



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 **Butylparaben (CAS No. 94-26-8, EC No. 202-318-7)**

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 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. Butylparaben is one of the above-mentioned substances for which the call for data took place.

2. Background on Butylparaben

Butylparaben (CAS No. 94-26-8, EC No. 202-318-7) with the chemical name 'Butyl 4-hydroxybenzoate' is currently regulated as a preservative (Annex V entry 12a) in a concentration up to 0.14 % (as acid) when used on its own or for the sum of its combined use with propylparaben and its salts (Annex V, entry 12a, column g).

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

Butylparaben has been subject to different safety evaluations by the SCCP in 2005 (SCCP/0874/05)⁶, 2006 (SCCP/1017/06)⁷ and 2008 (SCCP/1183/08)⁸ and by the SCCS in 2010 (SCCS/1348/10)⁹, 2011 (SCCS/1446/11)¹⁰ and 2013 (SCCS/1514/13)¹¹. In particular, the last SCCS opinion from 2013 states that *'The additional submitted data does not remove the concern expressed in the previous opinions on the relevance of the rat model for the risk assessment of parabens. Although much toxicological data on parabens in rodents exists, adequate evidence has not been provided for the safe use of propyl- or butylparaben in cosmetics'*.

During the call for data, stakeholders submitted scientific evidence to demonstrate the safety of Butylparaben as a preservative in cosmetic products. The Commission requests the SCCS to carry out a safety assessment on Butylparaben 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 Butylparaben, does the SCCS consider Butylparaben safe when used as a preservative in cosmetic products up to a maximum concentration of 0.14 %?*
- (2) *Alternatively, what is according to the SCCS the maximum concentration considered safe for use of Butylparaben as a preservative in cosmetic products?*
- (3) *Does the SCCS have any further scientific concerns with regard to the use of Butylparaben in cosmetic products?*

4. New Deadline

November 2022

5. Supporting documents

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

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

The extension of the deadline was agreed by DG GROW in June plenary meeting.

⁶ https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_00d.pdf and https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_019.pdf

⁷ https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_074.pdf

⁸ https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_138.pdf

⁹ https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_041.pdf

¹⁰ https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_069.pdf

¹¹ https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_132.pdf