INFORMATION

Quality Management



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Revision 4

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Natural Latex / Natural Rubber

FDA Guidance of Industry and Food and Drug Administration Stuff "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 US, GranuLac® 140 US, GranuLac® 200 US
- Anhydrous Lactose: DuraLac® H

Referring to the recommendation of mentionned FDA Guidance:

The mentionned 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.