BSE – Statement

Information for Japan / Canada

Product group:	Lactose and Inhalation
Brand name:	Lactochem®, Lactohale®, Lactopress®, Lactose FC, Pharmatose®, Respitose®, SuperTab®, Wynhale™
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Dear Customer,

We hereby certify that the milk used for the manufacturing of our pharmaceutical grade lactose is sourced from healthy animals under the same conditions as milk collected for human consumption. The sourcing and processing of the milk is constantly, officially supervised by the relevant Competent Authorities.

No other ruminant or animal materials than calf rennet have been used in the manufacturing of our pharmaceutical grade lactose. The production and/or import of calf rennet complies with the requirements defined in Regulation EC/999/2001 (as amended) and other applicable EU legislation, and is officially supervised by the Competent Authorities. The calf rennet is produced as indicated in the risk assessment report of the CPMP and its Biotechnology Working Party* and complies with the Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 Rev. 3**).

* 22 May 2002; CPMP BWP Public Report on Risk and Regulatory Assessment of Lactose and other products prepared using Calf Rennet. Section 3.3.

** Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 Rev. 3)

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For the legal situation in JAPAN the information in the table below is of importance:

Type of animal-derived material(s) used in production	Animal materials used in the production are cow's milk and in some cases calf rennet. The starting material for the production of pharmaceutical grade lactose are the following: Milk permeate, casein whey/ permeate and cheese whey/ permeate.
Origin of the material (e.g. Bovine, caprine, ovine, porcine, equine, avian)	Milk: Bovine Calf Rennet: Bovine
Country of the original source of material (country from where the animals originated)	Milk: Germany, Belgium, Luxembourg, The Netherlands, and New Zealand. All countries with a "negligible risk" of BSE as indicated in the Commission Decision 2007/453/EC (as amended). Vells (abomasa) used in the manufacturing of calf rennet: As certified by rennet producers rennet is sourced from areas with a "controlled risk" or "negligible risk" of BSE as indicated in the Commission Decision 2007/453/EC (as amended). In practice, rennet producers acquire vells for the production of rennet only from the following countries: Germany, the Netherlands, Belgium, France, Canada, USA, New Zealand, and Australia.
The quality system of DFE Pharma incorporates the following standards:	ISO 9001 Good Manufacturing Practices Guide for Bulk Pharmaceutical Excipients (IPEC). A cGMP system based on ICH Q7 (as revised).
Batch separation	Unprocessed pharmaceutical grade lactose is manufactured in a semi-continuous process from milk permeate, casein whey/ permeate and cheese whey/ permeate in dedicated facilities. Batches are defined as the lactose produced between two cleanings. Further processing is done in facilities that are in general dedicated to the processing of lactose. Occasionally, other products are

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	mixed with lactose. In those cases an extensive cleaning is performed.
Traceability	Traceability is installed according to ISO 9001. Correspondingly all suppliers of raw material also have a quality system in place including traceability. Traceability requirements for EU based production sites are laid down as a requirement in Regulation (EC) No 178/2002 (as amended). Traceability requirements for New Zealand based production sites is laid down in the Animal Product Notice on Production, Supply and Processing (as amended) All traceability information has to be made available to the relevant competent authorities on demand.
Age of Animals (Cows)	The calf rennet used in the manufacturing of the raw material whey is derived from calves that are in general less than 12 months of age. Milk can be derived from cows of any age.

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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