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SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS

SCHER

Opinion on

Risk Assessment Report on

2-NITROTOLUENE

Environmental Part

CAS No.: 88-72-2

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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. The conclusions are generally supported by enough information and by appropriate extrapolation procedures. Few information is only provided for the atmospheric compartment that, for a volatile chemical like 2-nitrotoluene, is not negligible.

The Report proposes Conclusion (ii)¹ for all compartments and for secondary poisoning.

The SCHER supports this Conclusion except for the atmospheric compartment, for which insufficient information is provided to support this conclusion.

3.2 Specific Comments

3.2.1 Exposure assessment

2-nitrotoluene is a highly volatile chemical, with a strong tendency to partition to air. It is used (generally on the same production site) in closed systems, as an intermediate for the synthesis of

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.*

other chemicals. Three producers are now active in Europe. Environmental releases have been calculated using emission data provided by the industry, whenever available. In other cases, air emissions have been estimated using the TGD default factors, even if there was some evidence of abatement processes. So, the calculated air emissions may reflect realistic worst case.

The chemical is relatively persistent in all compartments, non-biodegradable in water, inherently biodegradable in industrial sewage treatment plants.

It has a low bioaccumulation potential and is usually metabolised in vertebrates. A partial exception seems to be marine mammals due to their lower metabolic capability for some types of chemicals.

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

A comparison of the calculated PECs with monitoring data is problematic. European data refer only to the aquatic compartment and most of them are very old. The only relatively recent data refer to German surface water in 1997 and 1999. On this point the SCHER does not agree with the statement in the RAR that, from experimental data, concludes: "*the PEC_{local} obtained for site A is considered to be admissible*". Calculated PEC is substantially lower than 1997 data, while 1999 data are indicated as "<". Moreover we do not know if the German sampling points are close to production site (so they have to be considered as "local") or far from the site (so they have to be considered as "regional"). It is opinion of the SCHER that this comparison is impossible and cannot be used in support of predicted values.

3.2.2 Effect assessment

Aquatic compartment

Many data on the toxicity of 2-nitrotoluene to aquatic organisms are available, but most of them refer to static test procedures and use nominal concentrations. Considering the high volatility of the chemical, the SCHER cannot agree with the classification of "Valid" of long term (28d) fish tests, static and based on nominal concentrations (Table 3.15 of the RAR).

The SCHER agrees with the PNEC of 10 µg/L calculated by applying a factor of 50 to a long term NOEC on *Daphnia* obtained with a suitable test method.

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, the PNEC was calculated using the equilibrium partitioning method. The SCHER agrees with calculated PNECs for freshwater and marine sediments.

Soil compartment

In the absence of reliable data on soil organisms, the PNEC was calculated using the equilibrium partitioning method. The SCHER agrees with the calculated PNEC for soil.

Atmospheric compartment

No data are available on the effects on organisms exposed through the atmosphere. The SCHER cannot agree with the statement (pag. 57): “*volatilisation to the atmosphere may be likely to be limited due to the vapour pressure of the substance*”. This statement is in contradiction with the sentence at page 30 of the RAR: “*2-nitrotoluene has a strong tendency to migrate to air and water*”. It is opinion of the SCHER that a vapour pressure of 28 Pa and a Henry’s constant of 1.2 Pa m³/mol indicate a strong affinity for the atmospheric compartment.

Secondary poisoning

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

3.2.3 Risk characterisation

Aquatic and terrestrial compartments

All the calculated PEC/PNEC values are below (in most cases far below) the threshold of 1. Therefore the SCHER agrees with Conclusion (ii) for the aquatic (including marine and sediments) and terrestrial compartments.

Atmosphere

The SCHER support the statement that no adverse effects are likely at regional and continental level due to the low PECs. However, there is insufficient information for supporting this statement at the local level. Therefore, the SCHER cannot agree with Conclusion (ii) for the atmosphere. Even if the probability of risk is low, at least a preliminary assessment is needed, by using inhalation data from the Human Health assessment, by extrapolating information from comparable chemicals or by using QSAR approaches.

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
QSAR	Quantitative Structure-Activity Relationship
RAR	Risk Assessment Report
TGD	Technical Guidance Document

5. ACKNOWLEDGEMENTS

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