

THE SCIENTIFIC COMMITTEE ON COSMETIC PRODUCTS AND NON-FOOD PRODUCTS
INTENDED FOR CONSUMERS

OPINION

CONCERNING

DIBUTYLPHTHALATE

Adopted by the SCCNFP on 1 July 2004
By means of the written procedure

1. Term of References

1.1. Background

Article 4b of the Council Directive 76/768/EEC relating to cosmetic products stipulates that *“the use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction, of category 1, 2 and 3, under Annex I to Directive 67/548/EEC shall be prohibited. To that end the Commission shall adopt the necessary measures in accordance with the procedure referred to in Article 10(2). A substance classified in category 3 may be used in cosmetics if the substance has been evaluated by the SCCNFP and found acceptable for use in cosmetic products.”*

DG Enterprise took note of a publicly available final draft of a study on Dibutylphthalate (a substance classified as CMR Cat. 2) initiated by the European Chemicals Bureau under their Existing Chemicals program. The scientific work on this report has been prepared by the Netherlands Organization for Applied Scientific Research (TNO) and the National Institute of Public Health and the Environment (RIVM).

One of the exposure scenarios covered by the study is the use of DBP in cosmetics (nail care products). The overall result of the study regarding consumer safety was: “There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already”.

Meanwhile further data was submitted as well by the Nail Manufacturers Council

1.2. Request to the SCCNFP

In the light of its opinion of 25 May 2004 on substances classified as CMR and the data of the European Chemicals Bureau and the Nail Manufacturers Council, the SCCNFP was invited to express its opinion on safety of Dibutylphthalate (a substance classified as CMR Category 2) when used as a cosmetic ingredient.

2. Opinion of the SCCNFP

The SCCNFP opinion on the received request is based on review of the information from European Chemical Bureau, the Nail Manufacturers Council and its previous opinions SCCNFP/0474/01 and SCCNFP/0825/04.

The SCCNFP has previously given opinions on substances classified by the EU as CMR Category 1 and 2 (SCCNFP/0474/01 and SCCNFP/0825/04). Dibutylphthalate is classified as toxic to reproduction Category 2; R61 “May cause harm to the unborn child”.

Therefore SCCNFP is of the opinion that Dibutylphthalate is covered by its existing opinions and should not be intentionally added to cosmetic products.

3. Other considerations

Not applicable

4. Minority opinions

Not applicable