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

SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS

SCHER

Opinion on

Risk Assessment Report on

Vinyl acetate

Environmental Part

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Adopted by the SCHER
during the 10 plenary of 17 March 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 in general of good quality; the rapporteur has considered the particular characteristics of vinyl acetate and maximized the use of available information. However the methodology and criteria employed for the validation of this information by the rapporteur have not been included in all cases for reasons of confidentiality. As a consequence, the committee cannot establish if the deviations from the TGD principles and default values are really justified under scientific grounds.

The RAR focuses on the risk associated to the production, processing and use of the VAM. The report proposes conclusion (ii)[1] for the aquatic and atmospheric compartments, and conclusion (i) for the terrestrial (soil) compartment. The SCHER agrees with this conclusion for the aquatic and terrestrial compartments, but not with the conclusion presented for atmosphere. Due to the volatility of vinyl acetate, direct or indirect (deposition) atmospheric exposures should be considered as a significant route. The SCHER recognises that the TDG offers little guidance for assessing these risks; nevertheless, in the opinion of the Committee, efforts should be done for covering the risk associated to these exposures in a proper way. The exposure of soil organisms

[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.

is related to atmospheric deposition; thus, terrestrial plants will be exposed from the atmosphere as well as from the soil.

The SCHER suggests that the request for information on the toxicity of vinyl acetate to terrestrial plants should cover both soil and atmospheric exposures. This opinion is fully in agreement with previous opinions from the CSTEE. In addition, the European Chemicals Bureau has presented a document reporting discussion on this issue in 2001 (DOC ENV/D/430603/01 Rev 1 ECB 4/08/01[2]). The document states that "*ECB would prepare a proposal on the general implications of this recommendation. The implication would be that the plant test would be considered as a base-set test for substances which partition mainly to the atmosphere*" and offers the following proposal:

Awaiting the discussions on the implementation of the White Paper (WP) and the decisions on test requirements that need to be made within that process it is proposed to continue with the evaluation of the risks to the air compartment as done until now. This implies that:

1. *When information is available on toxicity to plants the Rapporteur carefully screens this information and if necessary comes with a proposal for further plant toxicity testing via airborne exposure.*
2. *When no specific information on toxicity to plants is available for the substance and considerable air emissions and exposure are expected the Rapporteur screens information on related substances (e.g. on toxicity, physico-chemical properties) and decides whether there is reason for concern and whether actual plant testing via airborne exposure should be considered.*
3. *When neither 1 nor 2 apply, no further plant testing is requested.*

For (relatively) volatile substances it should be considered to mention in the final OJ conclusions that this specific endpoint has not been considered in the risk assessment process.

Meanwhile in the context of the TGD revision a testing strategy on plant toxicity testing with selection criteria will be developed. This could serve as input for the decisions to be made in the context of the WP implementation.

However, the RAR only indicates that "*No experimental data on toxicity of VAM to terrestrial plants is available. Therefore no PNEC$_{air}$ can be calculated for terrestrial vegetation*", but still suggests conclusion (ii). This is not acceptable for the SCHER, which stresses the need for a proper assessment of HPVC which shows a significant partition to air. In addition, the Committee considers that the risk for terrestrial vertebrates exposed via air should be estimated from the inhalation toxicity studies.

3.2 Specific Comments

3.2.1 Exposure assessment

Vinyl acetate is used as an intermediate chemical for producing vinyl acetate polymers. The RAR considers that the main environmental emissions are related to the production and processing. The report mentions that additional emissions should be expected during the final phases of the life cycle of this chemical, due to the presence of residual vinyl acetate monomer in

[2] DOC ENV/D/430603/01 Rev 1 ECB 4/08/01 Existing Substances Technical Meeting proposal for endorsement by the Competent Authorities. Relating to the issue: whether information on toxicity to terrestrial plants via airborne exposure must be considered essential for certain priority substances.

the polymers and end-user products. An average figure of 3,000 ppm of VAM in the polymers is mentioned in the RAR.

