



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 Benzophenone-2 (BP-2) (CAS No. 131-55-5, EC No. 205-028-9) and Benzophenone-5 (BP-5) (CAS No. 6628-37-1, EC No. 613-918-7) as substances with potential endocrine disrupting properties in cosmetic products

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 explicit 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 to 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. Triclocarban and Triclosan are among the above-mentioned 14 substances for which the call for data took place.

2. Existing information on Benzophenone-2

The ingredient Benzophenone-2 (BP-2) (CAS No. 131-55-5, EC No. 205-028-9) with the chemical name '2,2',4,4'-tetrahydroxybenzophenone' is currently not regulated under the Cosmetics Regulation 1223/2009. According to CosIng database, Benzophenone-2 is reported to have the following functions: 'UV-filter', 'light stabilizers' and 'fragrance', protecting the cosmetic product from damage (i.e., deterioration effects) caused by light (including UV light) and enhancing the smell of a product and/or perfuming the skin. Benzophenone-2 is suspected of

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

being an endocrine disruptor, while it is also suspected of polluting surface waters and of endangering aquatic organisms.

3. Existing information on Benzophenone-5

In cosmetic products, the ingredient Benzophenone-5 (BP-5) (CAS No. 6628-37-1, EC No. 613-918-7) with the chemical name '2-Hydroxy-4-methoxybenzophenone-5-sodium sulfonate' is currently regulated as a UV-filter (entry 22 of Annex VI) at a maximum concentration of 5 % (as acid). Benzophenone-5 is the sodium salt of Benzophenone-4 that is also regulated under the same entry⁴ and which has been recently re-evaluated by the SCCS in view of its potential endocrine activity. In that Opinion⁵, the SCCS concluded on the safety (under certain conditions) of Benzophenone-4, when used as a UV-filter and light-stabilizer in cosmetic products. In view of its structural similarity to Benzophenone-4 (i.e., being its sodium salt), Benzophenone-5 is suspected of being an endocrine disruptor as well.

Given the possible health risks associated with these ingredients, their safe use in cosmetic products should be evaluated by the SCCS in view of technical and scientific progress. The Commission, therefore, requests the SCCS to provide a scientific advice on the safety of Benzophenone-2 and Benzophenone-5 when used in cosmetic products.

4. Terms of reference

In light of technical and scientific progress, available scientific literature, relevant in silico tools and the SCCS' expert judgement and taking under consideration in particular the concerns related to potential endocrine disrupting properties, the SCCS is requested:

- (1) *to identify and justify whether there are specific concerns regarding the use of Benzophenone-2 and Benzophenone-5 in cosmetic products;*
- (2) *to highlight if there is a potential risk for human health from the use of Benzophenone-2 and Benzophenone-5 in cosmetic products;*

5. Deadline

15 months.

6. Supporting documents

/

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

⁴ the SCCS has recently re-evaluated the safety of Bp-4: https://health.ec.europa.eu/publications/benzophenone-4-cas-no-4065-45-6-ec-no-223-772-2_en

⁵ SCCS (Scientific Committee on Consumer Safety), Opinion on benzophenone – 4 (CAS No. 4065-45-6, EC No. 223-772-2) used in cosmetics products. preliminary version of 14 December 2023, final version of 27 March 2024, SCCS/1660/23