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White Sapphire Alusion

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 one micrometer (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 biospersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm".

According to these definitions, our White Sapphire Alusion® Product is considered to be **non-nano**.

Additionally, no raw materials created by nanotechnology are used in the manufacturing process of our White Sapphire Alusion® product.

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Managing Director

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