



To whom it may concern

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Aflatoxins

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® 180, InhaLac® 230, InhaLac® 251, InhaLac® 300, InhaLac® 400, InhaLac® 500
- Co-processed excipients: Cellactose® 80, CombiLac®, MicroceLac® 100, RetaLac®, StarLac®

Lactose Monohydrate as such or used as component meets the requirements of

- Regulation (EU) 2023/915,
- German "Verordnung über das Verbot der Verwendung von mit Aflatoxinen kontaminierten Stoffen bei der Herstellung von Arzneimitteln (Aflatoxin VerbotsV) vom 19. Juli 2000".
- US FDA Compliance Policy Guide sec 527.400

Aflatoxin M1 is monitored as aflatoxins B and G are metabolized in cattle to aflatoxin M1. There is no evidence that Aflatoxins B and G are present in milk. A defined sample plan is installed.

The other components in MEGGLE Co-processed excipients meet the requirements of

- Regulation (EU) 2023/915,
- German "Verordnung über das Verbot der Verwendung von mit Aflatoxinen kontaminierten Stoffen bei der Herstellung von Arzneimitteln (Aflatoxin VerbotsV) vom 19. Juli 2000".
- as far as applicable US FDA Compliance Policy Guide sec 555.400.

Best regards

MEGGLE GmbH & Co. KG

Dr. Stefan Dreiheller

Regulatory Affairs / Specification Management