**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 (USP-NF / Ph. Eur. / JP): GranuLac® 70 US, GranuLac® 140 US, GranuLac® 200 US
- Anhydrous Lactose (USP-NF / Ph. Eur. / JP): DuraLac® H

The products are 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 USA inc.**

Dr. Gabriele Müller