EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C2 - Management of scientific committees; scientific co-operation and networks

Brussels, C2/GF/csteeop/SP/01042003D(03)

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

Opinion on the results of the Risk Assessment of:

SODIUM PERBORATE

ENVIRONMENTAL PART

CAS N° : 11138-47-9

EINECS N° : 234-390-0

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 37th plenary meeting of 1 April 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.

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

Opinion on the results of the Risk Assessment of:

SODIUM PERBORATE

ENVIRONMENTAL PART

CAS N° : 11138-47-9

EINECS N° : 234-390-0

Adopted by the CSTEE during the 37th plenary meeting of 1 April 2003

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:

Introduction

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

The environmental part of the document is of good technical quality. The report considers the available information and evaluates the difficulties for applying several default concepts and procedures described in the Technical Guidance Document (TGD). It is concluded that several risk assessment elements described in the TGD are unsuitable for inorganic compounds such as sodium perborate (PBS) and its degradation products. The CSTEE fully agree with these conclusions.

In addition, the report's authors also identify that due to the reactivity of sodium perborate, the environmental problems would be mostly related to the degradation products, particularly hydrogen peroxide and boric acid. As both substances are also within the list of priority HPVC, a cross reading to the respective RARs is conducted. Information on the risk assessment of hydrogen peroxide is included in the RAR of sodium perborate. However, boric acid is included in the fourth list and a RAR will only be produced in the future.

The RAR describes properly the fate and behaviour of sodium perborate, identifies boric acid as the chemical of long-term concern, and includes estimations of PEC values expressed as boron (B) equivalents. Available data on the toxicity of boric acid are also presented. However, the risk assessment is postponed until the RAR for boric acid will be produced.

The CSTEE considers that the RARs should be as complete as possible. It is essential to cover the risk of the assessed substance, but also the potential risks related to metabolites. Therefore, if a metabolite addressed in another RAR, the key information must be transferred between RARs and final conclusions must only be achieved when an essential information becomes available.

Nevertheless, the RAR still present conclusions (ii) for most scenarios. This conclusion is not accepted by the CSTEE as the real risk, linked to the emission of boric acid is not included when reaching this conclusion. In fact, the overall conclusions/results section does not even mention that the potential risk of boric acid is not addressed. Even more, a simply comparison of the estimated PECs and the reported toxicity values indicates a potential risk (PECs are very close to the lowest reported NOEC). Concluding low risk (conclusion ii) for a very reactive chemical, where the main metabolite is not covered in the assessment is not acceptable. It must also be considered that in this particular case the main use is done directly by consumers and represents diffuse emissions of 100% of the chemical to the environment, in the form of the metabolite.

Therefore, the CSTEE considers that if the risk of boric acid will only be addressed in a later RAR, because of the currently available information does not allow a proper assessment; the RAR of sodium perborate should present conclusion i) instead of conclusion ii).

Nevertheless, as a potential risk for boric acid has been identified by the CSTEE, accounting exclusively the amount produced by the use of sodium perborate, the Committee considers that the assessment of boric acid should be prioritised.

The CSTEE also considers that the risks for WWTPs and for the terrestrial compartment are not properly addressed. In the opinion of the CSTEE, a lower PNEC for WWTP biological processes should be considered and the reduction in the PNEC would have consequences on the risk assessment results.

Regarding the terrestrial compartment, the RAR identifies that boric acid is phytotoxic. Boric acid will be the main product present in the effluent and as the presence of boric acid corresponds to a massive use in detergent formulations, boric acid is expected in municipal WWTPs, even in those that do not receive industrial effluents. There is a significant tendency to use WWTP effluents for irrigation, particularly for non-food crops and recreational areas. The risk associated to the phytotoxicity of boric acid for the irrigated plants must be addressed, and as the presence of boric acid is directly related to the use of sodium perborate in detergents, this risk should be incorporated in the RAR of sodium perborate.

SPECIFIC COMMENTS

1. Exposure assessment

The RAR presents a good and comprehensive overview of the available information on the production, formulation and use of sodium perborate and the expected fate and behaviour of this substance in the environment.

The use of the TGD default concepts and methods has been specifically considered. The RAR authors consider that several TGD assumptions are not applicable to inorganic substances, and present alternative proposals based on data or expert judgement. The CSTEE recognises the difficulties and supports the RAR assessments.

The main use of sodium perborate is the incorporation as a component of detergents and other cleaning products, either for domestic or institutional users. This use represents an environmental emission of 100% of boron, in a very dispersed way, through municipal collectors and WWTPs. The RAR also presents enough information to conclude that due to the reactivity of the substance and the use patterns (the efficacy of the substance is directly associated to the rupture of the molecule), the main risks will be associated to the metabolites, hydrogen peroxide in the short-term and boric acid in the long-term. This conclusion is, in the CSTEE opinion, supported by available information.

The RAR offers PEC estimations (local, regional and continental) covering the metabolites, and particularly boric acid or total boron content.

