



To whom it may concern

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## Genotoxic impurities

(CPMP/SWP/5199/02, EMEA/CHMP/QWP/251344/2006)

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>, 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**

represented by MEGGLE Verwaltungs GmbH

  
Dr. Stefan Dreiheller