



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 Hydroxycitronellal (CAS No. 107-75-5, EC No. 203-518-7) when used in cosmetic products**

### 1. Background on Quantitative Risk Assessment (QRA)

Skin sensitisation leading to Allergic Contact Dermatitis (ACD) is a significant health concern associated with exposure to fragrance ingredients.

The Quantitative Risk Assessment (QRA) methodology, originally developed by industry, has undergone substantial refinement. Its updated version (QRA2) incorporates improved exposure assessment, including aggregate exposure across multiple product uses.

The SCCS acknowledged progress in QRA2 but also highlighted remaining uncertainties and methodological limitations, concluding that its suitability should be assessed on a case-by-case basis.

A recent SCCS evaluation of Citral<sup>1</sup> as a case study applying the QRA2 methodology concluded that the derived safe use levels may be considered safe with regard to the induction of skin sensitisation, while also identifying a number of methodological aspects requiring further clarification and refinement. The SCCS further indicated that the applicability of QRA2 should continue to be assessed on a case-by-case basis.

### 2. Background on Hydroxycitronellal

Hydroxycitronellal (CAS No. 107-75-5, EC No. 203-518-7) with the chemical name ‘7-hydroxy-3,7-dimethyloctanal’ is a fragrance ingredient widely used in cosmetic products due to its floral odour profile. It is also present in other consumer products such as household and air care products. Hydroxycitronellal is a well-known skin sensitiser and has been subject to previous safety evaluations<sup>2</sup>.

Hydroxycitronellal is currently regulated under Regulation (EC) No 1223/2009 as a fragrance allergen listed in entry 72 of Annex III, including specific restrictions and labelling requirements. In particular, its presence must be indicated in the list of ingredients when its concentration exceeds the established thresholds in leave-on and rinse-off products.

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<sup>1</sup> [https://health.ec.europa.eu/publications/sccs-opinion-citral-cas-no-5392-40-5-ec-no-226-394-6-sensitisation-endpoint\\_en](https://health.ec.europa.eu/publications/sccs-opinion-citral-cas-no-5392-40-5-ec-no-226-394-6-sensitisation-endpoint_en)

<sup>2</sup> SCCP/1153/08 and SCCS/1459/11

For fragrance ingredients, safety assessment for skin sensitisation differs from the classical substance-by-substance approach, as it aims to establish safe use levels across multiple product types. These levels are typically derived using a Quantitative Risk Assessment (QRA) approach. An updated methodology (QRA2), developed following the International Dialogue for the Evaluation of Allergens (IDEA) project<sup>3</sup>, incorporates improvements such as the consideration of aggregate exposure from multiple sources.

A dossier has been submitted applying the QRA2 methodology to Hydroxycitronellal, including the derivation of a No Expected Sensitisation Induction Level (NESIL) based on a weight-of-evidence approach and the proposal of corresponding safe use levels for different product categories.

In light of the information provided, the Commission requests the SCCS to assess whether the derived safe use levels for Hydroxycitronellal by application of the QRA2 based on the induction of skin sensitization is adequate to protect consumers.

## **2. Terms of reference**

*In light of all data submitted during the call for data:*

- 1. In light of the data provided and taking under consideration the derived upper safe levels using QRA2 methodology for the sensitisation endpoint, does the SCCS consider Hydroxycitronellal safe regarding its sensitisation potential when used as a fragrance ingredient in cosmetic products up to the maximum concentrations provided in the dossier submission?*
- 2. Does the SCCS have any further scientific concerns with regard to the use of QRA2 to derive safe upper levels for Hydroxycitronellal or for fragrance allergens in general?*

## **3. Deadline**

12 months.

## **4. Supporting documents**

- Dossier submission – Hydroxycitronellal (QRA2).

**→ The SCCS approved this mandate by written procedure on 30 April 2026.**

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<sup>3</sup> <https://ideaproject.info/>