



EUROPEAN COMMISSION

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

Consumer, Environmental and Health Technologies
Health Technology and Cosmetics

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion on Benzophenone-3 (CAS No 131-57-7, EC No 205-031-5)

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

1. Background on substances with endocrine disrupting properties

On 7 November 2018, the Commission adopted a review¹ of Regulation (EC) No 1223/2009 on cosmetic products ('Cosmetics Regulation') regarding substances with endocrine disrupting properties. The review concluded that the Cosmetics Regulation provides the adequate tools to regulate the use of cosmetic substances that present a potential risk for human health, including when displaying ED properties.

The Cosmetics Regulation does not have specific provisions on EDs. However, it provides a regulatory framework with a view to ensuring a high level of protection of human health. Environmental concerns that substances used in cosmetic products may raise are considered through the application of Regulation (EC) No 1907/2006 ('REACH Regulation').

In the review, the Commission commits to establishing a priority list of potential EDs not already covered by bans or restrictions in the Cosmetics Regulation for their subsequent safety assessment. A priority list of 28 potential EDs in cosmetics was consolidated in early 2019 based on input provided through a stakeholder consultation. The Commission then organised a public call for data² from 16 May 2019 – 15 October 2019 on 14³ of the 28 substances (to be treated with higher priority) in order to be able to prepare the safety assessment of these substances. Benzophenone-3 is one of the above-mentioned 14 substances for which the call for data took place.

2. Existing information on Benzophenone-3

In cosmetic products, the ingredient Benzophenone-3 (CAS No 131-57-7, EC No 205-031-5) with the chemical names Oxybenzone, 2-Hydroxy-4-methoxybenzone, (2-Hydroxy-4-methoxyphenyl) phenyl methanone and 2-Benzoyl-5-methoxyphenol is currently regulated as a UV-filter in sunscreen products in a concentration, in ready for use preparation, up to 6 %

¹ <https://ec.europa.eu/transparency/regdoc/rep/1/2018/EN/COM-2018-739-F1-EN-MAIN-PART-1.PDF>

² https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products_en

³ Benzophenone-3, kojic acid, 4-methylbenzylidene camphor, propylparaben, triclosan, resorcinol, octocrylene, triclocarban, butylated hydroxytoluene (BHT), benzophenone, homosalate, benzyl salicylate, genistein and daidzein

(Annex VI/4). Furthermore, Benzophenone-3 is also allowed in a concentration up to 0.5 % to protect product formulation in all other cosmetic products (Annex VI/4).

Benzophenone-3 has been subject to different safety evaluations by the SCCNFP in 1999⁴, and SCCP in 2006 (SCCP/1069/06) and 2008 (SCCP/1201/08). In particular, the last SCCP opinion from 2008 states that *'the use of benzophenone-3 as a UV-filter up to 6% in cosmetic sunscreen products and up to 0.5% in all types of cosmetic products to protect the formulation does not pose a risk to the health of the consumer, apart from its contact allergenic and photoallergenic potential'*.

During the call for data in 2019, stakeholders submitted scientific evidence to demonstrate the safety of Benzophenone-3 as a UV-filter in cosmetic products. The Commission requests the SCCS to carry out a safety assessment on Benzophenone-3 in view of the information provided.

2. Terms of reference

(1) In light of the data provided and taking under consideration the concerns related to potential endocrine disrupting properties of Benzophenone-3, does the SCCS consider Benzophenone-3 safe when used as a UV-filter in cosmetic products up to a maximum concentration of 6 % and up to 0.5 % in cosmetic products to protect product formulation?

(2) Alternatively, what is according to the SCCS the maximum concentration considered safe for use of Benzophenone-3 as a UV-filter in cosmetic products?

(3) Does the SCCS have any further scientific concerns with regard to the use of Benzophenone-3 in cosmetic products?

3. Deadline: 9 months, extended until January 2021.

4. Supporting documents:

Input from the call for data in 2019 on the safety of Benzophenone-3 in Cosmetic Products.

The SCCS approved this mandate by written procedure on 4 February 2020. The extension of deadline was agreed by DG GROW on 10 September 2020.

⁴https://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/sccnfp_opinions_97_04/sccp_out57_en.htm