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SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)
Opinion on the results of the Risk Assessment of:

Aniline
Environmental part

CAS N° : 62-53-3
EINECS N° : 200-539-3

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 38th plenary meeting of 12 June 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 environmental part of the document is of good quality and the CSTEE agrees with most of the conclusions, with only some minor points of disagreement. In particular:

- The CSTEE agrees with conclusion i) for:
  - formation of aniline from rubber chemicals
  - effect tests on soil and sediment organisms
  - tests on plants through atmospheric exposure
  - bio accumulation studies on soil and sediment organisms

- The CSTEE agrees with conclusion iii) for the aquatic environment and for micro-organisms on many production and processing sites.

- The CSTEE does not agree with conclusion ii) for the soil compartment. Even if a PEC/PNEC<1 was calculated, the low reliability of the PNECsoil is highlighted in the RAR. Therefore, this conclusion is in contradiction with the request, expressed in the RAR and supported by the CSTEE, of additional toxicity tests on soil organisms (see above).

SPECIFIC COMMENTS

Exposure assessment

Aniline releases into the environment may occur from production (European production volume 650,000 t/y) and processing in several industrial uses. Moreover many additional releases may occur from non-intentional aniline production processes (degradation of plant protection products, rubber chemicals and polyurethane, coal and oil industry, landfill).

Aniline is a volatile chemical (vapour pressure 40 Pa), but, due to the high solubility (35 g/L), Henry's constant is relatively low. Therefore, water must be assumed as the compartment of major concern.

It is readily biodegradable in water under aerobic conditions. The half-life for complete mineralisation ranges from 5 to 25 days. For the exposure calculations a half-life in water of 15 days (as suggested by the TGD for readily degradable chemicals) was assumed.

In soil, free aniline can be easily mineralised, but a large amount (about 80%) is bound to humic acids and hardly accessible to degradation. A half life in soil of 350 days is derived.

The same process occurs in sediments, thus, in the aerobic surface layer, the same half life as for soil was used. In deep, anaerobic sediments biodegradation of aniline is much slower and a half life of ten years was assumed.

Due to photochemical degradation in the atmosphere, the half life is 3.2 hours.

The low Kow indicate a negligible bio-accumulation potential in the aquatic environment. This is confirmed by an experimental study on bio-accumulation in fish.
In the terrestrial environment, due to the binding with humic acids, a bio-accumulation in soil dwelling organisms and a transfer in the trophic chain is likely to occur.

In the RAR, regional and continental concentrations in the different environmental compartments are calculated according to EUSES. The results are the following:

Compartments	**PEC regional**	**PEC continental**
Air	$2.2\ 10^{-4}$ µg/m^3	$2.9\ 10^{-5}$ µg/m^3
Water	0.13 µg/L	0.017 µg/L
Sediment	3.4 µg/kg	0.48 µg/kg
Natural and industrial soils	$36\ 10^{-3}$ µg/kg	$4.7\ 10^{-3}$ µg/kg
Agricultural soil	$14\ 10^{-3}$ µg/kg	$1.8\ 10^{-3}$ µg/kg
Agricultural soil porewater	$1.7\ 10^{-3}$ µg /L	$2.2\ 10^{-4}$ µg /L

Regional PEC in surface water is in reasonable agreement with some available monitoring data.

Local PECs are calculated for several production and processing sites according to the TGD.
For surface water, PEClocal ranges from a minimum of <0.14 and a maximum of 590 µg/L in freshwater and from a minimum of <0.15 and a maximum of 920 µg/L in estuaries.

For sediments, PEClocal has been calculated using the partitioning equilibrium method, according to the TGD. Calculated values range from <1.4 to 8900 μg/kg.

Air PEClocal, calculated according to the TGD, ranges from 0.00067 to 3900 μg/m^3.

PECsoil is calculated from indirect deposition from the atmosphere, using the highest emission among the different local sites. Calculated values are 5.6 μg/kg for natural and agricultural soils, 11 μg/kg for grassland. Lower values (1.6 and 3.2 μg/kg respectively) were calculated from rubber industry.

Effect assessment

Aquatic organisms

Several data are available on aquatic organisms, nevertheless, some of them are performed with unsuitable methodology (static tests, nominal concentrations, etc.). Therefore a careful check of the reliability is needed.

From the available database on acute tests on fish, a 96h LC50 of 10.6 mg/L on rainbow trout, with flow through test and measured concentration, is a reliable figure.

Short term data on *Daphnia* are relatively homogeneous, showing in any case EC50 values below 1 mg/L. The lowest figure, among the most reliable values, is a 48h EC50 of 0.16 mg/L, obtained with semi-static test and measured concentration.

On algae, a 96h EC50 of 19 mg/L and an NOEC of 2 mg/L were obtained with nominal concentrations.

In long term experiments with fish, very low values were found by Birge and Black, as for many other benzene derivatives (see the opinions on benzene and phenol). These authors reported values often not comparable with those found by other authors, and no explanations for these discrepancies were found. For aniline the doubt on these data are not relevant, because the lowest long term toxicity values were found on invertebrates. Three different 21d NOECs on *Daphnia* were found in the range 4-24 μg/L.

For the derivation of a PNEC for water, in the RAR a factor of 10 is applied to the average of the tree long term NOECs on Daphnia (15 μg/L). Therefore a PNEC 1.5 μg/L has been used in the risk characterisation.

Micro-organisms

A PNECmicro-organisms = 2 mg/L, as high as the NOEC on nitrification of activated sludge, is acceptable.

Terrestrial organisms

Although there is experimental evidence of severe damages on terrestrial plants from atmospheric exposure to aniline, the CSTEE agrees with the conclusion of the RAR, that relevant information in these experiments is missing. Therefore a NOEC is not reported and a PNEC cannot be calculated. Considering the evidence of a potential risk, additional tests are required.

Only data on terrestrial plants (*Lactuca sativa*, nominal concentrations) were used for calculating a preliminary PNECsoil of 24 mg/kg (wet weight). It is opinion of the CSTEE that the information is not sufficient. Additional test on terrestrial organisms are required.

Secondary poisoning

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

Due to the possibility of persistent bound residues in soil, bio-accumulation and bio-magnification processes cannot be excluded in the soil food chain.

Risk characterisation

Surface water

In many production and processing sites, a PEC/PNEC>1 is reported in the RAR.
These data clearly indicate a risk for the aquatic environment.

Waste water treatment plants

In a few cases, the ratio Clocal eff/PNECmicro-organisms is >1, indicating a risk for micro-organisms in waste water treatment plants.

Atmosphere

A risk for plants through atmospheric exposure to aniline seems highly probable. Due to the impossibility to derive a precise PNEC and to perform a quantitative risk characterisation, the need for more data is highlighted.

Terrestrial compartment

PEC/PNEC values lower than 1 were calculated, nevertheless, as previously mentioned, the PNECsoil value is not enough reliable. Therefore, additional information is required for a better assessment of PNEC.

Non compartment specific effects relevant to the food chain

Due to the low bio-accumulation potential, the CSTEE agrees with the assumption that a risk for the aquatic food chain, including fish eating higher vertebrates (mammals and birds), can be excluded.

The CSTEE also agrees on the possibility of bio-accumulation through the soil or sediment food chain. Bio-accumulation studies should be conducted with sediment and soil organisms.
Taking into account the high volatility, bio-concentration studies on plants are also suggested.