



An die interessierte Partei / To whom it may concern

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Ph. Eur., General texts 5.1.7., Viral safety, Heat treatment conditions

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[®] 160, InhaLac[®] 230, InhaLac[®] 250, InhaLac[®] 251, InhaLac[®] 400, InhaLac[®] 500, Lactose monohydrate Low Endotoxin
- Anhydrous Lactose USP-NF / Ph. Eur. / JP: DuraLac[®] H

In the manufacturing process of the products a heat treatment of min. 72°C (161 °F) for min. 15 seconds followed by a second heat treatment of min. 97°C (206 °F) for min. 30 minutes is performed.

The heat treatment conditions and the measurements to prevent recontamination of the product (closed production line, hygiene rules, etc) ensure that for the production of the products there should be no viral risk.

Freundliche Grüße / Best regards



Dr. Stefan Dreiheller