



# PROGRESS



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### Nanotechnology and Cosmetics - 2

As we highlighted in the previous issue of PROGRESS, the constantly increasing use of nanomaterials in manufactured products, particularly in cosmetics, can be explained by their special properties and the new ways these products are used. The lack of information available concerning the potential risks that could result from prolonged use and the constant contradictions in the scientific data available have prompted us to urge caution and promote a thorough evaluation, on a case by case basis, as to whether they are safe to use.

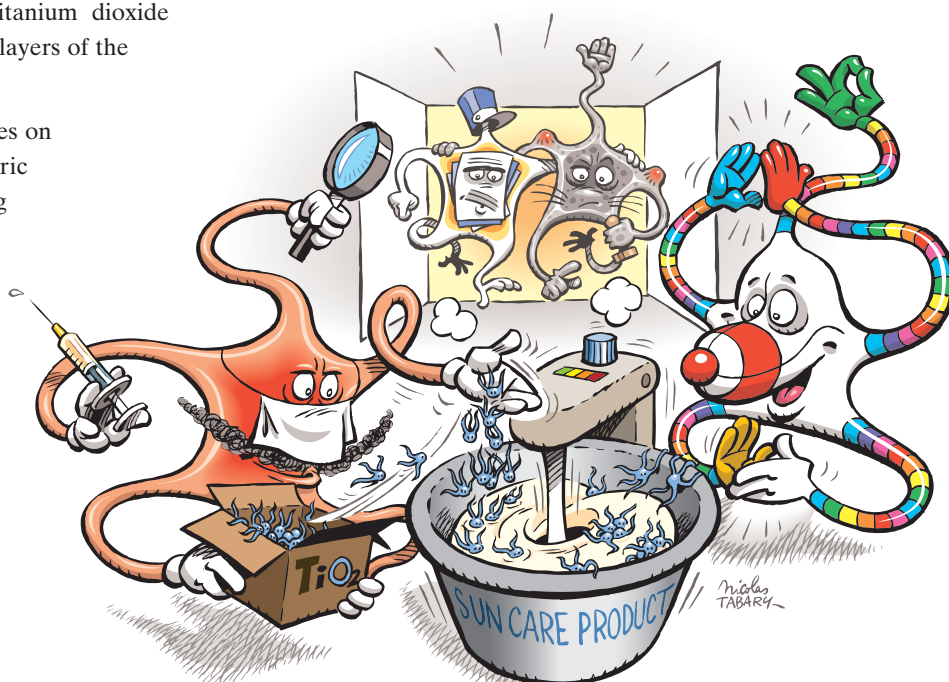
#### Does the use of nanometric titanium dioxide present a particular risk?

▶ Titanium dioxide ( $\text{TiO}_2$ ) is one of the best-known and widely-used nanomaterials - more than two million tons are produced globally each year. Used as a pigment and an opacifier, this nanomaterial is used in paint, cosmetics, medication, food colourings and many other commonly used products.

In cosmetics, this mineral filter, used for around twenty years in numerous sun protection products in nanoparticle form, is known for its ability to reflect, disperse and absorb ultra-violet (UV) rays and to protect against the harmful effects of prolonged exposure to the sun. In its nanometric form, titanium dioxide has the dual advantage of being a more efficient UV filter, whilst also being less white and more transparent than the micrometric form. When used with other filters, especially organic ones, titanium dioxide can protect equally against very broad spectrums of both UVA and UVB, an essential factor in the prevention of skin cancer.

In terms of safety, a thorough review of the scientific literature produced since 2006 by the Australian health authorities, confirmed in 2009, concluded that titanium dioxide nanoparticles do not penetrate deeper layers of the stratum corneum than the upper ones.

At the same time, around twenty studies on dermal penetration of nanometric titanium dioxide, carried out using different methods, in vivo as well as in vitro, after single and repeated application, to healthy and damaged skin, using many different galenic forms, with different types of titanium dioxide (coated or not, with different shapes and sizes of crystals), and carried out by workers as different as manufacturers, academic research teams and government agencies, have all shown that none of the forms tested penetrated the living layers of the skin.



