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SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)

Opinion on the results of the Risk Assessment of:

ETHYLENEDIAMINE TETRAACETATE (EDTA)

CAS N°: 60-00-4

EINECS N°: 200-449-4

ENVIRONMENTAL PART

Carried out in the framework of Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances[1]

Adopted by the CSTEE during the 39th plenary meeting of 10 September 2003

[1] Regulation 793/93 provides a systematic framework for the evaluation of the risks to human health and the environment of those substances if they are produced or imported into the Community in volumes above 10 tonnes per year. The methods for carrying out an in-depth Risk Assessment at Community level are laid down in Commission Regulation (EC)1488/94, which is supported by a technical guidance document.

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Terms of Reference

In the context of Regulation 793/93 (Existing Substances Regulation), and on the basis of the examination of the Risk Assessment Report the CSTEE is invited to examine the following issues:

(1) Does the CSTEE agree with the conclusions of the Risk Assessment Report

(2) If the CSTEE disagrees with such conclusions, the CSTEE is invited to elaborate on the reasons for this divergence of opinion.

GENERAL COMMENTS

EDTA is a complex chemical, likely to occur in the environment in different chemical forms and producing several reactions with other environmental chemicals. The environmental part of the document is of good quality and all these aspects of the complex behaviour of EDTA are taken into account.

Nevertheless, it is the opinion of the CSTEE that some of the conclusions, even if based on a proper application of the TGD procedures, are the result of the application of very conservative worst case assumptions, probably not completely realistic. In particular, PECs in surface water seem to be overestimated and not in agreement with most experimental monitoring data available.

It is opinion of the CSTEE that conclusion iii) for some use emissions in the aquatic environment should be accepted as preliminary and more information should be provided for a better assessment of exposure.

Moreover, the CSTEE doesn't agree with conclusion ii) for the terrestrial environment. The need for toxicity data on terrestrial organisms is supported.

SPECIFIC COMMENTS

1. Exposure assessment

Exposure assessment of EDTA (Ethylenediaminetetraacetic acid) is problematic due to the different chemical forms that can be present in the environment. Besides the acid form, it is present as salt of Na or many other cations. Moreover, it is able to form complexes with metals.

Due to major emission patterns and physico-chemical properties, water is the compartment of highest concern for EDTA and for all major chemical species present in the environment.

The negligible vapour pressure and the very low hydrophobicity allow concluding that there are no problems for the air compartment as well as for bioaccumulation and transfer through the trophic chain.

EDTA is not easily degraded. It is biodegraded in particular conditions that may occur in industrial treatment plants but that seem unlikely to occur in natural waters as well as in municipal treatment plants.

EDTA is also poorly degradable by abiotic processes (with the exception of the Fe complex that is photodegraded).

For the risk assessment the chemical has been assumed as persistent (degradation rate =0) in water and air. A half-life of 300 days was assumed for soil and aerobic sediment. Nevertheless, in anaerobic sediments EDTA is persistent. Therefore a half-life of 3000 days was assumed for total sediment.

These values seem to be the most reliable in the literature review. Nevertheless, some controversial data are also reported, showing lower persistency. Therefore, it is the opinion of the CSTEE that all these figures should be assumed as conservative worst cases, to be confirmed by additional experimental data.

PECs in water at local, regional and continental scale have been properly calculated according to the TGD procedures. Nevertheless, some monitoring data available for surface water indicate that in the large majority of samples concentrations are far below the regional value and even below the continental background. This seems to indicate that the calculated values are probably overestimated. It could be due to some particular aspects of the complex behaviour of EDTA in natural waters. This seems to be confirmed by the better agreement observed between calculated and experimental data in effluents.

In the RAR a good description is reported of the chemical behaviour of EDTA in the aquatic environment, taking into account speciation of metal complexes and partitioning in sediment and water, but even this assessment doesn't help in understanding the disagreement between theoretical and experimental values.

