



The SCCS Guidance on the safety assessment of nanomaterials in cosmetics gets second update

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WHAT IS THE PURPOSE OF THIS NANO GUIDANCE?

The Nano Guidance aims to help cosmetic manufacturers, importers or their appointed third parties prepare the safety dossiers that the Commission requires for certain categories of the ingredients used in cosmetic products sold on the EU market, and to assist risk assessors and risk managers ensure full compliance with the [EU Cosmetics Regulation](#).

The EU Cosmetics Regulation requires the pre-market notification, safety evaluation, and labelling of all cosmetics containing nanomaterial ingredients. It also created a central notification system for all cosmetic products placed on the EU market, called the Cosmetic Products Notification Portal [CPNP](#).

Manufacturers, importers or their appointed third parties need to register their cosmetics via this portal. If a product contains nanomaterials, the notifier needs to declare the nanomaterial and specify the likely route through which a person may be exposed to it.

WHAT DOES THE NANO GUIDANCE COVER?

All the essential elements that would be required in a nanomaterial's safety dossier are covered in this SCCS Nano Guidance ([SCCS/1655/23](#)), i.e. physicochemical characterisation, exposure assessment, toxicological evaluation and risk assessment.

This Guidance is specifically for nanomaterials and must be used in conjunction with the SCCS general Notes of Guidance ([SCCS/1647/22](#)), which covers the testing and safety evaluation for all cosmetic ingredients, and which has also recently been updated.

WHY DO NANOMATERIALS REQUIRE SPECIAL ATTENTION?

As defined in the EU Cosmetic Regulation, nanomaterials are any material whose particle size is less than 100nm and more than 1 nm. Many materials that are completely safe can become potentially problematic when in nano form, because when the particles are reduced in size, they can begin to function differently both chemically and physically, and potentially also biologically. The size and shape, as well as solubility, of these nano particles may affect their function. There is the potential risk that insoluble and persistent nanoparticles might penetrate the outer layers of the skin (or oral/lung membranes depending on the product type) to reach unintended sites in the body and interact with biological entities close to the molecular level.

WHY ARE NANOMATERIALS USED IN COSMETICS IF THEY MAY POSE RISKS?

Not all nanomaterials are harmful per se, and nano forms of cosmetic ingredients can provide certain enhanced or novel functions. Leading cosmetic companies around the world are using nanotechnology to produce state-of-the-art products that are more effective, more agreeable to use, more attractive and longer lasting. Nanomaterials are widely used in moisturisers, hair care products, make up and sunscreens. In cosmetics, they help deliver active ingredients deeper into the skin, and they improve the appearance and feel of the products. In sun protection products, they provide more effective UV protection, whilst still keeping the products transparent. The first cosmetic products to use nanotechnology were placed on the EU market in 1986, and their use has since increased.

WHAT IS NEW ABOUT THIS REVISION?

Many new sections have been introduced, including those on solubility and dissolution rates, solubility in non-aqueous media, evidence for the absence of nanoparticles, importance of particle dispersion, aspect ratio, uptake into cells, reproductive toxicity, and potential endocrine disruption. The section on the use of read-across and grouping approaches for nanomaterials has also been updated.

The new European Commission Recommendation for a definition of nanomaterials published in 2022 has also been introduced. According to this Recommendation: 'nanomaterial' means a natural, incidental or manufactured material consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50 % or more of these particles in the number-based size distribution fulfil at least one of the conditions listed under [2022/C229/01](#).

In addition to these updates, this revision looks at key aspects that should trigger safety concerns over a nanomaterial, based on a SCCS Scientific Advice published in 2020 ([SCCS/1618/20](#)) and includes a text explaining when historical/existing animal data can be used.

Due to the evolving nature of nanomaterials safety research, the Guidance may be further revised in the future to take account of any new scientific knowledge.

IS IT EASY TO TELL IF COSMETIC PRODUCTS CONTAIN NANOMATERIALS?

Yes, consumers can check if their cosmetic products contain nanomaterials by reading the product labels. In the EU, nanomaterials in cosmetic products must be labelled with the word 'nano' in brackets after the name of the ingredient. See the helpful interactive [infograph](#) by the European Observatory for Nanomaterials for more information.



This factsheet is based on the “SCCS - Guidance on the safety assessment of nanomaterials in cosmetics - 2nd revision” – June 2023

This Nano Guidance is available at:

https://health.ec.europa.eu/publications/sccs-guidance-safety-assessment-nanomaterials-cosmetics-2nd-revision_en

A checklist for submitting a safety dossier of a nanomaterial used in cosmetics is available on the SCCS website:

https://health.ec.europa.eu/publications/checklists-applicants-submitting-dossierscosmetic-ingredients-be-evaluated-sccs_en