

INFORMATION

Quality Management



EIP-0059-USA

Revision 3

Date of issue: 29.08.2023

1/1

Natural Latex / Natural Rubber

FDA Guidance of Industry and Food and Drug Administration Staff “Recommendation for Labeling Medicinal Products to Inform Users that the Product or Product Container is not made with Natural Rubber Latex”

MEGGLE USA Products:

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

Referring to the recommendation of mentioned FDA Guidance:

The mentioned MEGGLE USA Products are “not made with natural rubber latex”.

Latex and natural rubber are not

- used as ingredients and technical aids,
- contained in ingredients or technical aids as intentionally added substances,
- used as constituents in the packaging material.

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