

The SCCS Guidance on the safety assessment of nanomaterials in cosmetics



The Scientific Committee on Consumer Safety (SCCS) provides guidance to public authorities and the cosmetic industry to ensure compliance with the current cosmetic

EU legislation (EC No 1223/2009), in regard to safety assessment of nanomaterials intended for use as cosmetic ingredients.

Nanomaterials as cosmetic ingredients may have various functions, such as UV filters in sunscreens, preservatives or pigments, etc. The use of nanomaterials in cosmetics may bring certain benefits to the consumer. However, the same nano-scale features of a nanomaterial that give a cosmetic product useful properties, might also pose a risk to the consumer. This requires a thorough safety evaluation of any nanomaterial that is intended for use as a cosmetic ingredient, in the same way as other ingredients, but with special considerations to nano-features (e.g. extremely small size).

In Europe, safety assessment of regulated categories of chemical ingredients is mandatory before they can be used in a cosmetic product, including those ingredients that are in the form of nanomaterial. It is also necessary for a manufacturer to notify the use of other nanomaterial ingredients to the European Commission prior to placing the cosmetic product on the market, and provide specific information as laid down in article 16 of the Cosmetic Regulation. If the European Commission has concerns regarding the safety of a nanomaterial, it is referred to the SCCS for a scientific opinion. In addition to this oversight on

risk assessment, the SCCS also provides guidance on the requirements for safety evaluation of nanomaterials intended for use as cosmetic ingredients.

→ WHY THIS GUIDANCE?

In 2012, the SCCS published a Guidance on safety assessment of nanomaterials in cosmetics (SCCS/1484/12). A number of new developments have since taken place in the area of nanomaterial safety research. For example, a complete animal testing ban has come in force under the Cosmetics Regulation since March 2013, which poses a number of challenges in obtaining data from alternative methods for safety assessment of cosmetic ingredients in general, but more so for nanomaterials. The SCCS has also assessed several safety dossiers on nanomaterials since the Guidance of 2012 was published. The SCCS has therefore updated this Guidance with the aim to provide an overview of the key issues and data requirements relating to the safety assessment of NMs in cosmetics. It highlights the need for special considerations in relation to the safety of nanomaterials, in view of the distinct properties at the nanoscale, interactions, and/or effects that may differ from conventional form of the same materials. It also provides information and a list of non-animal methods that could be used for nanomaterials while considering nano-specific aspects.

Checklists have also been prepared along with the guidance to enable both the applicant and the SCCS to quickly assess if the dossiers are complete and to prevent submissions that are incomplete or contain inadequate/irrelevant data. This should streamline the safety evaluation process and save time and resources for both the applicants and the SCCS.

→ USING THIS GUIDANCE

The guidance gives key recommendations for safety assessment of nanomaterials intended for use in cosmetics and covers the main elements of risk assessment of nanomaterials in relation to possible use as cosmetic ingredients, i.e. general safety considerations, material characterisation, exposure assessment, hazard identification and dose-response characterisation, and risk assessment with due consideration of the animal testing ban in place for cosmetics. This guidance on nanomaterials should be used in conjunction with the general guidance for the submission of safety dossiers of cosmetic ingredients “The SCCS notes of Guidance for testing of cosmetics ingredients and their safety evaluation” (SCCS/1602/18).

This factsheet is based on the “SCCS Guidance on the safety assessment of nanomaterials in cosmetics”

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This guidance is available at:
https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_233.pdf