

COSMOS Position on Mineral UV-Filters in Organic and Natural Cosmetics

The precautionary principle and nanotechnology

The precautionary principle is one of the general principles of the COSMOS-standard (the standard). 5.1 of the standard prohibits the use of an ingredient, a technology or a process when there is scientific evidence concerning a health or environmental risk.

According to the precautionary principle, 5.1.1 of the standard does not allow nanomaterials. However, the standard recognizes that there may need to be exceptions, for which applications supported by technical dossiers will be considered.

Nanomaterial is defined in chapter 4 of the standard as “(taken from Regulation (EC) No. 1223/2009) - an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm”. However, it has since emerged that this EU definition is unclear and discussion about necessary amendments of the nanomaterial definition is going on.

By application of the precautionary principle, the COSMOS Board took the decision three years ago to ban TiO₂ and ZnO as UV filters due to the potential content of nanomaterial, in anticipation of the EU clarifying their definition within two years. As there is no sign of this happening at short notice, and taking into consideration the main conclusion of the SCCS¹ about the safety of TiO₂ and ZnO in their nano form as UV filters, we now feel obliged to reconsider our current position.

UV filters

TiO₂ and ZnO are globally used as UV Filters in sunscreens and other cosmetic products and are effective alternatives for other UV filters of petrochemical origin.

The COSMOS Board considers, on the one hand that these UV filters fulfil the requirements for natural ingredients according to the provisions of the standard and contribute significantly to the safety of consumers, but on the other hand that specific requirements have to be introduced in order to implement the precautionary principle and to minimise potential risks. Therefore, the COSMOS Board will recognize these UV filters as acceptable under the standard if the following conditions are met:

- The particle size distribution (number of particles) under 100 nm must be less than 50%
- The mass distribution (weight of particle fraction) under 100 nm must be less than 10%
- The raw material has to fulfill the recommendations in the conclusions in the Opinions of the Scientific Committee on Consumer Safety (SCCS) published on Titanium Dioxide (nano form)¹, as well as on Zinc Oxide (nano form)¹.

In any case, TiO₂ and ZnO as UV filters cannot be used in spray applications, such as aerosol or pump dispenser with spray nozzle, as recommended in the SCCS opinion².

¹ SCCS (2013), “Opinion on Titanium Dioxide (nano form)”, 22.07.2013. Available at http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_136.pdf
SCCS (2012), “Opinion on Titanium Dioxide (nano form)”, 18.09.2012. Available at http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_103.pdf
SCCS (2013), “Addendum to the Opinion on Titanium Dioxide (nano form)”, 23.07.2013.
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_137.pdf

COSMOS only sets the requirements for the certification and approval of natural and organic cosmetic products and ingredients according to the COSMOS-standard. The standard therefore does not imply that allowed materials are in compliance with any particular legal requirements that are applicable in different countries, whether for nanoparticles or other specifications or claims. It is the manufacturer's own responsibility to check legal requirements for the use and labelling of ingredients whether they are marketed in the EU or in other regions of the world.

¹ SCCS/1516/13 Revision of 22 April 2014 and SCCS/1489/12 Revision of 11 December 2012

http://ec.europa.eu/health/scientific_committees/consumer_safety

² Opinion for clarification of the meaning of the term "sprayable applications/products" for the nano forms of Carbon Black CI 77266, Titanium Oxide and Zinc Oxide.