



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:

Co-processed excipients: MicroceLac<sup>®</sup> 100

MicroceLac<sup>®</sup> 100 is a co-processed excipient and a spray dried mixture of  
75 parts Lactose Monohydrate Ph. Eur. / USP-NF / JP and  
25 parts Cellulose Microcrystalline Ph. Eur. / USP-NF / JP.

Starting material Lactose Monohydrate Ph. Eur. / USP-NF / JP:

For the manufacture of the products, only water intended for human consumption according Directive  
98/83/EC and demineralised 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".

Starting material Cellulose Microcrystalline Ph. Eur. / USP-NF / JP:

According to the confirmation of the supplier, raw materials, manufacturing process and product do not  
contain Organic solvents listed as class 1, 2, 3 solvents in the mentioned documents.

MicroceLac<sup>®</sup> 100:

In the manufacturing process (spray-drying of suspension), only water 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