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

Opinion on the results of the Risk Assessment of:

1,2-Benzenedicarboxylic acid di-C9-11-branched alkyl esters, C10-rich

and

di-"isodecyl"phthalate

CAS No.: 68515-49-1 and 26761-40-0
EINECS No.: 271-091-4 and 247-977-1

REPORT VERSION (Environment):
Final report, May 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 27th CSTEE plenary meeting

Brussels, 30 October 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 of good quality, but it suffers from a lack of data on the specific compound, therefore most conclusions are extrapolated from related compounds (DEHP, DINP, etc.).

In absence of specific data for this chemical, the RAR follows the recommendations of the TGD. However, the CSTEE considers that several of the assumptions and recommendations suggested by the TGD cannot be directly applicable to compounds such DIDP, with a log Kow of 10, a water solubility of 0.2 µg/l and which is highly persistent in soil and sediment.

Nevertheless, for the aquatic environment, there is enough evidence, on DIDP or related compounds, for supporting the conclusion of negligible risk related to waterborne exposures. Therefore, the CSTEE agrees with conclusion (ii) for the aquatic compartment related to direct exposures from water, which is basically the route covered by the TGD.

However, the risk of exposure from contaminated food, cannot be excluded for fish and invertebrates, including those grazing on plankton and on other invertebrates and fish. The experimental BCF of 4000 in mussels for DIDP was obtained for water concentrations of 4-41 µg/l clearly above the solubility limit of 0.2 µg/l, therefore the CSTEE questions the validity of this figure. On the basis of the simple equations to estimate the BCF from the Kow, it is also to be expected that the BCF is much higher. Based on these considerations the CSTEE is of the opinion that additional information and a proper model for assessing the food-web transfer is required.

In addition, considering the estimated persistence in sediments, a long-term PEC for sediment, assuming a regional river-basin model, when contaminated sediment is expected to move slowly down stream reaching the estuary, should be considered and a monitoring programme should be implemented. Sediments can be a source of the chemical for other environmental compartments, and this process must be taken in consideration.

For the terrestrial environment, information is inadequate, in particular with such a high volume chemical (more than 200000 t/a of production, with estimated soil release of more than 4600 t/a in Europe) with high potential for soil accumulation and for bioaccumulation. Due to the uncertainties in determining PEC and PNEC, the CSTEE does not agree with conclusion (ii) for the terrestrial environment and secondary poisoning. Information is needed for a more reliable assessment of the PNEC for terrestrial organisms and of the concentration

in biota, including a proper model for covering the potential for biomagnification through the food chain.

In addition, the problems observed by the CSTEE regarding the potential underestimation of the bioconcentration and bioaccumulation of this chemical may have consequences for the risk characterisation for humans exposed through the environment.

Moreover, it is opinion of the CSTEE that a risk assessment on the most relevant metabolite (monoisodecylphthalate) is needed.

SPECIFIC COMMENTS

Exposure assessment

DIDP is a very low soluble, low volatile, very highly lipophilic compound, therefore compartments more likely to be exposed are soil, sediments and biota.

The available data suggest that DIDP should be in theory easily metabolised by living organisms (from micro-organisms to vertebrates). However, the very high binding potential may drastically reduce the bioavailability of the chemical to the enzymatic machinery of the living organisms. This phenomenon may be observed both in the environment (resulting in persistence in soil and sediment) and within the organism (resulting in high levels in biota). The results is that a theoretically "readily biodegradable" chemical has a very high persistence in the environment, and that high concentrations are observed in biota (including marine mammals) for a chemical with a theoretically short depuration rate.

For these compartments experimental data on degradation are not available, therefore, half life values as high as 300 days for soil and aerobic sediments and 3000 days for anaerobic sediments were extrapolated from DEHP. A confirmation of these figures was made by soil monitoring data of DINP. Therefore, DIDP is likely to have a high accumulation potential in soil and sediments. Moreover all degradation data seem to indicate only primary degradation. The little evidence for mineralisation is supported by experimental data. No data are available on the most relevant metabolite (monoisodecylphthalate).

Due to lipophilicity and low depuration rate, DIDP has a high bioaccumulation potential in animals. A few experimental data on bioaccumulation of DIDP are available and conclusions are largely based on related compounds. Moreover, bioaccumulation of the major metabolite, MIDP, was not taken into account. The PECs are carefully calculated according to the TGD, at continental, regional and local level, taking into account different release scenarios. Very few monitoring data are available. In this case too, extrapolation from DEHP experimental data has been performed.

Effects assessment

Aquatic organisms

Acute toxicity effects were never observed on aquatic organisms at water saturation level of DIDP. Data on long term effects on fish exposed via water are not available on DIDP. Nevertheless, a large amount of information is available on long term effects on fish (including reproductive effects) for several C6-C11 phthalate esters. All these data seem to indicate no effects at solubility level. A two-generation feeding test on fish showed no effects on reproduction at a DIDP concentration in food of 20 mg/kg.

Due to the lack of reliable NOECs, a PNECwater was not calculated in the RAR, and the CSTEE agrees that with the available information a PNECwater cannot be estimated. Nevertheless, it is reasonable to assume that no effects on aquatic organisms exposed via water, are expected. However, this estimation does not cover aquatic organisms exposed via food, as included in the risk characterisation.

Tests on sediment dwelling invertebrates and on early life stage of amphibians (egg hatching, tadpole survival and malformations) gave no effects at the highest concentrations tested (3000 and 600 mg/kg dw respectively). Due to the lack of reliable NOECs, a PNECsediment was not calculated. The CSTEE also agrees that a PNECsediment cannot be estimated from the available data.

Terrestrial organisms

Short-term toxicity data are available for soil dwelling organisms. However, the derivation of a PNECsoil from short-term tests is not acceptable for this chemical, considering its long-term presence in the environment and its bioaccumulation potential. The CSTEE considers that long-term tests are required.

From mammalian studies a PNECoral of 50 mg/kg in food is calculated according to a NOAEL of 500 mg/kg. Nevertheless, a more restrictive NOAEL of 100 mg/kg has been suggested by the CSTEE (opinion on human health assessment). Therefore, a PNECoral of 10 mg/kg food should be assumed, with appropriate corrections for the daily food intake depending on the species.

Risk characterisation

Even if a PNECwater was not calculated, the CSTEE agrees with the conclusion that adverse effects on aquatic organisms exposed through water are unlikely.

A potential risk for fish exposed through contaminated food can be estimated from the data, but it has not been indicated in the RAR. A NOEC of 20 mg/kg food (feeding rate 5% body weight per day) may not be protective when compared to the estimated PECfish or measured concentrations in aquatic organisms, which are close to or higher than this NOEC.

For sediments maximum environmental concentrations approach or are similar to the highest tested concentrations in short-term sediment toxicity tests. Considering the high persistence in sediments and the scarce toxicity information, the CSTEE considers that a long-term risk for sediment dwelling organisms cannot be excluded, and therefore conclusion (ii) is not acceptable.

Due to the uncertainties in determining PEC and PNEC for soil and food chain, conclusion (ii) for the terrestrial ecosystem is not acceptable. Similarly, conclusion (ii) is not acceptable for the atmosphere. Additional information, and particularly long-term toxicity tests and proper model estimations for bioaccumulation and biomagnification are required.