# BSE - Statement

Product group: Lactose and Inhalation
Brand name: Lactochem®, Lactohale®, Lactopress®,Pharmatose®, Respitose®, SuperTab®


Dear Customer,

We herewith declare that our pharmaceutical grade lactose products have been produced from milk, that has been sourced from healthy cows in the same conditions as milk collected for human consumption. The sourcing of milk is supervised constantly by the competent authorities according to the EC milk hygiene Regulation 853/2004. Milk has been categorized by the Committee for Proprietary Medicinal Products (CPMP) and Committee for Veterinary Medical Products (CVMP) in its Guideline EMA/410/01 rev.3 as "Category IB: "Lower-infectivity tissues".
Our pharmaceutical grade lactose has been prepared, without the use of other ruminant material than calf rennet, according to the description as published in Public Statement EMEA/CPMP/571/02 of 27 February 2002. This Public Statement was, among others, based on EMEA/CPMP/BWP/337/02 and states the following:
"Taking all these factors and the scientific assessment performed by the Biotech Working Party into consideration, the Committee for Proprietary Medicinal Products (CPMP) concludes that **the BSE-risk in pharmaceutical grade lactose is negligible**.
Therefore our products mentioned above are considered safe regarding TSE."

Country/regulation specific BSE/TSE-Statements are available on request.

This statement substitutes all previous versions issued for the brand names mentioned above.
We trust this information, which is made up to the best of our knowledge, will be helpful to you.

With kindest regards,

**Name** : Armand M. Janssen
**Job title** : QA Regulatory Affairs Officer
**Signature** :

This document is controlled by a validated, electronic system and is valid without signature.
The above facsimile signature is only for display.

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