

Questions and Answers on the notification of cosmetic products containing nanomaterials

Following a number of requests received from responsible persons, the Commission services decided to provide the following “Questions and Answers” on the notification of cosmetic products containing nanomaterials.

1) Is my material a nanomaterial ?

It is not possible to decide whether a certain substance is a nanomaterial based only on the name of the substance mentioned in a notification according to art. 13 of Regulation (EC) No 1223/2009 (Cosmetics Regulation).

According to the Cosmetics Regulation, and for the purposes of this Regulation, ‘nanomaterial’ means 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. The definition does not establish a threshold for particle size distribution, but responsible persons can refer to the threshold of 50 % or more of the particles in the number size distribution, established in Commission Recommendation 2011/696 on the definition of nanomaterial.

It is up to the responsible person to decide whether or not a substance is a nanomaterial. If you do not have enough information, or you are unsure, please check with your supplier or seek the guidance of your national association for cosmetics.

2) Who notifies according to art 16 of the Cosmetics Regulation? What is to be notified?

According to art. 16 of the Cosmetics Regulation, in addition to the notification under Article 13, cosmetic products containing nanomaterials shall be notified to the Commission by the responsible person by electronic means six months prior to being placed on the market. The responsible person may designate another legal or natural person by written mandate for the notification of nanomaterials and shall inform the Commission thereof.

This means that:

- a) Each product containing nanomaterials (not used as colorants, preservatives or UV-filters) has to be notified individually according to art. 16, not the nanomaterial.
- b) The responsible person is responsible for the notification according to art. 16 for each of the product he places on the market.
- c) The responsible person may delegate another legal or natural person to insert the information on the nanomaterial in his art. 16 notification of a product containing a nanomaterial. The mechanism to do that is explained in the CPNP Art. 16 User Manual, which is available in all EU languages on http://ec.europa.eu/consumers/sectors/cosmetics/cpnp/index_en.htm.

Suppliers may claim that they have already notified the nanomaterial they sold to you. They may have already acted as “delegate” for the product of another responsible person, but the fact that the information was notified for another product of another responsible person does not relieve you

from notifying your own product(s) according to art 16. If you wish, you may delegate the supplier to fill out the information on the nanomaterial contained in the notification of your product.

3) Colorants, preservatives and UV-filters

Colorants, preservatives and UV-filters to be used in cosmetic products must be authorized through their addition in specific positive lists (Annexes IV, V and VI to Regulation (EC) No 1223/2009), and, when they are allowed as nanomaterials, this must be explicitly mentioned, as required by the Preamble to Annexes II to VI. This means that the substance must be listed in the Annexes “including as a nanomaterial” or with the INCI name followed by “(nano)”, otherwise it cannot legally be used in its nano form.

To date, no nanomaterials have been included in the positive lists, but positive opinions of the Scientific Committee on Consumers Safety (SCCS) have been adopted on titanium dioxide (nano), zinc oxide (nano) and carbon black (nano). These substances should be listed in Annexes IV or VI on the basis of the specifications of the materials assessed by the SCCS.

Products containing nano colorants, preservatives and UV-filters must not be notified according to art. 16 of the Cosmetics Regulation. If those nanomaterials are not covered by an authorization because they have different specifications, they cannot legally be used in cosmetic product placed on the EU market.

Those wishing to request the authorization of a nano colorant, preservative or UV-filter should send a full submission in accordance with the SCCS Notes of Guidance (http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_006.pdf) and Guidance on the Safety Assessment of Nanomaterials in Cosmetics (http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_005.pdf) to:

Unit B2 – Health Technology and Cosmetics
Directorate General for Health and Consumers
European Commission
1049 Brussels
Belgium

The Commission will request the SCCS to carry out a full risk assessment and take appropriate measures on the basis of the SCCS opinion.

4) Titanium Dioxide

Titanium Dioxide was authorized as a UV-filter under the Cosmetics Directive 76/768/EEC. As the SCCS opinion on which the authorization was based covered the nano form of that substance, the authorization was considered to cover the nanomaterial, though this was not explicitly indicated in the law.

The Cosmetics Regulation establishes that substances listed in Annexes III to VI do not cover nanomaterials, except where specifically mentioned. As a result, starting from 11 July 2013, titanium dioxide (nano) is no longer legally authorized as a UV-filter in cosmetics.

The SCCS adopted an opinion (SCCS/1516/13) which indicates that titanium dioxide (nano), with the physico-chemical specifications described in the opinion, and used according to the conditions indicated by the SCCS, is safe. The Commission is currently preparing measures to align the Cosmetics Regulation to the SCCS opinion.

To date, the Commission has received no request to authorize titanium dioxide (nano) as a colorant or as a preservative.

Any product containing titanium dioxide (nano) for any other function than colorant, preservative or UV-filter, must be notified to the Commission according to art. 16 of the Cosmetics Regulation, in addition to the notification according to art. 13.

5) Zinc Oxide

Under art. 8a of the Cosmetics Directive 76/768/EEC, Germany had decided to authorize the use within its territory of zinc oxide as a UV-filter, including the nano form. This authorization came to an end when, on 11 July 2013, the Cosmetics Regulation became fully applicable and replaced the Cosmetics Directive. Therefore, zinc oxide, including nano, is no longer authorized as a UV-filter in Germany, and never was authorized outside of Germany.

The SCCS adopted an opinion (SCCS/1489/12), followed by a clarification (ADDENDUM to the OPINION SCCS/1489/12 on Zinc oxide (nano form)), which indicates that zinc oxide (nano), with the physico-chemical specifications described in the opinion, and used according to the conditions indicated by the SCCS, is safe. The Commission is currently preparing measures to align the Cosmetics Regulation to the SCCS opinion.

To date, the Commission has received no request to authorize zinc oxide (nano) as a colorant or as a preservative.

Any product containing zinc oxide (nano) for any other function than colorant, preservative or UV-filter, must be notified to the Commission according to art. 16 of the Cosmetics Regulation, in addition to the notification according to art. 13.

6) Carbon Black

Carbon black (CI 77266) is currently allowed as a colorant. That authorization, however, does not cover its nano forms. This means that currently carbon black (nano) is not authorized.

The SCCS adopted an opinion (SCCS/1515/13), which indicates that carbon black (nano) with the physico-chemical specifications described in the opinion, and used according to the conditions indicated by the SCCS, is safe. The Commission is currently preparing measures to align the Cosmetics Regulation to the SCCS opinion.

7) Methylene bis-benzotriazolyl tetramethylbutylphenol (MBBT)

Methylene bis-benzotriazolyl tetramethylbutylphenol is currently allowed as a UV-filter. That authorization, however, does not cover its nano forms. This means that currently Methylene bis-benzotriazolyl tetramethylbutylphenol (nano) is not authorized.

The SCCS adopted an opinion (SCCS/1443/11), which indicates that “since no appropriate data on genotoxicity of nano form of MBBT were provided, no conclusion on the safety of this substance can be drawn”. Therefore, the Commission does not intend to authorize this nanomaterial. This position may change if genotoxicity data are provided and the SCCS is able to give a positive assessment of the material.