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Directorate C - Scientific Opinions
Unit C2 – Management of Scientific Committees; scientific co-operation and networks
**Scientific Committee on Toxicity, Ecotoxicity and the Environment**

Brussels, C2/JCD/csteeop/**EthylacetoHH22022002**/D(02)

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

**Opinion on the results of the Risk Assessment of:**

# Ethyl acetoacetate

**CAS No.: 141-97-9**
**EINECS No.: 205-516-1**

**REPORT VERSION (Environment): Draft of 09.01.2002**

**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 30th CSTEE plenary meeting**

**Brussels, 22 February 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.

# 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

There are currently two companies producing ethyl acetoacetate within the EU, each producing between 1000 and 5000 t/a. Ethyl acetoacetate is essentially used as an intermediate for plant production products, pharmaceuticals, stabilisers, additives, catalysts and other products (94.6%). Other uses are as a fragrant or odour agent in cleaners, washing detergents and air deodorants (3.8%) and as a solvent in paints and lacquers (1%).

# 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 releases into the environment during production is expected to occur to only a very small extent since production takes place water free and in a closed system and the exhaust gas is incinerated. Releases into the wastewater and into the exhaust air are expected during further processing and use of the substance.

A recent closed bottle study demonstrated that the substance is readily biodegradable. The calculated half-life for photochemical degradation in the atmosphere is 10.3 days and the calculated half-life for hydrolysis ranges from 15 to 149 days.

The theoretical environmental distribution of ethyl acetoacetate is estimated using the Mackay level I model. The estimated equilibrium distribution indicated that 96 %, 3.5, 0.25 and 0.25% of the substance is expected partition to water, air, soil and sediment, respectively.

No experimental bioaccumulation data are available, however the low Kow (0.25) indicates a low bioaccumulation potential.

The CSTEE agrees with the above analysis of the physico-chemical data.

No measured values of ethyl acetoacetate concentrations in surface waters are available. Local concentrations in water during production and processing were calculated using both a generic approach (Emission Scenario Document – IC3 using 5000 t/a) and a site specific approach using information for individual manufactures resulting in $Clocal_{water}$ of 2.84 µg/l and 1.45 to 1.70 µg/l, respectively.

Local concentrations in water during use in (1) household chemicals, (2) paints and lacquers and (3) paper coating and paper impregnation were calculated using reasonable worst case assumptions. $Clocal_{water}$ ranged from 3.9 tot 126 µg/l depending on the use scenario. The CSTEE agrees with the approach taken.

No measured ethyl acetoacetate concentrations in sediments and soils are available.

Releases into the atmosphere resulted in $Clocal_{air}$ and deposition quantities ranging from $1.4.10^{-3}$ to $5.5.10^{-5}$ mg/m$^3$ and from $1.1.\ 10^{-3}$ to $4.7.\ 10^{-5}$ mg/m$^3$.d, respectively.

Local soil and soil porewater concentrations as a result of deposition were calculated for (1) production and further processing at one site, (2) formulation for household products and (3) formulation of lacquers and paints. $Clocal_{soil}$ ranged from $1.6.10^{-5}$ to $3.8.10^{-5}$ mg/kg and from $5.3.10^{-5}$ to $1.10^{-4}$ mg/l.

Based on model calculations it was concluded that the substance does not adsorbe to sewage sludge; consequently risk of sludge application to soils were not assessed.

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: 0.04 µg/l
- Air: 0.37 ng/m$^3$
- Natural soil: 3.5 ng/kg

## 2. Effects assessment

The quality and relevance of the ecotoxicity data is discussed appropriately. Reliable acute toxicity tests results are available for 3 trophic levels. A 48h test with the fish *Leuciscus idus* resulted in the lowest EC50: 275 mg/l . As noted in the RAR this exposure period is shorter than recommended in OECD guideline 203. However, as supporting QSAR estimations were performed and none of these produced LC50 values lower that the observed toxicity results, the CSTEE supports the use of this EC50 value.

The PNECaquatic is 275 mg/L / 1000 = 275 µg/l

No toxicity data are available for terrestrial organisms. In approximation the PNECaquatic is used as the PNEC for soil porewater.

As no toxicity data for micro-organisms are presented in the RAR, no PNECmicro-organisms was determined. The CSTEE suggest that a justification is given on why the risk for this TGD protection goal was not assessed.

No sediment toxicity tests are presented in the RAR.

## 3. Risk characterisation

The risk characterisation in the Report is performed according to the procedure recommended by the TGD (1996). The calculated PEC/PNEC ratios are < 1 for all environmental compartments.

For the aquatic environment PEC/PNEC ratios range from 0.005 to 0.46 depending on the production/formulation site and area of use.

No risk characterisation was performed for sediments. The RAR states that based on the physico-chemical properties there is nothing to indicate 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.

Since no ecotoxicological information is available for the atmospheric compartment no risk characterisation was performed. Given the low calculated concentrations in air and the properties of the substance the RAR concludes that these types are not necessary. The CSTEE agrees with this.

For the soil compartment the risk characterisation is based on the PEC/PNEC ratio of the soil porewater compartment = 0.0003. The RAR consequently states that no risks to the soil compartment are expected. The CSTEE supports this conclusion.

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.

**Opinion/Conclusions**

The presented RA report is transparent and the applied science is sound.

The CSTEE notes that the environmental exposure and effects assessments and the risk characterisation are conducted using procedures recommended by the TGD (1996).

The CSTEE agrees with conclusion ii) for the environment.