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Scientific Committee on Toxicity, Ecotoxicity and the Environment

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

Opinion on the results of the Risk Assessment of:

Methyl acetate

CAS No.: 79-20-9
EINECS No.: 201-158-2

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 31th CSTEE plenary meeting

Brussels, 22 May 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.

CSTEE COMMENTS ON:

RISK ASSESSMENT REPORT ON:
Methyl acetate

CAS No.: 79-20-9
EINECS No.: 201-158-2

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.

Opinion

In general the presented RA report is transparent and the science applied is sound.

The CSTEE, however, notes that a number of sections of the Report contains 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 cannot agree with conclusion (ii) for:

- Surface waters because of the unclear selection of a particular toxicity test result (non adherence to the TGD not sufficiently - justified in the RAR).
- Atmosphere, because of the lack of relevant effect data.

Introduction

There are four companies producing methyl acetate within the EU, resulting in a total production of 30 000 t/a. The latter figure is based on 1993 production volumes.

Based on figures available for Germany, methyl acetate is used as a (1) solvent in e.g. adhesives, paint systems, cosmetic agents and cleaning products (70%), (2) and intermediate for plant production products and vitamins (10%, and (3) is also exported and used for an intermediate for the production of sweeteners (20%).
It is assumed that the use pattern of methyl acetate in Germany is also applicable to the EU. A mass balance of 30% non-dispersive use (as intermediates) and 70% wide dispersive use (as solvents personal domestic products and paints lacquers and varnishes) is proposed.

General comments

In general, the environmental exposure and effects assessments and the risk characterisation are conducted using procedures recommended by the TGD (1996).

Where appropriate, realistic worst scenarios were used.

Specific comments

1. Exposure assessment

The RA reports states that during production and use methyl acetate is expected to enter the environment via the waste water and the exhaust air.

A recently performed (1995) closed bottle study demonstrated that the substance is readily biodegradable. The calculated half-life for photochemical degradation in the atmosphere is 50.4 days; laboratory testing resulted is an observed half-live of 94 days.

Based on QSAR calculations a half-life for hydrolysis ranging from 63 to 624 days was established. A experimental study from 1935 reports a half-life for hydrolysis of 53 days.

The theoretical environmental distribution of methyl acetate is estimated using the Mackay level I model. The estimated equilibrium distribution indicated that 30.7, 69.9 0 and 0% of the substance is expected partition to water, air, soil and sediment, respectively.
Elimination in the waste water treatment plants was estimated using the SIMPLETREAT model: 88% of the substance is eliminated from the water.

No experimental bioaccumulation data are available, however the low Kow (0.18) indicates a low bioaccumulation potential. Similarly the calculated Koc does not indicate concern form soil accumulation. Consequently the risks of exposure via the food chain were not evaluated.
The CSTEE agrees with the above analysis of the physico-chemical data.

No measured values of methyl acetate concentrations in surface waters are available. Although not strictly required by the TGD, the CSTEE strongly recommends that this type of data is acquired – or at least a few strategic measurements be made - to ensure the validity of the model calculations.

Local concentrations in water during production and use as an intermediate were calculated using both a generic approach (Emission Scenario Documents) and a site specific approach using information for individual manufactures (3 of the 4 sites). For the generic approach a $Clocal_{water}$ of approximately 5 µg/l was obtained while for site-specific calculations resulted in $Clocal_{water}$ ranging from 0.07 to 1.95 µg/l.
Local concentrations in water during use of the substance in (1) household chemicals, (2) solvents for paints and lacquers, (3) solvent in adhesives for floor covering, (4) paints used in private domain and (5) processing of paints in paint shops were calculated using reasonable worst case assumptions. $Clocal_{water}$ ranged from 9.3 (4) to 278 µg/l (2 and 3).
It should be noted that in some places the RAR does not allow to check the calculations. This is for example the case with the hidden tonnages in the Table on page, which do not allow verification of the model calculations.
In general, the CSTEE agrees with the approach taken.

No measured methyl acetate concentrations in sediments and soils (monitoring data) are available. Although not strictly required by the TGD, the CSTEE strongly recommends that this type is data is acquired to ensure the validity of the model calculations.

Releases into the atmosphere as a result of production and processing: $Clocal_{air}$ and deposition quantities of methyl acetate range from 0.023 to 0.232 mg/m^3 and from 0.026 to 0.275 mg/m^2.d, respectively.
Releases into the atmosphere as a result of use of the substance: $Clocal_{air}$ and deposition quantities range from 0.002 to 0.048 mg/m^3 and from 0.002 to 0.057 mg/m^2.d, respectively.

It is suggested that the text on page 27 (§3 of 3.1.3) is rephrased as it may lead to confusion between PEClocal and PECregional when compared to the Table on page 29.
In general, the CSTEE agrees with the approach taken.

