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Directorate C - Public Health and Risk Assessment
C7 - Risk assessment

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SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS

SCHER

Opinion on

"Risk Assessment Report on Trisodium nitrilotriacetate Environmental Part"

CAS No.: 5064-31-3

EINECS No.: 225-768-6

Adopted by the SCHER
during the 2nd plenary meeting of 14 December 2004

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 (RAR) 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

(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. GENERAL COMMENTS

The environmental part of the draft RAR is of good quality. The risk assessment procedures proposed by the TGD are applied correctly and are based on a suitable amount of information on the most relevant issues.

Therefore the SCHER agrees with conclusion ii)[1].

This conclusion is supported by the low persistency, relatively low toxicity and absence of bioaccumulation potential of Na_3NTA.

Nevertheless, due to the peculiar properties of this compound (in particular its chelating capacity for metals and micronutrients), a too rigid application of the TGD could produce a misinterpretation of some results. However, in this case these properties have been taken into account appropriately and do not affect the conclusion of the report.

4. SPECIFIC COMMENTS

4.1. Exposure assessment

NTA is rapidly degradable, but complexation with metal ions can reduce degradation constant.

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[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.

This effect is particularly relevant for mercury. However, complex species can be transformed into more degradable forms by metal exchange reactions.

For NTA there is enough experimental evidence demonstrating mineralisation in treatment plants, natural waters and soil. The degradation rates assumed for the exposure assessment can be assumed as conservative.

Besides problems due to direct exposure to the chemical, compounds like NTA my produce environmental effects due to the potential of mobilisation of metals.

In the case of NTA there is enough experimental evidence to conclude that, at the concentrations likely to occur in water soil and sediments, this effect is not relevant.

4.2. Effect assessment

Effects on algal growth can be misinterpreted due to complexation of micronutrients inducing lower bioavailability and growth limitation. Therefore algal growth data must be evaluated with care. This problem has been properly taken into account in the report.

A PNEC of 0.93 mg/L has been calculated, for the aquatic environment, by applying a factor of 10 to a series of reliable NOECs available for fish, invertebrates and algae. The validity of the PNEC is also confirmed by the results of experimental pond studies.

The lack of data on terrestrial organisms can be assumed as non relevant due to the extremely low PECs in soil and air.

4.3. Risk characterisation

Calculated local PEC/PNEC ratios are usually far below the value of 1. The highest figure (0.54) refers to textile cleaning use.

Therefore a risk for the aquatic environment can be excluded.

5. LIST OF ACRONYMS AND ABBREVIATIONS

Na_3NTA	Trisodium nitrilotriacetate
NOEC	No Observed Effect Concentration
NTA	Nitrilotriacetate
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
RAR	Risk Assessment Report
TGD	Technical Guidance Document

6. ACKNOWLEDGEMENTS

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