



To whom it may concern

Dr. Stefan Dreiheller
Quality Unit / Regulatory Affairs

Date of issue: 01.07.2020
Page 1/1
Doc.-No. EIP-1030
Revision 8

Suitability as Ingredient in Food and Food Supplements

MEGGLE Products:

- Lactose Monohydrate (Ph. Eur. / USP-NF / JP): CapsuLac® 60, FlowLac® 90, FlowLac® 100, GranuLac® 70, GranuLac® 80, GranuLac® 140, GranuLac® 200, GranuLac® 230, PrismaLac® 40, SacheLac® 80, SorboLac® 400, SpheroLac® 100, Tablettose® 70, Tablettose® 80, Tablettose® 100

The product is manufactured and typically used as excipient in pharmaceutical industry. It conforms to the monograph "Lactose Monohydrate" in pharmacopoeias.

The product is the natural occurring sugar of milk (milk sugar) and is regarded as food (dairy product or sugar). It conforms to all relevant current EU and German food regulations.

The product is regarding the main chemical-physical characteristics in compliance with

- Codex Alimentarius Standard 212-1999
- Chinese Standard GB 25595-2018
- US Food Chemical Codex.
- US ADPI Product Standard
- US Standard of Identity 21CFR 186.122
- German Ordinance on Milk Products

(The product is not regarded as food additive. Therefore, JECFA and other food additive standards does not exist. An INS/E-number is not assigned.)

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

Best regards

MEGGLE GmbH & Co. KG


Dr. Stefan Dreiheller