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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
C7 - Risk assessment

SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS

SCHER

Opinion on

"Risk Assessment Report on Propan-1-ol Environmental Part"

CAS No.: 71-23-8

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Adopted by the SCHER
during the 3rd plenary of 28 January 2005

TABLE OF CONTENTS

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

(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

The environmental part of the RAR is of good scientific quality and the risk assessment is performed according to the principles and procedures recommended by the TGD. The amount of information presented in the RAR is limited both for the effect and exposure assessment. The exposure assessment was performed using realistic worst case assumptions and the exposure scenario's recommended by the TGD. In the effects assessment a lower assessment than one normally used for acute aquatic toxicity data was used. This was justified by the number and type of species tested and the non-specific mode of action of the substance. The RAR proposes conclusion ii)[1] for all environmental compartments. The SCHER agrees with the conclusion of the RAR.

3.1. Specific Comments

3.1.1. Exposure assessment

The RAR states that Propan-1-ol has a relatively high vapour pressure, high solubility, low K_{ow} and is easily biodegraded. It is noted that no values for water solubility and no results for a standard readily biodegradability test are given in the RAR. The SCHER supports the results of the distribution analysis given in the report. The RAR states that there is one production site in the EU. Although no specific information on the consumption volumes of individual companies using propan-1-ol in Europe are given the % use of propan-1-ol as solvent or as intermediate are

[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.

given. For the determination of the C_{local} water a generic approach (using a 'typical' quantity) was used. For production the C_{local} water was calculated using monitoring data from one company. From the RAR it is unclear whether this is the only producer in the EU. The C_{local} for water for the use of propan-1-ol was calculated using the 10% rule as recommended by the TGD. The SCHER agrees with the proposed approaches. The SCHER notes that emission data of the end users of the substances should be reported in the RAR

The approach taken for calculating the PECs $_{regional}$ is supported by SCHER.

3.1.2. Effect assessment

3.1.2.1. Aquatic organisms

The toxicity data presented in the RAR cover only acute toxicity data. The LC50s for eight vertebrate species ranged from 3200 to 5900 mg/l; the 96h LC50 of 3200 mg/l obtained for rainbow trout is taken as the lowest available effect value for this group. Eight L(E)C50s are available for the invertebrate group. The 48 h LC50 of 1000 mg/l obtained with *Gammarus pulex* was the lowest reported value. NOECs and TTC are available for five species of micro-algae. The lowest value was not selected as this TTC is based on an 8-day test. The justification (i.e. algae not in the exponential growth phase) given in the RAR for not selecting this value as the lowest effect concentration for this organism group is supported by the SCHER. Based on acute toxicity data only, an application factor of 1000 is usually applied to derive the PNEC. In the RAR, an application factor of 100 is used and justified as follows: 1) the taxonomic diversity of the species used for the acute toxicity testing, and 2) the non-specific mode of action of the substance. The SCHER agrees with the lower extrapolation factor and the proposed PNEC of 10mg/l.

The $PNEC_{microorganism}$ is based on results of toxicity tests with three species of microorganisms and one activated sludge test and was performed according to TGD procedures. The SCHER agrees with the proposed PNEC of 96 mg/l.

No PNEC for sediment was derived as there are no indications of absorption of this substance to sediments. The SCHER agrees with this conclusion.

3.1.2.2. Terrestrial organisms

No information on the toxicity of propan-1-ol to soil organisms is available. The RAR proposes the use of the aquatic PNEC for the purpose of a risk assessment for the terrestrial compartment through a comparison of the $PNEC_{aqua}$ with the calculated soil pore water concentrations. The SCHER agrees with the proposed calculations.

3.1.3. Risk characterisation

For all environmental compartments PEC/PNEC ratios are <0.01, except for the aquatic environment for which the uses 'formulation of paints' and 'processing of solvents' resulted in PEC/PNEC ratios of 0.03 and 0.02. Based on these risk quotients the SCHER supports the proposed conclusion (ii) for all compartments.

4. LIST OF ABBREVIATIONS

LC50	median Letal Concentration
L(E)C50	median Letal (Effect) Concentration
NOEC	No Observed Effect Concentration
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
RAR	Risk Assessment Report
TGD	Technical Guidance Document
TTC	Toxic Threshold Concentration

5. ACKNOWLEDGEMENTS

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