



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Dir F: Ecosystems I: Chemicals, food, Retail

Unit F2: Bioeconomy, Chemicals & Cosmetics

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific advice on the safety of Diethylamino Hydroxybenzoyl Hexyl Benzoate (CAS/EC No. 302776-68-7/443-860-6) from cosmetic products

Commission Department requesting the Opinion: **Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs**

1. Background

Diethylamino Hydroxybenzoyl Hexyl Benzoate (DHHB) (CAS/EC No. 302776-68-7/443-860-6) is the INCI name of the chemical compound ‘benzoic acid, 2-[4-(diethylamino)-2-hydroxybenzoyl]-, hexylester’ with reported functions in CosIng database as ‘UV-filter’, ‘UV-absorber’, and ‘light stabiliser’.

DHHB has been authorised for use in cosmetic products as a UV-filter (entry 28 of Annex VI to the Cosmetics Regulation (EC) No. 1223/2009). It is an organic compound highly valued for its exceptional UV-absorbing properties (especially UVA radiation), excellent photostability and compatibility with other UV absorbers/filters and other cosmetic ingredients, serving, therefore, as a key component in many cosmetic formulations included but not limited to sunscreens, moisturizers, foundations, and other skincare and makeup products.

DHHB has been assessed by the SCCNFP in 2003 (SCCNFP/0650/03¹ and SCCNFP/0756/03²) and by SCCP in 2006 (SCCP/0996/06³) and in 2008 (SCCP/1166/08⁴). In the last SCCP Opinion of 2008, the scientific committee concluded on the safety of DHHB when used as a UV-filter in cosmetic products up to a maximum concentration of 10 % w/w.

In 2024, the German authorities informed the Commission services on the detection of the degradation product of a plasticizer in urine samples of children. In particular, ‘mono-n-hexyl phthalate’ (MnHexP) was detected in urine samples. MnHexP can be a metabolite from various phthalates, such as di-n-hexyl phthalate (DnHexP), decylhexyl phthalate or certain other mixed-chain phthalates, or can be directly taken up in the form of hexyl hydrogen phthalate.

Phthalates are chemical compounds that are mainly used as plasticisers in plastics to make them soft but are not firmly bound in them and can be released. As phthalates are produced and used

¹ https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out223_en.pdf

² https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out241_en.pdf

³ https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_059.pdf

⁴ https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_130.pdf

in large quantities and in many applications, they can be detected almost ubiquitously in the environment (soil, water, air).

In particular, the assessment from the German Authorities illustrated that the presence MnHexP in urine samples could be from potential exposure to sunscreens. One of the phthalates that MnHexP could be produced from is DnHexP. Nevertheless, DnHexP is already prohibited in cosmetics (entry 1559 of Annex II to the Cosmetics Regulation), however, DnHexP could be a contaminant in the production process of an authorised UV-filter that is Diethylamino Hydroxy benzoyl Hexyl Benzoate (DHHB).

The BfR assessed whether cosmetic products containing a potentially contaminated UV filter with DnHexP (as could be the case of DHHB) could pose a health risk to consumers and concluded that this is very unlikely (i.e., there is a sufficient margin of safety in the use of sunscreen products containing up to 10 % of a UV filter contaminated with up to 0.3 % DnHexP). However, the BfR noted that the removal of DnHexP in DHHB is technically possible (i.e., the presence of DnHexP is technically avoidable) but requires special manufacturing and purification processes to ensure the lowest possible presence of this phthalate and may vary depending on the manufacturer.

Given the possible health risks, the safe use of DHHB in cosmetic products should be re-evaluated by the SCCS in view of technical and scientific progress and the concerns raised about the presence of potential contaminants, highlighting the importance of purity of ingredients used in cosmetic formulations. The Commission, therefore, requests the SCCS to provide a scientific advice on the safety of DHHB in cosmetic products and the presence of DnHexP.

2. Terms of reference

- (1) Considering the recent concerns over the presence of DnHexP as a contaminant in the production of Diethylamino Hydroxybenzoyl Hexyl Benzoate (DHHB) used as a UV-filter in cosmetic products, as well as in view of technical and scientific progress and taking under consideration in particular the various health concerns, the SCCS is requested to identify the maximum safe level of DnHexP as a contaminant in DHHB preparations,*
- (2) Does the SCCS have any further scientific concerns regarding the presence of DnHexP in DHHB used as a UV-filter in cosmetic products?*

3. Deadline

9 months.

4. Supporting documents

BfR report

➔ The SCCS approved this mandate by written procedure on 2 October 2024.

➔ The SCCS approved the revised question number 1 on 25 October 2024.