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Scientific Committee on Toxicity, Ecotoxicity and the Environment

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C2/JCD/csteeop/80.**1-Vinyl-2-PyrrolidoneENV11092001**/D(01)

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

Opinion on the results of the Risk Assessment of:

1-VINYL-2-PYRROLIDONE

ENVIRONMENTAL PART

CAS N°: 88-12-0

EINECS N°: 201-800-4

REPORT VERSION: November 1999

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 26th CSTEE plenary meeting

Brussels, 11 September 2001

[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

1-Vinyl-2-pyrrolidone (N-VP) is mainly used as a monomer to produce polyvinylpyrrolidone and copolymers. It is also used in some radiation-cured inks and coating. Total continental releases are estimated as high as about 20 kg/day, mostly in the water compartment.

GENERAL COMMENTS

It is to be noted that "*no information in quantities produced or used in the EU has been included in the assessment report on the grounds of confidentiality*". Therefore it is difficult to judge about the quality of the document, in particular on exposure assessment.

As a general rule, this lack of information should be unacceptable in a RAR. Nevertheless, for this specific compound, it seems reasonable that, even assuming worst-case scenarios, the risk for the environment would be very low or negligible.

Therefore, the CSTEE agrees with conclusion ii) for the aquatic and terrestrial environments.

SPECIFIC COMMENTS

Exposure assessment

1-vinyl-2-pyrrolidone is miscible with water and has a relatively low Henry's constant. Major releases are expected in water, therefore the aquatic environment is the compartment more likely to be exposed.

It is readily biodegradable, some experimental data show a 100% disappearance in water in 14 days. A conservative estimate of its half-life in water is of about two weeks.

It is very difficult to review the exposure assessment in this RAR without access to the Confidential Annex. From the present text there seems to be just two producers in the world, one of which located in the EU. This producer may thus synthesise larger amounts than those used to make polyvinylpyrrolidone (PVP), coatings and inks. The two last applications are assumed to use 75 tonnes per annum and the rest is used for PVP production. The amount of PVP used in the EU is estimated to be 20,000 tonnes per year, and this is thus by far the major use of this substance.

The producer of the monomer largely carries out the production of PVP in the EU, and the major releases can be expected to come from this company. It is not obvious that this production is located at one site, but if it is the case that region will receive most of the continental releases, which seems to be the case (Table 3.2). The regional releases from production and processing are estimated to be of about 2 kg/day to air and 20 kg/day to water.

Calculated PECwater at regional and continental level are about 40 and 1 ng/L respectively. The highest worst case site-specific local PEC is 44.3 μg/L. Assuming an emission of 20 kg/day, to obtain the latter figure, emissions have to be diluted in $4.5x10^5$ m^3 of water, which means a water flow of about 5 m^3/sec. This means that the hypothesis of one-site emission of the continental release, is not inconsistent with the highest worst-case PEC.

Comparable calculations can be made for the terrestrial environment. The highest worst-case PECsoil (14.3 μg/kg) is consistent with the hypothesis of one-site emission of the continental release.

No experimental monitoring data are quoted in the report.

No data on bioaccumulation are available, but due to the very low lipophilicity, (measured log Kow = 0.4 at 25°C) bioaccumulation potential is likely to be negligible.

Effects assessment

Aquatic organisms

Only acute toxicity data on fish, Daphnia and algae are available. Therefore a PNEC water of 45 μg/L has been derived using an application factor of 1000.

Terrestrial organisms

Considering the physical-chemical and toxicological profile, the use of the equilibrium partitioning method for the derivation of the PNECsoil is acceptable

Risk characterisation

Aquatic environment

The highest PEC/PNEC value is lower than 1, even if very close (0.98) Taking into account that PEC and PNEC figures are conservative worst cases, the CSTEE agrees with conclusion ii).

Terrestrial environment

The conclusion of low risk for terrestrial (soil), atmosphere and secondary poisoning are supported by the CSTEE. The CSTEE recognises the lack of toxicity data for assessing the risk for the atmospheric compartment. However, the expected concentrations are very low and considering the toxicological profile the likelihood for effects is very low.