



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 an addendum to SCCS/1658/23 to cover children's exposure to Hexyl Salicylate (hexyl 2-hydroxybenzoate; CAS/EC No. 6259-76-3/228-408-6) from cosmetic products

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

1. Background

Hexyl Salicylate (CAS/EC No. 6259-76-3/228-408-6) is the INCI name of 'hexyl 2-hydroxybenzoate', an ingredient with sweet, floral, and fruity odour used in formulations of fragrances in multiple consumer goods including cosmetic, household cleaning products, detergents, and air care products.

Hexyl Salicylate is not listed in the Annexes to the Cosmetic Regulation (EC) No. 1223/2009 and its use is not otherwise restricted in cosmetic products.

The European Risk Assessment Committee (RAC) of ECHA issued in March 2022 an opinion¹ recommending a 'Toxic for Reproduction Category 2' (i.e., suspected of damaging the unborn child) and 'Skin sensitizer Category 1' classification for Hexyl Salicylate. These classifications were based on the results of an LLNA assay and on 'read across' from the structural analogue Methyl Salicylate and the metabolite Salicylic Acid, respectively.

Hexyl Salicylate is the ester of 1-hexanol and Salicylic Acid, with the latter being the main metabolite. Salicylic Acid has been subject to a safety evaluation by SCCNFP in 2002² and SCCS in 2018³, while the SCCS has recently re-evaluating its safety in view of endocrine

¹ <https://echa.europa.eu/documents/10162/88845f59-c1f3-1302-2701-e684a9193ef7>

² https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out170_en.pdf

³ SCCS (Scientific Committee on Consumer Safety), Opinion on salicylic acid (CAS 69-72-7) - Submission I, SCCS/1601/18, preliminary version of 10 September 2018, final version of 21 December 2018, CORRIGENDUM on 20-21 June 2019.

disrupting concerns⁴. In addition, the scientific committee has concluded on the safety of Methyl Salicylate in 2021⁵.

Following the RAC opinion, it is expected that the European Commission will propose a classification for Hexyl Salicylate as a ‘Toxic for Reproduction Category 2’ and ‘Skin sensitizer Category 1’ (CLP Regulation Annex VI).

In December 2022, stakeholders submitted a dossier to support the safe use of Hexyl Salicylate according to Art. 15(1) Reg. 1223/2009 with specific concentration limits for various product types. The SCCS concluded in their Opinion SCCS/1658/23⁶ that Hexyl Salicylate is safe when used up to the maximum concentrations as provided in Table 1 of that Opinion. However, the scientific committee noted that the Applicant did not provide any specific scenarios for children applying cosmetic products on their skin (dermal exposure), nor were the differences between age categories in some exposure parameters (body weight, amount of the products applied, body surface, etc) taken into consideration. The SCCS, nevertheless stress that in view of the high MoS for adults, far above 100, the MoS will also be above 100 for children between 3 to 10, considering also the products categories used by children of these ages.

In May 2024, industry submitted additional information to address the SCCS concerns relevant to children’s exposure to Hexyl Salicylate, in particular for children below 3 years of age.

The Commission requests the SCCS to carry out a safety assessment on Hexyl Salicylate in view of the new information provided.

2. Terms of reference

- (1) *In light of the data provided and taking under consideration the CMR Cat.2 classification (to be introduced in Annex VI to Reg. 1272/2008), does the SCCS consider Hexyl Salicylate safe for children below 3 years of age when used up to the maximum concentrations provided in the dossier?*
- (2) *Alternatively, what is according to the SCCS the maximum concentration of Hexyl Salicylate that is considered safe for children below 3 years of age?*
- (3) *Does the SCCS have any further scientific concerns with regard to the use of Hexyl Salicylate in cosmetic products and children’s exposure?*

3. Deadline

2 months.

⁴ SCCS (Scientific Committee on Consumer Safety), Opinion on salicylic acid (CAS No. 69-72-7, EC No. 200-712-3), preliminary version of 14 December 2022, final version of 6-7 June 2023, SCCS/1646/22.

⁵ SCCS (Scientific Committee on Consumer Safety), Opinion on methyl salicylate (methyl 2-hydroxybenzoate), preliminary version of 24-25 June, final version of 26-27 October 2021, SCCS/1633/21. https://health.ec.europa.eu/publications/methyl-salicylate-methyl-2-hydroxybenzoate_en

⁶ SCCS (Scientific Committee on Consumer Safety), Scientific Opinion on Hexyl Salicylate (CAS/EC No. 6259-76-3/228-408-6), preliminary version of 26 October 2023, final version of 28 February 2024, SCCS/1658/23

4. Supporting documents

Final Dossier on Hexyl Salicylate
Safety assessment for children below 3 years of age

→ The SCCS approved this mandate by written procedure on 31 May 2024.