



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>;
EMA/CVMP/423/01-Final**

MEGGLE products:

- Lactose Monohydrate Ph. Eur. / USP-NF / JP: CapsuLac[®] 60, FlowLac[®] 90, FlowLac[®] 100, GranuLac[®] 70, 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: InhaLac[®] 70, InhaLac[®] 120, InhaLac[®] 160, InhaLac[®] 230, InhaLac[®] 250, InhaLac[®] 251, InhaLac[®] 400, InhaLac[®] 500, Lactose monohydrate Low Endotoxin
- Anhydrous Lactose USP-NF / Ph. Eur. / JP: DuraLac[®] H

For the manufacture of the products, only water intended for human consumption according Directive 98/83/EC and demineralized water made thereof is used.

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".

Freundliche Grüße / Best regards

Dr. Stefan Dreiheller