



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 Benzyl Salicylate (CAS No. 118-58-1, EC No. 204-262-9)**

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 data² in 2019 on 14³ of the 28 substances (to be treated with higher priority-Group A substances) in preparation of the safety assessment of these substances. Benzyl Salicylate is one of the above-mentioned 14 substances for which the call for data took place.

2. Background on Benzyl Salicylate

Benzyl Salicylate (CAS No. 118-58-1, EC No. 204-262-9) with the chemical name '2-hydroxybenzoic acid phenylmethyl ester' is produced naturally in a variety of plants and plant extracts where it can be extracted. In addition, Benzyl Salicylate can be synthesised for use, typically as a fragrance ingredient, in a range of manufactured goods (cosmetics, household

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

goods and medicines). In cosmetics, Benzyl Salicylate is used for its fragrance/perfuming function.

Benzyl Salicylate was assessed by the SCCNFP in 1999⁴ and by SCCS in 2012⁵ and it is considered as an established contact allergens in humans. It is currently regulated for labelling purposes as an allergen in entry 75 of Annex III to the Cosmetics Regulation. In particular, “*its presence must be indicated in the list of ingredients when its concentration exceeds 0.001% in leave-on products and 0.01% in rinse-off products*”.

During the call for data, stakeholders submitted scientific evidence to demonstrate the safety of Benzyl Salicylate as a fragrance ingredient in cosmetic products. The Commission requests the SCCS to carry out a safety assessment on Benzyl Salicylate in view of the information provided, taking into account the maximum concentration of Benzyl Salicylate in the different categories of cosmetic products listed in the table below:

Type of cosmetic product exposure	Maximum % concentration used
Hydroalcoholic-based fragrances (spray and non-spray)	4
Rinse-off skin & hair products (except rinse off body products)	0.5
Rinse off body products	1.3
Leave on skin & hair products (non-spray/non-aerosol)(except body lotion)	0.5
Leave on hair products (spray/aerosol)	0.5
Leave on body products (non-spray/spray/aerosol)	0.7
Face make-up products and make-up remover	0.2
Oral care	0.004
Deodorant products (spray/aerosol)	0.91

3. Terms of reference

(1) *In light of the data provided and taking under consideration the concerns related to potential endocrine disrupting properties of Benzyl Salicylate, does the SCCS consider Benzyl Salicylate safe when used up to the maximum concentrations provided in the dossier submission by the Benzyl Salicylate Consortium?*

(2) *Alternatively, what is according to the SCCS the maximum concentration considered safe for use of Benzyl Salicylate in cosmetic products?*

(3) *Does the SCCS have any further scientific concerns with regard to the use of Benzyl Salicylate in cosmetic products?*

⁴ https://ec.europa.eu/health/archive/ph_risk/committees/sccp/documents/out98_en.pdf

⁵ https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf

4. Deadline

9 months.

5. Supporting documents

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

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