

# INFORMATION

Quality Management



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## Thema

MEGGLE USA Products:

- Lactose Monohydrate: GranuLac® 70, GranuLac® 140, GranuLac® 200
- Anhydrous Lactose: DuraLac® H

The MEGGLE USA Products are manufactured and typically used as excipients in pharmaceutical industry. They conform to the respective monographs 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 and anhydrous lactose are both the natural occurring sugar of milk ("milk sugar") varying only in the last production / isolation process. They are gained from whey via crystallization, washing and refining. They are regarded as dairy product or as sugar. The products are 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 USA Products comply with these regulations they are "Affirmed as GRAS".

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

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