



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 Homosalate (CAS No 118-56-9, EC No 204-260-8) as a UV-filter 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

Homosalate (CAS No 118-56-9, EC No 204-260-8) with the chemical names ‘Benzoic acid, 2-hydroxy-, 3,3,5-trimethylcyclohexyl ester’ and ‘(3,3,5-trimethylcyclohexyl) 2-hydroxybenzoate’ has been evaluated for its safety by the SCCP in 2007 (SCCP/1086/07)¹ and is currently regulated as a UV-filter in sunscreen products in a concentration up to 10 % (Annex VI/3).

On 7 November 2018, the Commission adopted a review² of Regulation (EC) No 1223/2009 (i.e. ‘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.

In the review, the Commission established a priority list of potential EDs for their subsequent safety assessment. A priority list of 28 potential EDs was established in early 2019 based on stakeholder consultation. The Commission then organised a public call for data³ from 16 May 2019 to 15 October 2019 on 14⁴ of the 28 substances in order to mandate the SCCS on the safety of these substances. Homosalate was among the 14 substances for which the call for data took place.

On 24-25 June 2021, the SCCS adopted an Opinion (SCCS/1622/20)⁵ concluding that Homosalate could not be considered safe at concentrations of up to 10%. According to the SCCS’s opinion, the use of Homosalate is safe for the consumer up to a maximum concentration of 0.5% in the final product.

¹ https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_097.pdf

² <https://ec.europa.eu/transparency/regdoc/rep/1/2018/EN/COM-2018-739-F1-EN-MAIN-PART-1.PDF>

³ https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products_en

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

⁵ https://ec.europa.eu/health/sites/default/files/scientific_committees/consumer_safety/docs/sccs_o_244.pdf

On 30 July 2021, in order to ensure broad availability of UV-filters and consequently adequate sun protection for consumers, industry submitted a re-calculation of the Margin of Safety (MoS) based only on the use of Homosalate in face products (face cream and pump-spray products).

2. Terms of reference

- (1) *In light of the information provided and taking under consideration the concerns related to potential endocrine disrupting properties of Homosalate, does the SCCS consider Homosalate safe when used as a UV-filter in face products (face cream and pump spray) up to a maximum concentration of 7.34 %?*
- (2) *Alternatively, what is according to the SCCS the maximum concentration considered safe for use of Homosalate as a UV-filter in face products (face cream and pump spray)?*

3. Deadline

2 months

4. Supporting documents

Input from Cosmetics Europe on the safety of Homosalate in Cosmetic Products.

The SCCS approved this mandate by written procedure on 5 October 2021.