Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on Methenamine

Environmental Part

CAS No.: 100-97-0
EINECS No.: 202-905-8

The SCHER adopted this opinion at its 15th plenary on 30 January 2007

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 RAR is of sufficient quality, but it is biased by a substantial lack of information, in particular on data needed for a proper exposure assessment.

Some assumptions about degradation in water are not supported by sufficiently reliable information and cannot be endorsed by the SCHER.

However, taking into account the properties of the compound and its extremely low toxicity, and considering that exposure assessment has been based on worst case default scenarios, it is opinion of the SCHER that additional information is not necessary.

Therefore, the SCHER agrees with Conclusion (ii)[1] proposed for all environmental compartments.

3.2. Specific comments

3.2.1. Exposure assessment

Methenamine is a compound characterised by very high water solubility, moderate volatility and low Henry's constant, extremely low lipophilicity. Therefore water is the main compartment of concern.

Atmospheric half life is lower than one hour.

Persistence in water is more controversial. Methenamine is hydrolysed in a few hours in acidic conditions. Quantitative data are available up to pH 5.8. At higher pH values

[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.

hydrolysis decreases but no quantitative data are available. Several biodegradation tests are mentioned in the RAR, but all are methodologically weak, so reliable information on biodegradation is not available. Apparently, the compound is relatively persistent, with a half life probably in the order of some weeks. In the RAR a half life of 15 days is proposed as a realistic worst case, as a result of combined hydrolysis and biodegradation. It is opinion of the SCHER that this assumption is not adequately supported by the available information.

Major metabolites are formaldehyde and ammonia, which are more toxic than the parent compound. This is addressed in the RAR (see hereunder).

No reliable data were provided on local releases from production and processing sites. Therefore the standard scenarios proposed by the TGD, with several worst case assumptions, were applied for calculating continental, regional and local (for production, processing and formulation) PECwater.

The few data available from experimental monitoring close to emission sites are in reasonable agreement with calculated values.

Not enough data were available for the calculation of PECair and PECsoil. However, due to the properties of the substance and to emission patterns, exposure in these compartments is assumed as negligible. It is opinion of the SCHER that this assumption is acceptable.

3.2.2. Effect assessment

Aquatic compartment

Toxicity data are available for some species of fishes, invertebrates and algae in fresh and brackish water. For all the species the toxicity of methenamine is very low, with LC/EC50 of several g/L. The most sensitive organisms are algae with a 14d EC50 (growth rate reduction) of 3 g/L. Even if such a long term test is unusual for algae, it was performed with a EPA acceptable procedure and the value is reliable.

From these data, a PNECwater of 3 mg/L is calculated.

The toxicity of the main metabolites, formaldehyde and ammonia, is well studied and known. The RAR provides some general indicative ecotoxicity values of these substances, which are in the mg/L order. In the RAR there is no mention about the pH dependence of ammonia toxicity, being non-ionised ammonia (NH_3) the most toxic form. Relatively high concentrations of NH_3 are present at basic pH values, corresponding to slower hydrolysis of methenamine.

The RAR concludes that, in particular for formaldehyde, emissions should be included in a specific risk assessment for this compound. However, it is assumed that the contribution of methenamine degradation to total formaldehyde concentrations is negligible. Similar assumptions are proposed for ammonia. It is opinion of the SCHER that these assumptions are acceptable.

No toxicity data are available for sediment dwelling organisms. Due to the low affinity of the chemical to sediments, these data are assumed as irrelevant.

No effect has been observed on microorganisms. Even if the tests were not performed with standard procedures and are not suitable for a proper PNEC calculation, a tentative PNECwwtp of 100 mg/L is proposed, based on the NOEC for nitrifying bacteria.

Soil and atmospheric compartments

No toxicity data are available for these compartments. However, due to the properties of the chemical, these data are assumed as irrelevant.

Secondary poisoning

Bioaccumulation potential and secondary poisoning can be excluded for methenamine.

3.2.3. Risk characterisation

Aquatic compartment

PEC/PNEC values for production, processing and formulation are far below 1.

It must be taken into account that exposure was calculated by applying default worst case scenarios.

Therefore the SCHER agrees with conclusion (ii) for the aquatic compartment.

Soil compartment, atmosphere and secondary poisoning

The SCHER agrees with conclusion (ii).

4. LIST OF ABBREVIATIONS

NOEC	No Observed Effect Concentration
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
RAR	Risk Assessment Report
TGD	Technical Guidance Document
WWTP	Waste Water Treatment Plant