



**To whom it may concern**

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## **TSE / BSE-Statement**

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

The products comply to the Ph. Eur. General Text 5.2.8: Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products. The General Text is identical with the Note for guidance EMA/410/01 rev. 3, published in the Official Journal of the European Union (2011/C 73/01).

Requirements adequate to the Ph. Eur. General Text 5.2.8 do not exist in the USP-NF.

With reference to Ph. Eur. General Text 5.2.8:

- In the light of the current scientific knowledge and irrespective of the geographical origin, bovine milk is unlikely to present any risk of TSE/BSE contamination.
- The mentioned conditions regarding bovine milk derivatives are fulfilled and therefore, the products are unlikely to present any TSE/BSE risk and shall therefore be considered compliant with the Note for Guidance. The milk is sourced from healthy animals in the same conditions as milk collected for human consumption.

The sourcing of the milk is constantly, officially supervised according to the FDA Pasteurized Milk Ordinance in the current version. Besides milk, other ruminant material incl. calf rennet is not used.

Best regards

**MEGGLE USA inc.**



Dr. Gabriele Müller