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

Opinion on the results of the Risk Assessment of:

PHENOL

Environment

CAS N° : 108-95-2

EINECS N° : 203-632-7

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 36th plenary meeting of 6 February 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.

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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

The CSTEE agrees with most of the conclusions of the RAR. These are acceptable if one strictly considers only emission patterns due to production and processing of phenol.

Nevertheless, it must be taken into account that phenol can be released in the different environmental compartments through many intentional and unintentional emission patterns, and some of them are poorly known. The relevance of additional emission sources is demonstrated by the occurrence of some high figures from experimental monitoring data, indicating that PNEC values are sometimes exceeded in the aquatic compartment.

Therefore the CSTEE strongly recommends that a risk assessment on naphthalene be performed taking into account emissions other than production and direct uses, in order to assess the need and the technical likelihood of more stringent control measures to protect environment and human health.

Moreover, the CSTEE considers that the relevance and reliability of the data provided by Black et al. (1982; 1983) must be carefully evaluated. The decision for excluding these data for the PNEC derivation must be substantiated on scientific evidence and presented in the report in a transparent way. If not enough scientific evidence becomes available, the data should be included for the PNEC derivation or, alternatively, conclusion i), requesting information which could clarify the real sensitivity of aquatic vertebrates, should be considered.

SPECIFIC COMMENTS

1. EXPOSURE ASSESSMENT

Phenol is a high production volume chemical. European production is estimated as high as more than 1,800,000 tons per year.

Moreover a number of unintentional or uncontrollable releases (photochemical degradation of benzene, vehicular traffic, combustion processes, landfill, living organism metabolism or other natural processes) make difficult a precise assessment of total emissions in different environmental compartments.

Phenol has relatively high vapour pressure (20 Pa), but due to the high water solubility (84 g/L), Henry's constant is relatively low. According to the Mackay model level 1, the major amount of phenol (98.8%) is distributed in the aquatic compartment.

Phenol is readily biodegradable in water and soil and rapidly photodegraded in the atmosphere.

In the RAR, regional and continental concentrations in the different environmental compartments are calculated using the SimpleBox model. The results are the following:

Compartments	PEC regional	PEC continental
Air	0.026 µg/m^3	0.003 µg/m^3
Surface water	2.41 µg/L	0.32 µg/L
Sediment	5.83 µg/kg	0.78 µg/kg
Natural soil	0.59 µg/kg	0.064 µg/kg
Agricultural soil	0.17 µg/kg	0.018 µg/kg

Water concentrations seem very high. In particular PECregional in surface water is substantially higher (sometimes orders of magnitude) in comparison with $Clocal_{water}$ calculated for most production and processing sites. Therefore, with a few exceptions, PEClocal is mainly determined by PECregional.

The reliability of such a high background regional PEC should be checked with experimental monitoring data. It could be hypothesised that, due to the degradability of phenol, real concentrations are lower.

In the RAR very few monitoring data in water are reported. Moreover they mostly refer to the amount of total volatile phenols or to the Phenol Index, including many other substances, so they are not comparable with phenol PECs.

Local PECs in surface water have been properly calculated for production and processing sites.

Calculation was also performed to assess Clocal in municipal WWTPs due to phenol emissions via human metabolism.

Many other potential (point and non-point) emissions of phenol (refinery, pulp manufacture, landfill leachate, animal metabolism) were not taken into account due to the lack of information.

PEClocal for sediments was calculated by means of the equilibrium partitioning approach.

PEClocal for the atmosphere was calculated for production and processing sites. The impact of some, probably relevant, diffuse emission sources (such as vehicle fumes or other combustion) was not calculated due to the lack of information.

Due to the lack of information on terrestrial emissions in production and processing sites, and to the lower relevance of the soil compartment in the distribution of phenol, PEClocal for soil was not calculated.

It is not clear how in agricultural soils, were sewage sludge and animal manure can be applied, the PECregional is more than three times lower in comparison with natural soils, where only wet and dry deposition occur.

2. EFFECTS ASSESSMENT

Aquatic organisms

Reliable short-term toxicity data are available for aquatic organisms. Lowest values are 5 mg/L for 96h LC50 on fish (*Oncorhynchus mikiss*), 3.1 mg/L for 48h EC50 on invertebrates (*Ceriodaphnia dubia*) and 61 mg/L for 96h EC50 on algae (*Selenastrum capricornutum*).

More controversial are long-term data, available on various groups of aquatic organisms. The most sensitive organisms are aquatic vertebrates (fish and amphibians) and the lowest figures are reported by Birge et al. (1979) who calculated, in an embryo-larval test on *Oncorhynchus mikiss,* LC1 values of 0.2 and 9 µg/L in hard and soft water respectively.

