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

Opinion on the results of the Risk Assessment of:

Bis (2-ethylhexyl) phthalate (DEHP)

CAS No.: 117-81-7

EINECS No.: 204-211-0

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 substances[1]

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

INTRODUCTION

Bis (2-ethylhexyl)phthalate (DEHP), as other similar chemicals, is mainly used as plasticiser in polymer industry. Production volume in EU is about 600,000 t/a (1997).

Major emissions (63 %) occur in the disposal phase of the life cycle or as a consequence of polymer use (30%). In both phases, the main compartment involved is soil (about 77%) and, only to a minor extent (21%) water.

It is a lipophylic, low soluble, non-volatile and relatively persistent chemical. Therefore, soil is the most exposed compartment.

GENERAL COMMENTS

The quality of the report is unbalanced in the different parts and chapters. Information on exposure and emission patterns is detailed and supported, tough some figures are surprising (see Specific Comments). On the contrary, for other aspects (physical-chemical properties, PEC calculation, effects assessment), even if a large amount of information is reported, many assumptions are not justified well enough or supported by experimental evidence.

As for other high molecular weight phthalates (DINP, DIDP), the relatively high persistency and the potential for bioaccumulation and biomagnification are reasons for concern. This is enhanced by the fact that the PECregional for surface water is comparable to the saturation solubility level, indicating the likelihood for a long time exposure for aquatic organisms. 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.

The CSTEE agrees with conclusion ii) referred to surface water environment exposed via water and to the atmospheric compartment.

The CSTEE agrees with conclusion i) for secondary poisoning in the aquatic environment, though in some cases it seems evident that there is a need for limiting the risk.

The CSTEE does not agree with conclusion ii) for sediments and terrestrial (soil) compartment, as well as for secondary poisoning in the terrestrial food chain. In many cases there is a need for limiting the risk, or at least for more information and for a more sound justification of unclear assumptions.

SPECIFIC COMMENTS

General substance information

In the literature there is a very large range of values for the physical-chemical properties most relevant for environmental fate assessment. The results of the literature survey reported in the RAR show differences of many orders of magnitude between minimum and maximum values for water solubility, vapour pressure and Kow.

The values selected seem reasonable, also in comparison with other phthalates. Nevertheless, the rationale for the choice is not sufficiently described and justified. The selection of these values is very important in the report. For example, the extremely low water solubility (3 μg/L) strongly affects the evaluation of the validity of aquatic toxicology tests, as well the calculation of PEC for secondary poisoning. The solubility figure was selected according to the recommendation of the review of Staples *et al.* (1997). It is worth to note that the value selected by Staples *et al.* is a theoretical one, based on QSAR, while experimental data are substantially different.

As a minor comment, the unit of vapour pressure at page 15 is wrong (kPa instead of Pa).

Exposure assessment

The emission chapters (chapter 2 and 3.1.1) are very detailed and well developed. Emissions seem carefully evaluated, even if some data are surprising. In particular, emissions from municipal landfill (table 3.1.1.4d) seem very low. It is worth to note that, due to the behaviour of DEHP in landfill, the report hypothesise a probable future increase of landfill emissions.

DEHP is classified as readily biodegradable. Nevertheless, according to some experimental data, the default figure assumed for mineralisation in STP (DT50 = 0.029 days) is probably too optimistic and must be taken with care.

The chemical is relatively persistent in aerobic soil and sediments and very persistent in anaerobic conditions.

There is no mention of the potential for environmental risk of the major metabolite, mono (2-ethylhexyl)phthalate (MEHP).

Due to its lipophilicity, DEHP has a high potential for bioaccumulation. Experimental data indicate higher BCF in aquatic invertebrates than in fish. BCF generally decrease at relatively high (above the selected solubility value) water concentrations. This seems to confirm the reliability of the selected solubility value.

Reliable experimental data in terrestrial invertebrates are not available. Some studies seem to indicate a slow metabolism and a potential for bioaccumulation. Therefore, the figure assumed for earthworms (BCF = 1) is not acceptable. In the absence of less controversial data, the calculated figure of BCF = 43 should be a more reasonable worst case.

For both aquatic and terrestrial environments, no attempts are made for assessing the potential for biomagnification.

PEClocal for surface water is based on the removal rate in STP. Even if the degradation rate is probably overestimated, high removal rates (>90%) are confirmed by experimental data.

According to EUSES, PEClocal ranging between 2.2 and 220 µg/L for surface water and between 21 and 2058 mg/kg (dry wt) sediments are calculated. It must be noted that highest levels for water are far above the selected water solubility.

Calculated PECregional are 2.2 µg/L and 33.7 mg/kg (dry wt) for surface water and sediments respectively.

These values are in reasonable agreement with a large amount of monitoring data available.

For soil, a PEC for agricultural soil has been calculated assuming that sludge from STP at the production sites is not distributed to agricultural soil. PECS for urban/industrial soil have been calculated only on a regional/continental basis.

Taking into account that major emissions of DEHP (79%) are on urban/industrial soil, a PEClocal is needed.

Calculation of PEC for secondary poisoning is questionable. For fish and zooplankton, PEC was calculated by applying the BCF to PEClocal s.w. assuming that the highest local water concentration does not exceed the selected solubility level (3 µg/L). Only for mussels is the calculated PEClocal used.

