



To whom it may concern

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Revision 4

BSE/TSE – Standards for Biological Raw Materials

Notice of the MHLW, No 210, revised with Notice of the MHLW, No 375

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

It is certified that the products fulfill the requirements set up in Notice of the MHLW, No. 210, established on 20.5.2003, and revised on 26.09.2014 with Notice of the MHLW, No. 375.

The above mentioned products are or contain pharmaceutical grade Lactose Monohydrate as the only “ruminant-derived raw material” as defined in Article 4 1. (1) of above mentioned Notice.

Pharmaceutical grade Lactose Monohydrate is obtained from processed milk. According to Article 4 No. 1 (2) milk is regarded as “low risk raw material” for which restrictions regarding the country of origin do not apply.

The requirements mentioned in Article 4 No. 1 (3) do also not apply to low risk raw materials. Nevertheless we inform as follows: Based on the information on the product (e.g. Lot number) the above mentioned product can be identified and traced back to raw material including production date of the product by relevant documentation. All traceability data are recorded and stored at the manufacturer according to the installed quality system for 7 years. In case Japanese authorities request traceability data they will be made available in appropriate time.

Best regards

MEGGLE USA inc.



Dr. Gabriele Müller