



An die interessierte Partei / To whom it may concern

Dr. Stefan Dreiheller
Quality Unit / Regulatory Affairs

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Ph. Eur., General texts 5.1.7., Viral safety, Heat treatment conditions

Meggle products:

Co-processed excipients: CombiLac[®]

This statement is valid for all deliveries.

CombiLac[®] 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:

In the manufacturing process of the material a heat treatment of min. 72°C (161 °F) for min. 15 seconds followed by a second heat treatment of min. 97°C (206 °F) for min. 30 minutes is performed.

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

The materials are not of animal or human origin.

The heat treatment conditions and the measurements to prevent recontamination of the product (closed production line, hygiene rules, etc) ensure that for the production of the products there should be no viral risk.

Freundliche Grüße / Best regards

Dr. Stefan Dreiheller