



An die interessierte Partei / To whom it may concern

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Quality Unit / Regulatory Affairs

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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: RetaLac®

RetaLac® is a co-processed excipient and a spray dried mixture of
50 parts Lactose Monohydrate Ph. Eur. / USP-NF / JP and
50 parts Hypromellose 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 Hypromellose Ph. Eur. / USP-NF / JP:

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 2 solvent methanol (i.e.: < 100 ppm).

RetaLac®:

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 Hypromellose Ph. Eur. / USP-NF / JP: As mentioned above, the only class 2 solvent likely to be present is methanol. The total amount of methanol is typically < 50 ppm and does not exceed the 3000 ppm Option 1 limit.

Freundliche Grüße / Best regards


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