



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

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

1. Background

Titanium dioxide (TiO₂), (CAS/EC numbers 13463-67-7/236-675-5, 1317-70-0/215-280-1, 1317-80-2/215-282-2) is authorised both as colorant under entry 143 of Annex IV and as UVfilter under entries 27 and 27a (nano form) of Annex VI to Regulation (EC) No 1223/2009. TiO₂ is also used as a filler in cosmetic products (not subject to specific regulatory restrictions). In 2000, SCCNFP concluded that the toxicological profile of TiO₂ (opinion SCCNFP/0005/98): ‘... does not give rise to concern in human use, since the substance is not absorbed through the skin’.

In July 2013, SCCS delivered a new opinion on TiO₂ (nano) (SCCS/1516/1311). In that opinion, SCCS concluded that the use of TiO₂ (nano) as UV-filter in sunscreens and at a concentration up to 25%, can be considered not to pose any risk of adverse effects in humans. The SCCS also considered that applications that might lead to inhalation exposure to TiO₂ nanoparticles (such as powders or sprayable products) cannot be considered safe.

In 2014, SCCS provided clarifications of the meaning of the term ‘sprayable application/products’ (opinion SCCS/1539/14). Furthermore, SCCS issued an additional opinion in 2018 (SCCS/1583/17) on TiO₂ (nano form) as UV-Filter in sprays; it concluded that *‘the information provided is insufficient to allow assessment of the safety of the use of nano-TiO₂ in spray applications that could lead to exposure of the consumer’s lungs’*.

Finally, SCCS provided an opinion on TiO₂ (nano form) coated with Cetyl Phosphate, Manganese Dioxide or Triethoxycaprylylsilane as UV-filter in dermally applied cosmetics (SCCS/1580/16). The opinion confirmed previous assessment: safe use in cosmetics for products intended for application on skin. However, this opinion does not apply to applications that might lead to exposure of the consumer’s lungs by inhalation.

The European Risk Assessment Committee (RAC) of ECHA issued in September 2017 an opinion recommending a Carcinogen Category 2 classification (i.e. as a suspected human carcinogen) of TiO₂ (CAS 13463-67-7) by inhalation route only.

Following this RAC recommendation, the European Commission on 4 October 2019 adopted¹ for TiO₂ a classification as a ‘Carcinogen Category 2 (inhalation)’ for the purposes of adaptation to technical and scientific progress of the Regulation (EC) No 1272/2008 (CLP Regulation Annex VI entry); this classification applies to TiO₂ in powder form containing 1% or more of particles with aerodynamic diameter ≤ 10 μm’.

In addition, the following note applies to the classification of mixtures containing TiO₂: ‘The classification as a carcinogen by inhalation applies only to mixtures placed on the market in powder form containing 1% or more of titanium dioxide which is in the form of or incorporated in particles with aerodynamic diameter ≤ 10 μm’.

In January 2020, industry submitted a dossier to support the safety of TiO₂ according to Article 15(1) Regulation (EC) n.1223/2009. Since the nano form of TiO₂ is already restricted under entry 27a of Annex VI to Regulation 1223/2009 (i.e. not to be used in applications that may lead to exposure of the end-user's lungs by inhalation), this dossier covers only the non nano form of TiO₂. More specifically, this dossier is confined to the uses of TiO₂ (non nano) in cosmetic products that may give rise to consumer exposure by the inhalation route (i.e. aerosol, spray and powder form products).

The Commission requests the SCCS to carry out a safety assessment on TiO₂ in view of the information provided, for the purpose of the adoption of the necessary measures in accordance with Article 15(1) Regulation (EC) n.1223/2009.

2. Terms of reference

(1) In light of the data provided and of the possible classification as Carcinogen Cat. 2 (inhalation) in Annex VI to Regulation (EC) n.1272/2008, does the SCCS consider Titanium dioxide safe when used as a UV-filter (entry 27 Annex VI) in cosmetic products up to a maximum concentration of 25 %, as a colorant (entry 143 Annex IV) and as an ingredient in all other cosmetic products?

(2) Alternatively, if up to 25% use is not considered safe, what is according to the SCCS, the maximum concentration considered safe for use of Titanium dioxide as an ingredient in cosmetic products?

(3) Does the SCCS have any further scientific concerns with regard to the use of Titanium dioxide in cosmetic products?

3. Deadline: 6 months

4. Supporting documents:

Cosmetics Europe dossier on the safety of Titanium dioxide in Cosmetic Products

The SCCS approved this mandate by written procedure on 5 February 2020.

¹ COMMISSION REGULATION (EU) .../... amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2018/669 (C(2019) 7227 final).

<https://ec.europa.eu/transparency/regdoc/rep/3/2019/EN/C-2019-7227-F1-EN-MAIN-PART-1.PDF>