Vinyl acetate is a readily biodegradable, highly volatile, highly water soluble compound.

The emissions to water are estimated using an emission factor of 0.02% instead of the default value of 0.7% included in the TGD. This factor is supported by industry data included in a questionnaire which is not available to the SCHER; thus, the Committee cannot check the quality of these data; additional information on these estimations should be presented for allowing an opinion of this Committee on the validity of the employed approach.

The RAR does not include the employed dilution factors; it just mentions that all facilities are located at large rivers, estuaries or at the sea. Additional information should be convenient. The ECB stated in a communication to the SCHER that this information is considered confidential. The SCHER must express again the constraints for transparency and external validation related to the use of confidential data in the RARs.

The RAR considers that soil exposure is mostly expected from atmospheric deposition, while the contribution of sludge applications is assumed to be negligible; the rationale supporting this assessment is considered acceptable.

3.2.2 Effect assessment

A $PNEC_{aquatic\ organisms}$ is properly calculated by applying a factor of 50 to valid chronic NOECs covering fish and algae.

No data on sediment organisms are available and a PNEC for sediments is not calculated. Due to the low Koc value, accumulation in sediments is unlikely to occur.

A $PNEC_{microorganisms}$ is properly calculated from a suitable test on *Pseudomonas*.

For the terrestrial environment, fumigation tests with diptera and gastropods are available. These results cannot be used for a PNEC derivation but at least indicate that the acute toxicity is several orders of magnitude higher that the expected air concentration; the invertebrate figures are higher than the acute mammalian LC50s reported in the USEPA-IRIS web page (http://www.epa.gov/iris/subst/0512.htm#refinhal). A letter from the ECB includes several toxicity figures on mammalian inhalation studies; the SCHER recommends the inclusion of these values in the RAR, as well as preliminary risk estimation.

No data are available for soil organisms. A PNEC was calculated using the equilibrium partition method; however, it should be considered that due to the volatility of this chemical soil organism may also be exposed from the fraction of chemical in air.

3.2.3 Risk characterisation

For the aquatic compartment, the RAR indicates that all PEC/PNEC ratios are below 1 and proposes conclusion (ii). The SCHER agrees with the PNEC derivation but cannot establish the validity of the PECs as they are based on confidential data not presented to the committee. It must be stressed that the PECs water are estimated for large rivers, estuaries or the sea. The PEC/PNEC ratios are below but in same cases very close to 1, thus the low risk is related to the large dilution factors.

The Committee supports the qualitative assessment justifying conclusion (ii) for the sediment.

The SCHER also supports the need for additional information for assessing the risk for terrestrial (soil) organisms.

However, the proposal of low risk for the atmosphere is only supported for the abiotic hazards. For terrestrial plants, the exposure via air is considered relevant, and therefore the SCHER suggests conclusion (i) and to include atmospheric exposures in the requested ecotoxicity tests on plants.

Regarding terrestrial vertebrates and invertebrates, the Committee considers that a proper evaluation should be conducted. A Clocal air of 288 µg/m^3 has been estimated for one site (26). This value is higher than the inhalation RfC of 200 µg/m^3 proposed by the USEPA-IRIS. The ECB has confirmed the availability of mammalian data; thus the Committee suggests re-evaluating this potential risk on the basis of the validated inhalation toxicity studies to be included in the Human Health part of the RAR.

4. LIST OF ABBREVIATIONS

ECB	European Chemicals Bureau
HPVC	High Production Volume Chemicals
LC50	Lethal Concentration for 50% of the test organisms
NOEC	No Observed Effect Concentration
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
RAR	Risk Assessment Report
RfC	Reference Concentration
TGD	Technical Guidance Document
VAM	Vinyl Acetate Monomer

5. ACKNOWLEDGEMENTS

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