The increasing use of nanomaterials in a wide range of consumer products has prompted a re-evaluation of the safety of a number of substances, including titanium dioxide (TiO₂). Titanium dioxide, in the form of nanoparticles used to render creams and lotions transparent, is currently approved as a UV-filter in sunscreens. Are sunscreens with titanium dioxide nanoparticles safe? Do these nanoparticles behave differently than other particles of titanium dioxide? How are the risks of nanoparticles evaluated? This fact sheet tells you all about it.

> WHAT ARE ‘NANOMATERIALS’? WHAT ARE TITANIUM DIOXIDE NANOPARTICLES?

Titanium dioxide is used as a UV filter in sunscreen products to protect the skin from harmful UV rays when exposed to sunlight. Particles in nano form (also named ‘nanomaterials’, ‘nanoparticles’ or ‘micronized materials’) refer to very small sized materials and components that have a particle size range of 1 to 100 nanometre (one nanometre is one millionth of a millimetre, e.g. human hair is about 80 000 nanometres wide). Very small particles may, however, also be harmful (see further).

> IS THE USE OF TITANIUM DIOXIDE NANOPARTICLES IN SUNSCREENS SAFE?

On the basis of the available scientific evidence, the Scientific Committee on Consumer Safety (SCCS) confirmed that the evaluated titanium dioxide nanoparticles, used at a concentration up to 25% as a UV filter in sunscreens, can be considered safe for humans after application on a healthy, intact or sunburnt skin. Labelling of cosmetic products may not show this concentration on the package, but manufacturers have to respect this limit according to European legislation (annex III of the EU regulation on cosmetic products; regulation EC 1223/2009). Inspectors from public authorities can perform a check at any time. The safety assessment is based on the current scientific knowledge, which shows that neither titanium dioxide in nano form nor in non-nano form penetrates through the skin. This conclusion will need to be revised if new scientific evidence would arise, showing that nanoparticles behave differently.

> SAFE, BUT . . .

Breathing in nanoparticles can lead to lung toxicity and inflammation. Some tests suggest that this could also lead to cancer. In view of this, the SCCS advises not using titanium dioxide nanoparticles in applications that would lead to any significant inhalation exposure such as powders or sprayable products. There is also a very low risk for skin or eye irritation (painful reaction such as eczema with dry itchy skin) and skin sensitisation (response of the immune system resulting in an allergic reaction) from exposure to these nanomaterials. No relevant information on reproductive toxicity is yet available, but some scientific evidence suggests that titanium dioxide nanomaterials, if they penetrate the body, may cause damage to genetic material of cells (e.g. damage to cells in some organs may cause cancer and damage to spermatozoa cells may lead to infertility). However, such effects are unlikely to occur with dermal application. Titanium dioxide nanoparticles can also act, in certain cases, as a photocatalyst. This means that they can react with UV light (e.g. sun) to accelerate a photoreaction causing oxidation of some biological molecules and generating free radicals. The latter could enhance the toxic effects mentioned above. Not all titanium dioxide particles used in cosmetic products have this property. When appropriately coated, the nanoparticles do not remain photocatalysts but still retain their function as a UV filter. Nevertheless, sunscreen manufacturers are recommended to avoid the use of titanium dioxide nanoparticles that have a substantial photocatalytic activity, or to treat the surface of such nanoparticles properly with a stable and safe coating material.

> NEW CHALLENGES IN RISK ASSESSMENT OF NANOMATERIALS

This opinion refers to the titanium dioxide materials revised by the SCCS and to materials with similar characteristics of size, purity, coating and solubility. As the methodologies for evaluating the properties of nanomaterials in general are still in development, additional data may be required for a full assessment of the health impact of titanium dioxide in nano form. The development of new assessment methods is an ongoing process.

The SCCS published detailed guidance documents on the evaluation of risks of nanomaterials in cosmetics (SCCS/1484/12 and SCCS/1524/13).

For completeness, it should be noted that the impact of titanium dioxide nanoparticles released in the environment was not considered in this scientific opinion.

This fact sheet is based on the opinion of the independent Scientific Committee on Consumer Safety (SCCS): ‘Opinion on titanium dioxide (nano form) COLIPA n° S75’ (April 2014).

This opinion is available at: http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm