

# NANOS-INGREDIENTS

2024

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THE INGREDIENTS COLLECTION

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# Introduction

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Who says “nano”, “nanoparticle” or “nanomaterial” also says immediately suspicion of the general public, blacklisting by consumer protection associations and by cosmetic decoding applications, bad press and in a word: another category of controversial ingredients...

It is impossible to “hide” them since the regulations require that they be clearly identified in the list of ingredients that must appear on product labels, by the word [nano] after the INCI name of the substance concerned.

This already requires the ability to accurately identify and characterize a raw material to determine whether or not it falls within the definition of a nanomaterial. And it is still a big challenge for the industry since, on the one hand, there are several definitions (even if the one given by Regulation 1223/2009 prevails for cosmetic products), and on the other hand, it is still often difficult to choose the right analytical method depending on the raw material (all those available today sometimes lead to erroneous or contradictory results)...

Yes, nanomaterials are still “tricky” to deal with on a daily basis in the cosmetics sector.

Aware of these issues, the European Commission has set up a declaration system for nanomaterials present in cosmetic products, so that those on the market can be identified. This famous catalogue, which Regulation 1223/2009 gives it the task of establishing and regularly updating, is based on the declarations made by companies on the European notification portal and has highlighted the difficulties of stakeholders to determine whether an ingredient is nano or not. For example, after some discussions, it was concluded that no, water is not nano .

A first version, finally published in 2017 (when it was planned to be published in 2014), included 43 substances. In the second, in November 2019, only 27 substances were left, divided into three categories: “Colorants”, “UV Filters”, “Other functions”.

This catalogue, most likely still incomplete and/or containing inaccuracies, nevertheless constitutes today a reference list, allowing manufacturers to pay particular attention to the substances it contains.

But it is also the basis for uncertainties about the regulatory fate of the ingredients listed there. Indeed, the Cosmetics Regulation stipulates that if the European Commission has concerns about the safety of a nanomaterial, it must request, “without delay”, the opinion of the SCCS (Scientific Committee on Consumer Safety). And then take this opinion into account when deciding on possible restrictions or even bans.

A favourable SCCS opinion may also allow colorants, UV filters or preservatives to be added to the positive lists of the Annexes of the Cosmetics Regulation, for safe ( sanitary and regulatory ) use in cosmetic products. Because if they are not included, they are considered prohibited... and the competent authorities do not fail to check their presence in products on the market.

Since 2013 (and the entry into force of the Cosmetic Regulations and its new provisions on nanomaterials), requests for Opinions to the SCCS have been made one after the other.

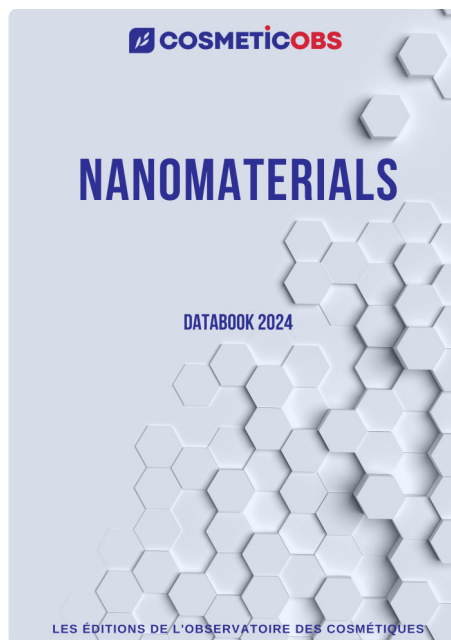
In a first step, this has allowed to define conditions for the safe use of UV filters in nano form (Titanium dioxide, Zinc oxide...) as well as a preservative (Methylene bis-benzotriazolyl tetramethylbutylphenol - MBBT) . But things got more complicated afterwards, and more and more frequently, the Scientific Committee can only conclude... that it cannot conclude, for lack of sufficient or adequate data. This

makes it impossible to decide on the regulatory status of substances, and leaves them, often for an indefinite period of time, in a most uncomfortable legal limbo... until the European Commission drew the consequences and eventually banned them.

As a result, today, as for several years now, and most certainly for many years to come, manufacturers of raw materials or cosmetic products are left with questions with often random answers: is my ingredient nano or not? Can I use it in my formulas? And if so, for how much longer? Should I label it nano or not?

It is to help them see more clearly and make the right decisions that CosmeticOBS has gathered in this ebook all the detailed sheets of ingredients listed in version 2 of the European catalogue of nanomaterials in cosmetics. With for each one, all the currently applicable regulations, the specifications to be respected for their use, their progress in the regulatory process, the blocking points that delay their evaluation...

To be read in addition to the **Databook Nanomaterials**, for a complete overview of the definitions, characterization, safety assessment and regulation, scientific studies, alerts and debates... that form the changing context in which nanomaterials are evolving today.



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# The Catalogue of Nanomaterials

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Entitled “Catalogue of nanomaterials in cosmetic products placed on the market” in its first version of June 2017, it became “Catalogue of nanomaterials in cosmetic products placed on the market, as notified to the European Commission by the Responsible Persons” for its second version of November 2019.

