



To whom it may concern

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Quality Unit

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## **DNA Reactive (Mutagenic) Impurities**

**EMA/CHMP/ICH/83812/2013**

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> 300, 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>, Reta M<sup>®</sup>, StarLac<sup>®</sup>

The substances are used as excipients for which – according chapter 2 – the guideline is not applicable.

Substances which can induce damage to the genetic material in the cells through interactions with the DNA sequence and structure are not used in the manufacturing process of the products.

Furthermore, the products as such and the components in the co-processed excipients respectively are well known and safe as food or food additive according to EU and German legislation.

Best regards

**MEGGLE GmbH & Co. KG**

A handwritten signature in purple ink that reads "i.V. Stefan Dreiheller".

**Dr. Stefan Dreiheller**

Regulatory Affairs / Specification Management