

# INFORMATION

Quality Management



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## Residual Solvents

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

MEGGLE USA Products:

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

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

For the manufacture of the MEGGLE USA Products, only drinking water intended according to the United States Environmental Protection Agency (EPA) – National Primary Drinking Water Regulations – 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 USA Information was electronically released and is valid without signature.*