



**An die interessierte Partei / To whom it may concern**

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## **Residual Solvents**

**ICH Q3C (R7) (EMA/CHMP/ICH/82260/2006); Ph. Eur. Chapter 5.4; USP-NF Chapter <467>; JP XVII  
Chapter 2.46; EMEA/CVMP/423/01-Final**

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> 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, Lactose monohydrate Low Endotoxin
- Anhydrous Lactose USP-NF / Ph. Eur. / JP: DuraLac<sup>®</sup> H

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 or according to the National Primary Drinking Water Regulations of United States Environmental Protection Agency (EPA) 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

Freundliche Grüße / Best regards

**Molkerei MEGGLE Wasserburg GmbH & Co. KG**

  
Dr. Stefan Dreiheller