

INFORMATION

Quality / Regulatory Affairs



EIP-1014

Revision 24

Date of issue: 03.05.2024

1/1

Residual Solvents

Ph. Eur. General Texts 5.4; USP-NF General Chapter <467>; JP General Tests 2.46, ICH Guideline Q3C (R9)

MEGGLE Products:

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

Raw materials do not contain organic solvents listed as class 1, 2, 3 solvents in the mentioned documents.

For the manufacture of the MEGGLE Products, only water intended for human consumption according to the German Drinking Water Ordinance based on Directive (EU) 2020/2184 and demineralised water made thereof is used.

Organic solvents listed as Class 1, Class 2 or Class 3 solvents or any other solvents are not used and are therefore "not likely to be present".

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