INFORMATION

Quality / Regulatory Affairs



EIP-1030

Revision 11

Date of issue: 03.05.2024

1/1

Suitability as Ingredient in Food and Food Supplements

MEGGLE Products:

- Lactose Monohydrate: CapsuLac® 60, FlowLac® 90, FlowLac® 90 MS, FlowLac® 100, FlowLac® 100 MS, FlowLac® 100 SD, GranuLac® 70, GranuLac® 70 MS, GranuLac® 80, GranuLac® 140, GranuLac® 140 S, GranuLac® 200, GranuLac® 200 MS, GranuLac® 200 S, GranuLac® 230, InhaLac® 70, InhaLac® 120, InhaLac® 140, InhaLac® 145, InhaLac® 150, InhaLac® 160, InhaLac® 180, InhaLac® 230, InhaLac® 251, InhaLac® 300, InhaLac® 400, InhaLac® 500, Lactose Monohydrate 200 Mesh IP, Lactose Monohydrate Impalpable, Lactose Monohydrate Low Endotoxin, PrismaLac® 40, SacheLac® 80, SorboLac® 400, SpheroLac® 100, Tablettose® 70, Tablettose® 80, Tablettose® 100, Tablettose® 100 MS

The MEGGLE Products are manufactured and typically used as excipients in pharmaceutical industry. They conform to the monograph "Lactose Monohydrate" in pharmacopoeias.

The MEGGLE Products can be used as ingredient in the production of food including infant formulae and for food supplement products. The use of the products for which food and food supplements regulations are applicable underlies the responsibility of the customer.

Lactose monohydrate is the natural occurring sugar of milk ("milk sugar"). It is gained from whey via crystallization, washing and refining. It is regarded as dairy product or as sugar. Lactose monohydrate is not regarded as food additive. Therefore, JECFA and other food additive standards does not exist.

The MEGGLE Products are - regarding the main chemical-physical characteristics - in compliance with

- Codex Alimentarius Standard 212-1999
- US Food Chemical Codex*
- US Standard of Identity 21CFR 186.122*
- US ADPI Product Standard
- Chinese Standard GB 25595-2018
- Indian Food Safety and Standards Regulations: 2.1.20 Standards for Edible Lactose
- German Ordinance on Milk Products
- * As the MEGGLE Products comply with these regulations they are "Affirmed as GRAS".

Furthermore, the above mentioned products are in compliance with general Codex, EU, German, US legislation, e.g. regarding residues and contaminants.