

# INFORMATION

Quality / Regulatory Affairs



EIP-0055

Revision 13

Date of issue: 29.08.2023

1/1

## Nanotechnology

MEGGLE Products:

- Lactose Monohydrate: CapsuLac<sup>®</sup> 60, FlowLac<sup>®</sup> 90, FlowLac<sup>®</sup> 90 MS, FlowLac<sup>®</sup> 100, FlowLac<sup>®</sup> 90 MS, FlowLac<sup>®</sup> 100 SD, GranuLac<sup>®</sup> 70, GranuLac<sup>®</sup> 70 MS, GranuLac<sup>®</sup> 80, GranuLac<sup>®</sup> 140, GranuLac<sup>®</sup> 140 S, GranuLac<sup>®</sup> 200, GranuLac<sup>®</sup> 200 MS, GranuLac<sup>®</sup> 200 S, GranuLac<sup>®</sup> 230, InhaLac<sup>®</sup> 70, InhaLac<sup>®</sup> 120, InhaLac<sup>®</sup> 140, InhaLac<sup>®</sup> 150, InhaLac<sup>®</sup> 160, InhaLac<sup>®</sup> 180, InhaLac<sup>®</sup> 251, InhaLac<sup>®</sup> 300, InhaLac<sup>®</sup> 400, InhaLac<sup>®</sup> 500, Lactose Monohydrate 200 Mesh IP, Lactose Monohydrate Impalpable, Lactose Monohydrate Low Endotoxin, PrismaLac<sup>®</sup> 40, Sachelac<sup>®</sup> 80, SorboLac<sup>®</sup> 400, SpheroLac<sup>®</sup> 100, StarLac<sup>®</sup>, Tablettose<sup>®</sup> 70, Tablettose<sup>®</sup> 80, Tablettose<sup>®</sup> 100, Tablettose<sup>®</sup> 100 MS
- Co-processed Excipients: Cellactose<sup>®</sup> 80, CombiLac<sup>®</sup>, MicroceLac<sup>®</sup> 100, RetaLac<sup>®</sup>, StarLac<sup>®</sup>

The mentioned MEGGLE Products are not manufactured with

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

The mentioned MEGGLE Products does not meet the following definitions:

- "engineered nanomaterial" according Article 3(2) point (f) of Regulation (EU) 2015/2283,
- "nanomaterial" according Article 2(1) point (k) of Regulation (EC) No 1223/2009,
- "substance at nanoscale" according French Decree no. 2012-232.

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

*This MEGGLE Information was electronically released and is valid without signature.*