



To whom it may concern

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Quality Unit

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Packaging Material

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®

In the absence of regulatory guidance regarding packaging material for excipients, the information which is made available from suppliers of the packaging material regarding compliance with food legislation is evaluated.

The packaging material of the above mentioned MEGGLE Products 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 ("Specific measures") based on this Regulation, in particular
- 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.

Best regards

MEGGLE GmbH & Co. KG

Dr. Stefan Dreiheller

Regulatory Affairs / Specification Management