EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on 6-acetyl-1,1,2,4,4,7-hexamethyltertraline (AHTN)

Environmental Part

CAS No.: 1506-02-1
or 21145-77-7

EINECS No.: 216-133-4
or 244-240-6

Scientific Committees
on consumer products
on emerging and newly identified health risks
on health and environmental risks

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

Scientific Committee members

Herman Autrup, Peter Calow, Wolfgang Dekant, Helmut Greim, Wojciech Hanke, Colin Janssen, Bo Jansson, Hannu Komulainen, Ole Ladefoged, Jan Linders, Inge Mangelsdorf, Marco Nuti, Anne Steenhout, Jose Tarazona, Emanuela Testai, Marco Vighi, Matti Viluksela

Contact:

European Commission
Health & Consumer Protection DG
Directorate C: Public Health and Risk Assessment
Unit C7 - Risk Assessment
Office: B232 B-1049 Brussels

Sanco-Sc8-Secretariat@ec.europa.eu

The opinions of the Scientific Committees present the views of the independent scientists who are members of the committees. They do not necessarily reflect the views of the European Commission. The opinions are published by the European Commission in their original language only.

http://ec.europa.eu/health/ph_risk/risk_en.htm

ACKNOWLEDGMENTS

The rapporteur is acknowledged for his valuable contribution to this opinion:

Prof. M. Vighi University of Milano Bicocca, Italy

Keywords: SCHER, scientific opinion, risk assessment, Regulation 793/93, 6-acetyl-1,1,2,4,4,7-hexamethyltertraline (AHTN), environment, CAS 1506-02-1 or 21145-77-7

Opinion to be cited as:

SCHER, scientific opinion on the risk assessment report on 6-acetyl-1,1,2,4,4,7-hexamethyltertraline (AHTN) (CAS 1506-02-1 or 21145-77-7), environmental part, 16 May 2008.

TABLE OF CONTENTS

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 AHTN (6-acetyl-1,1,2,4,4,7-hexamethyltertraline) 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)[1] proposed by the RAR for all the assessments.

3.2 Specific comments

3.2.1 Exposure assessment

European production of AHTN (only one production site) is between 1000 and 5000 tons/year, largely exported outside of Europe. European uses, mainly as ingredient of fragrance materials, are a few hundreds of tons/year, substantially decreasing after 1995 and, in particular, after 2000.

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 7.3 hours). From several tests on degradation in water and soil the compound has been defined as inherently biodegradable, but with a low degree of mineralization. Conservative half-lives

[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.*

of 150 and 365 days have been used in the RAR for surface water and soil-sediments respectively.

Half life in STP is less than 1 day.

Bioaccumulation experiments are available for fish and benthic invertebrates. Experimental BCFs in fish are substantially lower than those predicted from log Kow indicating biotransformation. In invertebrates different results have been obtained indicating the metabolism is active in some cases (e.g. *Chironomus*) and practically absent in others such as aquatic and terrestrial Annelids (e.g. *Lumbriculus*). A BCF=597 is proposed for fish and a BCF=3015 for earthworm.

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 PEClocal for surface water of 2.02 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 data. On these bases, PEClocal for surface water of 0.13 and 0.053 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 always lower than the proposed PEC.

It is opinion of the SCHER that the proposed PEClocal 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 of about 1.8), 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 PEClocal for sediments of 0.086 mg/kg ww (0.395 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 PEClocal for soil of 0.027 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 PEClocal for air ranging from 1.7 (northern Europe) and 3.7 (southern Europe) 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 PECfish=0.628 mg/kg ww is proposed, in good agreement with a large database of experimental data. No experimental data are provided for confirming the calculated PECworm=0.071 mg/kg ww. It is opinion of the SCHER that the proposed PECs 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 are acceptable.

3.2.2 Effect assessment

Reliable long term tests are available for freshwater algae, *Daphnia* and fish and for the marine crustacean *Acartia tonsa*. A PNECwater = 2.8 μg/L is calculated by applying a factor of 10 to the long term NOEC on *Acartia tonsa*.

Long term data on three taxonomic groups are also available for sediment dwelling organisms. A PNECsediment = 1.72 mg/kg dw is calculated. It is more conservative than those calculated, for comparison, using the equilibrium partitioning method (8.42 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 PNECstp > 3 mg/l is proposed.The SCHER agrees with the PNEC proposed for the freshwater environment.

For the marine environment a PNEC of 0.28 μg/L is calculated by applying a factor of 100 instead of 10 to long term NOEC on *Acartia tonsa*, 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 NOEC on *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 PNECsoil = 0.31 mg/L dw is based on two long term data on soil invertebrates, by applying a factor f 50 to the lowest NOEC. It is more conservative than those calculated, for comparison, using the equilibrium partitioning method (1.84 mg/kg dw). The SCHER agrees with the proposed PNECsoil.

No data are available for air exposure. So a PNECair cannot be calculated.

Due to the lipofilicity of AHTN, secondary poisoning is possible. A conservative PNECoral=1.1 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 = 0.05. This value confirms that, notwithstanding the concern about the procedure for calculating PEC, the proposed value can be assumed as enough 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, being impossible the calculation of a PNEC, risk characterisation has not been performed. Due to the low PEC in air and the short half life 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 AHTN does not meet the criteria for PBT chemicals.

4. LIST OF ABBREVIATIONS

AHTN	6-acetyl-1,1,2,4,4,7-hexamethyltertraline
BCF	Bio Concentration Factor
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