



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<sup>®</sup> 60, FlowLac<sup>®</sup> 90, FlowLac<sup>®</sup> 100, GranuLac<sup>®</sup> 70, GranuLac<sup>®</sup> 80, GranuLac<sup>®</sup> 140, GranuLac<sup>®</sup> 200, GranuLac<sup>®</sup> 230, PrismaLac<sup>®</sup> 40, SacheLac<sup>®</sup> 80, SorboLac<sup>®</sup> 400, SpheroLac<sup>®</sup> 100, Tablettose<sup>®</sup> 70, Tablettose<sup>®</sup> 80, Tablettose<sup>®</sup> 100
- Lactose Monohydrate (USP-NF / Ph. Eur. / JP): Lactose monohydrate Low Endotoxin
- Inhaler Grade Lactose Monohydrate (USP-NF / Ph. Eur. / JP): InhaLac<sup>®</sup> 70, InhaLac<sup>®</sup> 120, InhaLac<sup>®</sup> 140, InhaLac<sup>®</sup> 150, InhaLac<sup>®</sup> 160, InhaLac<sup>®</sup> 230, InhaLac<sup>®</sup> 250, InhaLac<sup>®</sup> 251, InhaLac<sup>®</sup> 400, InhaLac<sup>®</sup> 500
- Co-processed excipients: Cellactose<sup>®</sup> 80, CombiLac<sup>®</sup>, MicroceLac<sup>®</sup> 100, RetaLac<sup>®</sup>, StarLac<sup>®</sup>

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 consider such an adulteration.

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**

  
Dr. Stefan Dreiheller