



# Nano-Titanium Dioxide in Sunscreens

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# Cosmetic Use of Nanomaterials



In 2008, a survey of nanomaterials sold in EU cosmetic products amongst member companies of Colipa and national trade associations identified:

- Typical uses - inorganic sunscreens, cleaning and colorants
- Most frequently used - titanium dioxide, zinc oxide, silica
- Less frequently used - carbon black, iron oxide, aluminium oxide
- No use of fullerenes, gold or platinum has been reported by Colipa membership

Nano-TiO<sub>2</sub> (formely named ultrafine, micro-millimeter) has been used in cosmetic sunscreens for more than 25 years



# Why use Titanium Dioxide in its Nano-form?



- Sunscreens in general have the benefit of protecting consumers from UV light, which causes sunburns and skin cancer after prolonged exposure (EU and US >1.000.000 new cases of skin cancer per year)
- Titanium dioxide in its nano-form has improved UV attenuation properties, especially with regard to light scattering
- In combination with organic UV filters nano-TiO<sub>2</sub> is necessary for manufacturing products with a high Sun Protection Factor (SPF)
- Formulations with high concentrations of UV filters can become very sticky and difficult to apply
- The properties of nano-TiO<sub>2</sub> ensure that formulations are “lighter” and can be spread more evenly on the skin, which ensures better UV protection

# Regulation of Nanomaterials in Cosmetics



## Cosmetics Directive 76/768

- As for any other cosmetic ingredient, cosmetic manufacturers have to be able to demonstrate the safety of nanomaterials used in cosmetic products
- The most commonly used nanomaterials, i.e. zinc oxide and titanium dioxide, in cosmetics are probably those with the largest existing safety database
- Currently no specific regulatory requirements for the use of nanomaterials in cosmetic products

# Regulation of nanomaterials in cosmetics

## Recast of the Cosmetics Directive



### Notification

- Use of nanomaterials and relevant safety information need to be notified to the European Commission 6 months prior to marketing
- In case of questions, the European Commission can request a review by the SCCS
- Notification process has to be implemented in a way that ensures efficiency and gives all parties in this process the possibility to complete their tasks within the required timeframe

### Nanolabelling

- Identification of nanomaterials in the ingredient list
  - = consumer information
  - ≠ safety information or warning



# Safety Assurance

## Practical considerations



- Actual toxicological effects (endpoints) observed are still those that are characterised in the standard set of toxicology tests
- OECD Guidelines for testing of chemicals have been designed to be suitable for testing solids, liquids, powders, gases, aerosols – also suitable for testing hazard of nanoparticles, provided minor adjustments are made (physico-chemical characterisation, dosimetry aspects).
- Dermal penetration behaviour of materials used in cosmetics corresponds to their non-nano form, including use on damaged skin

# Safety Assurance: (Absence of) Dermal penetration is a key factor



ALL the evidence produced so far suggests that TiO<sub>2</sub> NPs do not penetrate into living skin, i.e. >20 studies conducted:

- *in vitro* or *in vivo*
- using mouse, pig or human skin
- after single or repeated administration
- using intact or damaged skin
- by various stakeholders including
  - regulatory authorities (eg FDA)
  - industry research groups
  - academic research groups/projects
- (...)

# Safety Assurance: (Absence of) Dermal penetration is a key factor



- (...)
- Using various formulation types, including
  - commercial or typical suncreams
  - gel formulations
  - simple o/w or w/o emulsions
  - micellar formulations
  - aqueous dispersions
- With TiO<sub>2</sub> concentrations ranging from 3 to 40%
- Using various types of TiO<sub>2</sub>
  - rutile/anatase
  - coated/uncoated
  - various crystal shapes
  - reported primary particle size ranging from 1 to 100 nm

Evidence summarized in Nohynek *et al* (2007), Nohynek *et al* (2008), US EPA (2009, draft), Australian TGA (2009)



# Safety Assurance – Regulatory dossier



- An industry consortium prepared a safety dossier for evaluation by the EU Scientific Committee (SCCP/SCCS) for listing of TiO<sub>2</sub> in nano and non-nano forms on the positive list of UV filters
- Data on both crystalline forms (anatase/rutile) over a range of sizes and formulations have been produced.
- Data collected in this dossier have been generated by many different groups – academia, governmental agencies and industry
- All studies re-confirm the safety of nano-TiO<sub>2</sub> in sunscreen products, even after intravenous administration

# Future Direction – Transparency & Consistency



Need to bring transparency and consistency internally (between EU agencies) and internationally to the application of the new regulation to assure consumer and regulator confidence

ICCR & ISO provide fora to achieve consistency in international regulations

Prerequisite is consistency in terminology and definitions:

- Will enable proportionate, clear and enforceable legislation
- Need to be precise, take account of sector specific needs & be internationally harmonised



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