Considering the physical-chemical properties, hydrosphere is identified as the compartment of higher potential risk. The RAR also considers that obviously sodium perborate is not the only substance producing emissions of boric acid, and that natural boron background levels and anthropogenic and natural emissions of different boron chemical species should be considered for a sound risk assessment of this element.

Assuming that boric acid will be the relevant chemical form in the WWTPs and in the effluents discharged in natural water bodies, information on the fate of this chemical is presented. The conclusions of low sorption potential to WWTP sludge, sediments and soils and low bio-accumulation potential are supported.

The RAR considers that atmospheric emissions will be limited to emissions of dust, subjected to rapid dry and wet deposition. No emissions to the terrestrial environment other than dust deposition are assumed, following the TGD scenarios (no emissions to soil associated to the use of WWTPs as fertiliser due to the low absorption on sludge).

However, the CSTEE considers that an additional scenario, not covered in the TGD, is relevant in this particular case. The extensive and diffuse domestic use of sodium perborate leads to the presence of boric acid in municipal WWTPs, even those that do not receive industrial effluents. The use of municipal WWTP effluents for irrigation, particularly for non-food crops and recreational areas, is receiving significant attention. In fact this is assumed to be a sustainable practice, which avoids the impacts associated to the discharge of these effluents into natural water bodies. This scenario should be considered for domestic use products, like sodium perborate, and therefore, emissions to the terrestrial compartment due to irrigation practices should be considered in the risk assessment.

2. Effects assessment

Aquatic organisms

The RAR presents information on the substance, sodium perborate with different hydration levels. It also presents data on hydrogen peroxide and boric acid. For the PNEC derivation it concludes that the short-term effects are assumed to be dominated by the peroxi group, and proposes the use of the PNEC of 10 μg/l agreed for hydrogen peroxide. This conclusion is agreed by the CSTEE who has also produced an opinion on the RAR of Hydrogen Peroxide agreeing with the proposed PNEC for aquatic organisms.

The RARs also indicates that undissociated boric acid is expected to be the predominant boron species in natural freshwater with pH of 6-9, and should be responsible for possible aquatic toxicity in this compartment. The RAR indicates NOECs for fish ranging from 0.75 to 18 mg B/l. and above 1 mg B/l for other taxonomic groups. The data set includes toxicity values for phytoplankton but not for aquatic vascular plants. Information on aquatic vascular plants is considered essential for a phytotoxic chemical due to possible large differences in sensitivity between algae and vascular plants.

The derivation of a PNEC for boric acid is postponed for a further risk assessment of boron compounds.

No information is presented for sediment dwelling organisms. The RAR indicates that the estimation method described in the TGD is not acceptable for this substance. The CSTEE supports this assessment and the final conclusion that the risk for sediment dwelling organisms will be covered by the risk for water column species.

Conflicting results are presented regarding effects on micro-organisms including protozoa. The PNEC is derived from a study measuring decreasing of MBAS and COD in a laboratory model reproducing WWTP conditions with adapted (2 weeks) microbial populations and short retention times (3 hours). The LOEC from this study, 500 mg PBS/l, with no additional application factor, is proposed as PNEC in the RAR. However, effects at much lower concentrations have been reported for protozoan, considered relevant for WWTP, with a LOEC of 14.3 mg PBS/l, and in a microcosms study with unicellular and small multicellular organisms, with a NOEC of 1.4 mg PBS/l. The later study is not accepted due to insufficient documentation. The CSTEE considers that this study is critical and the information should be requested. The PNEC derivation should consider both studies.

Atmosphere

No information is presented. This compartment is only relevant regarding dust emissions which could represent atmospheric depositions and will be addressed in the risk for terrestrial organisms.

Terrestrial organisms

No information on toxicity to terrestrial (soil) organisms is available. The RAR indicates that the estimation method described in the TGD is not acceptable for this substance. The CSTEE supports this assessment.

Boric acid is considered phytotoxic. Information of the effects of this chemical on terrestrial plants is considered essential for a proper risk assessment.

Secondary poisoning

The CSTEE agrees with the conclusion of low bio-accumulation potential.

3. RISK CHARACTERISATION

Aquatic compartment: The CSTEE agrees with the PEC/PNEC ratios for water presented for hydrogen peroxide. However, does not agrees with the final proposal of conclusion (ii) when the risk of boric acid is not included.

If the reported NOEC for boric acid is confirmed, a PNEC aquatic organisms of 0.075 mg B/l is expected applying a factor of 10 to the lowest NOEC. The reported PEClocal values range from 0.18 to 0.6 mg B/l and therefore PEC/PNEC values above 1 should be assumed.

The CSTEE does not agree with the presented PNEC for WWTP. The incorporation of the additional studies may reduce the PNEC. The risk should be revisited after receiving information on the key study.

Atmosphere: Conclusion (ii) is accepted.

Soil: The CSTEE considers that the risk associated to the phytotoxicity of boric acid when the WWTP effluent is used for irrigation should be considered. Conclusion ii) is not acceptable.

Secondary poisoning: The CSTEE considers that low risk is expected.