



An die interessierte Partei / To whom it may concern

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Quality Unit / Regulatory Affairs

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## TSE / BSE-Statement

Meggles products:

- Lactose Monohydrate Ph. Eur. / USP-NF / JP: CapsuLac<sup>®</sup> 60, FlowLac<sup>®</sup> 90, FlowLac<sup>®</sup> 100, GranuLac<sup>®</sup> 70, GranuLac<sup>®</sup> 140, GranuLac<sup>®</sup> 200, GranuLac<sup>®</sup> 230, PrismaLac<sup>®</sup> 40, SacheLac<sup>®</sup> 80, SorboLac<sup>®</sup> 400, SpheroLac<sup>®</sup> 100, Tablettose<sup>®</sup> 70, Tablettose<sup>®</sup> 80, Tablettose<sup>®</sup> 100
- Lactose Monohydrate USP-NF / Ph. Eur. / JP: InhaLac<sup>®</sup> 70, InhaLac<sup>®</sup> 120, InhaLac<sup>®</sup> 160, InhaLac<sup>®</sup> 230, InhaLac<sup>®</sup> 250, InhaLac<sup>®</sup> 251, InhaLac<sup>®</sup> 400, InhaLac<sup>®</sup> 500, Lactose monohydrate Low Endotoxin
- Anhydrous Lactose USP-NF / Ph. Eur. / JP: DuraLac<sup>®</sup> H

The product 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).

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.

For production sites Molkerei MEGGLE Wasserburg GmbH & Co.KG, Wasserburg, Germany and Micronisierungs-Kontor Oberrot GmbH, Oberrot, Germany:

The sourcing of the milk is constantly, officially supervised according to EC Hygiene Regulations (EC) No 852/2004 and (EC) No 853/2004. Besides milk, no other ruminant materials with the exception of calf rennet are used. The calf rennet is produced in accordance with the process described in the risk assessment report EMEA/CPMP/BWP/337/02/Public/Final performed by the Committee for Proprietary Medicinal Products (CPMP) and its Biotechnology Working Party (BWP). In accordance with Public Statement EMEA/CPMP/571/02 of February 27 2002 the TSE risk is negligible if the calf rennet is produced in accordance with the process described in this risk assessment.

For production site Agropur inc., Le Sueur, MN, USA:

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.

Freundliche Grüße / Best regards

  
Dr. Stefan Dreiheller