



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>; JP XVII Chapter 2.46; EMEA/CVMP/423/01-Final

MEGGLE product: MicroceLac® 100

MicroceLac® 100 is a co-processed, directly compressible spray agglomerate comprising 75 % Lactose Monohydrate (Ph. Eur.) and 25 % Microcrystalline Cellulose (Ph. Eur.). The monographs "Lactose Monohydrate" and "Microcrystalline Cellulose" are harmonized between Ph. Eur., USP-NF and JP.

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

Raw materials, manufacturing process and product do not contain organic solvents listed as class 1, 2, 3 solvents in the mentioned documents.

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® 100:

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

Molkerei MEGGLE Wasserburg GmbH & Co. KG


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