

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion: New coating for Titanium Dioxide (nano form) (Sodium Myristoyl Sarcosinate, CAS No. 30364-51-3/ EC No. 250-151-3) as UV-filter in dermally applied cosmetic products.

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 authorized both as colorant under entry 143 of Annex IV, as UV-filter under entry 27 of Annex VI, and in powder form in entry 321 of Annex III to Regulation (EC) No 1223/2009.

In July 2013¹, 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. Among the characteristics reported in that opinion, the SCCS indicated the substances considered safe for use as coating for TiO₂ (nano). Regarding the use of other coatings, not covered in the opinion, the SCCS concluded that:

‘Other cosmetic ingredients applied as stable coatings on TiO₂ 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 TiO₂ 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 August 2023, the Commission' services received a dossier related to a new nano-form of TiO₂ material (i.e., Eclipse 70) coated with ‘Aluminium Hydroxide’, ‘Sodium Myristoyl Sarcosinate’ and ‘Dimethicone’. ‘Aluminium Hydroxide’ and ‘Dimethicone’ coatings were already assessed by SCCS in 2014, while ‘Sodium Myristoyl Sarcosinate’ coating has not yet been assessed.

The Commission requests the SCCS to carry out a safety assessment on ‘Sodium Myristoyl Sarcosinate’ (CAS No. 30364-51-3/ EC No. 250-151-3) as a coating of Titanium Dioxide (nano) in view of the information provided.

2. Terms of reference

(1) *In light of the data provided, does the SCCS consider safe the use of Titanium Dioxide (nano) coated with a combination of w/w 6% Aluminium Hydroxide, 14% Sodium*

¹ SCCS (Scientific Committee on Consumer Safety), Opinion on titanium dioxide (nano form), 22 July 2013, revision of 22 April 2014

Myristoyl Sarcosinate and 10% Dimethicone, for use as UV filter in dermally applied cosmetic products?

- (2) *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

9 months.

4. Supporting documents

- a) Submission dossier by Miyoshi Europe SAS, August 2023.
- b) Folder with references