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

Opinion on the results of the Risk Assessment of:

STYRENE

ENVIRONMENTAL PART

CAS N°: 100-42-5

EINECS N°: 202-851-5

REPORT VERSION: Final draft, January 2001

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

Opinion expressed at the 26th CSTEE plenary meeting

Brussels, 11 September 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.

Introduction

Styrene is a High Production Volume chemical with more than 16 million t/y world production (1995), and a production range in Europe of about 2 to 5 million t/y. It is mainly used as a monomer in a range of polymers and synthetic rubbers and in unsaturated polyester resins for reinforced plastics.

GENERAL COMMENTS

Toxicological data on the effects of styrene on aquatic and terrestrial organisms are few and, in many cases methodologically unreliable. This is not acceptable for such a high volume chemical.

The procedures for calculating PNEC for water and soil compartments are not acceptable. More conservative PNECs should be adopted. Such an approach led to values of PEC/PNEC higher than 1, in particular for the aquatic and soil environments.

No data are available on terrestrial plants exposed through air: This is unacceptable, as air is the compartment more likely to be exposed. Therefore, the CSTEE does not agree with conclusion ii).

More information is needed on the effects, both for aquatic and for terrestrial organisms.

SPECIFIC COMMENTS

Exposure assessment

The exposure assessment is well performed and follows the TGD.

Styrene is a highly volatile chemical, of relatively low solubility (300 mg/L). Experiments carried out recently indicated a solubility of 40 mg/L and 20 mg/L in fresh and seawater respectively.

Even assuming the higher solubility, the very high Henry's constant indicates high losses from water to the atmosphere.

It is readily biodegradable, with a half-life in water of about two weeks. Even if water is not the compartment more likely to be exposed, detectable concentrations of styrene may occur at local level.

PECs are properly calculated according to TGD. An emission of 0.25 kg styrene per produced tonne and a plant capacity of 1,000,000 tonnes/year is used as a worst case in the RAR. It can be accepted as a worst case, even if, in the RAR, a producer is mentioned that declares a release of 0.5 kg/tonne direct to an estuarine/marine water (thus with higher dilution) without any treatment.

The measured concentrations in water vary considerably, which is often the case when lipophilic substances are determined in aqueous samples. It is therefore difficult to compare measured and predicted data, but they are generally in reasonable agreement.

The predicted local air concentrations of styrene are in good agreement with measured data. The few analysis of background air, on the other hand, indicate that it is much higher than the predicted regional concentrations. This is probably explained by other sources, such as automobile exhaust, which is the second strongest source identified.

There are, unfortunately, no measured data available to support the high concentrations of styrene in soil near production sites.

Styrene has a slight potential for bioaccumulation. A BCF of 74 was calculated from a log Kow of 3.02. This figure appears as an overestimation in comparison with the few available experimental data on bioaccumulation. On the other hand, no evidence for metabolism or clearance processes is available. More information is needed on the possibility of contaminated organisms producing styrene oxide via their metabolic pathways. In addition to a possible direct effect on the contaminated organism, styrene oxide may enter the food chain leading to secondary poisoning and eventually to a risk for humans exposed via food.

The predicted regional levels of styrene in biota are lower than what have been measured. Again, the explanation is probably that other sources were not included in the calculation.

Effects assessment

Aquatic organisms

Acute toxicity data on aquatic organisms are available in the literature, but very few can be assumed as reliable. Most information was produced in static tests with nominal concentrations, unacceptable for such a volatile chemical. As a conclusion, only a few reliable acute data on fish, *Daphnia* and algae can be used for deriving a PNEC.

No data on long-term effects are available. For these reasons, the use of an assessment factor of 100 for deriving a PNEC cannot be accepted. A factor of 1000 should be applied to the fish acute value of 4.02 mg/L, and a PNEC of 4 μg/L should be used.

Terrestrial organisms

The available information on earthworms has not been used for PNECsoil derivation. Under these circumstances (the available information is not complete) both the available information and the equilibrium partitioning method must be compared. The application of a factor of 1000 on the reported LC50 of 120 mg/kg gives a PNECsoil of 120 μg/kg which is lower than that estimated from the equilibrium partitioning method reported in the RAR.

In addition the PNECsoil must be re-estimated according to the new PNECwater suggested by the CSTEE and a value of 25.5 μg/kg should be used.

No information on the toxicity to plants exposed though air is presented. Air is a major compartment in terms of emission, therefore, this information should be requested.

A summary of the toxicity for mammals and a proposed PNECoral should be included.

Risk characterisation

Aquatic environment

Assuming a PNEC of 4 μg/L, PEC/PNEC values higher than 1 can be attained at local level. Even if water is not the more exposed compartment, it is the opinion of the CSTEE that a large uncertainty in the PNEC assessment is not acceptable.

Therefore it is opinion of the CSTEE that conclusion (ii) is not acceptable for the aquatic environment. More reliable toxicity data (short and long term) are needed.

Terrestrial environment

Table 3.29 should be corrected for the proper PNEC. Therefore, PEC/PNEC ratios higher than 1 must be considered for certain uses and sites. As a consequence, conclusion (i) must be suggested for soil (Note the units must be μg/kg not μg/l).

The conclusion of no risk for the atmosphere and no risk of secondary poisoning are not supported by toxicity data. Therefore, the CSTEE cannot agree with these conclusions. Conclusion i) for the atmospheric compartment, and a proper estimation of the risk for secondary poisoning are required.