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

Opinion on the results of the Risk Assessment of:

n-PENTANE

Environmental Part

CAS No.: 109-66-0

EINECS No.: 203-692-4

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

Opinion expressed at the 35th CSTEE plenary meeting

Brussels, 17 December 2002

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:

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 in general of very good quality. The exposure assessment identifies the atmosphere as the environmental compartment of concern. The RAR focuses on the production and use of pentane, however, it also states that other sources of pentane, particularly those related to the presence of pentane in petrol and petroleum products should be considered. The rapporteur has included in the risk assessment exposure comparisons for emission related to the production and use of n-pentane and those related to the presence of pentane in petroleum products. The CSTEE considers that this information is very valuable and should be considered when setting the risk reduction strategy.

The CSTEE presents below some specific comments on the exposure and effect assessments as well as on the risk characterization. Nevertheless, the CSTEE agrees with the conclusions presented by the rapporteurs.

The only potential environmental risk identified in the report corresponds to the contribution of pentane to the production of tropospheric ozone. Ozone is particularly toxic for terrestrial plants, and therefore the risk of pentane to this ecological receptor should be identified. The RAR states the need of an in-depth assessment where all pentane emissions should be considered. The CSTEE agrees with this proposal. Pentane is only one of the factors contributing to the formation of tropospheric ozone. The CSTEE considers that the complexity of this issue and its multi-factorial character requires a holistic approach which could not be achieved with the tools available under the Regulation of Existing Substances, which consider each substance independently. There is enough evidence to demonstrate that pentane contributes to a certain extent in the formation of tropospheric ozone, and there the

risk of the levels of tropospheric ozone observed in certain parts of Europe is well documented. Therefore, the CSTEE considers that conclusion (i) should not allow a sound refinement of the actual risk and agrees with the conclusion (iii) proposed in the RAR.

SPECIFIC COMMENTS

Exposure assessment

The RAR presents a good and comprehensive overview of the available information on potential emissions of n-pentane, including emissions related to petroleum products.

The available information on emissions has been incorporated in the assessment, and EUSES defaults have been used to complete the assessment. Measured data are very limited, and therefore a sound comparison of predicted and measured data is not possible.

Atmosphere is properly identified as the compartment of concern, and the creation of tropospheric ozone due to pentane emissions is described. Due to the complexity of this process, hazard comparative indices have been used to address this phenomenon. An in-depth analysis, covering all sources of pentane emission is recommended by the rapporteur, and the CSTEE fully supports this recommendation.

Effect assessment

Aquatic organisms

The RAR considers the validity of each test, with particular attention to the volatility of the substance. The PNECaquatic organisms is initially derived following the TGD, a factor of 1000 on acute toxicity data, but later a factor of 100 on the acute data is used under the justification of non-polar narcosis as the mechanisms of action. In the opinion of the CSTEE, there is enough evidence to consider that n-pentane is a non-polar narcotic chemical. However, the reduction of the application factor to 100 on the single justification of non-polar narcosis is not supported by the CSTEE. Instead, the CSTEE suggests the use of a factor of 100 on the NOEC for algae, resulting in a PNEC of 12.6 ug/l.

These changes, however, do not affect the conclusions.

Atmosphere

No direct toxicity data of pentane on terrestrial plants are available. The RAR presents a comparative assessment with related substances and concludes that direct toxicity is of no concern and no further data are required. The CSTEE agrees with this conclusion.

The risk related to the formation of tropospheric ozone is also addressed and the risk of ozone for humans and the environment briefly summarises.

Terrestrial organisms

No information on toxicity to terrestrial (soil) organisms is available. The use of the equilibrium partitioning method presents some conceptual problems, as the method considers the exposure through soil pore water when the physical chemical properties clearly demonstrate that in soil, pentane will partition mostly on the air fraction.

Nevertheless, considering the low expected exposure levels and the toxicological profile no additional tests are required.

Secondary poisoning

The K_{ow} higher than 3 indicates a potential risk for bioaccumulation on aquatic organism. Due to the rapid dissipation from the aquatic compartment and considering the rapid elimination suggested by the toxicokinetic data, no risk of biomagnification through the trophic chain is expected.

Risk characterisation

Aquatic compartment: Independently of the small discrepancy on the PNEC derivation, the CSTEE supports the proposed conclusion (ii).

Atmosphere: Conclusion (ii) for direct toxicity on terrestrial plants and conclusion (iii) for the effects associated to the formation of tropospheric ozone are also supported by the CSTEE. Regarding ozone formation, the CSTEE considers that although additional data are required, there is already enough information to conclude that pentane can contribute to tropospheric ozone formation. Regarding the risk of ozone, the CSTEE has already been consulted on this issue and reports indicating ozone levels above the recommended thresholds are relatively frequent in some part of Europe. The combination of both aspects justify conclusion (iii).

Soil: The CSTEE considers that using equilibrium comparisons based on the soil pore water, for a chemical which will mostly partition to in-soil air is not proper. However, considering the expected exposure levels and the toxicological profile of n-pentane conclusion (ii) is accepted.

Secondary poisoning: The CSTEE considers that for bioaccumulable chemicals the risk for secondary poisoning should be established in all cases, based on PEC/PNEC estimations, independently of the classification criteria. Nevertheless, the available information suggests low risk of secondary poisoning for n-pentane, and therefore, conclusion (ii) is supported.