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SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS

SCHER

Opinion on

Risk Assessment Report on

Ethylbenzene

Environmental Part

CAS No.: 100-41-4

EINECS No.: 202-849-4

Adopted by the SCHER
during the 11th plenary of 4 May 2006

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1. BACKGROUND

Council Regulation 793/93 provides the framework for the evaluation and control of the risk of existing substances. Member States prepare Risk Assessment Reports on priority substances. The Reports are then examined by the Technical Committee under the Regulation and, when appropriate, the Commission invites the Scientific Committee on Health and Environmental Risks (SCHER) to give its opinion.

2. TERMS OF REFERENCE

On the basis of the examination of the Risk Assessment Report the SCHER is invited to examine the following issues:

(1) Does the SCHER agree with the conclusions of the Risk Assessment Report?

(2) If the SCHER disagrees with such conclusions, it is invited to elaborate on the reasons.

(3) If the SCHER disagrees with the approaches or methods used to assess the risks, it is invited to suggest possible alternatives.

3. OPINION

3.1 General Comments

Ethylbenzene is a high production volume compound. Estimated production volume in the European Union is more than $5x10^6$ tons/y.

The RAR is supported by a large amount of information. Nevertheless, some parts are quite confused and not clearly explained. Moreover some statements are controversial or not enough justified. Some points have been clarified by additional information provided by JRC, but, for the sake of transparency, more details on the procedures should be added in the RAR.

Therefore, some of the conclusions cannot be endorsed by the SCHER. This is due, in some cases, to the need for more data, in other cases, to the need for a better justification and support of the assumptions used in the RAR. This is particularly relevant for such a high volume chemical that needs to be evaluated with special care. In particular:

- the SCHER does not agree with conclusion (ii)[1] for the aquatic compartment (freshwater and marine); better justification must be provided to support some assumptions of the RAR;

[1] *According to the Technical Guidance Document on Risk Assessment – European Communities 2003:*

- conclusion i): There is a need for further information and/or testing;
- conclusion ii): There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already;
- conclusion iii): There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

- the SCHER does not agree with conclusion (ii) for the atmospheric compartment; conclusion (i) is proposed and the need for toxicity data trough atmospheric exposure is supported;

- the SCHER agrees with conclusion (ii) for WWTP;

- the SCHER agrees with conclusion (ii) for the soil compartment;

- the SCHER agrees with conclusion (iii) for the formation of tropospheric ozone;

- the SCHER agrees with the conclusion that ethylbenzene does not meet PBT criteria; nevertheless the SCHER supports the need for more reliable data on accumulation and metabolism in order to exclude the likelihood of secondary poisoning.

3.2 Specific Comments

3.2.1 Exposure assessment

Ethylbenzene is a readily biodegradable, highly volatile, moderately water soluble, moderately lipophilic compound.

PECs are calculated at local and regional level, following the TGD procedures, for all relevant compartments. Nevertheless, some information is not easily understandable or not enough justified, in particular for the aquatic environment.

PEClocal for the aquatic compartment has been calculated for 16 production or processing sites, by assuming a maximum dilution factor of 1000 for freshwater and 100 for marine coastal zone. Calculated values are reported in table 3.9 (pages 26-27), where different dilution factors are applied (from 10 to 1000) but these factors are not clearly indicated and not justified in any part of the RAR. In particular, in site PP2, a factor of 1000 has been applied. A justification for this choice is relevant, because this site is the most critical one. Applying a more conservative factor would substantially change risk characterisation. The confidentiality of specific information cannot be accepted as a justification for the choice.

In table 3.9, only three sites are clearly indicated as “discharge to sea”. Going to table 3.27 (pages 58-59) it seems that marine sites are five. The reason for the inconsistency should be the presence of WWTP on two sites, so no direct discharge to the sea happens, but this is not clearly mentioned.

For the three clearly mentioned marine sites, $Clocal_{eff}$ has not been calculated and $Clocal_{water}$ has been derived from “specific information, or default assumption”, but what kind of specific information is not mentioned. Therefore, proposed PECs need to be better justified.

Several monitoring data are available for surface water. The large variability of measured values makes difficult a comparison, in particular because it is not clear if reported data are representative for background or hot spots. Some values for UK (90^{th} percentile of a high

number of samples) seem substantially higher than all calculated PEClocal (table 3.11). Anyway, the value indicated as “typical” is of the same order of magnitude (or lower) than the PECregional.

Concentration in soil has been calculated starting from a C_{sludge}=107 mg/kg dw. This value refers to a production site (PP3) and has been estimated using the Simple Treat model. Due to the properties of the chemical (highly volatile, moderately hydrophobic, readily biodegradable), soil probably is not a compartment of high concern. Moreover, available experimental data are lower than the estimated one. Therefore, it is opinion of the SCHER that the procedure is acceptable.

PECs in air seems properly calculated. Even if a large variability can be observed among monitoring data on air, concentrations in remote areas are of the same order of magnitude of the PEC regional or continental, while the highest measured values in industrial sites are of the same order of the highest PEClocal.

