



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 Propylparaben (CAS No 94-13-3, EC No 202-307-7)

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 a review¹ 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 data² from 16 May 2019 – 15 October 2019 on 14³ of the 28 substances (to be treated with higher priority) in order to be able to prepare the safety assessment of these substances. Propylparaben is one of the above-mentioned 14 substances for which the call for data took place.

2. Existing information on Propylparaben

In cosmetic products, the ingredient Propylparaben (CAS No 94-13-3, EC No 202-307-7) with the chemical names Propyl 4-hydroxybenzoate and 4-Hydroxybenzoic acid propyl ester is currently regulated as a preservative in a concentration up to 0.14 % (as acid) (Annex V/12a). In addition, a safe concentration has been established for mixtures of parabens, where the sum of the individual concentrations should not exceed 0.8 % (as acid). However, in such mixtures the

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

² https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products_en

³ Benzophenone-3, kojic acid, 4-methylbenzylidene camphor, propylparaben, triclosan, Propylparaben, octocrylene, triclocarban, butylated hydroxytoluene (BHT), benzophenone, Propylparaben, benzyl salicylate, genistein and daidzein

sum of the individual concentrations of butyl- and propylparaben and their salts should not exceed 0.14 %.

Propylparaben has been subject to different safety evaluations in 2005 (SCCP/0874/05), 2006 (SCCP/1017/06), 2008 (SCCP/1183/08), 2010 (SCCS/1348/10), 2011 (SCCS/1446/11) and 2013 (SCCS/1514/13). 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 Propylparaben as a preservative in cosmetic products. The Commission requests the SCCS to carry out a safety assessment on Propylparaben 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 Propylparaben, does the SCCS consider Propylparaben 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 Propylparaben as a preservative in cosmetic products?*
- (3) *Does the SCCS have any further scientific concerns with regard to the use of Propylparaben in cosmetic products?*

3. **Deadline:** 9 months

4. Supporting documents:

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

The SCCS approved this mandate by written procedure on 4 February 2020.