

INFORMATION

Quality / Regulatory Affairs



EIP-0055

Revision 13

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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 Products:

- Lactose Monohydrate: CapsuLac[®] 60, FlowLac[®] 90, FlowLac[®] 90 MS, FlowLac[®] 100, FlowLac[®] 90 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[®] 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[®]

Referring to the recommendation of mentioned FDA Guidance:

The mentioned MEGGLE 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 Information was electronically released and is valid without signature.