Suitability as Ingredient in Food and Food Supplements

MEGGLE Product:
Co-processed Excipient: CombiLac®

The mentioned MEGGLE Product is a spray dried mixture of 70 parts lactose monohydrate, 20 parts cellulose and 10 parts starch (maize / corn) and is manufactured and typically used as excipient in pharmaceutical industry.

The MEGGLE Product can be used as compound 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.

Lactose monohydrate is the natural occurring sugar of milk ("milk sugar"). It is gained from whey via crystallization, washing and refining. It is regarded as dairy product or as sugar. Lactose monohydrate is not regarded as food additive. Therefore, JECFA and other food additive standards does not exist.

Lactose monohydrate is – regarding the main chemical-physical characteristics – in compliance with
- Codex Alimentarius Standard 212-1999
- US Food Chemical Codex*
- US Standard of Identity 21CFR 168.122*
- 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 compound complies with these regulations they are "Affirmed as GRAS".

Cellulose complies with the specification for E 460 (i) in Regulation (EU) No 231/2012 laying down specifications for food additives. The rules for the use of food additives (e.g. Codex Stan 192-1995, Regulation (EC) No 1333/2008) has to be considered regarding the use in food and food supplements.

Starch is the natural occurring polysaccharide in maize / corn. It is gained via physical processes. It is a processed product of the milling industry. Starch is not regarded as food additive. Therefore, JECFA and other food additive standards does not exist.

Cellulose and Corn starch are both listed in the United States FDA SCOGS (GRAS) database with both the Type of Conclusion:

> *"There is no evidence in the available information on [substance] that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when they are used at levels that are now current or might reasonably be expected in the future."*

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

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