

BSE / TSE-Statement

MEGGLE USA Products:

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

The MEGGLE USA Products are lactose as only animal (milk from *Bos taurus*) ingredient. Besides milk, other ruminant material incl. calf rennet is not used.

The mentioned MEGGLE Products are in accordance with 9CFR 94.18 (b) as they are derived from bovines and, as milk products, may be imported into the United States without restriction regarding BSE.

Furthermore, the MEGGLE USA Products complies with 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 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 BSE / TSE contamination.
- It is confirmed that the mentioned conditions regarding bovine milk derivatives are fulfilled and therefore, the products are unlikely to present any BSE / TSE 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 and is constantly officially supervised ("controlled population").