SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion: Zinc oxide (CAS No 1314-13-2; EC No 215-222-5) Submission III

1. Background

Zinc oxide (CAS No 1314-13-2; EC No 215-222-5) has a widespread use in cosmetic products with the following functions: bulking, skin protecting and as UV absorber besides its authorized use in all cosmetics as a cosmetic colorant with the Colour Index no. CI 77947 in Annex IV.

Two former submissions on Zinc oxide in pigmentary form as well as in the form of a nanomaterial was submitted in order to have zinc oxide approved as an UV filter in cosmetic sunscreen products at a maximum level of 25%.

The first scientific opinion (SCCNFP/0649/03, final) on zinc oxide was adopted by the SCCNFP during its 24th plenary meeting of 24-25 June 2003 with the following conclusion: "*A considerable part of the investigations and their results submitted have been performed 15 or more years ago and consequently cannot fulfil modern requirements. However, there is a broad basic knowledge on Zn^{2+} and its compounds, e.g. ZnO.*
The physico-chemical specifications of ZnO used in many of the studies are incomplete, the purity/impurities not specified. On the other hand, ZnO is practically insoluble in water. Thus, in general, ZnO may be considered as a non-toxic substance, including when used in cosmetic products.
The main concern of the present evaluation is related to the risk assessment of micronized (approximately 0.2 µm) ZnO, which may be coated by other compounds, and which is used as an ingredient in sunscreen formulations.
Micronised ZnO has been demonstrated to be photoclastogenic, possibly photo-aneugenic, and a photo-DNA damaging agent in mammalian cells cultured in vitro. The relevance of these findings needs to be clarified by appropriate investigations in vivo.
There is a lack of reliable data on the percutaneous absorption of micronised ZnO and the potential for absorption by inhalation has not been considered.
As to a safety assessment of a use of UV-filters by children over the age of 1 year, the SCCNFP issued a position statement (SCCNFP/0557/02)."

In the statement (SCCP/0932/05) on zinc oxide adopted by SCCP 20 September 2005 the request for a safety dossier was repeated for microfine zinc oxide.

In the general opinion (SCCP/1147/07) on the use of nanomaterials in cosmetics adopted by the SCCP the 18th December 2007 it was concluded that "*A complete safety dossier on micronsized and nanosized ZnO was requested by SCCNFP in its opinion on ZnO in 2003 (SCCNFP/0649/03). An opinion on the safety of such materials will be dependent on the availability of an adequate dossier."*

Finally, a clarification (SCCP/1215/09) on the statement (SCCP/09328/05) on zinc oxide was adopted by SCCP the 21 January 2009 with the clarification that
"The SCCP considers that on basis of the dossier reviewed in 2003 the use of ZnO in its nonnano form (pigment grade, with particle sizes above 100 nm) is considered safe. The concern expressed in the SCCNFP opinion 0693/03 with regard to phototoxicity is not relevant for this form of ZnO due to the absence of dermal penetration."

The current submission III contains - according to Colipa - the information contained in the previous submissions I and II, presents the new information that became available since the last submission and provides an overall safety assessment for this ingredient, which takes into account the entire available information.

2. Terms of reference

1. *Does SCCS consider Zinc oxide in its nano-form safe for use as a UV-filter with a concentration up to 25 % in cosmetic products taking into account the scientific data provided?*

2. *Does SCCS confirm that Zinc oxide in its non-nano form is safe for use as a UV-filter with a concentration up to 25 % as stated in the SCCP clarification (SCCP/1215/09)?*

3. *And/or does the SCCS have any further scientific concern with regard to the use of Zinc oxide in cosmetic products?*