



To whom it may concern

Dr. Stefan Dreiheller
Quality Unit / Regulatory Affairs

Date of issue: 01.07.2020
Page 1/1
Doc.-No. EIP-5030
Revision 2

Suitability as Ingredient in Food and Food Supplements

MEGGLE Product: RetaLac®

The product is a spray-dried mixture of 50 parts Lactose and 50 Hydroxypropyl methyl cellulose and is manufactured as excipients for pharmaceutical industry. The compounds conform to the relevant monographs in pharmacopoeias.

Lactose is the natural occurring sugar of milk (milk sugar) and is regarded as food (dairy product or sugar). It conforms to all relevant current EU and German food regulations.

The component 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 component is not regarded as food additive. Therefore, JECFA and other food additive standards does not exist. An INS/E-number is not assigned.)

Hydroxypropyl methyl cellulose is regarded as food additive. It conforms to all relevant current EU and German food regulations. It complies with the specification for E 464 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.

The product can be used as compound ingredient in the production of food and for food supplement products. The both components has to be considered as "ingredients" of the final product. The use of the product for which food and food supplements regulations are applicable underlies the responsibility of the customer.

Best regards

MEGGLE GmbH & Co. KG


Dr. Stefan Dreiheller