



## 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 of the substance Methyl Salicylate (methyl 2-hydroxybenzoate, CAS/EC No. 119-36-8/204-317-7) used in cosmetics products – Submission II

**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).

*Table 1: Currently allowed concentrations of Methyl Salicylate in cosmetic products.*

Product type, Body parts	Maximum concentration in ready for use preparation	Other
(a) Leave-on skin products (except face makeup, spray/aerosol body lotion, spray/aerosol deodorant and hydroalcoholic-based fragrances) and leave on hair products (except spray/aerosol products)	(a) 0,06 %	Not to be used in preparations for children under 6 years of age, with the exception of (k) “Toothpaste”
(b) Face makeup (except lip products, eye makeup and makeup remover)	(b) 0,05 %	
(c) Eye makeup and makeup remover	(c) 0,002 %	
(d) Leave-on hair products (spray/aerosol)	(d) 0,009 %	
(e) Deodorant spray/aerosol	(e) 0,003 %	

(f) Body lotion spray/aerosol	(f) 0,04 %	
(g) Rinse-off skin products (except hand wash) and rinse-off hair products	(g) 0,06 %	
(h) Hand wash	(h) 0,6 %	
(i) Hydroalcoholic-based fragrances	(i) 0,6 %	
(j) Lip products	(j) 0,03 %	
(k) Toothpaste	(k) 2,52 %	
(l) Mouthwash intended for children aged 6–10 years	(l) 0,1 %	
(m) Mouthwash intended for children above 10 years of age and adults	(m) 0,6 %	
(n) Mouth spray	(n) 0,65 %	

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) considering that the combined exposure to Methyl Salicylate from oral and non-oral products is above the Margin of Safety (MoS). The Commission, therefore, requests the SCCS to carry out a safety assessment on Methyl Salicylate in view of the information provided.

## 2. Terms of reference

*In the SCCS/1633/21 Opinion, the Committee concluded that Methyl Salicylate in toothpaste is safe for children under 6 years of age when used up to the maximum concentration of 2,52%.*

- (1) *In light of the data provided and taking under consideration the conclusions of SCCS/1633/21 and the aggregate exposure, does the SCCS consider Methyl Salicylate safe for children of age 0-3, when used up to a maximum concentration of 0.02% in all of the currently regulated cosmetic products included in Table 1 (except toothpaste in which up to 2.52% can be used)?*
- (2) *In light of the data provided and taking under consideration the conclusions of SCCS/1633/21 and the aggregate exposure, does the SCCS consider Methyl Salicylate safe for children of age 3-6, when used up to the allowed maximum concentrations for each of the currently regulated cosmetic products included in Table 1 (except toothpaste in which up to 2.52% can be used) ?*

## 3. Deadline

3 months.

## 4. Supporting documents

Cosmetics Europe additional information on the safety of Methyl salicylate in Cosmetic Products.

**→ The SCCS approved this mandate by written procedure on 20 December 2022.**