

## SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

**Request for a scientific opinion:** Three coatings for Titanium Dioxide (nano) (CAS/EC numbers 13463-67-7/236-675-5, 1317-70-0/205-280-2, 1317-80-2/215-282-2) as UV-filter in dermally applied cosmetic products.

### 1. Background

Titanium Dioxide, TiO<sub>2</sub>, (CAS/EC numbers 13463-67-7/236-675-5, 1317-70-0/205-280-2, 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) delivered an opinion on Titanium Dioxide (nano) (SCCS/1516/13<sup>1</sup>) to assess the safety of the nano form of Titanium Dioxide. In the opinion, the SCCS concluded that the use of Titanium Dioxide (nano) as UV-filter in sunscreens, with the characteristics indicated in the opinion, and at a concentration up to 25 %, can be considered not to pose any risk of adverse effects in humans after application on healthy, intact or sunburnt skin.

Among the characteristics reported in the SCCS opinion (SCCS/1516/13), there are indicated the substances considered safe for use as coating for TiO<sub>2</sub> (nano). Consequently as for the use of other coatings, not covered in the opinion, the SCCS concluded that: *‘Other cosmetic ingredients applied as stable coatings on TiO<sub>2</sub> 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<sub>2</sub> 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 September 2015, the Commission' services received data from industry in order to assess the safety of the following coatings for Titanium Dioxide (nano form) used as UV-filter in in dermally applied cosmetic products:

- Cetyl Phosphate (CAS 3539-43-3 )
- Manganese Dioxide (CAS 1313-13-9)
- Triethoxycaprylylsilane (CAS 2943-75-1)

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<sup>1</sup> [http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_136.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_136.pdf)

## 2. Terms of reference

- (1) *In light of the data provided, does the SCCS consider safe the use of Cetyl Phosphate, Manganese Dioxide and Triethoxycaprylylsilane as coatings for Titanium Dioxide (nano) used as UV-Filter in dermally applied cosmetic products?*
- (2) *Does the SCCS have any further scientific concerns regarding the use of the above mentioned additional coatings for Titanium Dioxide (nano) used as UV-Filter in dermally applied cosmetic products?*

**3. Deadline:** June 2016

**4. Supporting documents:**

1. EFfCI Documents package to support the use of additional coatings for Titanium Dioxide (nano) as UV-Filter in dermal applied cosmetic products.
2. EFfCI Document on Titanium Dioxide (nano) – Measurement of Photocatalytic Activity of additional Coatings