



To whom it may concern

Dr. Stefan Dreiheller
Quality Unit / Regulatory Affairs

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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[®] 230, InhaLac[®] 250, InhaLac[®] 251, InhaLac[®] 400, InhaLac[®] 500
- Co-processed excipients: Cellactose[®] 80, CombiLac[®], MicroceLac[®] 100, RetaLac[®], Reta M[®], StarLac[®]

Lactose Monohydrate as product or component in co-processed excipients meets the requirements of

- Regulation (EC) No 1881/2006,
- US FDA Compliance Policy Guide sec 527.400
- the German "Verordnung über das Verbot der Verwendung von mit Aflatoxinen kontaminierten Stoffen bei der Herstellung von Arzneimitteln (Aflatoxin VerbotsV) vom 19. Juli 2000".

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 co-processed excipients meet the requirements of

- Regulation (EC) No 1881/2006,
- the 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

represented by MEGGLE Verwaltungs GmbH

i.v. Stefan Dreiheller
Dr. Stefan Dreiheller