



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-1005
Revision 8

Gluten

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

The mentioned MEGGLE products are not produced from materials, do not contain any ingredients, are not produced with the help of processing aids which are derived from or contain unintentional amounts of cereals containing gluten, namely wheat, rye, barley, oats, spelt, kamut or their hybridised strains and products thereof.

Cross-contamination by intentionally used cereals containing gluten, namely wheat, rye, barley, oats, spelt, kamut or their hybridised strains and products is excluded.

The presence of gluten is not expected.

MEGGLE products are specified as "suitable for people with celiac disease ("gluten-free", max. 20 ppm gluten)" and meet the requirements of Implementing Regulation (EU) No 828/2014. Furthermore, the products meet the requirements of 21 CFR 101.91 "Gluten-free labelling of food".

Freundliche Grüße / Best regards

Molkerei MEGGLE Wasserburg GmbH & Co. KG


Dr. Stefan Dreiheller