



To whom it may concern

Dr. Stefan Dreiheller
Quality Unit / Regulatory Affairs

Date of issue: 01.07.2020
Page 1/1
Doc.-No. EIP-1012
Revision 8

REACH

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 intended use of the above mentioned products is relevant regarding registration under REACH. According to Regulation (EC) No 1907/2006, Art. 2 No. 5 a) and b), the provisions of Titles II (registration), V (downstream users), VI (evaluation) and VII (authorization) do not apply to the extent that a substance is used in medicinal products for human or veterinary use and to the extent that a substance is used in food or feedingstuffs.

Furthermore, Lactose is included to Annex IV of Regulation (EC) No 1907/2006. According to Regulation (EC) No 1907/2006 Art. 2 No. 7, the provisions of Titles II (registration), V (downstream users), VI (evaluation) do not apply to substances listed in Annex IV as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties.

Safety data sheets are available on request.

Best regards

MEGGLE GmbH & Co. KG


Dr. Stefan Dreiheller