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 opinion on Benzophenone-4 (CAS No.4065-45-6, EC No. 223-772-2)

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 the review[1] of Regulation (EC) No 1223/2009 on cosmetic products ('Cosmetics Regulation') regarding substances with endocrine disrupting (ED) 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 carried out a public call for data in 2019[2] for 14 substances (Group A)[3] and a second call in 2021[4] for 10 substances (Group B)[5] in preparation of the safety assessment of these substances. Benzophenone-4 is one of the above-mentioned substances for which the call for data took place.

2. Background on Benzophenone-4

Benzophenone-4 (CAS No. 4065-45-6, EC No. 223-772-2) with the chemical name '2-Hydroxy-4-methoxybenzophenone-5-sulphonic acid' is currently regulated as a UV-filter in sunscreen products in a concentration up to 5 % (Annex VI/22). Benzophenone-4 absorbs UV light across

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[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%20products_en
[3] Benzophenone-3, kojic acid, 4-methylbenzylidene camphor, propylparaben, triclosan, Homosalate, octocrylene, triclocarban, butylated hydroxytoluene (BHT), benzophenone, homosalate, benzyl salicylate, genistein and daidzein
[4] https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products-0_en
[5] Butylparaben, Methylparaben, Ethylhexyl Methoxycinnamate (EHMC)/Octylmethoxycinnamate (OMC)/Octinoxate, Benzophenone-1 (BP-1), Benzophenone-2 (BP-2), Benzophenone-4 (BP-4), Benzophenone-5 (BP-5), BHA/Butylated hydroxyanisole/tert-butyl-4-hydroxyanisole, Triphenyl Phosphate and Salicylic Acid

a broad range of UV wavelengths and, therefore, protects the skin from damage by UVB and UVA light. In addition, in the European database for information on cosmetic substances and ingredients (CosIng) Benzophenone-4 is also reported with the functions of 'UV-stabiliser' and UV-absorber' protecting cosmetic formulations against sunlight.

Benzophenone-4 has been subject to a safety evaluation by SCCNFP in 1999[6], where the committee concluded that *'…2-Hydroxy-4-methoxybenzophenone-5-sulphonic acid can be used safely in cosmetic sunscreen formulations at a maximum concentration of 5%, expressed as acid'* and proposed *'…no further restrictions or conditions for its use in cosmetic products'.*

During the call for data, stakeholders submitted scientific evidence to demonstrate the safety of Benzophenone-4 as UV-filter in cosmetic products. The Commission requests the SCCS to carry out a safety assessment on Benzophenone-4 in view of the information provided.

3. Terms of reference

(1) *In light of the data provided and taking under consideration the concerns related to potential endocrine disrupting properties of Benzophenone-4, does the SCCS consider Benzophenone-4 safe when used as UV-Filter in cosmetic products up to a maximum concentration of 5%?*

(2) *Alternatively, what is according to the SCCS the maximum concentration considered safe for use of Benzophenone-4 in cosmetic products?*

(3) *Does the SCCS have any further scientific concerns with regard to the use of Benzophenone-4 in cosmetic products?*

4. Deadline

9 months.

5. Supporting documents

Input from the call for data on the safety of Benzophenone-4 in Cosmetic Products.

➔ **The SCCS approved this mandate by written procedure on 17 April 2023.**

[6] https://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/sccnfp_opinions_97_04/sccp_out57_en.htm