



To whom it may concern

Dr. Stefan Dreiheller
Quality Unit / Regulatory Affairs

Date of issue: 01.07.2020
Page 1/1
Doc.-No. EIP-1007
Revision 8

GRAS / Inactive Ingredients Database (IID)

MEGGLE Products:

- Lactose Monohydrate (Ph. Eur. / USP-NF / JP): CapsuLac® 60, FlowLac® 90, FlowLac® 100, GranuLac® 70, GranuLac® 80, GranuLac® 140, GranuLac® 200, GranuLac® 230, PrismaLac® 40, SacheLac® 80, SorboLac® 400, SpheroLac® 100, Tablettose® 70, Tablettose® 80, Tablettose® 100
- Lactose Monohydrate (USP-NF / Ph. Eur. / JP): Lactose monohydrate Low Endotoxin
- Inhaler Grade Lactose Monohydrate (USP-NF / Ph. Eur. / JP): InhaLac® 70, InhaLac® 120, InhaLac® 140, InhaLac® 150, InhaLac® 160, InhaLac® 230, InhaLac® 250, InhaLac® 251, InhaLac® 400, InhaLac® 500

The products conform to the monograph "Lactose Monohydrate" in the Ph. Eur, USP-NF and JP. The monograph has undergone pharmacopoeial harmonisation.

The above mentioned products are considered "Affirmed as GRAS" as they are in compliance with FCC monograph "Lactose" and 21 CFR §168.122.

The above mentioned products are listed on the United States FDA Inactive Ingredients Database.

Best regards

MEGGLE GmbH & Co. KG


Dr. Stefan Dreiheller