



To whom it may concern

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Quality Unit / Regulatory Affairs

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Page 1/1
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Residual Solvents

ICH Q3C (R8) (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® 60, FlowLac® 90, FlowLac® 100, GranuLac® 70, GranuLac® 80, GranuLac® 140, GranuLac® 200, GranuLac® 230, PrismaLac® 40, Sachelac® 80, SorboLac® 400, SpheroLac® 100, Tablettose® 70, Tablettose® 80, Tablettose® 100
- Lactose Monohydrate (USP-NF / Ph. Eur. / JP): Lactose monohydrate Low Endotoxin
- Inhaler Grade Lactose Monohydrate (USP-NF / Ph. Eur. / JP): InhaLac® 70, InhaLac® 120, InhaLac® 140, InhaLac® 150, InhaLac® 160, InhaLac® 230, InhaLac® 250, InhaLac® 251, InhaLac® 300, InhaLac® 400, InhaLac® 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

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