



To whom it may concern

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Melamine

FDA Guidance for Industry: Pharmaceutical Components at Risk for Melamine Contamination

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® 230, InhaLac® 250, InhaLac® 251, InhaLac® 400, InhaLac® 500
- Co-processed excipients: Cellactose® 80, CombiLac®, MicroceLac® 100, RetaLac®, StarLac®

The products are or contain lactose.

They are not covered by the definition for an “at-risk component” as referenced in footnote 3 of the FDA Guidance for Industry. On the other side Lactose is listed as an example of an “at-risk pharmaceutical component” as “sourced starting material can be derived from milk”.

Any addition of melamine would lead to OOS-results. In this respect there is no motivation to add melamine to the products.

Nevertheless, a monitoring program for melamine and cyanuric acid is implemented. Testing is performed by an independent laboratory using the following method:

Liquid Chromatography/Tandem Mass Spectrometry (LC-MS-MS).

Detection limit melamine: 0.05 mg/kg. Detection limit cyanuric acid: 0.5 mg/kg.

Melamine and cyanuric acid are not detectable in the products.

Best regards

MEGGLE GmbH & Co. KG

represented by MEGGLE Verwaltungs GmbH


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