



An die interessierte Partei / To whom it may concern

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Page 1/1  
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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> 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: InhaLac<sup>®</sup> 70, InhaLac<sup>®</sup> 120, InhaLac<sup>®</sup> 160, InhaLac<sup>®</sup> 230, InhaLac<sup>®</sup> 250, InhaLac<sup>®</sup> 251, InhaLac<sup>®</sup> 400, InhaLac<sup>®</sup> 500, Lactose Monohydrate Low Endotoxin
- Anhydrous Lactose USP-NF / Ph. Eur. / JP: DuraLac<sup>®</sup> H
- 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.

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.

Results show that melamine and cyanuric acid are not detectable in raw material whey.

Lactose Monohydrate Ph. Eur. / USP-NF / JP and Anhydrous Lactose Monohydrate USP-NF / Ph. Eur. / JP has a nitrogen content typically below 0,008%, and is therefore not covered by the definition for an "at-risk component" as referenced in footnote 3 of the FDA Guidance for Industry.

Freundliche Grüße / Best regards

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