



To whom it may concern

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Quality Unit

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## Residual Solvents

**Ph. Eur. General Texts 5.4; USP-NF General Chapter <467>; JP General Tests 2.46  
ICH Guideline Q3C (R8)**

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> 180, InhaLac<sup>®</sup> 230, InhaLac<sup>®</sup> 251, InhaLac<sup>®</sup> 300, InhaLac<sup>®</sup> 400, InhaLac<sup>®</sup> 500

Raw materials do not contain organic solvents listed as class 1, 2, 3 solvents in the mentioned documents.

For the manufacture of the products, only water intended for human consumption according to the German Drinking Water Ordinance based on Directive 98/83/EC is used. Demineralized water is made thereof.

Organic solvents listed as Class 1, Class 2 or Class 3 solvents or any other solvents are not used and are therefore "not likely to be present" in the product.

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