

NANOMATERIALS

MINIBOOK 2021

INTRODUCTION	p. 2
DECLARATION	p. 3
NOTIFICATION	p. 4
Nanos exempt from notification	p. 4
The data to be notified	p. 5
THE SAFETY ASSESSMENT	p. 6
LABELLING	p. 7
THE DEFINITION ISSUE	p. 8
Some notions to understand these definitions	p. 8
CHARACTERIZATION CHALLENGES	p. 10
The SCCS Guidelines	p. 10
The choice of technique	p. 10
The techniques of the control authorities	p. 10
THE EUROPEAN COMMISSION CATALOGUE	p. 12
SOME POSSIBLE DEVELOPMENTS	p. 18
Commission Report - Section 1	p. 18
Commission Report - Section 1	p. 18

Introduction

Since the Cosmetics Regulation 1223/2009 established very specific rules for them, sometimes even before their implementation is concretely possible, nanomaterials are still a source of questioning, regulatory headaches, practical problems, interpretation discrepancies, and even uncertainties about the reality of their nano nature...

Multiple declarations, European notification, safety assessment, labelling, characterization, definition(s)... many of the steps required to properly manage nano cosmetic ingredients are still in clear and unclear areas, making each decision an arduous process with uncertain success.

And yet, these ingredients are very difficult to avoid completely, as they are sometimes unavoidable in certain product categories (UV-filters in sun protection products), and they can also be present in formulas without being really desired (titanium dioxide in toothpaste, powder pigments in makeup)...

However, today, only five of them have been included in the annexes of the Cosmetics Regulation, which ensures their (more) simple and safe use! This Minibook provides an overview of what you need to know about nano-ingredients, the obligations associated with them, the procedures to follow and the best ways to identify them. It provides the essential basics to avoid the main pitfalls they pose for all cosmetics manufacturers.

It also details the next developments that could affect them, through the recent report of the European Commission on their use and the ways to adapt the Cosmetics Regulation.

Declaration

It is mandatory, as per the Article 13 of the Regulation, by the notification procedure that shall be implemented before placing a new cosmetic product on the market.

In addition to information required for the notification of the product, add to this the substances present as nanomaterials.

Then, two kinds of information are required:

- The chemical identification of the substance(s)
- The reasonably foreseeable exposure conditions (topically, orally, inhaled, for instance)

The obligation comes for any cosmetic product of any category that contains nanomaterials; it helps in the establishing of an exhaustive data basis for the sanitary authorities.

THE REACH REGISTRATION

*Even if it was with a certain delay, the REACH Regulation has integrated the issues of nanomaterials. Its annexes have been adapted and, **as from 1 January 2020**, reporting requirements (including shape, specific surface area or number size distribution with an indication of the fraction of particles with sizes between 1 and 100 nm), where substances will be produced above one tonne, are foreseen. ECHA will also have the possibility to request additional information for nano substances produced above 10 tonnes.*

R-NANO DECLARATION

At the French level, since January 2013, all nanoparticulate substances produced, integrated into a product, imported or distributed at more than 100 g per year must be declared in the R-Nano register maintained by ANSES. The declaration must include several of their characteristics, such as shape, size, size distribution, functionalized surface, speciation and agglomeration state. And it is requested to specify the analytical methods used.

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