



To whom it may concern

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Quality Unit

Date of issue: 2.Mai.2023  
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Doc.-No. EIP-1007  
Revision 10

## Inactive Ingredients Database (IID) / GRAS

MEGGLE Products:

- Lactose Monohydrate (Ph. Eur. / USP-NF / JP): CapsuLac<sup>®</sup> 60, FlowLac<sup>®</sup> 90, FlowLac<sup>®</sup> 100, GranuLac<sup>®</sup> 70, GranuLac<sup>®</sup> 80, GranuLac<sup>®</sup> 140, GranuLac<sup>®</sup> 200, GranuLac<sup>®</sup> 230, PrismaLac<sup>®</sup> 40, Sachelac<sup>®</sup> 80, SorboLac<sup>®</sup> 400, SpheroLac<sup>®</sup> 100, Tablettose<sup>®</sup> 70, Tablettose<sup>®</sup> 80, Tablettose<sup>®</sup> 100
- Lactose Monohydrate (USP-NF / Ph. Eur. / JP): Lactose monohydrate Low Endotoxin
- Inhaler Grade Lactose Monohydrate (USP-NF / Ph. Eur. / JP): InhaLac<sup>®</sup> 70, InhaLac<sup>®</sup> 120, InhaLac<sup>®</sup> 140, InhaLac<sup>®</sup> 150, InhaLac<sup>®</sup> 160, InhaLac<sup>®</sup> 180, InhaLac<sup>®</sup> 230, InhaLac<sup>®</sup> 251, InhaLac<sup>®</sup> 300, InhaLac<sup>®</sup> 400, InhaLac<sup>®</sup> 500

The products conform to the monograph "Lactose Monohydrate" in the Ph. Eur, USP-NF and JP. The monograph has undergone pharmacopoeial harmonisation.

Lactose Monohydrate is listed in the United States FDA Inactive Ingredients Database. The Inactive Ingredient Database provides information on inactive ingredients present in FDA-approved drug products. This information can be used by industry as an aid in developing drug products. For new drug development purposes, once an inactive ingredient has appeared in an approved drug product for a particular route of administration, the inactive ingredient is not considered new and may require a less extensive review the next time it is included in a new drug product. This does not necessary mean that higher daily exposures cannot be justified.

The above mentioned products are considered "Affirmed as GRAS" as they are in compliance with FCC monograph "Lactose" and 21 CFR §168.122.

Best regards

**MEGGLE GmbH & Co. KG**

**Dr. Stefan Dreiheller**

Regulatory Affairs / Specification Management