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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 Benzyl Butyl Phthalate (BBP) Human Health Part"

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

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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

The health part of the document is of good quality, it is comprehensive and the exposure and effects assessment follows the TGD. The RAR covers most of the studies relevant for exposure and hazard assessment of BBP, a number of more recent studies should by included into the reference list. However, use of the data from these studies does not change the conclusions made in the RAR.

The studies used as a basis for effects assessment are described in much detail. However, sometimes comparisons of the effects in different studies should have been made. Furthermore, the supportive arguments for the conclusions drawn are missing in some cases. Editorial aspects such as typographical errors and incomplete sentences also require attention.

Human exposure to BBP may occur during occupational scenarios by inhalation and skin contact; consumer exposure may be due to skin contact with BBP-containing materials or ingestion. The RAR uses measured data, physico-chemical properties of BBP, and information on production processes in combination with model predictions (EASE) for exposure assessment. Three general scenarios for occupational exposures (with subscenarios) are evaluated for risk characterisation. Inhalation exposure is estimated based on measured data, extent of skin contact and dermal uptake is modelled. Regarding direct consumer exposure, three scenarios were developed. Indirect exposure via the environment is based on concentrations of BBP in food, indoor air and baby articles. Estimated combined exposures for children and adults are supported by results on biomonitoring of BBP-metabolite excretion. The exposure assessment based on the biomonitoring data is carried forward to the risk assessment. This approach is supported by the SCHER.

The overall conclusions on dermal absorption in humans, suggesting a reasonable worst-case of 5 % uptake, which is carried forward to the risk assessment, are supported.

A large number of repeated dose toxicity (ranging from duration of 28 days to up to 2 years, dietary and inhalation exposures) studies are available. For oral administration, a NOAEL of 62.8 mg/kg/day calculated from the effects from an inhalation study, which gave a NOAEC of 218 mg/m^3, is carried forward to the risk characterization for workers. No NOAEL for dermal exposure is derived. Regarding reproduction and development as endpoints, the RAR uses the NOAEL of 50 mg/kg/day derived from a recent two-generation study on BBP.

The mode of action for reproductive toxicity is elaborated and the same mode of action also applies to other phthalates. Since there is a common mechanism of action for the reproductive toxicity of phthalates, which needs to be discussed, additivities should be considered in the risk characterisation. This may not be a problem with BBP due to the very large MOS derived for consumer exposures, but may be relevant for other phthalates.

Most of the MOS calculated for the worker exposure scenarios are > 100, when a MOS of < 100 is derived, the RAR adequately justifies conclusion ii)[1] due to a conservative exposure and effects assessment. Risk characterization for consumers uses the NOAEL for developmental toxicity as a starting point and the MOS-values derived are >> 1 000.

The SCHER agrees with conclusion ii) for all exposure scenarios.

Because BBP is not mutagenic in vivo and in vitro, this endpoint was not considered further in the assessment. The SCHER agrees with this approach and supports conclusion ii). However, more detailed support for the statement that BBP is not considered to be carcinogenic should be given in the RAR.

Regarding classification for reproductive toxicity, SCHER agrees with the proposal (category 2 for developmental effects, category 3 for fertility).

4. LIST OF ABBREVIATIONS

BBP	Butyl Benzyl Phthalate
EASE	Estimation and Assessment of Substance Exposure Physico-chemical properties [model]
MOS	Margin of Safety
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
RAR	Risk Assessment Report

[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.

TGD Technical Guidance Document

5. REFERENCES

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6. ACKNOWLEDGEMENTS

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