



An die interessierte Partei / To whom it may concern

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Suitability as Ingredient in Food Products

MEGGLE product(s):

- Lactose Monohydrate Ph. Eur. / USP-NF / JP: CapsuLac® 60, FlowLac® 90, FlowLac® 100, GranuLac® 70, GranuLac® 140, GranuLac® 200, GranuLac® 230, PrismaLac® 40, SacheLac® 80, SorboLac® 400, SpheroLac® 100, Tablettose® 70, Tablettose® 80, Tablettose® 100
- Lactose Monohydrate USP-NF / Ph. Eur. / JP: GranuLac® 70 US, GranuLac® 140 US, GranuLac® 200 US, Lactose monohydrate Low Endotoxin
- Anhydrous Lactose USP-NF / Ph. Eur. / JP: DuraLac® H

The product(s) are MEGGLE brand names for lactose monohydrate or anhydrous lactose and conform to the monograph "Lactose Monohydrate" or "(Anhydrous) Lactose" in the Ph. Eur, USP-NF and JP. The monograph has undergone pharmacopoeial harmonisation. The product is typically used as excipients in pharmaceutical industry.

Lactose is the natural occurring sugar of milk (milk sugar). It is gained from whey via crystallization, washing and refining as monohydrate or in the anhydrous form. In this meaning, it is also regarded as food (dairy product or sugar). 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 is regarding the main chemical-physical characteristics in compliance with

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

The lower pH value of the MEGGLE products is due to the refining process. This deviation does not impose any risk for the use.

Furthermore, the above mentioned product is in compliance with general EU and German legislation.

The product is sold worldwide and may be used as pharmaceutical excipients or food ingredients including for infant formulae without any restrictions.

Freundliche Grüße / Best regards

Molkerei MEGGLE Wasserburg GmbH & Co. KG


Dr. Stefan Dreiheller