



## EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Resources Based, Manufacturing and Consumer Goods Industries

**Consumer Industry**

### SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

#### **Request for a scientific Opinion on 4-Methylbenzylidene camphor (4-MBC) (CAS No 36861-47-9/38102-62-4, EC No 253-242-6/-)**

**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<sup>1</sup> 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 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 carried out a public call for data<sup>2</sup> in 2019 on 14<sup>3</sup> of the 28 substances (to be treated with higher priority-Group A substances) in preparation of the safety assessment of these substances. 4-Methylbenzylidene camphor (hereinafter 4-MBC) is one of the above-mentioned 14 substances for which the call for data took place.

#### **2. Background on 4-Methylbenzylidene camphor (4-MBC)**

In cosmetic products, the ingredient 4-MBC (CAS No 36861-47-9/38102-62-4, EC No 253-242-6/-) with the chemical name 3-(4'-methylbenzylidene)-camphor is currently regulated as a UV-filter in sunscreen products in a concentration up to 4% (Annex VI/18).

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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

The safety of 4-MBC was assessed several times: by the SCCNFP in 1998<sup>4</sup>, 2001<sup>5</sup> and 2004<sup>6</sup> and by SCCP in 2006<sup>7</sup> and 2008<sup>8</sup>. In particular, the SCCP Opinion from 2008 (SCCP/1184/08) concluded that ‘...4-MBC can be considered safe for use in finished cosmetic products (whole body application) at a concentration of up to 4%. It must be emphasized that this opinion is restricted to the safety evaluation of 4-MBC after dermal application of a cosmetic product containing this UV filter. Exposure scenarios via the inhalation route (through aerosols, sprays, etc.) or the oral route (through e.g. lip care products) are not covered. In these cases, risk cannot be excluded’.

During the call for data, stakeholders submitted scientific evidence to demonstrate the safety of 4-MBC as a UV-filter in cosmetic products. The Commission requests the SCCS to carry out a safety assessment on 4-MBC 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 4-Methylbenzylidene camphor (4-MBC), does the SCCS consider 4-MBC safe when used as a UV-filter in cosmetic products up to a maximum concentration of 4%?*
- (2) *Alternatively, what is according to the SCCS the maximum concentration considered safe for use of 4-MBC as a UV-filter in cosmetic products?*
- (3) *Does the SCCS have any further scientific concerns with regard to the use of 4-MBC in cosmetic products?*

### **4. Deadline**

9 months.

### **5. Supporting documents**

Input from the call for data on the safety of 4-Methylbenzylidene camphor (4-MBC) in Cosmetic Products.

The SCCS approved this mandate by written procedure on 8 March 2021.

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<sup>4</sup>[https://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/opinions/sccnfp\\_opinions\\_97\\_04/sccp\\_out27\\_en.htm](https://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/sccnfp_opinions_97_04/sccp_out27_en.htm)

<sup>5</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)

<sup>6</sup>[https://ec.europa.eu/health/ph\\_risk/committees/sccp/documents/out282\\_en.pdf](https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out282_en.pdf)

<sup>7</sup>[https://ec.europa.eu/health/ph\\_risk/committees/04\\_sccp/docs/sccp\\_o\\_075.pdf](https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_075.pdf)

<sup>8</sup>[https://ec.europa.eu/health/ph\\_risk/committees/04\\_sccp/docs/sccp\\_o\\_141.pdf](https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_141.pdf)