About secondary poisoning, the chemical has a moderate bioaccumulation potential (logKow=3.13). In the RAR, assessment of secondary poisoning has not been made because it is stated that “experimental data (see 3.1.3.3) indicate that bioaccumulation of ethylbenzene is lower than predicted”. Nevertheless, the conclusion of chapter 3.1.3.3 is that, for many reasons “the validity of the available bioconcentration studies is limited”. In particular, besides other weak points, no information was provided whether steady state was reached. So, experimental evidence is not adequate for supporting that experimental bioaccumulation is lower than predicted. It follows that the position on secondary poisoning is strongly controversial.

3.2.2 Effect assessment

Aquatic compartment

Toxicity data for the aquatic environment have been properly selected among those more reliable as a function of the properties (high volatility) of the chemicals. So, all selected data have been performed with suitable procedures, such as flow trough, closed bottles, measured concentrations, etc.

A 7-day test on the freshwater invertebrate (not saltwater, as stated at page 45) *Ceriodaphnia dubia*, was assumed as a long term test. Having *Ceriodaphnia* a shorter life cycle than *Daphnia*, the procedure is acceptable.

The SCHER agrees with the definition of ethylbenzene as a narcotic (baseline toxicity) chemical. This is also confirmed by the good agreement between the available experimental data and the predicted ones calculated using QSAR equations for non-polar narcosis. The fish NOEC calculated using the QSAR equation is higher than the experimental NOEC on invertebrates. Therefore, the use of a factor of 10 applied to the NOEC on *Ceriodaphnia* is acceptable.

According to the TGD, a $PNEC_{microorganisms}$ should be set up by selecting the lowest value among those obtained by applying different factors to different types of test. In the RAR a PNEC of 1.3 mg/L was obtained by applying a factor of 100 to an EC50 on activated sludge respiration inhibition, and a PNEC of 9.6 mg/L was obtained by applying a factor of 10 to an EC50 on *Nitrosomonas* activity inhibition. The second one, even if higher, was selected without sufficient justification.

For the marine environment, a PNEC has been calculated by dividing the $PNEC_{water}$ by 10. This procedure is those proposed by the TGD. Nevertheless, being the substance a non-polar narcotic, the additional factor should not be applied.

Soil compartment

Available data on earthworm are judged as unreliable for methodological reasons, and other data on soil organisms are not available, thus the equilibrium partitioning method has been applied. The method presents some conceptual problems, as, due to the physical chemical properties, ethylbenzene will probably partition mostly on the air fraction of soil. Considering the low expected exposure, the procedure can be accepted. Nevertheless, assuming a different $PNEC_{water}$, it results $PNEC_{soil}$=264 μg/kg (wet weight).

Atmospheric compartment

The only available data on atmospheric exposure derive from fumigation studies on two plants. The RAR considers these data non sufficient for the derivation of a $PNEC_{air}$. Taking into account that atmospheric exposure can be very relevant for ethylbenzene; the SCHER agrees with this opinion and supports the need for data on inhalation toxicity.

3.2.3 Risk characterisation

Aquatic environment

In all production sites PEC/PNEC values are below 1. Nevertheless, as previously mentioned, some PEClocal need to be better justified and supported.
On the basis of the provided information, it is opinion of the SCHER that conclusion (ii) cannot be endorsed for all production and processing studies. Additional information should be provided, at least to justify the dilution factors applied.

Waste water treatment plants

As previously mentioned, the used PNEC cannot be accepted. Nevertheless, even using the lowest PNEC, PEC/PNEC values are below 1 in all sites. Therefore, it is opinion of the SCHER that conclusion (ii) can be accepted for WWTP.

Terrestrial environment

The procedure used for the assessment of PEC_{soil} should be better justified, and PNEC should be reduced. Nevertheless, using the corrected PNEC and the PEC proposed by the RAR, PEC/PNEC values are substantially lower than 1.

Therefore, taking into account that soil is a compartment at low concern for ethylbenzene, it is opinion of the SCHER that conclusion (ii) can be accepted for the soil compartment.

Atmosphere

Unlike soil, the atmosphere is a compartment of high concern, due to the high volatility of ethylbenzene.

Therefore, it is opinion of the SCHER that conclusion (ii) cannot be accepted for the atmospheric compartment. The SCHER proposes conclusion (i) and support the need for more toxicological data from atmospheric exposure.

The SCHER agrees with conclusion (iii) for the contribution of ethylbenzene to the formation of tropospheric ozone.

Secondary poisoning

A risk characterisation for secondary poisoning has not been performed. It is opinion of the SCHER that the bioconcentration potential of ethylbenzene is moderate and the biomagnification capability is likely to be low. Nevertheless the justifications proposed in the RAR are controversial and cannot be accepted. The SCHER supports the need for more reliable data on accumulation and metabolism.

Marine assessment

The SCHER agrees with the conclusion that ethylbenzene does not meet the PBT criteria.

Even assuming the corrected PNEC, PEC/PNEC values are lower than 1. Nevertheless, for three cases, the procedure for deriving PECs has not been enough justified. Therefore, it is opinion of the SCHER that conclusion (ii) cannot be accepted.

4. LIST OF ABBREVIATIONS

NOEC	No Observed Effect Concentration
PBT	Persistent Bioaccumulative Toxic
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
RAR	Risk Assessment Report
TGD	Technical Guidance Document
WWTP	Wastewater Treatment Plant

5. ACKNOWLEDGEMENTS

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