

EUROPEAN COMMISSION HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Brussels, C7/VR/csteeop/Na4edta-env/100903 D(03)

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

Opinion on the results of the Risk Assessment of:

TETRASODIUM ETHYLENEDIAMINE TETRAACETATE (NA4EDTA) CAS N°: 64-02-8

ENVIRONMENTAL PART

Carried out in the framework of Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances¹

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

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

Na₄EDTA is one of the two most important forms of EDTA usually produced.

It is very difficult to assess separately these compounds due to their environmental behaviour and to the possibility of forming different chemical species and reacting with other environmental chemicals.

Therefore besides some minor differences in the general substance information and in the physico-chemical properties, the environmental part of this report is practically identical to the one on EDTA. In particular, conclusions are the same.

The CSTEE recognizes the practical identity (in environmental terms) of the two compounds.

The opinion of the CSTEE is the same already developed for the report on the acid form of EDTA (opinion adopted on 10 September 2003).