



**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: StarLac®

This statement is valid for all deliveries.

StarLac® is a co-processed excipient and a spray dried mixture of  
85 parts Lactose Monohydrate Ph. Eur. / USP-NF / JP and  
15 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 Maize Starch Ph. Eur. / USP-NF:

The material is 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



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