



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 the safety of Titanium dioxide (TiO₂) (CAS/EC numbers 13463-67-7/236-675-5, 1317-70-0/215-280-1, 1317-80-2/215-282-2) in cosmetic products

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1. Background

Titanium dioxide (TiO₂) (CAS/EC No. 13463-67-7/236-675-5, 1317-70-0/215-280-1, 1317-80-2/215-282-2) is a white, insoluble, inert substance with a high refractive index. In its microcrystalline form, it is used as a white pigment or opacifying agent in make-up, skin care, hair and oral products. In addition, since TiO₂ absorbs and scatters both UVA and UVB rays it is also used as inorganic UV-filter primarily in sunscreens, but also in day creams, foundations and lip balms, to provide protection against UV radiation. The introduction of colourless, ultrafine nanoparticles of TiO₂ improved its application on the skin while maintaining and enhancing its UV-filter properties.

TiO₂ is authorized both as colorant under entry 143 of Annex IV and as UV-filter under entries 27 and 27a (nano form) of Annex VI to Regulation (EC) No. 1223/2009 (Cosmetics Regulation). In light of its classification as a Carcinogen Category 2 (i.e. suspected human carcinogen) by inhalation route only and its inclusion in Annex VI to Regulation (EC) No. 1272/2008 (CLP Regulation) TiO₂ was re-assessed by the SCCS¹. Subsequently, entry 321 in Annex III was introduced and additional provisions in the existing entries of 143 of Annexes IV and 27 and 27a of Annex VI were added that further restricted the use of TiO₂ in cosmetic products.

In March 2021, the Panel on Food Additives and Flavourings (FAF Panel) of the European Food Safety Authority (EFSA) issued an opinion on the safety of TiO₂ (E171) as a food additive². In particular, based on new relevant scientific evidence considered by the panel to be reliable, including data obtained with TiO₂ nanoparticles and data from an extended one-generation reproductive toxicity (EOGRT) study, the panel indicated that a concern for genotoxicity could not be ruled out. In light of this and given the many uncertainties, the panel concluded that E171 should no longer be considered as safe when used as a food additive.

In May 2022, the Commission services received a dossier submission by industry accompanied by a comprehensive and up to date review of the genetic toxicity database for TiO₂ providing

¹ https://ec.europa.eu/health/sites/default/files/scientific_committees/consumer_safety/docs/sccs_o_238.pdf

² <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2021.6585>

scientific evidence to demonstrate the safety of non-nano (pigmentary) and nano form of TiO₂ in cosmetic products.

The Commission requests the SCCS to re-assess the safety of TiO₂ with focus on genotoxicity and exposure via the inhalation and oral route (lip care, lipstick, toothpaste, loose powder, hair spray), since the currently available scientific evidence supports an overall lack of dermal absorption of TiO₂ particles³.

2. Terms of reference

(1) *In light of the EFSA Opinion on genotoxicity concerns for E171, does the SCCS consider Titanium dioxide safe in oral cosmetic products?*

(2) *In light of the EFSA Opinion, does the SCCS consider that previous Opinions issued by the SCCS on inhalation and dermal exposure to Titanium dioxide need to be revised?*

In the event that the estimated exposure to Titanium dioxide from cosmetic products is found to be of concern, SCCS is asked to recommend safe concentration limits for each category of products and types of use.

(3) *In light of the potential removal of the E 171 purity specification from the food additives Regulation. The SCCS is requested to review and indicate the respective specifications for Titanium dioxide when used in cosmetics.*

(4) *Does the SCCS have any further scientific concerns regarding the use of Titanium dioxide in cosmetic products?*

3. Deadline: 9 months

4. Supporting documents: ‘Report on the Human Safety Evaluation of TITANIUM DIOXIDE (TiO₂) in Cosmetics (Submission with focus on genetic toxicity)’ and ‘A weight of evidence review of the genotoxicity of titanium dioxide (TiO₂)’.

➔ **The SCCS approved this mandate in the plenary meeting on 21-22 June 2022.**

³ https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_136.pdf