EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Scientific Committee on Health and Environmental Risks

SCHER

Opinion on

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

CAS No: 1222-05-5
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Scientific Committees
on consumer products
on emerging and newly identified health risks
on health and environmental risks

The SCHER adopted this opinion at its 22nd plenary on 12 March 2008

About the Scientific Committees

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.

They are: the Scientific Committee on Consumer Products (SCCP), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Evaluation Agency (EMEA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCHER

Questions relating to examinations of the toxicity and ecotoxicity of chemicals, biochemicals and biological compound whose use may have harmful consequences for human health and the environment.

In particular, the Committee addresses questions related to new and existing chemicals, the restriction and marketing of dangerous substances, biocides, waste, environmental contaminants, plastic and other materials used for water pipe work (e.g. new organics substances), drinking water, indoor and ambient air quality. It addresses questions relating to human exposure to mixtures of chemicals, sensitisation and identification of endocrine disrupters.

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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 health part of the document is of good quality, it is comprehensive, and the exposure and effects assessment follow the Technical Guidance Document. The RAR covers all studies relevant for exposure and hazard assessment of 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta-γ-2-benzopyran (HHCB).

3.2 Specific comments

3.2.1 Exposure assessment

HHCB is a synthetic fragrance compound which is widely used.

Regarding occupational exposure assessment, the RAR develops four scenarios and performs a detailed exposure assessment for each of the scenarios. Exposures by dermal contact and by inhalation are assessed by a combination of modelling, measured data on air concentrations of HHCB, and air concentrations of chemicals with similar physico-chemical properties.

Consumer exposure assessment also develops probable scenarios for inhalation and dermal exposures to HHCB based on modelling and concentrations of HHCB in products. Indirect exposures are assessed by modelling supported by a small number of measured data.

3.2.2 Effect assessment

The RAR describes all toxicity studies performed with HHCB in sufficient detail. Regarding repeated-dose toxicity, a number of studies are available for evaluation and SCHER agrees with NOAELs derived from the evaluation of these studies.

Regarding toxicokinetics, SCHER agrees with the derived 50 % absorption factor for HHCB after oral uptake, the default use of 100 % absorption after inhalation and the 5 % absorption allocated to dermal exposures in humans. Based on the available data, no concern regarding skin irritation and skin sensitisation is derived and SCHER agrees with these conclusions.

SCHER also agrees that there is no concern regarding carcinogenicity since HHCB is uniformly negative in the large number of available genotoxicity studies and the absence of structural alerts in the molecule.

3.2.3 Risk characterisation

The risk characterization performed in the RAR uses the margin-of-safety (MOS) approach. The SCHER agrees with conclusion ii)[1] for all scenarios.

The SCHER also agrees with conclusion ii) regarding carcinogenicity and mutagenicity and conclusion ii) regarding reproductive toxicity due to large MOS. However SCHER questions the use of a minimum MOS of 50 regarding reproductive toxicity assessment. The default MOS of 100 should be applied.

4. LIST OF ABBREVIATIONS

MOS	Margin of Safety
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
RAR	Risk Assessment Report
TGD	Technical Guidance Document

[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.