



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® 240, 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 (besides pH value as indicated) in compliance with

- Codex Alimentarius Standard 212-1999¹
- US Food Chemical Codex^{1, 2}
- US Standard of Identity 21CFR 168.122^{1, 2}
- US ADPI Product Standard
- Chinese Standard GB 25595-2018³
- Indian Food Safety and Standards Regulations: 2.1.20 Standards for Edible Lactose¹
- German Ordinance on Milk Products

¹ The mentioned standards are describing the properties of unrefined lactose. The lower pH value of the MEGGLE Products is solely due to the refining process leading to a higher purified product. Typical applications for refined lactose products: excipient in pharmaceutical industry, ingredient in food supplements and other food.

² As the MEGGLE Products comply with these regulations they are "Affirmed as GRAS".

³ Raw materials (milk, whey) shall also comply with the corresponding food standards. Monitoring of pesticides and veterinary drugs is installed in lactose-reduced whey powder according to Chinese legislation. This material is a by-product in the production of lactose. This monitoring is regarded as instrument to verify that the Chinese requirements for corresponding milk is met as accumulation of residues and contaminants occurs in this material.

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

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