



## 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 Homosalate (CAS No 118-56-9, EC No 204-260-8)

**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 review<sup>1</sup> 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 data<sup>2</sup> from 16 May 2019 – 15 October 2019 on 14<sup>3</sup> of the 28 substances (to be treated with higher priority) in order to be able to prepare the safety assessment of these substances. Homosalate is one of the above-mentioned 14 substances for which the call for data took place.

#### 2. Existing information on Homosalate

In cosmetic products, the ingredient 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 is currently regulated as a UV-filter in sunscreen products in a concentration up to 10 % (Annex VI/3).

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

<sup>2</sup> [https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products\\_en](https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products_en)

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

Homosalate has been subject to safety evaluations from SCCP in 2001<sup>4</sup> and 2007 (SCCP/1086/07). In particular, the SCCP Opinion from 2007 concluded that ‘... *the use of Homosalate at a maximum concentration of 10% w/w in cosmetic sun screen product does not pose a risk to the health of the consumer. Uses of homosalate in other types of cosmetic products at concentrations up to 10.0% also does not pose a risk to the health of the consumer*’.

During the call for data, stakeholders submitted scientific evidence to demonstrate the safety of Homosalate as a UV-filter in cosmetic products. The Commission requests the SCCS to carry out a safety assessment on Homosalate 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 Homosalate, does the SCCS consider Homosalate safe when used as a 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 Homosalate as a UV-filter in cosmetic products?*
- (3) *Does the SCCS have any further scientific concerns with regard to the use of Homosalate in cosmetic products?*

**3. Deadline:** 9 months

**4. Supporting documents:**

Input from the call for data in 2019 on the safety of Homosalate in Cosmetic Products.

The SCCS approved this mandate by written procedure on 4 February 2020. Following the submission of additional data, DG GROW agreed with an extension of the deadline until June 2021.

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<sup>4</sup>[https://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/opinions/sccnfp\\_opinions\\_97\\_04/sccp\\_out145\\_en.htm](https://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/sccnfp_opinions_97_04/sccp_out145_en.htm)