



Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on p-tert-butylphenol

Environmental Part

CAS No.: 98-54-4  
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The SCHER adopted this opinion at its 19<sup>th</sup> plenary on 20 September 2007

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Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

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### SCHER

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[http://ec.europa.eu/health/ph\\_risk/risk\\_en.htm](http://ec.europa.eu/health/ph_risk/risk_en.htm)

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**TABLE OF CONTENTS**

ACKNOWLEDGMENTS ..... 3

1. BACKGROUND..... 5

2. TERMS OF REFERENCE ..... 5

3. OPINION ..... 5

    3.1 General comments..... 5

    3.2 Specific comments..... 5

        3.2.1 Exposure assessment ..... 5

        3.2.2 Effect assessment ..... 6

        3.2.3 Risk characterisation..... 6

4. LIST OF ABBREVIATIONS..... 7

## 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 environmental part of the RAR on p-tert-Buthylphenol (ptBP) is of good quality and, in general, it is based on a sufficient amount of reliable information.

Major doubts are related to the possible endocrine disrupting potential of ptBP. The RAR underlines that uncertainty already exists and, therefore, there is a need for more information, in particular on the effects on fish. As a consequence, the RAR suggests that some of the conclusions must be taken as provisional.

It is opinion of the SCHER that, considering the need for more information on endocrine disruption effects in fish, the conclusion (ii)<sup>1</sup>, proposed as provisional in the RAR for some production sites cannot be accepted and should be substituted by conclusion (i).

The SCHER supports conclusion (iii) proposed for some production scenarios for aquatic and terrestrial compartments and for micro-organisms in WWTP.

### 3.2 Specific comments

#### 3.2.1 Exposure assessment

According to its physical-chemical properties, ptBP can be a potential contaminant of all major environmental compartments (water, air, soil, and biota). Some data on degradation are controversial, therefore conservative values (50 days in water, 90 days in soil, 0,4 days in air) are used in the RAR as a worst case. The SCHER supports this approach.

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<sup>1</sup> 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.*

Exposure has been assessed taking into account different phases of the life cycle: production, processing and uses.

Exposure from production has been calculated for the three European production sites by applying the TGD procedure to scenarios partially based on actual site-specific data.

The same has also been done for some processing sites, while for other sites default TGD scenarios have been applied.

Exposures from private uses and for disposal of ptBP containing products are assumed as negligible.

It is opinion of the SCHER that procedures for calculating continental, regional and local PECs are appropriate.

A comparison between monitoring data and calculated regional PEC for surface water shows a reasonable agreement.

A moderate bioaccumulation potential can be predicted according to physical-chemical properties. However, due to evidence of metabolism in living organisms, transfer in the trophic chain is unlikely.

### **3.2.2 Effect assessment**

Reliable acute data on three trophic levels and chronic data on two trophic levels are available. PNEC water was calculated by applying a factor of 50 on a NOEC for algae. An additional factor of 10 was applied for the marine environment.

For STP, a PNEC micro-organisms has been calculated from data on bacteria and protozoans. However, the RAR highlights the potential for endocrine disruption of ptBP and reports a review of available information on this topic. Most relevant points are the following:

- many alkylphenols are well known as potent estrogenic compounds;
- there is evidence for the estrogenic potency of ptBP *in vitro*, but little or no data is available *in vivo*;
- a pilot study on fish seems to confirm the hypothesis of endocrine disrupting effects, but the methodological approach used is not reliable.

In conclusion a high level of uncertainty is still present and the information available is not sufficient for calculating a PNEC. Therefore, an additional long term test on fish is required. The RAR proposes that the calculated PNEC water, based on traditional toxicity data, should be taken as provisional.

The SCHER does not support this position since a final PNEC should be calculated using reliable data on endocrine disrupting effects.

No data are available for other compartments.

For sediments, the equilibrium partitioning method was not applied. Being PEC calculated with the same approach, calculating a PEC/PNEC ratio is irrelevant, being the value the same as for water.

For soil, the equilibrium partitioning method was applied based on the PNEC for water. The PNEC for soil must be recalculated when a final PNEC for water will be available.

For the atmosphere, due to the negligible PEC air, PNEC calculation has been assumed as irrelevant. The SCHER supports this position.

### **3.2.3 Risk characterisation**

The risk characterization for the aquatic environment (freshwater and marine) is presented as provisional, due to doubts on endocrine disrupting effects, already

described. Therefore, conclusion (i) is proposed for endocrine disrupting potential. The SCHER supports this conclusion.

Using the provisional PNECs, in many production and processing sites PEC/PNEC values are lower than 1. For these sites conclusion (ii) is proposed as provisional. The SCHER does not support this conclusion. Conclusion (i) should be adopted in relation to the need for determining endocrine disruption potency.

Values higher than 1 were calculated for some of the sites where standard TGD scenarios were applied, since site specific information were not available. For some of these sites conclusion (i) was proposed, to allow a more refined exposure assessment.

For three sites conclusion (iii) is proposed, due to the very high PEC/PNEC values (28 to 121) and to the difficulties in getting more precise data for a refined PEC assessment.

Comparable conclusions are proposed for WWTP assessment.

For the soil compartment, a PEC/PNEC higher than 1 was calculated for all the scenarios where soil emission is possible. Therefore, conclusion (iii) is proposed.

For the atmosphere and for secondary poisoning, no risk characterisation is performed. However, conclusion (ii) is proposed, being atmospheric exposure and transfer in the trophic chain assumed as negligible, as explained above.

The SCHER supports these conclusions.

#### **4. LIST OF ABBREVIATIONS**

NOEC	No Observed Effect Concentration
PNEC	Predicted No Effect Concentration
PEC	Predicted Environmental Concentration
ptBP	p-tert-Buthylphenol
RAR	Risk Assessment Report
WWTP	Waste Water Treatment Plants
TGD	Technical Guidance Document