



An die interessierte Partei / To whom it may concern

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Page 1/1
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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
- Anhydrous Lactose USP-NF / Ph. Eur. / JP: DuraLac® H

The product is the MEGGLE brand name for lactose monohydrate or anhydrous lactose. The product conforms to the monograph "Lactose Monohydrate" in the Ph. Eur. or to "Anhydrous Lactose" in the USP-NF. The monographs are harmonized between Ph. Eur., USP-NF and JP. 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.

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 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


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