



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate C - Public Health and Risk Assessment
C7 - Risk assessment

SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS

SCCP

Statement

on

Zinc oxide used in sunscreens

Adopted by the SCCP during the 5th plenary meeting
of 20 September 2005

Statement on the Zinc oxide used in sunscreens

The SCCNFP previously adopted an opinion on the safety of zinc oxide when used as a sunscreen (Adopted by the SCCNFP during the 24th plenary meeting of 24-25 June 2003). This was in response to the question: *Is Zinc oxide safe for use in cosmetic products as a UV filter up to 25 %?*

The dossier reviewed at the time contained data primarily derived from pigment grade zinc oxide. However, microfine powders of zinc oxide, used in sunscreen products, are understood to have an average particle size of approximately 0.20 microns or less with a narrow distribution.

The SCCNFP pointed out that the physico-chemical specifications of ZnO used in many of the submitted studies were incomplete, and the purity/impurities not specified. The main concern related to the risk assessment of microfine (approximately 0.2 µm) ZnO, which may be coated by other compounds, and which is used as an ingredient in sunscreen formulations.

Microfine ZnO has been demonstrated to be photoclastogenic, possibly photo-aneugenetic, and a photo-DNA damaging agent in mammalian cells cultured in vitro. Clarification of the relevance of these findings is required by appropriate investigations *in vivo*.

There is a lack of reliable data on the percutaneous absorption of microfine ZnO and the potential for absorption by inhalation.

The SCCNFP was of the opinion that more information is required to enable a proper safety evaluation of microfine Zinc oxide for use as a UV filter in cosmetic products. Consequently, an appropriate safety dossier on microfine ZnO itself, including possible pathways of cutaneous penetration and systemic exposure, is required.

The 2004 report of the Royal Society (Nanoscience and nanotechnologies: opportunities and uncertainties' - published on 29 July 2004, page 73)) states:

We recommend that industry submit the additional information on microfine zinc oxide that is required by the SCCNFP as soon as reasonably practicable so that the SCCNFP can deliver an opinion on its safety. The uncertainties about the safety of nanoparticles of zinc oxide are not just applicable to its use as a UV filter. Further information from industry may demonstrate that microfine zinc oxide does not penetrate the skin or that the activity seen in vitro does not occur in vivo, in which case the SCCNFP will be able to deliver a positive opinion on its safety. However, until the safety dossier is provided to the SCCNFP the uncertainties remain.

Hitherto, the requested safety dossier has not been provided. It is understood that microfine and ultrafine zinc oxide is widely used in sunscreen products on the European market. The safety to the consumer of this use remains to be assessed. The attention of the Commission and the Member States is drawn to this.