Foot and Mouth Disease

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

Herewith, we certify that the processing of dairy raw materials to pharmaceutical grade lactose and processing to different lactose grades take place in officially approved establishments. The Health marks for these establishments are:

- FrieslandCampina Ingredients B.V. (Needseweg 23, 72701 AB Borculo, The Netherlands): NL Z0199 EC.
- DFE Pharma B.V. Pharma Plant (Needseweg 23, 72701 AB Borculo, The Netherlands): NL Z0984 EC.
- DFE Pharma GmbH & Co.KG (Lauenförder Strasse 5, 37176 Nörten-Hardenberg, Germany): DE NI200 EG.
- FrieslandCampina DMV B.V. (NCB-Laan 80, 5462GE Veghel, The Netherlands): NL Z0032 EC.
- Fonterra Limited (879 Manaia Road, Kaponga, New Zealand): NZ 9370.
- DFE Pharma(NZ) Limited (879 Manaia Road, Kaponga, New Zealand): NZ 9369.

Milk is sourced from The Netherlands, Belgium, and New Zealand. All the aforementioned countries have officially been declared Foot and Mouth Disease free by the World Organisation for Animal Health (WOAH). This information can be found on the WOAH website.

All the countries mentioned above are regions listed in 9 Code of Federal Regulations 94.1(a)(2) as free of foot-and-mouth disease. The milk/milk product have never been in any region where foot-and-mouth-disease exists, except when moving under seal as described in 9 Code of Federal Regulations 94.16 (c).

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 relevant Competent Authorities.
- The raw milk ingredients used to manufacture pharmaceutical grade lactose were initially pasteurized at 72°C for 15 seconds, and were subjected to an additional treatment of:
  - at least 95°C for on average 30 minutes in Europe.
  - at least 90°C for at least 15 minutes in New Zealand.

  The aforementioned heat treatment meets the requirements of risk-mitigating treatments of milk and milk products in accordance with Annex VII in Reg. (EU) 2020/687.
- Shipment of the lactose is executed in new, sealed containers and directly made from our warehouse to the customer.

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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 : Lorina Bisharat
Job title : Regulatory Affairs Manager
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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