



## 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 **Salicylic acid (CAS No. 69-72-7, EC No. 200-712-3)**

**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. Salicylic acid is one of the above-mentioned substances for which the call for data took place.

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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

## 2. Background on Salicylic acid

Salicylic acid (CAS No. 69-72-7, EC No. 200-712-3) with the chemical name ‘benzoic acid, 2-hydroxy’ is used in cosmetic products with reported functions as a denaturant, hair and skin conditioning agent, exfoliant/keratolytic, anti-sebum agent, anti-dandruff/anti-seborrheic agent and a product preservative. Salicylic acid has been subject to a safety evaluation by SCCNFP in 2002<sup>6</sup> and SCCS in 2018<sup>7</sup>. In particular, the last SCCS assessment was performed in view the classification of Salicylic acid as a CMR2 (Repr.2) substance under the CLP Regulation and in accordance to the provisions laid out in Article 15 of the Cosmetics Regulation. It is currently regulated under Annex III (entry 98) and Annex V (entry 3), with specific maximum concentrations and conditions of use.

During the call for data, stakeholders submitted scientific evidence to demonstrate the safety of Salicylic acid in cosmetic products. The Commission requests the SCCS to carry out a safety assessment on Salicylic acid in view of the information provided, taking into account the maximum concentration and relevant provisions for different categories of cosmetic products listed in Annex III and V to the Cosmetics Regulation, as well as the intention of industry to use Salicylic acid in oral products as well.

## 3. Terms of reference

- (1) *In light of the data provided and taking under consideration the concerns related to potential endocrine disrupting properties of Salicylic acid,*
  - a) *does the SCCS consider Salicylic acid safe when used as a preservative in cosmetic products up to a maximum concentration of 0.5%?*
  - b) *does the SCCS consider Salicylic acid safe when used in cosmetic for purposes other than inhibiting the development of micro-organisms at a concentration up to:*
    - i. *3.0% for the cosmetic rinse-off hair products,*
    - ii. *2.0% for other products except body lotion, eye shadow, mascara, eyeliner, lipstick, non-spray deodorant, and*
    - iii. *0.5% for body lotion, eye shadow, mascara, eyeliner, lipstick, oral products and non-spray deodorant*
- (2) *Alternatively, what is according to the SCCS the maximum concentration considered safe for use of Salicylic acid in cosmetic products?*
- (3) *Does the SCCS have any further scientific concerns with regard to the use of Salicylic acid in cosmetic products?*

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<sup>6</sup>[https://ec.europa.eu/health/ph\\_risk/committees/sccp/documents/out170\\_en.pdf](https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out170_en.pdf)

<sup>7</sup>[https://ec.europa.eu/health/sites/default/files/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_223.pdf](https://ec.europa.eu/health/sites/default/files/scientific_committees/consumer_safety/docs/sccs_o_223.pdf)

#### **4. Deadline**

9 months.

#### **5. Supporting documents**

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

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