



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 Ethylhexyl Methoxycinnamate (EHMC) (CAS No. 5466-77-3/83834-59-7, EC No. 226-775-7/629-661-9)

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 review¹ 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 2019² for 14 substances (Group A)³ and a second call in 2021⁴ for 10 substances (Group B)⁵ in preparation of the safety assessment of these substances. Ethylhexyl Methoxycinnamate (EHMC) is one of the above-mentioned substances for which the call for data took place.

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

²https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic%20products_en

³Benzophenone-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

2. Background on Ethylhexyl Methoxycinnamate (EHMC)

Ethylhexyl Methoxycinnamate (EHMC) (CAS No. 5466-77-3/83834-59-7, EC No. 226-775-7/629-661-9) with the chemical name '2-ethylhexyl 4-methoxycinnamate' (also known as Octylmethoxycinnamate (OMC) and Octinoxate) is regulated as a UV-filter in sunscreen products in a concentration up to 10 % (Annex VI/12).

Ethylhexyl Methoxycinnamate absorbs only UVB radiation and, therefore, protects the skin only from damage caused by UVB light and not UVA. It has been used for decades as a UV filter in cosmetics, pharmaceuticals, intermediates and fine chemicals and it is also reported to be used as a UV stabiliser protecting cosmetic formulations against sunlight. Ethylhexyl Methoxycinnamate has been subject to a safety evaluation by SCC in 1991 and 1993⁶ and by SCCNFP in 2001⁷.

During the call for data, stakeholders submitted scientific evidence to demonstrate the safety of Ethylhexyl Methoxycinnamate as UV-filter in cosmetic products. The Commission requests the SCCS to carry out a safety assessment on Ethylhexyl Methoxycinnamate 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 Ethylhexyl Methoxycinnamate, does the SCCS consider Ethylhexyl Methoxycinnamate safe when used as UV-Filter in cosmetic products up to a maximum concentration of 10%?*
- (2) *Alternatively, what is according to the SCCS the maximum concentration considered safe for use of Ethylhexyl Methoxycinnamate in cosmetic products?*
- (3) *Does the SCCS have any further scientific concerns with regard to the use of Ethylhexyl Methoxycinnamate in cosmetic products?*

4. Deadline

9 months.

5. Supporting documents

Input from the call for data on the safety of Ethylhexyl Methoxycinnamate in Cosmetic Products.

→ **The SCCS approved this mandate by written procedure on 28 February 2024.**

⁶https://ec.europa.eu/health/sites/default/files/scientific_committees/consumer_safety/docs/scc_o_9.pdf

⁷https://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/sccnfp_opinions_97_04/sccp_out145_en.htm