A way for the Commission to take a slight distance from the relevance of its content.

Let’s look back at the two texts, the first one as a reminder, and the second one which is in force today.



# NANOMATERIALS: THE CATALOGUE

It is an understatement to say it had been long-awaited: the Commission was to publish it in January 2014. Tricky to set up, reported to late 2015, and then early 2016, in its first version, the catalogue compiling the nanomaterials used in cosmetics comprised a considerable number of ill-characterized substances, based on the industry's data: even water had been added to the list. At last, a reviewed, corrected... and purged, but also more credible version was published on June 15, 2017. It only counts 43 substances now.

The actual list of nanomaterials is preceded with a preamble to provide the context of the catalogue.

## Preamble

According to Article 16(10)(a) of Regulation (EC) No 1223/2009 on cosmetic products, the Commission shall make available a catalogue of all nanomaterials used in cosmetics placed on the market, including those used as colorants, UV-filters and preservatives in a separate section, indicating the categories of cosmetic products and the reasonably foreseeable exposure conditions. This catalogue shall be regularly updated and be made publicly available.

The catalogue lists the nanomaterials used in cosmetics placed on the market. It is based on information notified electronically by responsible persons to the European Commission through the Cosmetic Products Notification Portal (CPNP). The European Commission takes no responsibility for the content and the scientific qualification of the notifications made in the CPNP.

Based on the current knowledge on nanomaterials, there may be some uncertainties regarding the status as nanomaterials of some notified substances. The catalogue remains a work in progress subject to modifications and will be updated regularly.

The functions of the nanomaterials listed in this catalogue (12 as colorants, 6 as UV-filters and 25 as other functions) are based on the names of substances notified and, generally, on the corresponding functions that are displayed in the CosIng database<sup>6</sup> and where relevant on other information at the disposal of the Commission. Some substances may have more than one function.

This catalogue has an informative value only and is not in any case a list of authorised nanomaterials.

## The list

### Colorants

#### Acid Yellow 23 / CI 19140

- Category of cosmetics: body or face paint, including carnival make-up; eye shadows; lip sticks; nail varnish and nail make-up
- Exposure: dermal

#### Barium sulfate / CI 77120

- Category of cosmetics: nail care products; nail hardeners; nail varnish and nail make-up
- Exposure: dermal

#### Carbon black / CI 77266

- Category of cosmetics: body or face paint, including carnival make-up; bath/shower products; eye contour products; eye-liners; eye pencils; eye shadows; face masks; foundations; mascaras; nail

sculpting products; nail varnish and nail make-up; non-oxidative hair colour products; other eye make-up products; other face make-up products; other hair colouring products; other lip make-up products; other make-up products; other nail and cuticle products; other nail varnish and remover products; other skin products; oxidative hair colour products; products for temporary hair styling; soap products

- Exposure: dermal, oral, inhalation

#### **CI 77288 (Chromium oxide greens)**

- Category of cosmetics: eye shadows; nail sculpting products; soap products
- Exposure: dermal

#### **CI 77491 (Iron oxide red)**

- Category of cosmetics: bath/shower products; eye-liners; eye shadows; foundations; lip sticks; mascaras ; nail sculpting products; nail varnish and nail make-up ; other face make-up products; other skin cleansing products; soap products
- vExposure: dermal

#### **CI 77499 (Iron oxide black)**

- Category of cosmetics: eye-liners; eye shadows; foundations; lip sticks; mascaras; nail varnish and nail make-up; other eye make-up products; other face make-up products
- Exposure: dermal

#### **CI 77510 (Ferric Ammonium Ferrocyanide)**

- Category of cosmetics: eye-liners; eye shadows; nail varnish and nail make-up; other face make-up products
- Exposure: dermal

#### **CI 77891 (Titanium dioxide)**

- Category of cosmetics: body or face paint, including carnival make-up; bath/shower products; before and after sun products; concealers; eye contour products; eye-liners; eye shadows; face care products other than face masks; face masks; foundations; hand care products; lip care products; lip sticks; make-up remover products; nail care products; nail hardeners; nail sculpting products; nail varnish and nail make-up; other face make-up products; other lip make-up products; other make-up products; other nail care/nail hardeners; other nail varnish and remover products; products for temporary hair styling; shaving products; skin lightening products; soap products; sun protection products
- Exposure: dermal, oral, inhalation

#### **Copper / CI 77400**

- Category of cosmetics: body care products; external intimate hygiene products; face care products other than face masks; mouth wash; soap products; foundations; lip care products; nail sculpting products; other face make-up products; shampoos
- Exposure: dermal

#### **Gold / CI 77480**

- Category of cosmetics: body care products; face care products other than face masks; face masks; foundations; hydro-alcoholic perfumes; other face make-up products; other lip make-up products; other skin cleansing products
- Exposure: dermal, oral

#### **Pigment Red 57 / Pigment Red 57:1 / CI 15850**

- Category of cosmetics: body or face paint, including carnival make-up; eye shadows; lip sticks; nail sculpting products; nail varnish and nail make-up; other eye make-up products; other face make-up