



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 Hexyl Salicylate (hexyl 2-hydroxybenzoate; CAS/EC No. 6259-76-3/228-408-6) used in 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 opinion<sup>1</sup> 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 ‘read across’ from the structural analogue Methyl Salicylate and the metabolite Salicylic Acid and on the results of an LLNA assay, 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 2002<sup>2</sup> and SCCS in 2018<sup>3</sup> and the SCCS is currently re-evaluating its safety in view of endocrine disrupting concerns. The scientific committee has concluded on the safety of Methyl Salicylate in 2021<sup>4</sup>.

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

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

<sup>2</sup> [https://ec.europa.eu/health/ph\\_risk/committees/sccp/documents/out170\\_en.pdf](https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out170_en.pdf)

<sup>3</sup> [https://ec.europa.eu/health/sites/default/files/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_223.pdf](https://ec.europa.eu/health/sites/default/files/scientific_committees/consumer_safety/docs/sccs_o_223.pdf)

<sup>4</sup> [https://health.ec.europa.eu/publications/methyl-salicylate-methyl-2-hydroxybenzoate\\_en](https://health.ec.europa.eu/publications/methyl-salicylate-methyl-2-hydroxybenzoate_en)

types (see Table 1). The Commission requests the SCCS to carry out a safety assessment on Hexyl Salicylate in view of the information provided.

*Table 1: Maximum concentrations of Hexyl Salicylate in cosmetic products as reported in the dossier submission.*

<b>Product type, Body parts</b>	<b>Maximum concentration</b>
Hydroalcoholic-based fragrances	2
All Rinse-off products	0.5
All Leave on products	0.3
Oral care (toothpaste and mouthwash)	0.001

## **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 when used up to the maximum concentrations provided in the dossier?*
- (2) *Does the SCCS have any further scientific concerns with regard to the use of Hexyl Salicylate in cosmetic products?*

## **3. Deadline**

9 months.

## **4. Supporting documents**

- Final Dossier on Hexyl Salicylate
- Annex 1 Summary of additional studies conducted post-2013
- References

➔ **The SCCS approved this mandate by written procedure on 10 February 2023.**

➔ **For clarity, mandating DG GROW modified the order of some words in a sentence in the third paragraph of the background on 22 July 2024.**