

## Use in Food and Food Supplements

MEGGLE USA Products:

- Lactose Monohydrate: GranuLac® 70 US, GranuLac® 140 US, GranuLac® 200 US
- 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 USA 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 USA Products are regarding the main chemical-physical characteristics (besides pH value as indicated) in compliance with

- Codex Alimentarius Standard 212-1999<sup>1</sup>
- US Food Chemical Codex<sup>1, 2</sup>
- US Standard of Identity 21CFR 168.122<sup>1, 2</sup>
- US ADPI Product Standard
- Chinese Standard GB 25595-2018
- Indian Food Safety and Standards Regulations: 2.1.20 Standards for Edible Lactose<sup>1</sup>
- German Ordinance on Milk Products

<sup>1</sup> 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.

<sup>2</sup> Therefore "Affirmed as GRAS".

Furthermore, the above mentioned MEGGLE USA Products are in compliance with horizontal regulation e.g. regarding residues and contaminants in Codex, EU, German, US legislation.