PEC for earthworm is calculated assuming the non acceptable BCF = 1.

Effects assessment

Aquatic organisms

It is difficult to assess the reliability of toxicity tests on aquatic organisms exposed via water due to the extremely low solubility (selected value 0.003 mg/L). From the high number of short and long term experiments reported for fish and Daphnia, it is reasonable to conclude that nor acute neither chronic effects were observed on aquatic organisms at the solubility level, even if a precise NOEC cannot be estimated.

Some effects observed in invertebrates at levels far above solubility are reasonably of physical nature and have negligible relevance in natural environments.

The results of some experiments on fish exposed via the diet are also reported. In these experiments end-points related to the potential endocrine-disrupting effect of DEHP were also measured (reproduction, sex ratio, steroid metabolism).

From a long-term experiment on Atlantic salmon, a NOEC of 60 mg/kg food (wet wt) has been calculated and used for risk assessment.

Nevertheless other data on cod indicate a NOEC of 10 mg/kg food (wet wt). No justifications are given for not using this value.

In the report a PNEC for secondary poisoning is not mentioned. Even assuming a factor of 10, a PNEC as low as 1 mg/kg (or 6 if the salmon value is used) should be calculated.

For invertebrates exposed via sediment, a NOEC of 780 mg/kg (dry wt) has been observed. It is not clear why this value was not used for calculating a PNEC. A PNEC=100 mg/kg (dry wt) based on frog egg experiments was used in the risk characterisation.

For micro-organisms in STP the calculated PNEC = 200 mg/kg is acceptable.

Terrestrial organisms

The results of a study on plants exposed via air indicate no effect at a foliar deposition of 8.75 $\mu g/cm^2$. It is questionable if the results of a study on topical application on insects may be considered as atmospheric exposure. Anyway, atmospheric exposure can be considered as not being relevant for such a low volatile chemical.

For soil exposure, NOEC of 130 mg/kg (dry wt) was derived from a 18 d seed germination test on plants and a NOEC of 1000 mg/kg (dry wt) was observed for 14 d toxicity to earthworms. Some controversial data are available on micro-organisms, but the calculation of a worst case NOEC of 300 mg/kg (dry wt) is acceptable.

Results of a study on topical application on insects also show low toxicity. However, it is questionable if a single dose test can be relevant for assessing chemicals with high potential of long term exposure.

On these bases, a PNECsoil = 13 mg/kg (dry wt) has been calculated, using an assessment factor of 10. The CSTEE cannot agree with this proposal. First, no chronic toxicity data on invertebrates are available, therefore a factor of 50 should be used, according to the TGD. Second, the exposure duration of the plant test is less than three weeks, while the persistence in soil is much higher.

Risk characterisation

Aquatic environment

A PEC/PNEC ratio for aquatic organisms exposed via water cannot be properly calculated due to the impossibility of precisely evaluating a PNEC. If the solubility limit of 3 µg/L could be confirmed on a more sound basis, the hypothesis of low concern for this exposure route could be accepted.

For the sediment compartment, PEC/PNEC>1 can be calculated for many local sites. This is also confirmed by some high values experimentally measured in sediments. Moreover DEHP is highly persistent in sediments, in particular in anaerobic conditions. Nevertheless, the report concludes that DEHP is not of concern for sediments and the previously selected PNEC is defined as unreliable, without any acceptable justification. Therefore conclusion ii) is unacceptable. It is the opinion of the CSTEE that there is a need for risk reduction measures for sediment dwelling organisms.

For secondary poisoning, even with the disputable assumptions in assessing PECs, the PEC/PNEC ratio is always above 1. It is the opinion of the CSTEE that there is a need for limiting the risk, though conclusion i) may also be accepted. Besides the proposed fish multi-generation study with exposure both via food and water, it is the opinion of the CSTEE that a proper model for the estimation of biomagnification should be developed.

Terrestrial environment

The CSTEE agrees with conclusion ii) for the atmospheric compartment. This conclusion is mainly based on the low relevance of the air compartment in the environmental fate of DEHP.

On the contrary, soil is the most relevant compartment, both for emissions and for environmental fate. For agricultural soil PEC/PNEC is often above 1, nevertheless, in this case too, the report supports the conclusion with a low reliability of PNEC. Therefore conclusion ii) is not acceptable.

For urban/industrial soil, where the major amount of DEHP is emitted, PEC/PNEC is calculated only on a regional/continental basis.

There is a need for a local risk characterisation, even if a local scenario is not available in the TGD for urban/industrial soils. A suitable scenario should be developed for calculating a PEClocal for urban/industrial soils.

Finally, even if the secondary poisoning is based on the unacceptable PEC on earthworms, PEC/PNEC >1 are calculated for some local sites. Notwithstanding these results, the report supports conclusion ii) based on the hypothesis that soil PEC are probably overestimated. Therefore the CSTEE does not agree wit this conclusion. There is a need for more information for a better assessment of soil PEClocal and for BCF in terrestrial invertebrates. Moreover, as for the aquatic environment, it is opinion of the CSTEE that a proper model for the estimation of biomagnification should be developed.