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

Product group: Lactose and Inhalation

Brand name: Lactochem®, Lactohale®, Lactopress®, Pharmatose®, Respitose®, SuperTab®

Manufactured in the EU

Dear Customer,

Herewith we certify that under the responsibility of DFE Pharma GmbH & Co.KG, FrieslandCampina Domo B.V. and FrieslandCampina DMV B.V. milk is processed to lactose. The processing takes place in officially approved establishments. The Health marks for these establishments are:

- FrieslandCampina Domo B.V. (Needseweg 23, 72701 AB Borculo, The Netherlands): NL Z0199 EC (Manufacturing of pharmaceutical grade lactose)
- DFE Pharma B.V. Pharma Plant Borculo (Needseweg 23, 72701 AB Borculo, The Netherlands): NL Z0984 EC (Manufacturing of pharmaceutical grade lactose)
- DFE Pharma GmbH & Co.KG (Lauenförder Strasse 5, 37176 Nörten-Hardenberg, Germany): DE NI200 EG (Manufacturing of pharmaceutical grade lactose)
- FrieslandCampina DMV Veghel (NCB-Laan 80, 5462GE Veghel, The Netherlands): NL Z0032 EC (Manufacturing of pharmaceutical grade lactose)

For the above mentioned lactose milk is sourced only in Germany, Belgium, Luxembourg and The Netherlands. The lactose is processed in The Netherlands and in Germany for some products (granulation, spray-drying and roller drying). All these countries 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.

The milk/milk product was processed in The Netherlands (and in Germany), regions listed in 9 Code of Federal Regulations 94.1(a)(2) from milk produced in the EU countries mentioned above.
The Netherlands and Germany are regions listed in 9 Code of Federal Regulations 94.1(a)(2) as free of foot-and-mouth disease and Rinderpest. The milk/milk product has never been in any region where foot-and-mouth-disease or Rinderpest exists except when moving under seal as described in 9 Code of Federal Regulations 94.16 (c).

DFE Pharma GmbH & Co. KG
Klever Strasse 187, 47574 Goch, Germany, P.O. Box 20 21 20, 47568 Goch, Germany, T. +49 2823 9288 770, F. +49 2823 9288 7799

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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.

The Netherlands, Germany, Luxembourg and Belgium are 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:

- The above mentioned facilities are under continuous veterinary state control by the Competent Authorities in The Netherlands and Germany.
- The raw milk ingredients used to manufacture pharmaceutical grade lactose were initially pasteurized at 72°C for 15 seconds, and have undergone an additional treatment of at least 95°C for on average 30 minutes.

Shipment of the lactose is executed in new, sealed containers and directly made from our warehouse 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.

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.

DFE Pharma GmbH & Co. KG
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