



To whom it may concern

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Residual Solvents

**ICH Q3C (R8) (EMA/CHMP/ICH/82260/2006); Ph. Eur. Chapter 5.4; USP-NF Chapter <467>;
EMA/CVMP/423/01-Final**

MEGGLE Products:

- Lactose Monohydrate (USP-NF / Ph. Eur. / JP): GranuLac® 70 US, GranuLac® 140 US, GranuLac® 200 US
- Anhydrous Lactose (USP-NF / Ph. Eur. / JP): 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 products, only drinking water in accordance with 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” in the product.

Best regards

MEGGLE USA inc.

Dr. Gabriele Müller