An die interessierte Partei / To whom it may concern

Dr. Stefan Dreiheller
Quality Unit / Regulatory Affairs

Date of issue: 11.12.2019
Page 1
Doc.-No. EIP-1003
Revision 12

TSE / BSE-Statement
MEGGLE products:
- Lactose Monohydrate Ph. Eur. / USP-NF / JP: CapsuLac® 60, FlowLac® 90, FlowLac® 100, GranuLac® 70, GranuLac® 140, GranuLac® 200, GranuLac® 230, PrismaLac® 40, SacheLac® 80, SorboLac® 400, SpheroLac® 100, Tablettose® 70, Tablettose® 80, Tablettose® 100
- Anhydrous Lactose USP-NF / Ph. Eur. / JP: DuraLac® H


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.

Regarding the production sites located in 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.

Regarding the production sites located in the United States of America:
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

Molkerei MEGGLE Wasserburg GmbH & Co. KG

Dr. Stefan Dreiheller