



Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8,-  
hexamethylcyclopenta- $\gamma$ -2-benzopyran (HHCB)

Environmental Part

CAS No.: 1222-05-5  
EINECS No.: 214-946-9



The SCHER adopted this opinion by written procedure on 16 May 2008

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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)

## **ACKNOWLEDGMENTS**

The rapporteur is acknowledged for his valuable contribution to this opinion:  
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Keywords: SCHER, scientific opinion, risk assessment, Regulation 793/93, 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylcyclopenta- $\gamma$ -2-benzopyran (HHCb), environment, CAS 1222-05-5

Opinion to be cited as:

SCHER, scientific opinion on the risk assessment report on 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylcyclopenta- $\gamma$ -2-benzopyran (HHCb), CAS 1222-05-5, environmental part, 16 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 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8,-hexamethylcyclopenta- $\gamma$ -2-benzopyran (HHCb) is of good quality and is based on a large amount of information on exposure and effects.

The SCHER agrees with most of the assumptions of the RAR, with a few exceptions, such as the proposed PNEC for the marine environment. However, the minor disagreements do not affect the final conclusions.

Therefore the SCHER agrees with conclusion (ii)<sup>1</sup> proposed by the RAR for all the assessments.

### 3.2 Specific comments

#### 3.2.1 Exposure assessment

European production of HHCb (only one production site) is between 1000 and 5000 tons/year, largely exported outside of Europe. European uses are less than 1500 tons/year, mainly as ingredient of fragrance materials.

Major emissions occur as a consequence of consumer use. Uses in southern Europe are substantially higher than in northern Europe, due mainly to the higher use of detergents.

The chemical is rapidly photo-degraded in the atmosphere (half-life 3.7 hours). In water and soil the parent compound disappears relatively rapidly, but with a low degree of mineralization. Conservative half-lives of 60 and 150 days have been used in the RAR for surface water and soil respectively.

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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.*

Results of predictive approaches for removal in sewage treatment plants are controversial. Extensive experimental monitoring data in STP effluents are available and are used for refining predicted concentrations.

Bioaccumulation experiments are available for fish and benthic invertebrates. Experimental BCFs are slightly lower or comparable to those predicted from log K<sub>ow</sub> indicating that biotransformation is moderate (fish) or absent (invertebrates).

Experimental data on terrestrial plants indicate that transport within the plant is negligible.

PECs are calculated for production, formulation and private use. The highest values are expected for use.

According to the TGD, a PEC<sub>local</sub> for surface water of 8.7 µg/L has been calculated. This value is considered as overestimated in the RAR, since predicted data in urban discharges (influent and effluent from STP) are substantially higher (more than one order of magnitude) than those measured in extensive monitoring campaigns in different northern and southern European countries. Therefore PEC was recalculated by applying the TGD procedure to the 90 percentile of experimental monitoring data. On these bases, PEC<sub>local</sub> for surface water of 0.49 and 0.14 µg/L are proposed for southern and northern EU respectively. The highest value is proposed for the risk assessment.

A large amount of experimental monitoring data is available. Being uses decreasing since 1995, data measured after 2000 are assumed as more reliable for the comparison. All these experimental data are comparable, as order of magnitude, and are always lower than the proposed PEC.

It is opinion of the SCHER that the proposed PEC<sub>local</sub> for surface water, not derived by applying the TGD procedure, must be considered with care. In particular, the use of the 90 percentile of monitoring data *implies* that the 10% of cases could be not adequately protected. This is particularly relevant if related to private use, affecting all water bodies receiving municipal discharges. In the present assessment, considering the large amount of monitoring data available and taking into account that the difference between the 90 percentile and the maximum measured value is small (differing by a factor lower than 1.5), it is opinion of the SCHER that the proposed PEC can be used for risk characterisation. However, it should not be assumed as a precedent and it must be underlined that procedures deviating from the TGD have to be carefully considered case by case.

On the same bases, a PEC<sub>local</sub> for sediments of 0.262 mg/kg ww (1.21 mg/kg dw) is proposed. It is opinion of the SCHER that the calculation of PEC for sediment is appropriate.

For the terrestrial compartment, emissions derive from sludge application on soil and atmospheric deposition. A PEC<sub>local</sub> for soil of 0.06 mg/kg ww is calculated. In this case too, all available experimental data are below the proposed PEC. It is opinion of the SCHER that the proposed PEC is acceptable.

