To whom it may concern

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Quality Unit

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

MEGGLE Products:
- Lactose Monohydrate (Ph. Eur. / USP-NF / JP): CapsuLac® 60, FlowLac® 90, FlowLac® 100, GranuLac® 70, GranuLac® 80, GranuLac® 140, GranuLac® 200, GranuLac® 230, PrismaLac® 40, SacheLac® 80, SorboLac® 400, SpheroLac® 100, Tablettose® 70, Tablettose® 80, Tablettose® 100
- Lactose Monohydrate (USP-NF / Ph. Eur. / JP): Lactose monohydrate Low Endotoxin
- Inhaler Grade Lactose Monohydrate (USP-NF / Ph. Eur. / JP): InhaLac® 70, InhaLac® 120, InhaLac® 140, InhaLac® 150, InhaLac® 160, InhaLac® 230, InhaLac® 250, InhaLac® 251, InhaLac® 300, InhaLac® 400, InhaLac® 500
- Co-processed excipients: Cellactose® 80, CombiLac®, MicroceLac® 100, RetaLac®, StarLac®

The products are or contain lactose as only animal derived ingredient. They are produced from milk gained from the animal species Bos Taurus. Milk from other species is not used. Purchased raw material, used in the manufacture of the products is whey.

The necessity of virus validation studies is defined in Note for Guidance CPMP/BWP/268/95 and included the following products:
- products derived from in vitro cell lines of human and animal origin,
- products derived from in vivo culture of cell lines or from organs or tissues of human or animal origin,
- products derived from blood or urine or other biological fluids of human or animal origin.

In chapter 2 of the Note for Guidance some cases of sources of viral contamination are mentioned. None of the contamination sources are applicable to milk as source material for lactose.

The sourcing (primary production) or the raw milk meets the requirements of Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I and is constantly, officially supervised.
The raw milk originates from healthy cows
- that do not show any symptoms of infectious diseases communicable to humans through milk
- that are in a good general state of health, present no sign of disease that might result in the contamination of milk and, in particular, are not suffering from any infection of the genital tract with discharge, enteritis with diarrhea and fever, or a recognizable inflammation of the udder;
- that do not have any udder wound likely to affect the milk

For the manufacture of lactose no virus validation studies have been performed, because:
- The source material milk is not considered to be an (important) source of viruses, and is fit for human consumption (see above),
- Virus validation studies could compromise the safety of our manufacturing equipment,
- The product is prepared from milk, which has been heat-treated in accordance with the Regulation (EC) No 853/2004, Annex III, Section IX, Chapter II, II. 1. (a). Pasteurization is achieved by a treatment involving a high temperature for a short time (at least 72 °C for 15 seconds) or a low temperature for a long time (at least 63 °C for 30 minutes); or any other combination of time-temperature conditions to obtain an equivalent effect such that the products show, where applicable, a negative reaction to an alkaline phosphatase test immediately after such treatment. Furthermore, a second heat treatment typically at a minimum of 97 °C (and in any case at more than 90 °C) for min. 30 minutes is carried out.

These treatments are recognized to provide sufficient guaranties with regard to the destruction of e.g. the foot and-mouth disease virus in milk and milk products for human consumption according Delegated Regulation (EU) 2020/687 and for other viruses.

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 product there should be no viral risk.

Best regards
MEGGLE GmbH & Co. KG

i.V. Stefan Dreiheller

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