



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- γ -2-BENZOPYRAN
(HHCb)
Human Health Part (indirect exposure)

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



The SCHER adopted this opinion at its 23rd plenary on 6 May 2008

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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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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

SCHER had previously commented on the Risk Assessment Report for 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta- γ -2-benzopyran (HHCB). SCHER agreed with the conclusions regarding hazard assessment and risk assessment made. However, in the previous RAR, risk assessment for humans exposed via the environment was not performed since the RAR covering the environmental aspects of HHCB was not completed. This opinion now addresses the risk assessment for indirect exposures via the environment.

3.2 Specific comments

3.2.1 Exposure assessment

The RAR considers exposure with food, drinking water and human milk as potential relevant pathways. SCHER agrees with this assessment and also agrees that inhalation is not a relevant exposure pathway due to very low concentrations of HHCB in ambient air. Food and water exposure assessment is performed by using EUSES and total daily intake of HHCB is estimated as 2.6 $\mu\text{g}/\text{kg}$ bw per day for the local scenario and 0.097 $\mu\text{g}/\text{kg}$ bw per day for the regional scenario. Exposure assessment for infants regarding uptake with mothers milk has been addressed in the RAR in July of 2006.

3.2.2 Effect assessment

No new information besides that already reviewed by SCHER was available.

3.2.3 Risk characterisation

The risk characterization performed in the RAR uses the MOS approach and is performed for oral exposures with food and water for adults and for breast-fed babies. For adults, the MOS regarding combined exposures and repeated dose toxicity are very high and SCHER therefore agrees with conclusion ii)¹. Conclusion ii) is also supported regarding

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*

mutagenicity and carcinogenicity since HHCB is non-genotoxic. An additional reference to 4.1.3.4.2, reproductive toxicity, may help to clarify which toxicity studies were used as basis to derive an MOS of 106 based on the maximal combined exposure of app. 0.1 mg/kg bw/day and to give a better justification for the selected minimal MOS of 50. However, SCHER agrees with conclusion ii) for reproductive and developmental effects since a conservative assessment of hazard and exposures gives a MOS slightly above 100. SCHER suggests including a table with an overview of estimated exposures, NOAELs for the toxicity endpoints relevant to the risk assessment, and derived MOS-values.

4. LIST OF ABBREVIATIONS

EUSES	European Union System for the Evaluation of Substances
MOS	Margin of Safety
NOAEL	No Observed Adverse Effect Level
RAR	Risk Assessment Report