



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies
Health Technology and Cosmetics

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion on Methyl salicylate (methyl 2-hydroxybenzoate; CAS: 119-36-8; EC number: 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: 119-36-8; EC number: 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. It is manufactured in and imported into the European Economic Area in quantities of 1000-10000 tonnes per year (ECHA website, 2018).

Methyl salicylate is not listed in the Annexes to the EU Cosmetic Products Regulation n. 1223/2009 on cosmetic products (Cosmetics Regulation) and its use is not otherwise restricted in cosmetic products.

The European Risk Assessment Committee (RAC) of ECHA issued in September 2019 an opinion recommending for Methyl salicylate a classification as 'Toxic for Reproduction Category 2' (i.e. suspected of damaging the unborn child) and 'Skin sensitizer Category 1B'. <https://echa.europa.eu/documents/10162/ea33d742-d73f-a7a7-8bca-be3679b713e0>. This opinion was based on a read across with data available on Salicylic acid.

Methyl salicylate is the ester of methyl alcohol and Salicylic acid. Different studies have shown that Salicylic acid is the main metabolic product of Methyl salicylate by hydrolysis. SCCS has issued an opinion on the safety of Salicylic acid in 2018 (Corrigendum 2019).

Following the RAC opinion, it is expected that the European Commission will propose a classification for Methyl salicylate as a 'Toxic for Reproduction Category 2' and 'Skin sensitizer Category 1B' (amending Annex VI to Regulation (EC) 1272/2008 on classification, labelling and packaging of chemical substances and mixtures, so called CLP Regulation).

Article 15 of the Cosmetics Regulation lays down that substances which have been classified as carcinogenic, mutagenic or toxic for the reproduction (CMR) under Annex VI to the CLP Regulation shall be prohibited for use in cosmetic products, unless an exemption has been granted.

In particular, Article 15.1 of the Cosmetics Regulation provides that a CMR classified in category 2 may be used in cosmetic products where the substance has been evaluated by the SCCS and found safe for use in cosmetic products.

Considering the abovementioned RAC opinion and the expected classification of Methyl salicylate as a ‘Toxic for Reproduction Category 2’ substance in Annex VI to the CLP Regulation, on 25th May 2020, Cosmetics Europe, or “the applicant”, submitted a dossier to support the safety of Methyl salicylate and the granting of an exception under Article 15.1 of the Cosmetics Regulation. The Commission requests, therefore, the SCCS to carry out a safety assessment on Methyl salicylate in view of the information provided by the applicant, taking into account the maximum concentration of Methyl salicylate in the different categories of cosmetic products listed in the table below

Type of cosmetic product exposure	Maximum % concentration
Hydroalcoholic-based fragrances	0.600%
Rinse-off skin & hair products (except hand wash products)	0.060%
Hand wash products	0.600%
Leave on skin & hair products (non aerosol)	0.060%
Face Make up products	0.050%
Lipsticks & lip balm	0.030%
Eye make up products & Make up remover	0.002%
Toothpaste	2.520%
Mouthwash	0.600%
Mouth spray	0.650%
Deo spray	0.003%
Hair products (spray/aerosol)	0.009%
Body Lotion Spray	0.040%

2. Terms of reference

1. *In light of the data provided and taking under consideration the RAC Opinion on Methyl salicylate and the expected new classification as Toxic for Reproduction Category 2 of Methyl salicylate (to be introduced by an update of Annex VI Reg. 1272/2008), does the SCCS consider Methyl salicylate safe when used up to the maximum concentrations provided in the dossier submitted by the applicant?*
2. *Does the SCCS have any further scientific concerns with regard to the use of Methyl salicylate in cosmetic products, also in relation to the RAC recommended classification of Methyl salicylate as ‘Skin sensitizer Category 1B’?*

3. Deadline: 9 months

4. Supporting documents:

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

The SCCS approved this mandate by written procedure on 16 September 2020.