Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on 1-(5,6,7,8-tetrahydo-3.5.56.8.8-hexamethyl-2-naphthyl)ethan-1-one (AHTN)

Human Health Part

CAS No.: 1506-02-1
EINECS No.: 216-133-4

The SCHER adopted this opinion at its 19th 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

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-(5,6,7,8-tetrahydo-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one (AHTN), human health, CAS 1506-02-1

Opinion to be cited as:

SCHER, scientific opinion on the risk assessment report on 1-(5,6,7,8-tetrahydo-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one (AHTN), CAS 1506-02-1), human health part, 20 September 2007

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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-(5,6,7,8-tetrahydo-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one.

3.2 Specific comments

3.2.1 Exposure assessment

The RAR considers inhalation of AHTN dusts and vapour and dermal exposures as relevant for the occupational exposure scenarios. The occupational exposure assessment develops four scenarios based on industrial use patterns for AHTN. Occupational exposure by inhalation is in part based on measured data, in part on modelling; dermal exposures are mainly assessed based on modelling using EASE. For most of the scenarios, both dermal and inhalation exposures are predicted to be low.

Consumers will be exposed to AHTN due to its use as a fragrance in perfumes and body care products. The RAR develops two scenarios for consumer exposures to AHTN by dermal contact and by inhalation integrating concentrations of AHTN in these products and information on use patterns and reasonable worst case assumptions. Based on the calculations, dermal uptake is much more relevant as compared to inhalation for consumers.

Indirect exposures from the environment will be assessed after completion of the environment part. The SCHER agrees with this approach.

3.2.2 Effect assessment

The ADME-data available cover dermal, oral, and intravenous application in rodents and a study in humans after dermal application. For risk characterisation, the RAR assumes 100 % absorption after inhalation, 50 % after oral absorption, and 4.1 % after dermal application with adequate justification. The SCHER supports the use of these conclusions in the risk characterisation.

SCHER also agrees that AHTN should not be considered as an eye or skin irritant. A potential for photo-irritation is indicated based on animal studies. Based on the results of human studies, AHTN also should not be regarded as a skin sensitizer.

Regarding repeated dose toxicity study, dermal and oral studies with application periods from 28 days to 90 days were available for evaluation. AHTN gavage in doses of up to 50 mg/kg bw/day for 90 days caused some changes in blood clinical chemistry and haematology with an NOAEL of 5 mg/kg bw/day. SCHER agrees with this evaluation and also supports the conclusions on the 13-week dermal studies which are not used in the risk assessment due to many limitations (unoccluded application, limited reporting).

Genotoxicity studies with ANHT in bacteria and mammalian cells and an in vivo mouse micronucleus test were consistently negative. The SCHER agrees that AHTN should not be considered as genotoxic and also supports the conclusion on absence of carcinogenicity.

Regarding reproductive and developmental effects, the SCHER agrees with the conclusion of an overall NOAEL of 20 mg/kg bw/day for developmental toxicity used in the risk characterisation.

3.2.3 Risk characterisation

The risk characterization performed in the RAR uses the margin-of-safety (MOS) approach and is performed for inhalation and dermal exposures.

The SCHER agrees with conclusions iii)[1] for some of the occupational exposure scenarios regarding dermal exposures and photo-irritation. In the opinion of SCHER, conclusion iii) results in adequate worker protection and will mandate the use of protective equipment.

The SCHER also supports conclusion ii) for all other endpoints in the occupational exposure assessments and in consumers exposures due to high MOS as delineated in the RAR.

4. LIST OF ABBREVIATIONS

LOAEL	Lowest Observed Adverse Effect Level
LOAEC	Lowest Observed Adverse Effect Concentration
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.*