



Scientific Committee on Health and Environmental Risks

SCHER

N-cyclohexylbenzothiazole-2-sulfenamide
(CBS)
Environmental Part

CAS Number: 95-33-0

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Opinion adopted by the SCHER during the 22nd plenary of 12 March 2008

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Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

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SCHER

Questions relating to examinations of the toxicity and ecotoxicity of chemicals, biochemicals and biological compound whose use may have harmful consequences for human health and the environment.

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Scientific Committee members

Herman Autrup, Peter Calow, Wolfgang Dekant, Helmut Greim, Wojciech Hanke, Colin Janssen, Bo Jansson, Hannu Komulainen, Ole Ladefoged, Jan Linders, Inge Mangelsdorf, Marco Nuti, Anne Steenhout, Jose Tarazona, Emanuela Testai, Marco Vighi, Matti Viluksela

Contact:

European Commission
Health & Consumer Protection DG
Directorate C: Public Health and Risk Assessment
Unit C7 - Risk Assessment
Office: B232 B-1049 Brussels

Sanco-Sc8-Secretariat@ec.europa.eu

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http://ec.europa.eu/health/ph_risk/risk_en.htm

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Prof. Jose V. Tarazona, Spanish National Institute for Agriculture and Food Research and Technology, Spain

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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

The SCHER on the basis of the examination of the Risk Assessment Report is invited to examine the following issues:

1. Does the SCHER find the conclusions of the targeted risk assessment appropriate?
2. If the SCHER finds any conclusion not appropriate, the SCHER is invited to elaborate on the reasons for this divergence of opinion.
3. If the SCHER finds any specific approaches or methods used to assess the risks inappropriate, the SCHER is invited to suggest possible alternative approaches or methods meeting the same objectives.

3. OPINION

3.1 General Comments

The environmental part of the risk assessment of CBS is of variable quality. The RAR identifies the release of vulcanization breakdown products as the main concern regarding environmental releases and tries to use available information. The weaknesses related to data availability are identified in the report, as well as the complexity for assessing a mixture of benzothiazole derivatives for which CBS is only responsible for part of the releases. However, in the SCHER opinion the rapporteur goes too far in the effect assessment.

Although the RAR recognises that the ecotoxicity assays on CBS and some derivatives are not valid, and when valid, are incomplete, tentative PNECs are presented and used to estimate processes with low environmental risk. The Committee considers that the use of non valid studies as the basis for the PNEC derivation is not acceptable. In particular, for chemicals with very low water solubility and relatively high K_{ow} such as CBS, the lack of effects in short-term test should not be considered as a sign of low toxicity, and the derivation of a PNEC for these chemicals should in all cases be based on chronic studies. In addition it should be noted that benzothiazole derivatives should be considered reactive chemicals, and as suggested from the RAR measured ecotoxicity data tend to be lower than QSAR estimations.

The PNEC for MBT and MBTS does not consider the available evidence and a lack of effect information is also observed for other derivatives. It should be noticed that a more conservative effect assessment would modify the RAR conclusions.

As a consequence, the SCHER agrees with the need for further information regarding the release of vulcanization breakdown products, but also considers essential to request additional ecotoxicity tests on CBS and the breakdown products. Thus, conclusion i)¹ for the

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;*

aquatic (including sediment) and terrestrial (soil) compartments is proposed for CBS and for the release of vulcanization breakdown products from rubber.

The RAR proposal for conclusion ii) for the atmosphere is also agreed, but not for the aquatic environment (including sediment) and soil.

In the risk characterization it should be noticed that the releases of the breakdown products are widely distributed in the environment and may affect a large percentage of European water bodies. Therefore, the ecological consequences, if any, would not be restricted to a few locations receiving industrial emissions.

3.2 Specific Comments

3.2.1 Exposure assessment

CBS is produced in the EU, imported and exported, with a balance of ca 6000 t/a used in the EU, additional imports not covered by Regulation 93/793/EEC are identified in the RAR, producing a total market of 20 000 t/a within the EU-15.

CBS is exclusively used as vulcanization accelerator in rubber goods manufacture. During the process several benzothiazole derivatives are produced and incorporated into the rubber. It should be noticed that other benzothiazole compounds are also used as vulcanization accelerators. According to the RAR CBS represents about one half of the total employed amount. The RAR also includes related compounds with other uses and a reference to natural benzothiazole compounds.

The exposure assessment for CBS is based on industry measurements, the quality and characteristics of this industry information is not presented in the RAR, and therefore, SCHER cannot comment on the PEC estimations.

The assumption of zero emissions for CBS for the use of CBS according to the OECD report should be better justified.

The Committee recognises the lack of enough information for assessing the release of vulcanization breakdown products from tires and other sources, and supports the need for further information.

3.2.2 Effect assessment

The study recognises the lack of valid assays for the effect assessment of CBS but, nevertheless, presents a tentative PNEC for aquatic organisms. This approach is considered unacceptable by SCHER. The PNEC for MBT does not consider the evidence of an algae NOEC expressed as less than the nominal concentration and the fact that "the effective concentration may be significantly lower" due to photolysis. For MBTS, the PNEC is derived from a value which is above the water solubility limit.

The discussion on the methods for adding the toxicological information is relevant but useless until a proper effect assessment for CBS and its breakdown products could be presented.

The use of an additional factor of 10 for the marine environment is not justified.

The PNEC derivation for mammals is based on an ecologically relevant endpoint and, therefore, seems acceptable. Nevertheless a more in depth description of available mammalian toxicity data should be welcomed.

- conclusion iii): *There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account*

3.2.3 Risk characterisation

The RAR indicates conclusion i) for several scenarios, including tire recycling activities; road runoff, in receiving waters and in road border soil, due to substances originate from tire abrasion; and leachate from landfilled general products, deposited tires and landfills in general. Conclusion ii) is presented for CBS emissions from the three CBS production sites to the aquatic environment, secondary poisoning, the combined exposure of CBS and its breakdown products in the aquatic environment and waste water treatment plants at producer sites; and use in the rubber industry.

SCHER considers that the available information is not sufficient for a proper assessment and suggests conclusion i) for all scenarios related to the aquatic environment (including sediment) and soil. It should be noticed that the proposed PEC/PNEC ratios based on tentative PNECs are close to 1 and in one case may exceed this value; the statement that "confidential information indicates low risk" cannot be validated by the Committee.

Low risk for the atmosphere is expected from the physical-chemical properties of CBS.

The low risk for secondary poisoning of CBS could be considered acceptable if a proper justification is presented for assuming no emissions from its use.

4. LIST OF ABBREVIATIONS

| | |
|------|--|
| CBS | N-cyclohexylbenzothiazole-2-sulfenamide |
| MBT | 2-Mercaptobenzothiazole |
| MBTS | 2,2`-Dithio-bis-benzothiazole |
| OECD | Organisation for Economic Co-operation and Development |
| PEC | Predicted environmental concentration |
| PNEC | Predicted no effect concentration |
| RAR | Risk assessment report |