



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 two coatings for Titanium Dioxide (nano form) (Methicone CAS/EC 9004-73-3/236-675-5 and Perfluorooctyl Triethoxy silane CAS/EC 51851-37-7/257-473-3) as UV-filter in dermally applied cosmetic products - Submission II

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

1. Background

Titanium Dioxide, TiO_2 , (CAS/EC numbers 13463-67-7/236-675-5, 1317-70-0/215-280-1, 1317-80-2/215-282-2) is authorized both as colorant under entry 143 of Annex IV and as UV-filter under entry 27 of Annex VI to Regulation (EC) No 1223/2009.

In July 2013, the Scientific Committee on Consumer Safety (SCCS) issued the safety evaluation on Titanium Dioxide (nano) concluding that the use of Titanium Dioxide (nano) as UV-filter, at concentrations up to 25 % and with the characteristics indicated in the opinion, can be considered not to pose any risk of adverse effects in humans after application on healthy, intact or sunburnt skin (SCCS/1516/13).

Among the characteristics reported in the opinion SCCS/1516/13, the SCCS indicated the substances considered safe for use as coating for TiO_2 (nano). Regarding the use of other coatings, not covered in the opinion, the SCCS concluded that:

‘Other cosmetic ingredients applied as stable coatings on TiO_2 nanomaterials can also be used, provided that they can be demonstrated to the SCCS to be safe and the coatings do not affect the particle properties related to behaviour and/or effects, compared to the nanomaterials covered in this opinion’.

The SCCS conclusion clarifies that for the use of a substance as coating on TiO_2 nanomaterials, the applicant has to demonstrate that properties/behaviour of the particles with the new coating are not significantly different compared to those already covered in the SCCS opinion. This would need provision of data on physico-chemical properties (in line with those provided in Tables 1-3 of the SCCS/1516/13 opinion), and data on dermal penetration.

In November 2017, the Commission' services received a dossier relates to two nano-forms of TiO₂ materials coated with the following substances:

- Material A: Methicone + Hydrated Silica + Aluminum Hydroxide
- Material B: Perfluorooctyl Triethoxysilane + Hydrated Silica + Aluminum Hydroxide

2. Terms of reference

- (1) *In light of the data provided, does the SCCS consider safe the use of Methicone with a maximum concentration of 2% (when applied in combination with hydrated silica and aluminium hydroxide) as coatings on Titanium Dioxide (nano) for use as UV filter in dermally applied cosmetic products?*
- (2) *In light of the data provided, does the SCCS consider safe the use of Perfluorooctyl Triethoxysilane with a maximum concentration of 3% (when applied in combination with hydrated silica and aluminium hydroxide) as coatings on Titanium Dioxide (nano) for use as UV filter in dermally applied cosmetic products?*
- (3) *Does the SCCS have any further scientific concerns regarding the use of Titanium Dioxide (nano) coated with the above mentioned materials when used as UV-filter in dermally applied cosmetic products?*

3. Deadline: October 2018

The SCCS adopted this mandate at the SCCS plenary meeting on 21/22 February 2018.