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SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS

SCHER

Opinion on

Risk Assessment Report on Benzyl butyl phthalate

Environmental Part

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during the 12th plenary of 4 July 2006

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1. BACKGROUND

Council Regulation 793/93 provides the framework for the evaluation and control of the risk of existing substances. Member States prepare Risk Assessment Reports on priority substances. The Reports are then examined by the Technical Committee under the Regulation and, when appropriate, the Commission invites the Scientific Committee on Health and Environmental Risks (SCHER) to give its opinion.

2. TERMS OF REFERENCE

On the basis of the examination of the Risk Assessment Report the SCHER is invited to examine the following issues:

(1) Does the SCHER agree with the conclusions of the Risk Assessment Report?

(2) If the SCHER disagrees with such conclusions, it is invited to elaborate on the reasons.

(3) If the SCHER disagrees with the approaches or methods used to assess the risks, it is invited to suggest possible alternatives.

3. OPINION

3.1 General Comments

The assessment is well done and follows the procedure recommended in the TGD. The fact that some of the data used in the assessment are not available to the SCHER presents some problems in the review of this RAR (as in several others). BBP is mainly used as a plasticizer in PVC, and especially for flooring materials used indoors, which makes the emission scenario rather special. The SCHER support the use of the emission scenario document for additives in plastics recently produced by OECD. There are relatively few monitoring data for BBP available, and the older may represent a time with higher use of this substance, and/or the awareness of the risk for contamination of samples may have been lower.

Several of the studies of aquatic effects have been performed with nominal concentrations above the solubility of BBP. Unless a properly measured concentration is given such studies should not be used in the assessment.

The SCHER supports the request for a long term study on reproductive and endocrine effects as several other phthalates have been suspected to cause effects on endocrine systems in wildlife (conclusion i)[1].

[1] *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.

The SCHER agrees with most of the conclusions drawn in the report, but thinks that the fact that the few measured concentrations in marine water should at least result in a request for more data (conclusion i).

The fast metabolic degradation of BBP makes it interesting to assess also the breakdown products. The primary metabolites monobutyl and monobenzyl phthalates seem to be as potent as the mother substance, and may even be responsible for the effects of BBP. This is well described in the exposure and effect parts of the RAR, but forgotten in the risk characterisation part. The same is true for the possible additive effects between BBP and DEHP.

3.2 Specific Comments

3.2.1 Exposure assessment

BBP is a large volume chemical and it is surprising how industry can give data for the vapour pressure that spread over four orders of magnitude. Fortunately there are several results reported that makes it possible to give a good estimate for this critical property.

There seems to be uncertainties regarding the production volumes of BBP. Industry estimates that the use in the EU 2004 was about 19500 tons, which is half of what was reported in the mid-90s. It is assumed that this reduction mainly is a result of the labelling T; R61-62 and R50-53. There may even be a further reduction in 2005, and one of the three producers is reported to have stopped the production. The assessment is based on the by industry estimated 2004 production, something that needs to be remembered when the uncertainty in the outcome of the assessment has to be judged.

BBP is mainly used as a plasticizer in PVC for flooring and in polysulfide sealants. The remaining 30 % is also mainly used in consumer products. The release of BBP from end products play an important role with this use pattern and human exposure is significant. For the environment the assessors are using an exposure scenario document from OECD on additives in plastics, a use that is supported by the SCHER. The emissions from sealants are not estimated, as “at least an estimate of the tonnage used for these products would be necessary”. The SCHER is of the meaning that a high estimate should then be used and the users would have to support better data if it is too high. The assessors identified a use of BBP in grouting agents mainly for sealing cracks in rocks, and the amount used in Norway corresponds to more than 100 kg/a, while the industry estimates the total use for this purpose in the EU to 50 kg/a.

The recently measured data on BBP in the environment agree reasonably well with the predicted regional concentrations. Some older monitoring data exceeds the predicted and may represent a time with higher production of the substance, but may also be due to difficulties to avoid background contamination of the samples. It has, however, to be kept in mind that many of the end products, especially the building materials, are being in use for a long time.

The bioaccumulation assessment is properly conducted. The measured BCFs are lower than predicted from Kow and a rapid metabolism is confirmed. The assessment is based on a conservative BCF obtained from total radioactivity which includes the metabolites.

3.2.2 Effect assessment

There are a number of toxicity data available for several aquatic organisms, including fish, invertebrates and algae. Several of the studies used in the assessment have been looking at

effects close to or above the solubility of BBP in the water phase. It is then pointed out in the report that those results should be "used with caution"; the SCHER would rather say that they should not be used unless the true concentration has been measured accurately. In Table 3.24 for example, a test has been regarded as valid although the resulting LC50 value is twice the water solubility.

The SCHER does not support the use of an additional factor of 10 for the derivation of the PNEC for marine organisms considering the available information and that the PNEC for aquatic organisms is already derived from a marine invertebrate.

Several phthalates have been suspected to have endocrine disruption effects in wildlife, and several studies with BBP have been performed. So far only weak effects have been seen, but a test on fish has been requested from industry. The final assessment of these effects has to await the outcome of that study.

Nevertheless, as the chronic fish study is essential in this particular case, no provisional PNECs should be derived as the TGD assessment factors may be insufficient to cover the endocrine related effects.

No data on sediment organisms are available and a PNEC for sediments is calculated by the equilibrium partition method. The approach is considered acceptable in this case, but in the PNEC calculation the assessors seem to have been using default values (from TGD) for suspension rather than sediment ($Fwater_{sed}$ = 0.8; $Fsolid_{sed}$ = 0.2).

Just one study has been available for the assessment of terrestrial effects, and this did not manage to identify an LC50 value as no effect could be seen at the highest dose.

No effect has been seen on plant growth even at air levels of almost 6 µg/m^3 and only a qualitative assessment could be performed for this medium.

In the assessment of secondary poisoning a reproduction study on rat has been used. The studied endpoint for that NOAEL should have been mentioned.

3.2.3 Risk characterisation

For the aquatic environment PEC/PNEC ratios over 1 was found for the processing/formulation of flooring plus a confidential use, while for the other assessed life cycle stages the ratio was below 1. This is not supported by the SCHER, which is of the meaning that no conclusions on aquatic organisms should be presented before the fish chronic assay becomes available. However, already for the marine environment the few measured data exceeds the present $PNEC_{marine}$ and this would according to the SCHER imply at least a request for further data (conclusion i).

The predicted concentrations of BBP in the atmosphere are below the highest tested level, which didn't give any effects. Several processing and formulation operations are assessed give cause for concern in the terrestrial environment, and the SCHER agrees with these conclusions.

The assessors have been using a conservative approach for the estimation of the bioaccumulation potential and suggests conclusion (ii) for secondary poisoning and that the chemical is not a PBT. Both aspects are acceptable.

4. LIST OF ABBREVIATIONS

BBP	Benzyl Butyl Phthalate
BCF	Bio Concentration Factor
DEHP	Diethylhexyl Phthalate
Kow	Octanol-Water Partition Coefficient
LC50	Median Lethal Concentration
NOAEL	No Observed Adverse Effect Level
OECD	Organisation for Economic Co-operation and Development
PBT	Persistence Bioaccumulation Toxicity
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
PVC	Polyvinyl Chloride
RAR	Risk Assessment Report
TGD	Technical Guidance Document

5. ACKNOWLEDGEMENTS

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