ value of 0.81 mg/L has not been considered. As stated in the annex, the authors of the original report considered that results below about 0.2 mg/l were questionable, but the study gave an EC₅₀ value of 0.81 mg/L. If valid, this study could change the conclusions, but as this result was not used in the original study, it is probably justified to exclude it in the risk assessment.

For sediments, the partition method is used for the calculation of PNEC. The approach is suitable for this kind of chemicals, nevertheless it is not clear how the Kp of 3.16 has been derived from the properties of the compound (log Kow=2.29 and log Ksed/wat=2.1). Some mistakes seem to have been made in applying the formula.

Calculation of PNECmicroorganisms, done by applying a factor of 10 to the lowest valid EC50 figure, is acceptable.

Terrestrial organisms

Available tests for trichloroethene effects on terrestrial organisms are limited to short term on earthworms and plants, and the PNEC has been derived using the equilibrium partitioning method, as well as available information including comparisons with plants exposed through hydroponic solutions. The CSTEE supports this procedure and agrees with the proposed PNEC value.

The PNEC for plants have been derived from studies of tetrachloroethene, assuming that that compound and trichloroethene are acting through the same mechanism, as they are both chlorinated solvents. There is no proof that this is the case, and exposures of cuttings of hybrid popular to the two compounds in hydroponic solutions indicate a lower toxicity of trichloroethene.

Risk characterisation

The risk characterisation for the aquatic compartment is based on a PNEC excluding the low EC_{50} found for micro-organisms. The risk for groundwater is not calculated in the report, and the CSTEE realises that it is difficult to assess this medium. It should, however, at least have influenced the calculation of indirect exposure to humans, as high levels have been found in this medium.

For the atmosphere, PEC/PNEC ratios above 1 are obtained for both production and some use categories, and the CSTEE agrees with conclusion iii) for these, as well as the need for further data on emissions from use of trichloroethene as an intermediate. It should be noticed that the PNEC has been derived from information on tetrachloroethene, not on trichloroethene, and therefore a further refinement of the effects assessment should be possible by conducting specific tests on this particular substance.

The risk connected to dichloroacetic acid, based on the predicted exposure data, is estimated to be low in the aquatic compartment. As there may be also other sources for this compound, the CSTEE would have recommended measurements in surface waters close to point sources for trichloroethene. There are no test data available for dichloroacetic acid toxicity in soil organisms, but the same molar value as for trichloroacetic acid has been used in the RAR. The CSTEE is not able to see the rationale for this extrapolation and would have preferred to see a demand for further information.