EUROPEAN COMMISSION
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

2,4-DINITROTOLUENE

Environmental Part

CAS No.: 121-14-2

EINECS No.: 204-450-0

Adopted by the SCHER
during the 13th plenary of 19 September 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

The RAR is of good quality. The TGD procedures have been properly applied. A critical evaluation of the available data, aimed at selecting information reliable for the assessment was made and is supported by SCHER. The conclusions are supported by a large amount of information and by appropriate extrapolation procedures.

The Report proposes Conclusion (iii)[1] for the freshwater compartment (including sediments) and Conclusion (ii) for all other compartments and for secondary poisoning.

The SCHER supports these Conclusions.

3.2 Specific Comments

3.2.1 Exposure assessment

2,4-dinitrotoluene is a relatively high production volume compound. The estimated production volume in the European Union is about $5x10^5$ tons/y, mainly used in closed systems as intermediate for the synthesis of other chemicals.

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[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.

Emissions are expected only in water and were calculated from information provided for the production sites.

From the physical-chemical properties and the Level I Fugacity Model, the preferred environmental compartment is water.

It is relatively persistent and non-ready biodegradable.

The potential for bioaccumulation is low.

PECs (continental, local and regional) have been properly calculated according to TGD procedures.

Relatively recent monitoring data from German surface waters, substantially lower than the predicted ones, cannot be used for comparison at the local scale. Comparison is also difficult with monitoring data on soil.

3.2.2 Effect assessment

A large amount of reliable toxicity data (short and long term) are available for aquatic organisms.

The SCHER agrees with the PNEC of 2 μg/L calculated by applying a factor of 10 to a long term NOEC on *Daphnia*.

The SCHER also agrees with the proposed PNECs for the marine environment and for micro-organisms.

In the absence of reliable data on sediment organisms, PNEC was calculated using the equilibrium partitioning method. The SCHER agrees with calculated PNECs for freshwater and marine sediments.

Soil compartment

Several toxicity data on terrestrial organisms are available, however, only a few have been considered reliable and valid for PNEC calculation.

A PNEC of 4.9 μg/kg was calculated by applying a factor of 1000 to the lowest acute toxicity value. It can be noted that the PEC calculated using the equilibrium partitioning method was 5.5 μg/kg, practically identical to the PEC based on terrestrial ecotoxicity data.

Moreover a PNEC of 2.1 μg/L has been calculated for pore water, using data on hydroponic toxicity tests on plants.

The SCHER agrees with the proposed values.

Atmospheric compartment

No data are available on effects through atmospheric exposure.

Secondary poisoning

The SCHER support the statement that no secondary poisoning is expected.

3.2.3 Risk characterisation

Aquatic compartment

For two local sites (B and C) PEC/PNEC ratio was higher than 1 (in site C two orders of magnitude higher) for water, as well as for sediments.

Therefore the SCHER agrees with Conclusion (iii) for the freshwater compartment at the local level.

The SCHER also agrees with Conclusion (ii) applied to the marine compartment.

Soil compartment

All calculated PEC/PNEC ratios below 1 (generally orders of magnitude lower). Therefore the SCHER supports conclusion (ii) proposed by the RAR.

Atmosphere

Due to the low volatility of the chemical, concentrations in air are negligible even at the local scale, with a maximum around $1*10^{-5}$ $\mu g/m^3$. Therefore, even in absence of specific toxicity data, the SCHER agrees with Conclusion (ii).

Secondary poisoning

The SCHER agrees with Conclusion (ii) for secondary poisoning.

4. LIST OF ABBREVIATIONS

NOEC	No Observed Effect Concentration
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
RAR	Risk Assessment Report
TGD	Technical Guidance Document

5. ACKNOWLEDGEMENTS

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