



To whom it may concern

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Quality Unit

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DNA Reactive (Mutagenic) Impurities

ICH Guideline M7(R1)

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® 180, InhaLac® 230, InhaLac® 251, InhaLac® 300, InhaLac® 400, InhaLac® 500
- Co-processed excipients: Cellactose® 80, CombiLac®, MicroceLac® 100, RetaLac®, StarLac®

The mentioned MEGGLE products are used as excipients for which – according chapter 2 – the guideline is not applicable.

Substances which can induce damage to the genetic material in the cells through interactions with the DNA sequence and structure are not used in the manufacturing process of the products.

Furthermore, the products as such and the components in the co-processed excipients respectively are well known, has a long history of safe use and are in compliance with EU and German legislation for food and food additives, respectively.

Best regards

MEGGLE GmbH & Co. KG

Dr. Stefan Dreiheller

Regulatory Affairs / Specification Management