

Nanotechnology

MEGGLE USA Products:

- Lactose Monohydrate: GranuLac® 70 US, GranuLac® 140 US, GranuLac® 200 US
- Anhydrous Lactose: DuraLac® H

It is the aim of nanotechnology to achieve new material properties which were previously unknown via building up nanostructures in materials.

The mentioned MEGGLE USA Products are not engineered to have at least one external dimension, or an internal or surface structure, in the nanoscale range (approximately 1 nm to 100 nm).

The products are not engineered to exhibit properties or phenomena, including physical or chemical properties or biological effects, that are attributable to its dimension(s), even if these dimensions fall outside the nanoscale range, up to one micrometer (1,000 nm).

The products do not contain any other material as constituents as mentioned in the MEGGLE Specification.

The mentioned MEGGLE USA Products are not manufactured with

- "nanotechnology" according EMEA/CHMP/79769/2006.

The mentioned MEGGLE USA Products do not meet the following definitions:

- "engineered nanomaterial" according to Regulation (EU) 2015/2283 Article 3 No 2 (f),
- "nanomaterial" according to Regulation (EC) No 1223/2009 Article 2 No 1 (k),
- "substance at nanoscale" according to French Decree no. 2012-232,
- "nanomaterial" according to USP-NF General Chapter <1153>.

Remark: The Commission Recommendation 2022/C 229/01 on the definition of nanomaterial merely serves as a template for nano-definitions (to be) implemented in individual regulations and therefore does not entail any direct consequences.