It is the opinion of the CSTEE that more information should be made available for a better assessment of exposure. In particular, a systematic experimental monitoring, properly planned in order to assess the concentration gradients from relevant emission sites to less polluted areas, would be helpful for better describing and understanding the behaviour of EDTA and related compounds in the aquatic environment

For the soil compartment, EDTA concentrations are calculated taking into account the EDTA dust fall-out in industrial soils close to production sites. Moreover, the application on agricultural soils of EDTA present in sewage sludge, of metal-EDTA complexes mixed into fertilisers. Calculated PECs were not compared with monitoring data.

2. Effects assessment

Aquatic organisms

As for exposure, the assessment of effects of EDTA and related compounds is not an easy task. Besides a possible toxic effect on living organisms, many other reactions may occur, directly or indirectly related to biological activity:

- EDTA is used in nutrient solutions for algae for increasing bioavailability of many micronutrients;
- it also increases metal solubility by forming complexes, but usually the toxicity of metals is strongly reduced in presence of EDTA;
- the effects of EDTA and related compounds are hardness dependent and usually EDTA toxicity is lower in hard water; nevertheless, the toxicity of Zn-EDTA increases in hard water, probably due to Zn release as a consequence of competition with Ca and Mg;
- the high concentrations of the acid EDTA needed to produce a toxic effect on some aquatic organisms allow a lowering of pH up to levels dangerous for fish and strongly affecting the chemical characteristics of water.

Several short and long-term data are available on aquatic organisms but results are often controversial due to the different behaviour of various chemical forms and the influence of environmental parameters (pH, hardness).

A PNECwater of 2,2 mg/L was calculated by applying a factor of 10 to the lowest reliable long term NOEC available (22 mg/L on Daphnia). The CSTEE agrees with this figure.

For intermittent emission (to be applied on emissions of oil production sites) a PNEC of 6,4 mg/L was calculated by applying a factor of 100 to a 24h EC50 on Daphnia. The rationale of this procedure is not clear and the figure cannot be accepted by the CSTEE.

Microorganisms

A PNEC of 50 mg/L was properly calculated by applying a factor of 10 to an EC10 on sludge respiration.

Atmosphere

No toxicity data through atmospheric exposure are available.

Terrestrial organisms

No toxicity data on terrestrial organisms are available.

Secondary poisoning

No bioaccumulation data are available.

3. Risk characterisation

Aquatic compartment

In production sites and for many use pattern scenarios PEC/PNEC are below 1 and the CSTEE agrees wit conclusion ii).

For some uses (in particular: industrial detergents, pulp and paper, metal plating, disposal) a PEC/PNEC higher than 1 has been calculated and a risk to aquatic organisms cannot be excluded. Therefore, the CSTEE agrees with conclusion iii) as a preliminary approach.

Nevertheless, as previously mentioned, exposure assessment is controversial and probably overestimated. Therefore the CSTEE supports the need for a better assessment of exposure by suitable *ad-hoc* experimental monitoring in relevant emission sites.

For the use in oil production sites, with intermittent emissions in marine water, the CSTEE asks for a better clarification of the rationale for calculating intermittent PNEC and for the application of the marine assessment described in the new updated version of the TGD.

Risk for sediments has not been calculated. Due to the absence of data on exposure and effects, the partitioning approach should be applied and toxicity data should be extrapolated from aquatic organisms. In these conditions, PEC/PNEC values are the same as for the water compartment. On the other hand, due to physico-chemical properties, accumulation in sediments is assumed as negligible.

Wastewater treatment plant

Calculated PECs and measured levels are far below the PNEC microorganisms. The CSTEE agrees with conclusion ii).

Atmosphere

A proper risk assessment has not been performed. Nevertheless, due to the low volatility, EDTA can only be present as dust in very high emission sites. The CSTEE agrees with the opinion that there is no need for further information.

Terrestrial compartment

A proper risk assessment has not been performed due to the lack of data on effects on soil organisms. Soil contamination by EDTA being likely to occur, the CSTEE doesn't agree with conclusion ii). Toxicity data on terrestrial organisms are required.

Non compartment specific effects relevant to the food chain

Due to the low bioaccumulation potential, the CSTEE agrees with the assumption that a risk characterisation is not required.