



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[®] 145, InhaLac[®] 150, InhaLac[®] 160, InhaLac[®] 180, InhaLac[®] 230, InhaLac[®] 240, 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, MicroceLac[®] Plus, RetaLac[®], StarLac[®]

All "Low Nitrite" Grades are included.

The mentioned MEGGLE Products meet the requirements of

- Regulation (EU) 2023/915
- US FDA Compliance Policy Guide sec 527.400 or 555.400 (as far as applicable)
- 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 is manufactured and released at MEGGLE.

The substance is manufactured from whey which is a by-product at the manufacturing of cheese from bovine milk. There is no evidence that aflatoxins B and G are present in milk as these are metabolised in bovines to aflatoxin M1. Therefore this contaminant is tested only.

Due to processing and nature of the product a contamination with aflatoxin M1 is not expected. Risk-based periodical testing (1 / year) as verification is installed.

Also due to the origin and processing, the issue of a potential heterogeneous distribution of the contamination is not applicable.

The other components in MEGGLE Co-processed Excipients are manufactured and released at approved suppliers.

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