Black et al. (1982; 1983) found comparable data on two fish and three amphibian species. These data are also confirmed by other tests on amphibians reported by Birge et al. (1980).

In the RAR the use of LC1 values was assumed as not acceptable as NOEC because an effect of 1% compared with control is not significant, therefore EC10-values were calculated with the probit analysis. The lowest EC10, assumed as a NOEC for *Oncorhynchus mikiss* after 22 days exposure, was 2 µg/L.

Even with these changes, all the data from the Birge et al. (1979; 1980) and Black et al. (1982; 1983) papers were not used for the derivation of a PNEC for water.

Therefore, a PNEC for water of 7.7 µg/L was calculated by applying a factor of 10 to the NOEC of 77 µg/L obtained on larvae of *Cirrhina mrigala* by Verma et al. (1984).

The CSTEE agrees on the opinion that data reported by Birge et al. (1979; 1980) and Black et al. (1982; 1983) are controversial. These authors report data on many benzene derivates indicating toxicity levels that are not in agreement with all other literature data. Nevertheless, there are no elements for supposing serious methodological faults and the reasons for discarding these data are not enough justified.

The CSTEE does not accept the justification for discarding LC1 and using EC10. If 10% is assumed as the lowest significant difference in comparison with control, an EC10 cannot be considered as a no effect concentration and should be used as a LOEC. Moreover, all these values are theoretically calculated and cannot be assumed as NOEC that, by definition, is the highest experimental concentration that does not produce any significant effect.

Taking into account that several data on different aquatic organisms are available, it is the opinion of the CSTEE that, for a preliminary risk assessment, the PNEC for water of 7.7 µg/L can be accepted; nevertheless, additional data to confirm the level of phenol toxicity on aquatic vertebrates are strongly recommended.

Microorganisms

A PNECmicroorganism of 2.1 mg/L has been properly derived from available data.

Terrestrial organisms

Data on plants (*Lactuca sativa*, 14d EC50 = 149 mg/kg), earthworms (*Eisenia phetida*, 14d LC50 = 136 mg/kg), and soil microorganisms (NOEC>100 mg/kg) were available.

A PNEC of 136 µg/kg was calculated by applying a factor of 1,000 to earthworm data.

No toxicity data through atmospheric exposure are available. Due to the relatively low affinity for the air compartment and to the rapid photodegradation, the CSTEE agrees that relevant adverse effects are not likely to occur. Nevertheless, for such a high production volume chemical, a complete lack of information on toxicity through atmospheric exposure is not acceptable.

Secondary poisoning

Due to the low lypophylicity of the substance, a risk for secondary poisoning can be assumed as negligible.

3. RISK CHARACTERISATION

Waste water treatment plants

A PEC/PNEC ratio higher than 1 was calculated for all these production and processing sites (8 of 32) for which site-specific data on exposure were not available and default parameters were used to calculate exposure.

Therefore the CSTEE does not agree with conclusion iii) and support the need for further information to calculate exposure (conclusion i).

Aquatic compartment

A PEC/PNEC ratio higher than 1 was calculated only for one production and processing site discharging into the sea. In the RAR this value is assumed as non-relevant for many reasons. In particular, the default dilution factor of 10 is assumed as too low for a discharge into the sea.

Taking into account that most default assumptions are overestimated and that phenol is rapidly degradable, the justification is acceptable.

Therefore the CSTEE agrees with conclusion ii) for surface water.

The CSTEE also agrees with conclusion ii) for sediments.

Atmosphere

A risk characterisation is not possible for this compartment due to the absence of toxicity data. Therefore, even if the low possibility of adverse effect occurrence can be supported, the CSTEE cannot accept conclusion ii).

Therefore, the CSTEE suggests at least the use of inhalation data on mammals if they are available in the part of the RAR concerning human risk assessment.

In absence of these data, the CSTEE supports the need for further information (conclusion i).

Terrestrial compartment

Taking into account the relatively low toxicity for terrestrial organisms, the low relevance of soil as an exposed compartment, and the relatively low persistence, the CSTEE agrees with conclusion ii), even if a precise assessment of soil exposure is not available.

Non compartment specific effects relevant to the food chain

Due to the low bioaccumulation potential, the CSTEE agrees with the assumption that a risk characterisation is not required.

Unintentional releases

The CSTEE agrees with conclusion ii) for all these unintentional releases in the water, air and soil compartments for which a precise assessment of emissions and exposure was possible.

The CSTEE also agrees with the need for more information (conclusion i) for all these unintentional releases for which it was not possible to quantify emissions.