Foot and Mouth Disease
(R i n d e r p e s t)

Product group: Lactose and Inhalation

Brand name: Lactohale®, Pharmatose®, SuperTab® and Wynhale™

Manufactured in New Zealand

Document No.: PD-0492

Dear Customer,

Herewith we certify that under the responsibility of DFE Pharma GmbH & Co.KG, Fonterra Cooperative Group Ltd. milk is processed to lactose. The processing takes place in an officially approved establishment, namely:

- Fonterra Ltd (879 Manaia Road, Kapuni, Taranaki, New Zealand) manufacturing Pharmaceutical Grade Lactose

For the above mentioned lactose milk is sourced only in New Zealand. New Zealand have officially been declared Foot and Mouth Disease free as well as free of Rinderpest by the Office International d' épizoties (OIE). This information can be found on the OIE website (links at the end of the document).

In addition, there is a national monitoring program 'New Zealand's animal health situation' including Foot and Mouth Disease which is covered by the New Zealand Ministry for Primary Industries (MPI-formerly MAF/NZFSA, effective 30 April 2012). (links at the end of the document).

As per the statement from the above link, the New Zealand Ministry of Primary Industries has declared in this memo the "Absence of specified animal diseases including but not limited to Foot and Mouth Disease and Rinderpest from New Zealand".

New Zealand is officially free of Foot and Mouth disease and Rinderpest for more than 12 months. However, DFE Pharma continues to apply measures to avoid any risk of transmitting these diseases. These measures are:

- All facilities listed above and all Fonterra manufacturing facilities are under the NZ Product Safety Risk Management Program which operates an HACCP including a Risk Organism Response Plan (RORP).
- The raw milk ingredients used to manufacture pharmaceutical grade lactose were initially pasteurized at min. 72°C for 15 seconds, and have undergone an additional treatment of at least 90°C for at least 15 minutes.

DFE Pharma GmbH & Co. KG
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Pharmaceutical grade Lactose is derived from milk. No specified risk materials (as mentioned in the Regulation (EC) 999/2001 as amended) or any proteins derived from them have been used in the preparation of the product.

Shipment of the lactose is executed in new, sealed containers and directly made between our warehouses and to the customer.

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.

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.

Supporting Links

Foot and Mouth Disease:
http://www.oie.int/en/animal-health-in-the-world/official-disease-status/fmd/list-of-fmd-free-members/

Rinderpest:
http://www.oie.int/en/animal-health-in-the-world/official-disease-status/rinderpest/list-of-free-countries-and-territories/

New Zealand's animal health situation:
http://www.biosecurity.govt.nz/files/pests/surv-mgmt/surv/absence-specified-animal-diseases.pdf

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