An die interessierte Partei / To whom it may concern

Dr. Stefan Dreiheller
Quality Unit / Regulatory Affairs

Date of issue: 11.12.2019
Page 1/1
Doc.-No. EIP-1014
Revision 13

Residual Solvents
ICH Q3C (R7) (EMA/CHMP/ICH/82260/2006); Ph. Eur. Chapter 5.4; USP-NF Chapter <467>;
EMEA/CVMP/423/01-Final
MEGGLE products:
- Lactose Monohydrate Ph. Eur. / USP-NF / JP: CapsuLac® 60, FlowLac® 90, FlowLac® 100, GranuLac® 70,
  GranuLac® 140, GranuLac® 200, GranuLac® 230, PrismaLac® 40, SacheLac® 80, SorboLac® 400,
  SpheroLac® 100, Tablettose® 70, Tablettose® 80, Tablettose® 100
- Lactose Monohydrate USP-NF / Ph. Eur. / JP: InhaLac® 70, InhaLac® 120, InhaLac® 140, InhaLac® 150,
  InhaLac® 160, InhaLac® 230, InhaLac® 250, InhaLac® 251, InhaLac® 400, InhaLac® 500, Lactose
  monohydrate Low Endotoxin
- Anhydrous Lactose USP-NF / Ph. Eur. / JP: DuraLac® H

For the manufacture of the products, only water intended for human consumption according to the German
Drinking Water Ordinance based on Directive 98/83/EC or according to the National Primary Drinking Water
Regulations of United States Environmental Protection Agency (EPA) is used. Demineralized water is made
thereof.

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”.

Freundliche Grüße / Best regards

Molkerei MEGGLE Wasserburg GmbH & Co. KG

[Signature]

Dr. Stefan Dreiheller