



An die interessierte Partei / To whom it may concern

Dr. Stefan Dreiheller
Quality Unit / Regulatory Affairs

Date of issue: 02.09.2016
Page 1/1
Doc.-No. EIP-2003-E
Revision 3

TSE / BSE-Statement

Meggle products:

Co-processed excipients: Cellactose® 80

This statement is valid for all deliveries.

The product is a co-processed excipient and a spray dried mixture of 75 parts Lactose Monohydrate Ph. Eur. / USP-NF / JP and 25 parts Cellulose Powder Ph. Eur. / USP-NF / JP.

Starting material Lactose Monohydrate Ph. Eur. / USP-NF / JP

The starting material 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.
- It is confirmed that 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 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.

Starting material Cellulose Powder Ph. Eur. / USP-NF / JP

The starting material is not of animal origin.

Freundliche Grüße / Best regards

Dr. Stefan Dreiheller