However, a recent recommendation from the SCCP concluded that in the case of nanomaterials, the conventional calculation of the margin of safety is probably not appropriate. Therefore additional investigations were requested on different types of damaged skin in order to understand the impact of the mechanical properties on the percutaneous penetration. For its part, the IARC (International Agency for Research on Cancer) has put forward the hypothesis that titanium dioxide could be carcinogenic if it comes into contact with lung cells. As a consequence the nanometric titanium dioxide has been classified 2B since 2006: “possibly carcinogenic in humans by inhalation”.

Therefore the difficulty in drawing any definitive safety recommendations one way or the other based on the available data referring to genotoxicity, systemic toxicity and carcinogenicity, leads us to advise against the application of cosmetic preparations containing nano titanium dioxide when the skin barrier cannot totally assume its protective role allowing increased potential risks to human health. On the other hand, using nanometric titanium dioxide in cosmetic products is not particularly risky if it is used in accordance with the last updated legal restrictions and concerns products designed to be applied to healthy skin with no risk of ingestion or inhalation.

It should also be borne in mind as far as safety is concerned that often titanium dioxide does not remain in its nanometric state once it is formulated, but rapidly joins together in aggregates and agglomerates of 1 to 3 microns with no toxicological concern.

### Where are we in terms of regulatory supervision?

Under current law, there is no specific text suitable for manufactured particles themselves. However in its vote of March 2009 the European Parliament allowed the cosmetic sector to be the first one to create a framework specific to nanomaterials. It requires that any manufacturer or distributor wishing to sell a product containing nanomaterials informs the European Commission 6 months before it goes on sale. In the event of any uncertainty, the Commission may request the opinion of the Scientific Committee for Consumer Safety.

Moreover, the company will have to indicate to the consumers the presence of these nanomaterials among the other ingredients of the cosmetic product as already compulsory in the cosmetics’ labelling regulation.

However, these measures are considered insufficient to truly survey the number and volume of nanomaterials available on the market. Indeed, as the BEUC (the European Consumers’ Organisation) revealed, if certain nanomaterials used as colourings, conservatives or UV filters are subjected to safety evaluations before being authorised for market release, the adopted text would leave out of any control other possible uses for hundreds of nanomaterials.

In the light of this risk, it seems necessary to subject nanoparticles to preliminary evaluations based on the principle of caution. In this regard, the Strategic Analysis Center recommends to make compulsory nanomaterials’ identification from the moment they are created, to measure and guarantee their traceability, to control their impact on the environment as well as in the own workers concerned, from a worldwide observatory. But these are still just recommendations. In the absence of established standards for exposure to nanoparticles, everyone is continuing to produce nanomaterials and to sell products which contain them with no obligation to inform.

There a lot remains to be done before creating a true regulatory framework for nanomaterials and more generally for nanotechnologies, at risk of not being able to follow a too rapid expansion of this new sector.

**The fact that the legislator is currently restricting the definition of “nanomaterial” as “a natural material, obtained by accident or manufactured, containing free particles, aggregates or agglomerates, of which at least 50% of the particles, by number or by size, show one or more external dimensions of between 1 nm and 100 nm” should not lead us to exclude considering larger nanometric particles which can also pass natural biological barriers.**

**In the absence of sufficiently conclusive elements allowing to analyse properly the balance in terms of benefit and risk for these new ingredients, the enthusiasm of manufacturers is tempered by a growing mistrust from the consumers’ side, widely orchestrated by the media, themselves often insufficiently and badly informed.**

**Thanks to this confused situation, but considering also the current silence from the cosmetosurvey, the presumption of innocence still prevails, therefore fortunately allowing us to improve the knowledge and to reinforce the regulatory supervision of the nanometric sector which remains today mostly unknown.**



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**Next topic: Natural substances and products**



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