



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 Salicylic Acid (CAS No. 69-72-7, EC No. 200-712-3) from cosmetic products

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

1. Background

The ingredient 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 is currently regulated under Annex III (entry 98) and Annex V (entry 3) with specific maximum concentrations and conditions of use.

Salicylic acid has been subject to safety evaluations by SCCNFP in 2002¹ in the context of the Cosmetic Directive 76/768/EEC for use other than preservative, while in 2018² it was assessed in view of its classification as a CMR cat.2 (Reprotoxic category 2) substance under Regulation (EC) No 1272/2008 (i.e., CLP Regulation). In particular, according to Article 15(1) of the Cosmetics Regulation *'the use in cosmetic products of substances classified as CMR substances, of category 2, under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited. However, a substance classified in category 2 may be used in cosmetic products where the substance has been evaluated by the SCCS and found safe for use in cosmetic products'*.

In 2022³, the SCCS re-assessed the safety of Salicylic Acid in view of its potential endocrine effects following a call for data where stakeholders submitted scientific evidence to demonstrate the safety of Salicylic Acid in cosmetic products. In the SCCS/1646/22 Opinion, the scientific committee confirmed the current allowed maximum concentration limits for Salicylic Acid for the relevant product types. However, the SCCS concluded that *'In the absence of exposure data of Salicylic Acid in cosmetic products for children, safety concerns have been noted for the younger age groups (between 3-10 years)'*.

¹ https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out170_en.pdf

² https://ec.europa.eu/health/sites/default/files/scientific_committees/consumer_safety/docs/sccs_o_223.pdf

³ https://health.ec.europa.eu/publications/salicylic-acid-cas-no-69-72-7-ec-no-200-712-3_en

In November 2023, the Commission received additional information from industry to defend the use of Salicylic Acid in cosmetic products used in children of 3-10 years of age. Cosmetic products intended for children between 3-10 years cover (i) *leave-on* products such as face cream, hand cream, body lotion, (ii) *rinse-off* products such as hand soap, shower gel, shampoo and hair conditioner, and (iii) *oral care* products such as toothpaste and mouthwash with the latter allowed only for children above 6 years. The Commission, therefore, requests the SCCS to carry out a safety assessment on Salicylic Acid 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/1646/22 Opinion on children exposure, does the SCCS consider Salicylic Acid safe for children between 3-10 years of age:*
 - (a) *when used as a preservative in cosmetic products up to a maximum concentration of 0.5 %?*
 - (b) *when used for purposes other than inhibiting the development of micro-organisms at a concentration up to:*
 - i. *3.0 % for cosmetic rinse-off products*
 - ii. *2.0 % for cosmetic leave-on products except body lotion and oral products, and*
 - iii. *0.5 % for body lotion and oral products*
- (2) *Alternatively, what is according to the SCCS the maximum concentration of Salicylic Acid that is considered safe for children 3-10 years of age?*
- (3) *Does the SCCS have any further scientific concerns with regard to the use of Salicylic Acid in cosmetic products and children's exposure?*

3. Deadline

8 months.

4. Supporting documents

Salicylic Acid and children exposure dossier

→ The SCCS approved this mandate during plenary meeting on 27 March 2024.