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 aggregate exposure to Salicylic Acid from salicylic esters used in cosmetic product

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

1. Background

Regulation (EC) No 1223/2009 on cosmetic products lays down that cosmetic products made available on the Union market must be safe for human health when used under normal or reasonably foreseeable conditions of use. In this framework, the European Commission relies on the independent scientific advice of the Scientific Committee on Consumer Safety (SCCS) for the assessment of substances used in cosmetics that may raise concerns for consumer health.

Salicylic Acid (CAS/EC No. 69-72-7/200-712-3) is a substance with established regulatory relevance under the Cosmetics Regulation, notably due to concerns associated with certain hazard endpoints and the need to ensure that consumer exposure remains within safe limits. In recent years, questions have arisen over the potential overexposure of consumers to Salicylic Acid from various salicylates, which may undergo metabolic conversion to Salicylic Acid after dermal application of cosmetic products. These esters include, among others, well-known cosmetic ingredients used as UV filters, fragrance ingredients, or emollients. The SCCS has already provided opinions on several individual salicylates, and in doing so has noted that the potential aggregate exposure to salicylic acid derived from multiple esters could be of relevance for the overall risk to consumers.

In order to obtain a clearer understanding of the actual contribution of salicylic esters to systemic exposure to Salicylic Acid, and to assess whether the combined exposure from their concurrent use in different cosmetic products might reach levels of safety concern, the Commission launched a two-step data-collection exercise. The first call for data[1], published in 2023, sought information on the identity of salicylic esters used in cosmetic products, their physicochemical and metabolic characteristics, their typical concentrations in cosmetic formulations, and any information on dermal absorption or toxicokinetics relevant to their conversion to salicylic acid. This initial step confirmed that a number of salicylic esters are indeed widely used across several product categories, and that existing information on their metabolic fate indicates the potential release of salicylic acid.

[1] https://single-market-economy.ec.europa.eu/consultations/call-data-ingredients-used-cosmetic-products_en

A second, more targeted call for data was launched in 2024[2]. This call focused specifically on obtaining exposure-related information needed to assess aggregate consumer exposure to Salicylic Acid resulting from the use of salicylic esters in cosmetics under realistic use scenarios. Stakeholders were invited to submit detailed use and concentration data, exposure modelling inputs, dermal absorption information, and any other elements needed to construct a comprehensive exposure scenario that reflects actual consumer habits and practices. This two-tier approach was adopted to allow systematic identification of relevant esters before proceeding to more refined assessment based on realistic exposure patterns.

On the basis of the information received through these calls for data, as well as data available in the scientific literature and in previous SCCS assessments, the Commission considers that sufficient information is now available to request a structured and scientifically robust evaluation by the SCCS. Given the complexity of cumulative exposure patterns, the possibility of metabolic conversion from a range of esters, and the need to ensure that total consumer exposure remains within safe limits established for Salicylic Acid, an assessment is warranted in order to determine whether current regulatory conditions are adequate or should be adapted.

Against this background, the Commission requests the SCCS to assess the aggregate exposure to Salicylic Acid resulting from the use of salicylic esters in cosmetic products and to determine whether such exposure is safe for consumers of different age groups under realistic conditions of use.

2. Terms of reference

In light of all data submitted during the two calls for data, which include a wide industry use survey and covers consumer's habits and practices:

1. *Does the SCCS consider that the aggregate exposure to Salicylic Acid from the current uses of Salicylic Acid and esters of Salicylic Acid is safe for adults when used as ingredients in cosmetic products?*

2. *Alternatively, what is according to the SCCS, the maximum concentration considered safe for the aggregate exposure to Salicylic Acid?*

3. *Besides the esters of Salicylic Acid already regulated in the Annexes to the Cosmetic Products Regulation, does the SCCS have any concern about other compounds that may release Salicylic Acid?*

3. Deadline

12 months.

4. Supporting documents

Input from the two Calls for data.

➔ **The SCCS approved this mandate by written procedure on 12 January 2025.**

[2] https://single-market-economy.ec.europa.eu/consultations/call-data-ingredients-used-cosmetic-products-1_en