



An die interessierte Partei / To whom it may concern

Dr. Stefan Dreiheller
Quality Unit / Regulatory Affairs

Date of issue: 11.12.2019
Page 1/1
Doc.-No. EIP-0018
Revision 7

Packaging material

MEGGLE products:

- Lactose Monohydrate Ph. Eur. / USP-NF / JP: CapsuLac® 60, FlowLac® 90, FlowLac® 100, GranuLac® 70, 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: InhaLac® 70, InhaLac® 120, InhaLac® 140, InhaLac® 150, InhaLac® 160, InhaLac® 230, InhaLac® 250, InhaLac® 251, InhaLac® 400, InhaLac® 500, Lactose monohydrate Low Endotoxin
- Anhydrous Lactose USP-NF / Ph. Eur. / JP: DuraLac® H
- Co-processed excipients: Cellactose® 80, CombiLac®, MicroceLac® 100, RetaLac®, StarLac®

The packaging material of the above mentioned products conforms to all relevant legal requirements for food contact material.

Regarding the production sites located in Germany:

The packaging material is in accordance with

- Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food as well as with legislation based on this Regulation ("Specific measures"), e.g. Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food,
 - Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended for food contact,
- and all other legal requirements of Germany and EU laid down for packaging material which is intended to come into direct contact with food.

Regarding the production sites located in the United States of America:

The packaging material is in accordance with the requirements for Indirect Food Additives following 21 CFR 174-186.

Freundliche Grüße / Best regards

Molkerei MEGGLE Wasserburg GmbH & Co. KG


Dr. Stefan Dreiheller