**SCIENTIC COMMITTEE ON CONSUMER SAFETY (SCCS)**

**Request of clarifications on scientific opinion SCCS/1489/2012 on Zinc oxide nano (CAS 1314-13-2, EC 215-222-5) as UV-filter**

## 1. Background

In the opinion on Zinc oxide adopted on the 18 September 2012 (SCCS/1489/12), the SCCS considers that the use of nano forms and non-nano forms of ZnO at concentrations of up to 25% as a UV filter in sunscreens are safe, with the specific following considerations:

In summary, it is concluded on the basis of available evidence that the use of ZnO nanoparticles with the characteristics as indicated below, at a concentration up to 25% as a UV-filter in sunscreens, can be considered not to pose a risk of adverse effects in humans after dermal application. This does not apply to other applications that might lead to inhalation exposure to ZnO nanoparticles (such as sprayable products). Also, this assessment only applies to ZnO nanoparticles that are included in this dossier, or are similar materials that have the following characteristics:

- ZnO nanoparticles of purity ≥99%, with wurtzite crystalline structure and physical appearance as described in the dossier, i.e. clusters that are rod-like, star-like and/or isometric shapes.
- ZnO nanoparticles with a median diameter (D50: 50% of the number below this diameter) of the particle number size distribution between 30 nm and 55 nm, and the D1 (1% below this size) above 20 nm.
- ZnO nanoparticles that are either uncoated, or coated with triethoxycaprylylsilane, dimethicone, dimethoxydiphenylsilanetriethoxycaprylylsilane cross-polymer, or octyl triethoxy silane.
- ZnO nanoparticles that have a comparable solubility to that reported in the dossier, i.e. below 50 mg/L (approximately the maximum solubility of the ZnO nanomaterials for which data are provided in the dossier).

In January 2013, Cosmetics Europe[1] submitted a document in which they proposed their own – broader - interpretation of the characteristics laid out in the scientific opinion on zinc oxide in nano form. In particular, they proposed the purity requirements to be reduced to 96% (as data on one of the material with 96% purity were provided in the submission), the median diameter of the particle number size distribution to be accepted when it is greater than 30 nm, the possible coatings to be extended to all (authorized or not prohibited) cosmetic ingredients, and the omission of the solubility specification.

Both the Commission's services and the Member States expressed doubts regarding this interpretation, and therefore seek a clarification from the SCCS.

[1] *Cosmetics Europe, ex- COLIPA –: European Cosmetics Toiletry and Perfumery Association*

## 2. Terms of reference

1. On the basis of the submitted document, does the SCCS consider safe the use of ZnO nanoparticles at a concentration up to 25% as a UV-filter in sunscreens with the characteristics as following indicated:

• ZnO nanoparticles of purity ≥96%, with wurtzite crystalline structure and physical appearance as clusters that are rod-like, star-like and/or isometric shapes.

• ZnO nanoparticles with a median diameter (D50: 50% of the number below this diameter) of the particle number size distribution above 30 nm, and the D1 (1% below this size) above 20 nm.

• ZnO nanoparticles that are either uncoated, or coated with cosmetic ingredients

• ZnO nanoparticles without specifying any solubility