



## 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 advice** on Methyl Salicylate (methyl 2-hydroxybenzoate; CAS/EC No. 119-36-8/204-317-7) used in cosmetic products.

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

#### 1. Background

Methyl Salicylate (CAS/EC No. 119-36-8/204-317-7) is the INCI name of ‘methyl 2-hydroxybenzoate’ an ingredient used in many fragrance mixtures and as flavouring and soothing agent in oral hygiene products.

Following its classification as ‘Toxic for Reproduction Category 2’ by the Commission Delegated Regulation (EU) 2021/849 and the submission of an exception dossier by industry, the Commission services mandated the SCCS to assess its safety following the provisions of Article 15(1) of the Cosmetics Regulation (EC) No. 1223/2009. On 27 October 2021, the SCCS concluded on the safety of Methyl Salicylate and Regulation (EU) 2022/1531 restricted its use in cosmetic products. Methyl Salicylate is currently listed in entry 324 of Annex III to the Cosmetic Regulation (EC) No. 1223/2009, with specific concentration limits for various product types and age groups (see Table 1).

In November 2022, industry submitted additional data to support the use of Methyl Salicylate in cosmetic products intended for children (age groups 0-3 and 3-6). On 14 September 2023, the SCCS concluded in their Opinion SCCS/1654/23<sup>1</sup> on the safety of Methyl Salicylate in cosmetic products intended for children of age 0.5-3 and 3-6 years in specific types of cosmetic products and with defined concentration limits.

On 29 July 2024, the SCCS published a preliminary Opinion (addendum to SCCS/1658/23)<sup>2</sup> on the safety of Hexyl Salicylate, where the scientific committee noted that the amount of toothpaste ingested by children below 3 years old (considered in the calculation of the margin of safety) has been adapted based on available data and is much higher than the one used in previous opinions including their Opinion on Methyl Salicylate (i.e., SCCS/1654/23). The SCCS concluded that this may raise concerns on the safety of such substances, where the MoS is close to 100. In view of this, the Commission, requests the SCCS to re-assess the safety of Methyl Salicylate in cosmetic products intended for children.

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<sup>1</sup> [https://health.ec.europa.eu/publications/sccs-scientific-advice-children-exposure-methyl-salicylate-methyl-2-hydroxybenzoate\\_en](https://health.ec.europa.eu/publications/sccs-scientific-advice-children-exposure-methyl-salicylate-methyl-2-hydroxybenzoate_en)

<sup>2</sup> [https://health.ec.europa.eu/publications/sccs-addendum-scientific-opinion-hexyl-salicylate-sccs165823-case-no-6259-76-3228-408-6-children\\_en](https://health.ec.europa.eu/publications/sccs-addendum-scientific-opinion-hexyl-salicylate-sccs165823-case-no-6259-76-3228-408-6-children_en)

## **2. Terms of reference**

- (1) *Taking under consideration the conclusions of SCCS/1658/23 and the aggregate exposure, the SCCS is requested to re-assess the maximum concentration of Methyl Salicylate that is considered safe when used in products intended for children of age 0-3.*
- (2) *Does the SCCS have any further scientific concerns with regard to the use of Methyl Salicylate in cosmetic products and children's exposure?*

## **3. Deadline**

2 months.

## **4. Supporting documents**

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**→ The SCCS approved this mandate by written procedure on 2 October 2024.**