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

Opinion on the results of the Risk Assessment of:

CYCLOHEXANE

CAS No.: 110-82-7
EINECS No.: 203-806-2

REPORT VERSION (Environment)

DRAFT 2 - October 2001

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

Opinion expressed at the 29th CSTEE plenary meeting

Brussels, 09 January 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.

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.

INTRODUCTION

Cyclohexane is a high volume chemical, approximately 900 000 tons are used per year in the EU. Cyclohexane may either be synthesised from benzene or isolated from petroleum hydrocarbons. The majority of the produced Cyclohexane is used as an intermediate in chemical industry (96%) and 2% is used as a solvent in chemical production and as solvent in adhesives and coatings, respectively.

General comments

In general, the environmental exposure and effects assessments and the risk characterisation are conducted using procedures recommended by the TGD (1996). However, for some aspects the text is too concise to support the scientific statements made (see Specific comments). Without the referenced annexes, most of the calculations and some of the conclusions cannot be verified.

Specific comments

1. Exposure assessment

In the general discussion on the environmental exposure, the RAR states that hydrolysis is not expected (based on theoretical considerations) and that the atmospheric half-life of Cyclohexane is estimated to be 52 hours. However, the statement on the readily biodegradability of Cyclohexane does not seem to be supported by the data provided in the RAR. Indeed, the cited studies seem to give conflicting results. The text and arguments in the RAR do not provide the scientific bases to justify the statement 'readily biodegradable'. It is recommended that this section is re-examined and that additional evidence or argumentation is given to support this statement. This is especially important as the biodegradation constants for the different environmental compartments are estimated from and based on this readily biodegradability 'assumption'.

The theoretical environmental distribution of Cyclohexane is estimated using the Mackay level I model. The estimated equilibrium distribution indicated that 99.98 % of the substance is expected to be partition to air.

A bioconcentration factor of 129, an experimental value taken from literature, is used in the assessment.

The section on the releases of Cyclohexane during production mentions that these will probably be low and are, compared to other applications, negligible. Some data are given (table 3.5) and some generalised assumptions are derived. From the RAR, however, it is unclear if these figures are used in the subsequent calculations for the regional RA. There is a reference to Annex I but this deals with metabolism studies.

In general, the calculated releases to the water compartment seem to reflect (the limited) monitoring data. The RAR has used 'realistic worst case' data in the subsequent PEC calculations.

The releases to water from formulation and use of adhesives and coatings are estimated using TGD default %. No comparison with measured data was given.

PECs for local aquatic environments are calculated for some production sites using site-specific production data and using TGD default values for stream flow rate and dilution rate. No monitoring data are given.

The presented PECs can be considered as realistic worst case values. It is, however, unclear if the data presented for the five production sites are representative for all EU sites.

It is unclear why the local PECs were not calculated for all sites.

The same comment can be made for the use as intermediates (3.1.2.2.2.) and solvents (3.1.2.2.3).

Few monitoring data (some of which exceed the calculated value) are provided to support the calculated regional PECwater. It may be suggested that additional data (if available) be incorporated in the RAR.

The same comment can be made for the regional and local PECair, *i.e.* no to little comparison of calculated values with monitoring data. Consequently, a similar recommendation is made for this environmental compartment.

PECs for soil and groundwater are calculated using standard TGD procedures.

2. Effects assessment

The quality and relevance criteria used to screen the ecotoxicity data are unclear. It is consequently unclear which data are retained and which are rejected (and for what reasons). A re-organisation of this section to enhance transparency of data selection is recommended. A limited number of toxicity values are presented in the RAR; it is suggested that a further literature search be conducted. The use of a lower assessment, *i.e.* 100 instead of the standard 1000 with acute toxicity test results is not sufficiently justified. The RAR states *'as it assumed that Cyclohexane acts by a non-specific mechanism…'.*

In the absence of experimental evidence for the mode of action and considering the very limited acute data set available, an assessment factor 1000 should be used.

The CSTEE thus suggests that additional data be provided before a lower assessment is applied.

The CSTEE does not support the PNEC of 9 µg/L and recommends using an assessment factor of 1000 resulting in PNEC of 0.9 µg/L.

The lack of transparency for the PNEC derivation is also valid for the PNECmicroorganism derivation. Same recommendation as above.

For the atmosphere, the discussion on the (only) plant test available is not clear. Similarly, it is unclear what is meant with the conclusion: *'no PNEC can be derived from these results as the exposure duration was very low'*.

As Cyclohexane mainly partitions to the atmospheric compartment, it is felt that this effects section on air needs be substantially revised to allow a scientifically based PNEC derivation.

Based on the fact that delayed effects on plants after (only) very short exposures to high concentrations were found, the CSTEE does not accept that these results can be used for this risk assessment. Toxicity test results on plants exposed through the air at realistic concentrations are required to allow a proper risk characterisation.

Additionally, the Report states that Cyclohexane can undergo photochemical oxidation in the lower atmosphere and may contribute to tropospheric ozone formation. In section 3.3.2. it is mentioned that this POCP has been reported even though the atmospheric lifetime is low. Atmospheric effects cannot be ruled out and this provides additional arguments for not accepting conclusion ii) (see below).

The PNEC for the terrestrial environment is based on the PNECwater using the equilibrium partitioning procedure. No data on soil organisms is available.

Considering the PNECsoil was derived from the PNECsurface water and the fact that the latter was lowered by a factor 10 (see above), the PNECsoil should be 14.7 µg/kg (dry weight).

3. Risk characterisation

The risk characterisation in the Report is performed according to the procedure recommended by the TGD (1996). The calculated PEC/PNEC ratios are < 1 for all environmental compartments, except for the atmosphere.

However, considering the comments mentioned above, the CSTEE cannot support conclusion ii) for:

- The surface water and sediment compartment because of use an incorrect assessment factor. The use of an assessment factor of 1000, does lead to RCR > 1 for some uses

- The soil compartment, as PNEC soil was calculation from the (incorrect) PNEC surface water. The use of the corrected PNEC soil indicates RCR > 1 for Cyclohexane uses.
- The atmosphere compartment, as no quantitative risk characterisation because of the lack of appropriate effect data. There is a clear conflict between the conclusion noted on page 40 (*'no conclusion can be drawn'*) and the conclusion on page 5: *'no unacceptable risk for the atmosphere'*.

The CSTEE also suggests that for the secondary poisoning assessment, the lack of oral toxicity should be confirmed (see human health part).

Opinion / Conclusions

The CSTEE notes that a number of sections of the Report contain insufficient information or unclear arguments to support the overall conclusion ii) for all environmental compartments. General and specific comments and suggestions for improvement are given hereunder.

The CSTEE does not agree with conclusion ii) for:

- Surface waters and sediments, because of the use of an inappropriate assessment factor
- Atmosphere, because of the lack of relevant effect data
- Soil compartment, because of the use of an inappropriate assessment factor (see surface water)