Local soil and soil porewater concentrations as a result of deposition were calculated for (1) production and further processing, (2) formulation for household products and (3) formulation of lacquers and paints. $Clocal_{soil}$ ranged from 3.8 to 20 µg/kg and from 11 to 59 µg/l. Based on model calculations it was concluded that the substance does not adsorbe to sewage sludge; consequently risk of sludge application to soils was not taken into account in this risk assessment.
The CSTEE agrees with the above assessment.

Regional exposures were calculated using sound science. The CSTEE supports the approach taken. Resulting PECs regional were:

- Aquatic: 0.85 µg/l
- Air: 0.13 µg/m^3
- Natural soil: 0.022 µg/kg
- Agricultural soil: 0.013 µg/kg

For all of the assessments and model calculations it should be noted that the CSTEE was not able to verify the detailed calculations as the Annexes to the RAR were not available.

2. Effects assessment

The discussion of quality and relevance of the ecotoxicity data is too brief to allow adequate assessment. However, it seems that reliable acute toxicity tests results are available for two fish species and one invertebrate. The respective effect concentrations were: 225, 320 and 1027 mg/L. Although a growth inhibition test with a unicellular algal species was performed, the reported test results are of limited value as the maximum tested concentration did not encompass the 72h EC50 values. Consequently only a NOEC of 120 mg/L is reported and the EC50 is > 120 mg/L.
The derivation of the $PNEC_{aqua}$ is not based on the lowest available on effect concentration (i.e. *Leuciscus idus* 48h LC50=225 mg/L) but on a higher value (i.e*. Pimephales promelas* 96h EC50 = 320 mg/L). Both test results are based on measured concentrations. The preference for selecting the later result as a basis for PNEC derivation (i.e. the later test was performed in flow conditions, the former in static conditions) does not seem to be justified.

Consequently, the CSTEE does not agree with the PNEC derived in the RAR and proposes to the lowest available effect concentration as the basis for the PNEC derivation.
Subsequently, the $PNEC_{aquatic}$ should be 225 mg/L / 1000 = 225 µg/L.

For micro-organisms, toxicity test results for two species are presented. The CSTEE supports the use of the 16h EC10 for *Pseudomonas putida* as the basis for the $PNEC_{micro\text{-}organisms}$ (or $PNEC_{WWTP}$ as noted in the RAR) as the toxicity data obtained with *Photobacterium* are less relevant in this context.
The CSTEE agrees with the $PNEC_{WWTP}$ derivation: 1830 mg/L / 1= 1830 mg/L.

No sediment toxicity tests are presented in the RAR.

No toxicity data are available for soill organisms. In approximation the $PNEC_{aquatic}$ is used as the PNEC for soil porewater. Considering the CSTEE comments (above) on the aquatic environment the $PNEC_{soil}$ should be 225 µg/L (pore water). Considering the physical-chemical properties and the toxicological profile of this molecule, the use of the equilibrium partitioning method is considered appropriate.

As methyl acetate partitions for approximately 70% to the atmospheric compartment and appreciable PECair are calculated, the CSTEE is of the opinion that an effects on organisms exposed through gaseous phase (i.e. plant test) should be performed.

3. Risk characterisation

The risk characterisation in the Report is performed according to the procedure recommended by the TGD (1996).

In the presented RAR, the PEC/PNEC ratio's for the aquatic environment range from 0.003 to 0.872 depending on the production/formulation site and area of use. However given the comments on the aquatic effect data and the change in PNEC proposed by the CSTEE, the PEC/PNEC is > 1 for formulation is household chemicals, formulation of paints and lacquers and formulation of adhesives.
Considering the very brief discussion on the effects data, the CSTEE suggest that this section is revised and elaborated before changing the conclusion of the RAR (ii).

The RAR states that based on the physico-chemical properties there is no indication that the substance accumulates in sediments and therefore it is not necessary to perform a risk characterisation for this compartment. The CSTEE agrees with this conclusion (ii).

Since no ecotoxicological information is available for the atmospheric compartment no risk characterisation was performed. Given the calculated concentrations in air and the properties of the substance the RAR concludes that the type of assessment is not necessary.
The CSTEE does not agree with this conclusion (ii) and proposes that the effect evaluation and a quantitative risk assessment is performed.

For the soil compartment the RAR reports a PEC/PNEC ratio (soil porewater) of 0.18. Considering the revised PNECaquatic and consequently changed PNECsoil, the PEC/PNEC now becomes 0.26. Despite these changes, the conclusion that no risk to the soil compartment are expected is still valid.
The CSTEE supports this conclusion (ii).

Based on the low bioaccumulation potential, the RAR concludes that no risk characterisation for exposure via the food chain is required.
The CSTEE supports this conclusion.