EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Resources Based, Manufacturing and Consumer Goods Industries
Health Technology and Cosmetics

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion on three coatings for Zinc oxide (nano form) [Methicone (CAS/EC 9004-73-3/ 236-675-5), Silica (CAS/EC 7631-869/231-545-4) and Isostearic acid (CAS/EC 30399-84-9/250178-0)] as UV-filter in dermally applied cosmetic products

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

1. Background

Zinc oxide, ZnO, (CAS/EC numbers 1314-13-2/215-222-5) is authorized both as colorant under entry 144 of Annex IV and as UV-filter under entry 30 and 30a (nano) of Annex VI to the Cosmetics Regulation (EC) No 1223/2009.

The Scientific Committee on Consumer Safety (SCCS) has delivered an Opinion on Zinc oxide (nano) (SCCS/1489/12) and an ADDENDUM (SCCS/1518/13) concerning the safety of the nano form of ZnO and its coating (triethoxycaprylylsilane, dimethicone, dimethoxydiphenylsilanetriethoxycaprylylsilane cross-polymer and octyl triethoxy silane). The SCCS committee concluded that the use of ZnO (nano) as UV filter in sunscreens, with the characteristics laid out in this Opinion, and at a concentration of up to 25 %, can be considered to "pose no or limited risk for use on the skin as UV filter in sunscreen formulations".

Regarding the use of other coatings, not covered in the opinion, the SCCS concluded that: "Other cosmetic ingredients can be used as coatings as long as they are demonstrated to the SCCS to be safe and do not affect the particle properties related to behaviour and/or effects, compared to the nanomaterials covered in the current opinion"(SCCS/1518/13).

The SCCS conclusion clarifies that for the use of a substance as coating on ZnO 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 and data on dermal penetration.

The Commission services have received two safety dossiers regarding nano-forms of ZnO materials coated with the following substances:

- Material A (BCSI ZNO-650): Zinc oxide coated with 3.0% Methicone
- Material B (BCSI SHOSEI ZNO-650): Zinc oxide coated with 3.0% Methicone and 8.0% Silica

- Material C (ALIS-Z-031)1: Zinc oxide coated with 2.0% Triethoxycaprylylsilane and 4% Isostearic Acid.

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 3% as coating on Zinc oxide (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 Methicone with a maximum concentration of 3% when applied in combination with 8% silica as coatings on Zinc oxide (nano) for use as UV filter in dermally applied cosmetic products?*

3. *In light of the data provided, does the SCCS consider safe the use of Isostearic Acid with a maximum concentration of 4% when applied in combination with 2.0% Triethoxycaprylylsilane as coatings on Zinc oxide (nano) for use as UV filter in dermally applied cosmetic products?*

4. *Does the SCCS have any further scientific concerns regarding the use of Zinc oxide (nano) coated with the above mentioned materials when used as UV-filter in dermally applied cosmetic products?*

3. **Deadline:** March 2020

The SCCS adopted this mandate by written procedure on 29 July 2019.