

Wasserburg, 01.01.2010
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Ref.: Compliance with TSE Directive 2001/83/EC and EMEA/410/01 rev 2 including Public Statement EMEA/CPMP/571/02 of February 27 2002 and MRFG Report of 27 May 2002 (excluding special veterinary medicinal products submitted to EMEA/CVMP/121/01)
Meggle products: **Lactose Monohydrate Ph.Eur.**

To whom it may concern,

with reference to Amending Directive 2001/83/EC and corresponding guideline (EMEA/410/01 rev 2) milk is unlikely to present any risk of TSE contamination in the light of the current scientific knowledge and irrespective of the geographical origin.

Calf rennet used in production of raw material whey has been submitted to risk assessment by the European Agency for the Evaluation of Medicinal Products (EMA). The results of this risk assessment are published in Public Statement EMEA/CPMP/571/02 of February 27 2002.

We herewith certify that the milk is sourced from healthy animals in the same conditions as milk collected for human consumption (EMEA/410/01 rev 2) and the lactose is prepared without the use of other ruminant materials than calf rennet. The calf rennet is in accordance with Public Statement EMEA/CPMP/571/02 of February 27 2002. The sourcing of the milk is constantly, officially supervised according to EC Hygiene Regulations (EC) No 852/2004 and (EC) No 853/2004.

Molkerei Meggle Wasserburg GmbH & Co. KG confirms that Meggle Pharmaceutical Lactose is produced in accordance with the general procedure published in the journal "Die Pharmazeutische Industrie" Vol. 56, (1994) No. 9, p. 835. The supreme drugs authority of Germany (Bundesinstitut für Arzneimittel und Medizinprodukte) evaluated the above mentioned process as sure. This was published in the Official Journal of Germany (Bundesanzeiger Nr. 33, P. 1545, February 16th 1996).

Best regards

A handwritten signature in purple ink that reads "T. Schmidt".

Molkerei Meggle Wasserburg
GmbH & Co. KG
Quality Assurance