Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on 4-tert- Butylbenzoic acid (PTBBA)

Environmental Part

CAS No.: 98-73-7
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The SCHER adopted this opinion at its 23rd plenary on 6 May 2008

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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 RAR on 4-tert-butylbenzoic acid is of good scientific quality and is based on information available in open literature and confidential data supplied by industry. The confidential data used in the RAR was not accessible to the SCHER and as such the committee was not able to check most of the exposure calculations presented in the RAR. The SCHER assessment of the RAR on PTBBA is based on the assumption that the confidential data used are accurate and that the exposure calculations performed using these data are correct.

The SCHER notes that the risk assessment which was performed adhered to a large extent to TGD procedures and supports most of the assumptions used in the RAR.

The SCHER agrees with conclusion (ii)[1] for all environmental compartments proposed by the RAR.

3.2 Specific comments

3.2.1 Exposure assessment

Currently, there is no production of PTBBA in the EU (ceased in 2006). Eighty percent of the EU's annual market volume is used by about 30 costumers. The RAR states that the approximate EU market supply of PTBBA is in the range of 2000 to 4000 t/a. Two HPV-importers and one LPV-scale importer operate at this moment.

Based on the production- and use information provided by industry, the following exposure scenarios were discussed in the RAR:

- Production: not examined as production ceased in 2006

[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.

- Use as intermediate: not examined as this use (at one site) was terminated in 2007.
- Use as stabiliser in PVC (production of PTBBA metal salts): examined and environmental exposure assessed.
- Use as stabiliser in PVC (compounding and conversion): examined and environmental exposure assessed.
- Use as stabiliser in PVC (service life): examined and environmental exposure assessed.
- Use as stabiliser in PVC (disposal): examined and environmental exposure assessed.
- Use as modifier in resins (processing): not examined as it is assumed that the downstream uses of resins are not relevant for the environmental risk assessment.

The release estimations and the calculation of environmental concentrations were carried out using EUSES 2.0.3. The SCHER supports the use of this model for the exposure assessment of this compound.

PTBBA is expected to be present in the environment mainly as its ionic form p-tert-bytylbenzoate. This substance has a vapour pressure of 0.057 Pa (20°C), a water solubility of 47.1 and 12600 mg/l (at pH 4.3 and 7, respectively) and a log Kow of 3.4 (21°C). The chemical has a calculated atmospheric half-life of 6.3 days. As the substance has not functional groups which facilitate hydrolysis and no photo-degradation data in water are available, the abiotic degradation in water was assumed to be zero for exposure assessment purposes. Based on the available standard ready biodegradability tests, PTBBA was classified as not readily biodegradable in water. For soil and sediment no experimental studies were available and degradation was thus assumed to be zero in these compartments.

Based on these properties and using Level I Mackay modelling the RAR concludes that at an environmentally relevant pH, PTBBA mainly partitions into the water compartment (99.8%) and insignificant amounts of the substance end up in air, soil and sediment. The SCHER agrees with this conclusion.

Both the available experimental BCF data (between 1.1 and <4.6) and the calculated bioaccumulation values indicate that PTBBA has a low potential to bioaccumulate at environmentally relevant pHs. Consequently, the assessment of secondary poisoning was not conducted. The SCHER supports this conclusion.

As indicated, based on the site-specific information made available by industry, the PEC_{local} for the various environmental compartments were calculated for production (for information only, as EU production has ceased) and the various industrial/professional uses (cf. above). For the use as stabilisers in PVC (production of PTBBA metal salts), the PEC_{local} values (for the different sites) for water varied 0.14 to 1.52 mg/l (at pH 7) and from 0.13 to 1.39µg/kg for sediment. For the other uses, the calculated concentrations in the aquatic environmental were considerably lower. PEC_{local} for the terrestrial compartment and the atmosphere were 0.015 µg/kg (pH 7) and 1.65×10^{-5} $mg.m^{-3}$, respectively. For all compartments a comparison between predicted and measured concentrations of PTBBA was attempted but could not be performed due to the very limited availability of measured data. As mentioned above, the SCHER could not examine the accuracy of these PEC calculations as the use data were not presented in the RAR.

3.2.2 Effect assessment

A limited number of effect data for the aquatic environment is presented in the RAR. An appropriate validity evaluation was performed. Except for one species, all toxicity test results were based on nominal PTBBA concentrations. Valid acute effect concentrations

ranged from 4 (pH 5) to > 96 mg/l (pH 7). The PNEC for the (fresh) water compartment was calculated using an assessment factor of 1000: i.e. 4 µg/l at pH 5 and 33 µg/l at pH 7. Based on a respiration test with activated sludge a PNEC for micro-organisms of 32 mg/l was derived. As no experimental toxicity data with sediment and soil organisms was available, the PNEC for these compartments were calculated using the recommended (TGD) equilibrium partitioning method. The SCHER agrees with the PNECs for these compartments.

For the marine environment a PNEC of 3.3 µg/L is calculated (using the TGD procedure) by applying a factor of 10000 to a freshwater LC50 (lowest at pH). As indicated in previous opinions, the SCHER does not support this TGD procedure in absence of sufficient justification for the use of the additional factor (in comparison with those used for the freshwater environment).

3.2.3 Risk characterisation

SCHER notes that the RAR on 4-tert-butylbenzoic acid is partly based on confidential data supplied by industry. The confidential data used in the RAR was not accessible to SCHER and as such the committee was not able to check most of the exposure calculations presented in the RAR. The SCHER assessment and its conclusions on the RAR are based on the assumption that the confidential data used are accurate and that the exposure calculations performed using these data are correct.

For the aquatic environment, including sediments and STP, all PEC/PNEC values are below 1 (from 0.004 to 0.77 for the aquatic compartment and from 0.0001 to 0.0009 for the STP). Conclusion (ii) for production and the various uses is proposed in the RAR. SCHER supports these conclusions.

For the soil compartment all PEC/PNEC values are below 1 (0.01 to 0.0006). Conclusion (ii) for production and the various uses is proposed in the RAR. SCHER supports these conclusions.

For the atmospheric compartment, the RAR concludes that (due to the low volatility of PTBBA) emissions are not a relevant exposure route and thus proposes conclusion (ii). SCHER supports this conclusion.

For the marine compartment all PEC/PNEC values are below 1 (0.09 to 0.046). SCHER supports the conclusion (ii) proposed in the RAR.

Finally SCHER agrees with the conclusion that PTBBA does not meet the criteria for PBT chemicals.

4. LIST OF ABBREVIATIONS

BCF	Bio Concentration Factor
EUSES	European Union System for the Evaluation of Substances'
HPV	High Production Volume
LC50	Lethal Concentration for 50% of the test organisms
LPV	Low Production Volume
PBT	Persistent, Bioaccumulative and Toxic
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
PTBBA	4-tert-butylbenzoic acid
PVC	Polyvinyl chloride
RAR	Risk Assessment Report
STP	Sewage Treatment Plants
TGD	Technical Guidance Document