

ZinClear US Non-Nano Statement

In the US there is no current legal definition of what constitutes a nanoparticle as stated by the FDA. In June 2014, FDA issued a guidance for industry titled "Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology". As described in that guidance, when considering whether an FDA-regulated product involves the application of nanotechnology, the FDA will ask: (1) whether a material or end product is engineered to have at least one external dimension, or an internal or surface structure, in the nanoscale (approximately 1 nm to 100 nm); and (2) whether a material or end product is engineered to exhibit properties or phenomena, including physical or chemical properties or biological effects, that are attributable to its dimension(s), even if the dimensions fall outside of the nanoscale range, up to (1,000 nm).

There are however, other government bodies outside of the US that make such statements.

The French decree n°2010-232 issued on 17.02.2012 defined a nanomaterial in article 3 of Regulation (EC) n°1907/2006 (REACH) as "a substance intentionally manufactured at nanoscale, containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range of 1 nm and 100 nm"

The Cosmetic Product Group Standard 2017 – HSR002552 of New Zealand Government Environmental Protection Authority defines nanomaterial as "an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm".

In a literature review on the safety of titanium dioxide and zinc oxide nanoparticles in sunscreens published by the **Therapeutic Goods Administration** of Australia in August 2016, nanoparticles are defined as "materials within the nanosize range of 1 to 100 nm".

According to these definitions, our range of ZinClear Products are considered to be **non-nano**.

Additionally, no raw materials created by nanotechnology are used in the manufacturing process of our ZinClear range of products.



Geoff Acton, B. Com. CA

Managing Director

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ZinClear European Non-Nano Statement

French decree n°2010-232 issued on 17.02.2012

In regard to the French nanomaterial decree n°2012-232, a nanomaterial is defined in article 3 of Regulation (EC) n°1907/2006 (REACH) as a substance intentionally manufactured at nanoscale, containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm and 100 nm.

Our ZinClear product range is **non-nano** according to the above definition.

Cosmetic regulation EC 1223/2009

In regard to the Cosmetic Regulation EC 1223/2009, a nanomaterial is defined as *an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.*

Our ZinClear product range is **non-nano** according to the above definitions.

Additionally, no raw materials created by nanotechnology are used in the manufacturing process of our ZinClear range of products.



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ZinClear Australian & New Zealand Non-Nano Statement

Australia

The **Australian Government Department of Health and Ageing – NICNAS 2010**, defines a nanomaterial as: “Industrial materials intentionally produced, manufactured or engineered to have unique properties or specific composition at the nanoscale, that is a size range typically between 1 nm to 100 nm, and is either a nano-object (i.e. that is confined in one, two, or three dimensions at the nanoscale) or is nanostructured (i.e. having an internal or surface structure at the nanoscale). Aggregates and agglomerates are included and apply to materials where 10% or more of the particles by number count meet the above definition.”

In a **Literature Review on the safety of titanium dioxide and zinc oxide nanoparticles in sunscreens** published by the **Therapeutic Goods Administration** of Australia in August 2016, nanoparticles are defined as “materials within the nanosize range of 1 to 100 nm.”

New Zealand

As stated in the **Cosmetic Products Group Standard 2017 – HSR002552**, the **New Zealand Government of Environmental Protection Authority** define a nanomaterial as: “an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.”

Our ZinClear product range is **non-nano**, according to the above definitions.

Additionally, no raw materials created by nanotechnology are used in the manufacturing process of our ZinClear range of products.



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