



Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on 1-(5,6,7,8-tetrahydro-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one (AHTN)  
Human Health Part (indirect exposure)

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



The SCHER adopted this opinion at its 23<sup>rd</sup> plenary on 6 May 2008

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Prof. W. Dekant Universität Würzburg, Germany

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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 ..... 5

        3.2.3 Risk characterisation..... 5

4. LIST OF ABBREVIATIONS..... 6

## **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 RAR for 1-(5,6,7,8-tetrahydro-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one (AHTN). 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 AHTN 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, 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 AHTN in ambient air. Food and water exposure assessment is performed by using EUSES and total daily intake of AHTN is estimated as 1.8 µg/kg bw per day for the local scenario and 0.012 µg/kg bw per day for the regional scenario. Exposure assessment for infants regarding uptake with mothers milk is based on comparison of concentrations of AHTN in human milk samples and milk uptake by infants of different ages.

#### **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 with mothers milk in infants. For adults, the MOS regarding repeated dose toxicity and reproductive toxicity are very high and SCHER therefore agrees with conclusion ii). Conclusion ii) is also supported regarding mutagenicity and carcinogenicity since AHTN is non-genotoxic. The detailed assessment of infant exposures with mothers milk also gives MOEs of at least 1000 and conclusion

ii)<sup>1</sup> is therefore supported by SCHER. The detailed assessment derives actual doses received by infants with mothers milk and compares these doses with the doses received by lactating rat pups in a postnatal developmental toxicity study which did not show effects on pups at doses 3 order of magnitudes above those predicted for infants.

#### 4. LIST OF ABBREVIATIONS

AHTN	1-(5,6,7,8-tetrahydro-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one
EUSES	European Union System for the Evaluation of Substances
MOE	Margin of Exposure
MOS	Margin of Safety
NOAEL	No Observed Adverse Effect Level
RAR	Risk Assessment Report

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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*