

INFORMATION

Quality Management



EIP-0052-USA

Revision 6

Date of issue: 02.11.2023

1/1

Aflatoxins

MEGGLE USA Products:

- Lactose Monohydrate: GranuLac® 70, GranuLac® 140, GranuLac® 200
- Anhydrous Lactose: DuraLac® H

The mentioned MEGGLE USA Products meet the requirements of

- US FDA Compliance Policy Guide sec 527.400.
- 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".

The MEGGLE USA Products are 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 metabolized 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 (2 / 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.

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