



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: CombiLac<sup>®</sup>

CombiLac<sup>®</sup> is a co-processed excipient and a spray dried mixture of  
70 parts Lactose Monohydrate Ph. Eur. / USP-NF / JP,  
20 parts Cellulose Microcrystalline Ph. Eur. / USP-NF / JP and  
10 parts Maize Starch Ph. Eur. / USP-NF.

### 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.

### Starting material Maize Starch Ph. Eur. / USP-NF:

According to the confirmation of the supplier, organic solvents listed as class 1, 2, 3 solvents in the mentioned documents are not used in the manufacturing process. The product may contain traces of class 3 solvent is acetic acid (i.e.: < 20 ppm).

### CombiLac<sup>®</sup>:

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.

Due to Starting material Maize Starch Ph. Eur. / USP-NF: As mentioned above, the only class 3 solvent likely to be present is acetic acid. The total amount of acetic acid is typically < 2 ppm and does not exceed the 5000 ppm Option 1 limit.

Freundliche Grüße / Best regards

Dr. Stefan Dreiheller