



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 Tea Tree Oil (CAS/EC No. 68647-73-4 /285-377-1) used in cosmetic products.

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

1. Background

Tea Tree Oil (TTO) (CAS/EC No. 68647-73-4 /285-377-1) is known with the INCI name 'Melaleuca Alternifolia Leaf Oil' and is reported in CosIng database to have multiple functions including antioxidant, skin conditioning, anti-microbial and perfuming. TTO is currently not regulated under the Cosmetic Regulation (EC) No. 1223/2009, however, TTO is used in various skin and hair care products as well as oral care products.

It should be noted that TTO has also non-cosmetic uses, in particular as a fragrance ingredient in household cleaning products. These non-cosmetic consumer and professional uses are included in the EU REACH registration dossier. In addition, TTO is used as active ingredient in plant protection for the prevention and control of plant diseases on horticultural and agricultural crops, while the active ingredient is currently in a re-approval process. Lastly, TTO is also used as herbal medicine and as food flavouring ingredient.

The Scientific Committee on Consumer Product (SCCP) has previously assessed the safety of Tea Tree Oil in 2004¹ and in 2008², remarking that TTO is a skin sensitiser and could induce skin and eye irritation and contact allergy. However, the SCCP was not able to calculate a margin of safety in the absence of reliable data on dermal absorption studies.

The European Risk Assessment Committee (RAC) of ECHA issued in February 2024 (adopted in November 2023) an opinion recommending among others a classification for TTO as 'Reprotoxic of Category 1B (H360Fd)'. Following the RAC opinion, the European Commission may propose a classification for TTO as a 'Repr.1B' (CLP Regulation Annex VI entry).

According to Article 15(2) of the Cosmetics Regulation, *'The use in cosmetic products of substances classified as CMR substances, of category 1A or 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited.'*

However, such substances may be used in cosmetic products by way of exception where, subsequent to their classification as CMR substances of category 1A or 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008, all of the following conditions are fulfilled:

¹ https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_00c.pdf

² https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_160.pdf

- (a) *they comply with the food safety requirements as defined in Regulation (EC) No 178/2002³ of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;*
- (b) *there are no suitable alternative substances available, as documented in an analysis of alternatives;*
- (c) *the application is made for a particular use of the product category with a known exposure; and*
- (d) *they have been evaluated and found safe by the SCCS for use in cosmetic products, in particular in view of exposure to these products and taking into consideration the overall exposure from other sources, taking particular account of vulnerable population groups.'*

In view of the above, regulatory measures must be adopted by the Commission services within 15 months of the classification as CMR 1A or 1B of the substance(s) concerned in Part 3 of Annex VI to Regulation (EC) No 1272/2008.

In August 2024, the Commission services received a dossier to defend the safe use of Tea Tree Oil (CAS/EC No. 68647-73-4 /285-377-1) as an ingredient with anti-seborrheic and anti-microbial function in rinse-off and leave-on cosmetic products according to Article 15(2) of the Cosmetics Regulation (EC) No. 1223/2009. The Commission, therefore, requests the SCCS to carry out a safety assessment on this ingredient in view of the information provided.

2. Terms of reference

(1) In light of the data provided and taking under consideration the possible classification as 'Repr.1B' under Regulation (EC) No 1272/2008 (CLP Regulation) and the conditions laid out in Article 15 (2) (d) of the Regulation (EC) No 1223/2009, does the SCCS consider TTO safe when used as an anti-seborrheic and anti-microbial agent in rinse-off and leave-on cosmetic products up to the maximum concentrations provided by the applicant?

(2) Alternatively, what is according to the SCCS, the maximum concentration considered safe for use of TTO in cosmetic products?

(3) Does the SCCS have any further scientific concerns regarding the use of TTO in cosmetic products?

3. Deadline

6 months.

4. Supporting documents

TTO dossier

→ The SCCS approved this mandate by written procedure on 2 October 2024.

³ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2002:031:FULL&from=EN>