Requirements of the TGA

Product group:	Lactose and Inhalation	
Brand name:	Lactochem®, Lactohale®, Lactopress®, Lactose FC, Pharmatose®, Respitose®, SuperTab®	
Document No.:	PD-0584	

Dear Customer,

Introduction:
The Therapeutic Goods Administration requires that products of animal origin (http://www.tga.gov.au/industry/tse-approach.htm) comply with the Ph. Eur. general monograph 1483: "Products with risk of transmitting agents of animal spongiform encephalopathies", including General Text "5.2.8: Minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products." (This document is equal to **Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev.3);** (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003700.pdf)
For low risk materials this can be done by a self-assessment. Eligible for self-assessment are (among others):

1. the final therapeutic goods are for oral or topical applications only;
   and
2. contain ruminant derived materials that:
   a. are one of the following materials, and are compliant with the relevant sections of the Ph. Eur. monograph:

      - bovine milk and milk derivatives

Statements in relationship to the self-assessment requirements of the TGA:

We herewith certify that all pharmaceutical lactose qualities manufactured under the responsibility of DFE Pharma and FrieslandCampina DMV BV are prepared in accordance with the relevant requirements laid down in Note for Guidance EMA/410/01 rev 3*:

- We, DFE Pharma, confirm that the lactose complies with the Ph. Eur general monograph 1483: Products with risk of transmitting agents of animal spongiform encephalopathies, including General Text 5.2.8: Minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products.
- Milk is unlikely to present any risk of TSE contamination in the light of the current scientific knowledge and irrespective of the geographical origin.
- The lactose is prepared without the use of other ruminant materials than milk and calf rennet.

DFE Pharma GmbH & Co. KG
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- We herewith certify that the milk is sourced from healthy animals in the same conditions as milk collected for human consumption. The sourcing of the milk is constantly, officially supervised according to the EU food hygiene regulations in force since 1 January 2006. The milk for the manufacturing of pharmaceutical grade lactose in our facilities in the European Union is sourced from Germany, Belgium, Luxembourg and The Netherlands.
- The milk for the manufacturing of pharmaceutical grade lactose in our facilities in the New Zealand is sourced from New Zealand. The New Zealand establishments where lactose is produced are on the list of approved dairy establishments of the European Union.
- The calf rennet is typically sourced from abomasa from Germany, the Netherlands, Belgium, France, Canada, USA, New Zealand and Australia.
- The current list of Geographic BSE Risk (GBR) according to the OIE can be found at (5 November 2014): http://www.oie.int/animal-health-in-the-world/official-disease-status/bse/list-of-bse-risk-status/
  All countries mentioned above are in the classes "negligible BSE risk" or "controlled BSE risk"
- The requirements for a self-assessment as mentioned in http://www.tga.gov.au/transmissible-spongiform-encephalopathies-tse-tga-approach-minimising-risk-exposure are met for pharmaceutical grade lactose. This is documented in two reports viz.:

  1 THE SAFETY OF ANIMAL RENNET IN REGARD TORISKS FROM ANIMAL TSE AND BSE IN PARTICULAR (2002) from the Scientific Steering Committee of the European Union (https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_ssc_out265_en.pdf)

  2 Public Statement: Lactose Prepared Using Calf Rennet: Risk Assessment in relationship to Bovine Spongiform Encephalopathies (BSE) (www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500017496)

- The production 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.
- We confirm that the above mentioned product is produced in accordance with the process described in the risk assessment report of the CPMP Biotech Working Party and that is published in "Die Pharmazeutische Industrie" Vol. 56, (1994) No. 9, p. 835. This process is the one considered by the BioTech Working Party of the CPMP and the Scientific Steering Committee in 2002.
- DFE Pharma manufactures excipients (including pharmaceutical grade lactose) according IPEC/PQG GMP for excipients. This system may be audited by competent authorities (like the TGA) and documented evidence to show compliance is available for review on site.

- For the raw materials used the tracking and tracing requirements of the European General Food Law (Regulation (EC) 178/2002) apply. This means that products can be followed back in the chain (one) step by step and that records of compliance are available.

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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