



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 children's exposure to Butylparaben (CAS No. 94-26-8, EC No. 202-318-7) from cosmetic products

Commission Department requesting the Opinion: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

1. Background

The ingredient 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 propyl paraben and its salts (Annex V, entry 12a, column g).

Butylparaben has been subject to different safety evaluations by the SCCP in 2005 (SCCP/0874/05)¹, 2006 (SCCP/1017/06)² and 2008 (SCCP/1183/08)³ and by the SCCS in 2010 (SCCS/1348/10)⁴, 2011 (SCCS/1446/11)⁵ and 2013 (SCCS/1514/13)⁶.

In 2023, the SCCS re-assessed the safety of Butylparaben in view of its potential endocrine effects following a call for data where stakeholders submitted scientific evidence to demonstrate the safety of Butylparaben in cosmetic products. In the SCCS/1651/23⁷ Opinion, the scientific committee confirmed the safety of Butylparaben as a preservative in cosmetic products at concentrations of up to 0.14% (expressed as acid). Nevertheless, the experts noted that '*In the absence of exposure data specific for children to Butylparaben in cosmetic products, potential safety concerns cannot be excluded.*'

In March 2024, the Commission services received additional information from industry to defend the use of Butylparaben in cosmetic products used in children⁸. This submission is based on the product categories used in different age groups of children as they appear in *Table A.7.2*

¹ 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

² https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_074.pdf

³ https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_138.pdf

⁴ https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_041.pdf

⁵ https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_069.pdf

⁶ https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_132.pdf

⁷ https://health.ec.europa.eu/publications/butylparaben-cas-no-94-26-8-ec-no-202-318-7_en

⁸ covering infants (6-12 months), toddlers (1-3 years) and children (3-10 years)

of the 12th edition of the SCCS Notes of Guidance⁹. The Commission, therefore, requests the SCCS to carry out a safety assessment on Butylparaben in view of the new information provided.

2. Terms of reference

- (1) *In light of the data provided and taking under consideration the conclusions of the SCCS/1651/23 Opinion on children exposure, does the SCCS consider Butylparaben safe for children between 3-10 years of age, when used as a preservative up to a maximum concentration of 0.14 %?*
- (2) *Alternatively, what is according to the SCCS the maximum concentration of Butylparaben that is considered safe for the age groups of children considered in this opinion?*
- (3) *Does the SCCS have any further scientific concerns regarding the use of Butylparaben in cosmetic products and children's exposure?*

3. Deadline

8 months.

4. Supporting documents

Butylparaben and children exposure dossier

- ➔ **The SCCS approved this mandate during plenary meeting on 27 March 2024.**
- ➔ **For clarity, mandating DG GROW modified the wording in the second question on 22 July 2024.**

⁹https://health.ec.europa.eu/latest-updates/sccs-notes-guidance-testing-cosmetic-ingredients-and-their-safety-evaluation-12th-revision-2023-05-16_en