A PEC<sub>local</sub> for air ranging from 3.8 (northern Europe) and 14.5 (southern Europe) ng/m<sup>3</sup> is calculated. A reasonable agreement was found with available experimental data. It is opinion of the SCHER that the proposed PEC is acceptable.

For secondary poisoning, a PEC was calculated for fish and earthworm. The proposed PEC<sub>fish</sub>=0.41 mg/kg ww is in good agreement with a large database of experimental data. No experimental data are provided for confirming the calculated PEC<sub>worm</sub>=0.14 mg/kg ww. It is opinion of the SCHER that the proposed PECs for secondary poisoning are acceptable.

PECs are also calculated for marine water and sediments, as well as for secondary poisoning in marine predators. It is opinion of the SCHER that the proposed PECs for the marine environment is acceptable.

### 3.2.2 Effect assessment

For aquatic organisms a PNEC<sub>water</sub> = 4.4 µg/L is calculated by applying a factor of 10 to reliable long term data on algae, crustaceans and fish.

Long term data on three taxonomic groups are also available for sediment dwelling organisms. A PNEC<sub>sediment</sub> = 2.0 mg/kg dw is calculated. It is more conservative than those calculated, for comparison, using the equilibrium partitioning method (10.9 mg/kg dw).

Tests on aquatic bacteria are not available. However, from degradation tests inhibitory effects were not observed at levels one order of magnitude higher than water solubility. A PNEC<sub>stp</sub> > 2 mg/l is proposed.

The SCHER agrees with the PNEC proposed for the freshwater environment.

For the marine environment a PNEC of 0.44 µg/L is calculated by applying a factor of 100 instead of 10 to long term NOEC, according to the TGD. However, the SCHER disagrees with the TGD procedure in absence of enough justification for supporting the application of the additional factor. Moreover, the EC10 on the marine crustacean *Acartia tonsa* is comparable to NOEC on *Daphnia*, an additional reason for not supporting the need for a higher factor. Therefore, the SCHER does not support the proposed PNEC for the marine environment.

No data are available for terrestrial plants and soil microorganisms. A PNEC<sub>soil</sub> = 0.31 mg/L is based on two long term data on soil invertebrates, by applying a factor of 50 to the lowest NOEC. It is more conservative than those calculated, for comparison, using the equilibrium partitioning method (1.54 mg/kg dw). The SCHER agrees with the proposed PNEC<sub>soil</sub>.

No data are available for air exposure. So a PNEC<sub>air</sub> cannot be calculated.

Due to the lipophilicity of HHCb, secondary poisoning is possible. A conservative PNEC<sub>coral</sub> = 3.33 mg/kg food is calculated from data from the Human Health part.

From a series of *in vitro* and *in vivo* studies, endocrine effects were not observed.

### 3.2.3 Risk characterisation

For the aquatic environment, including sediments and STP, all PEC/PNEC values are below 1. Therefore, conclusion (ii) for production, formulation and private use is proposed. In particular, for private use, PEC/PNEC = 0.11. This value confirms that, notwithstanding the concern about the procedure for calculating PEC, the proposed value can be assumed as sufficiently protective. Therefore, the SCHER agrees with this conclusion.

For the soil compartment all PEC/PNEC values are below 1. Therefore, conclusion (ii) for production, formulation and private use is proposed. The SCHER agrees with this conclusion.

For the atmospheric compartment, since it was not possible to calculate a PNEC, risk characterisation has not been performed. Due to the low PEC in air, the short half life, and the relatively low toxicity of the chemical, it is opinion of the SCHER that additional tests are not required. However, a provisional risk characterisation should be performed using inhalation studies from the human health assessment, if available.

For the secondary poisoning all PEC/PNEC values are below 1, both for aquatic (fish) and terrestrial (earthworm) environment. Therefore, conclusion (ii) for production, formulation and private use is proposed. The SCHER agrees with this conclusion.

For the marine environment all PEC/PNEC values are below 1. Therefore, conclusion (ii) for production, formulation and private use is proposed.

The SCHER does not agree with the proposed PNEC for marine environment. However, a less conservative PNEC would not affect risk characterisation. Therefore, the SCHER agrees with conclusion (ii).

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

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

BCF	Bio Concentration Factor
HHCb	1,3,4,6,7,8-hexahydro-4,6,6,7,8,8,-hexamethylcyclopenta- $\alpha$ -2-benzopyran
NOEC	No Observed Effect Concentration
PBT	Persistent, Bioaccumulative and Toxic
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
RAR	Risk Assessment Report
STP	Sewage Treatment Plants
TGD	Technical Guidance Document