



## 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 **Methylparaben (CAS No. 99-76-3, EC No. 202-785-7)**

**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 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<sup>2</sup> for 14 substances (Group A)<sup>3</sup> and a second call in 2021<sup>4</sup> for 10 substances (Group B)<sup>5</sup> in preparation of the safety assessment of these substances. Methylparaben is one of the above-mentioned substances for which the call for data took place.

#### 2. Background on Methylparaben

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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%20products\\_en](https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic%20products_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

<sup>4</sup> [https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products-0\\_en](https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products-0_en)

<sup>5</sup> 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

Methylparaben (CAS No. 99-76-3, EC No. 202-785-7) with the chemical name 'Methyl 4-hydroxybenzoate' is currently regulated as a preservative (Annex V, entry 12) in a concentration up to 0.4 % (as acid) when used on its own or up to 0.8% for mixtures of esters (Annex V, entry 12, column g).

Methylparaben is produced naturally in a variety of plants, but it is also synthesised for use in a range of products including, but not limited to cosmetics, food products and pharmaceuticals, since it has a wide spectrum of antimicrobial activity and is also effective against yeasts and moulds.

Methylparaben has been subject to different safety evaluations by the SCCP in 2005 (SCCP/0874/05)<sup>6</sup> and (SCCP/0874/05)<sup>7</sup>, 2006 (SCCP/1017/06)<sup>8</sup>, 2008 (SCCP/1183/08)<sup>9</sup> and by the SCCS in 2010 (SCCS/1348/10)<sup>10</sup> and 2011 (SCCS/1446/11)<sup>11</sup>.

During the call for data, stakeholders submitted scientific evidence to demonstrate the safety of Methylparaben as a preservative in cosmetic products. The Commission requests the SCCS to carry out a safety assessment on Methylparaben 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 Methylparaben, does the SCCS consider Methylparaben safe when used as a preservative in cosmetic products up to a maximum concentration of 0.4% (as acid) when used on its own and up to 0.8% for mixtures of esters as indicated in entry 12 of Annex V to the Cosmetics Regulation?*
- (2) *Alternatively, what is according to the SCCS the maximum concentration considered safe for use of Methylparaben as a preservative in cosmetic products?*
- (3) *Does the SCCS have any further scientific concerns with regard to the use of Methylparaben in cosmetic products?*

### 4. Deadline

9 months.

### 5. Supporting documents

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

**→ The SCCS approved this mandate by written procedure on 3 February 2022.**

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<sup>6</sup> [https://ec.europa.eu/health/ph\\_risk/committees/04\\_sccp/docs/sccp\\_o\\_019.pdf](https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_019.pdf)

<sup>7</sup> [https://ec.europa.eu/health/ph\\_risk/committees/04\\_sccp/docs/sccp\\_o\\_00d.pdf](https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_00d.pdf)

<sup>8</sup> [https://ec.europa.eu/health/ph\\_risk/committees/04\\_sccp/docs/sccp\\_o\\_074.pdf](https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_074.pdf)

<sup>9</sup> [https://ec.europa.eu/health/ph\\_risk/committees/04\\_sccp/docs/sccp\\_o\\_138.pdf](https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_138.pdf)

<sup>10</sup> [https://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_041.pdf](https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_041.pdf)

<sup>11</sup> [https://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_069.pdf](https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_069.pdf)