

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion: Titanium Dioxide (CAS 13463-67-7), (EC 236-675-5) (S75)

1. Background

The first scientific opinion on the safe use of titanium dioxide as a UV-filter at a maximum concentration of 25% in cosmetic products was adopted 24 October 2000 by the SCCNFP (SCCNFP/0005/98).

However, a review of the substance in its nanoform deems necessary according to the opinion on Safety of Nanomaterials in Cosmetic Products adopted on 18 December 2007 (SCCP/1147/07), where it is stated that:

"The SCCNFP opinion from 2000 (SCCNFP/0005/98) is on micro-crystalline preparations of TiO₂ and preparations of coarse particles. However, since this opinion new scientific data on nanosized particles, including TiO₂ has become available. Therefore, the SCCP considers it necessary to review the safety of nanosized TiO₂ in the light of recent information. Also, a safety assessment of nanosized TiO₂, taking into account abnormal skin conditions and the possible impact of mechanical effects on skin penetration need to be undertaken".

Supplementary information on nanosized Titanium dioxide was submitted following a meeting with stakeholders on 1 October 2008, where data requirements were agreed.

Titanium Dioxide is currently regulated - basically irrespectively of its form - as an UV-filter in a concentration up to 25% in cosmetic products in Annex VII, entry 27 of the Cosmetics Directive.

2. Terms of reference

1. *Does SCCS consider that use of titanium dioxide in its nanoform as an UV-filter in cosmetic products in a concentration up to maximum 25.0 % is safe for the consumers taken into account the scientific data provided?*
2. *In order for the COM to differentiate in the regulation between materials in its nanoform and its non-nano form, can the SCCS give quantitative and qualitative guidance on how this differentiation should be given based on the particle size distribution or other parameters?*