EUROPEAN COMMISSION

Directorate-General for Health & Consumers

Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on

p-tert-butylphenol

Human Health Part

CAS No: 98-54-4

EINECS No: 202-679-0

Scientific Committees

on consumer products

on emerging and newly identified health risks

on health and environmental risks

The SCHER adopted this opinion at its 25th plenary of 9 September 2008

About the Scientific Committees

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.

They are: the Scientific Committee on Consumer Products (SCCP), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Evaluation Agency (EMEA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCHER

Questions relating to examinations of the toxicity and ecotoxicity of chemicals, biochemicals and biological compounds whose use may have harmful consequences for human health and the environment.
In particular, the Committee addresses questions related to new and existing chemicals, the restriction and marketing of dangerous substances, biocides, waste, environmental contaminants, plastic and other materials used for water pipe work (e.g. new organics substances), drinking water, indoor and ambient air quality. It addresses questions relating to human exposure to mixtures of chemicals, sensitisation and identification of endocrine disrupters.

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

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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 Risk (SCHER) to give its opinion.

2. TERMS OF REFERENCE

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

(1) Does SCHER agree with the conclusions of the Risk Assessment Report?

(2) If SCHER disagrees with such conclusions, it is invited to elaborate on the reasons.

(3) If 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 health part of the document is of a good quality and has been developed according to the Technical Guidance Document (TGD). It is a comprehensive survey and no additional references could be identified. In some cases, especially in the area of endocrine modulation a comparison with other phenols has been made, but p-tertbutylphenol (ptBP) is far less potent.

3.2 Specific comments

3.2.1 Exposure assessment

The occupational exposure is assumed to be by inhalation and dermal contact and has been assessed for three major scenarios, I) production of ptBP, II) users of ptBP as an intermediate, and III) professional end users, e.g., resins, paints. As relative few measurements are available, exposures have been calculated by the EASE program. PPE used for the different working conditions, e.g., gloves and goggles, is taken into considerations. Based upon biological monitoring data and ambient air concentrations, it was anticipated that in scenario I, the major route of exposure was through the skin, whereas in the other scenarios the dermal exposure is considered negligible. In case of scenario II assessment, four different sub-scenarios were considered based upon the end-product.

Consumer exposure is through the use of products with resins containing residual amounts of ptBP monomers, and the use of products made of polycarbonates, and exposure occurs mainly through the dermal and oral routes. Four different scenarios were considered 1) use of adhesives containing ptBP, 2) drinking of water from reservoirs and pipelines, 3) polycarbonate used for food contact applications, 4) epoxy resins used for canned food.

Human exposure through the environment occurs through inhalation and through intake of contaminated water and food, and was determined through the use of EUSES, as was assessed for different sub-scenarios.

3.2.2 Effect assessment

The RAR describes in detail all relevant toxicity studies performed, and SCHER agrees with the health effects described.

Toxicokinetic studies show that the uptake of ptBP following oral exposure was 100%. Thus this value was used as the default value for the modelling of inhalation and dermal exposure. SCHER agrees that the likely bioaccumulation is low. PtBP has low acute toxicity by all three exposure routes.

PtBP is severely irritant to skin, respiratory system and eyes and recommends the classification (Xi, R37/38-41)and SCHER agrees with this recommendation. However, there is no evidence for skin sensitisation, either in animals or in humans, and SCHER agrees with the Technical Committee on Classification and Labelling, that the classification criteria for R43 was not met.

For repeated dose toxicity, SCHER agrees with a NOAEL of 70 mg/kg bw/day based on reduction of relative weights of ovaries and adrenal glands in females in the 2-generation reproduction study in rats.

Skin depigmentation was observed both in experimental animals and in workers exposed to ptBP, and a LOAEL of 103 mg/kg bw/day was established based upon oral administration in mice.

SCHER agrees with the conclusion, that ptBP does not fulfil the criteria for classification as a mutagen and that the substance is not carcinogenic.

SCHER agrees that the NOAEL of 70 mg/kg bw/day should be used in risk characterisation for effects on fertility and development. In *in vitro* studies ptBP has only shown very week estrogenic activity, i.e.,1.500.000 times less potent than 17β-estradiol in the receptor binding assay.

3.2.3 Risk characterisation

The risk characterisation performed in the RAR used the margin of safety approach (MOS) and is performed for inhalation and dermal exposure for workers, dermal and oral exposure for consumers, and inhalation and oral exposure for exposures from the environment. Minimal MOS for occupational exposures were calculated from assessment factors based on default values resulting in 50 for chronic toxicity (interspecies 10 x intraspecies 5), 100 for development toxicity (interspecies 10 x intraspecies 10) and 525 for depigmentation (interspecies 17.5 x intraspecies 5 x duration of exposure 2 x dose-response 3.

SCHER agrees with the conclusion iii)[1] for some occupational scenarios for repeated toxicity following dermal exposures, and for inhalation and dermal exposure in end users.

SCHER agrees with the conclusion iii) for development toxicity for some occupational scenarios.

Minimal MOS for systemic acute toxicity used for consumers exposures were 300 (10x10x1x3), repeated dose toxicity 100 (10x10x1) and depigmentation 1050 (17.5x10x2x3).

SCHER agrees with the conclusion ii) for all scenarios and endpoints for consumers, and for humans exposed via the environment.

[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.*

4. LIST OF ABBREVIATIONS

EASE	Estimation and Assessment of Substance Exposure
EUSES	EU System for the Evaluation of Substances
LOAEL	Lowest Observed Effect Level
MOS	Margin of Safety
NOAEL	No Observed Adverse Effect Level
PPE	Personal Protective Equipment
ptBP	para-tertiary butylphenol
RAR	Risk Assessment Report
TGD	Technical Guidance Document