

INFORMATION

Quality / Regulatory Affairs



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Revision 15

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Aflatoxins

MEGGLE Products:

- Lactose Monohydrate: CapsuLac[®] 60, FlowLac[®] 90, FlowLac[®] 90 MS, FlowLac[®] 100, FlowLac[®] 100 MS, FlowLac[®] 100 SD, GranuLac[®] 70, GranuLac[®] 70 MS, GranuLac[®] 80, GranuLac[®] 140, GranuLac[®] 140 S, GranuLac[®] 200, GranuLac[®] 200 MS, GranuLac[®] 200 S, GranuLac[®] 230, InhaLac[®] 70, InhaLac[®] 120, InhaLac[®] 140, InhaLac[®] 150, InhaLac[®] 160, InhaLac[®] 180, InhaLac[®] 251, InhaLac[®] 300, InhaLac[®] 400, InhaLac[®] 500, Lactose Monohydrate 200 Mesh IP, Lactose Monohydrate Impalpable, Lactose Monohydrate Low Endotoxin, PrismaLac[®] 40, SacheLac[®] 80, SorboLac[®] 400, SpheroLac[®] 100, Tablettose[®] 70, Tablettose[®] 80, Tablettose[®] 100, Tablettose[®] 100 MS
- Co-processed Excipients: Cellactose[®] 80, CombiLac[®], MicroceLac[®] 100, RetaLac[®], StarLac[®]

Lactose Monohydrate as MEGGLE Product or used as component and 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".

Lactose Monohydrate meets the requirements of 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, as far as applicable the requirements of US FDA Compliance Policy Guide sec 555.400.

This MEGGLE Information was electronically released and is valid without signature.