Requirements of the TGA

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

Introduction:
The Therapeutic Goods Administration requires that products of animal origin (https://www.tga.gov.au/resources/guidance/transmissible-spongiform-encephalopathies-tse-tga-approach-minimising-risk-exposure) comply with 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.". Ph. Eur. General Text 5.2.8 is identical to the EMA Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev.3) (https://www.ema.europa.eu/en/minimising-risk-transmitting-animal-spongiform-encephalopathy-agents-human-veterinary-medicinal-products-scientific-guideline).

For low risk materials, compliance may be demonstrated by industry 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 GmbH & Co. KG are prepared in accordance with the relevant requirements laid down in Note for Guidance EMA/410/01 rev 3* and shall be considered compliant with the Note for Guidance:

- 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.
- The lactose is prepared without the use of other ruminant materials than milk and in some cases calf rennet.
- Bovine 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 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

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grade lactose in our facilities in the European Union is sourced from Germany, Belgium 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 current BSE risk status of countries is based on the official classifications published by the World Organisation for Animal Health (WOAH). The current list is available at: https://www.woah.org/en/disease/bovine-spongiform-encephalopathy/
  All countries mentioned above are in the classes "negligible BSE risk".
- Calf rennet is not used in the lactose manufacturing processes at the EU production sites. Where calf rennet is used in New Zealand it is typically sourced from abomasa from New Zealand and Australia.
- The calf rennet is produced in accordance with the process described in the risk assessment report of the CPMP Biotechnology Working Party https://www.ema.europa.eu/en/risk-regulatory-assessment-lactose-other-products-prepared-using-calf-rennet-scientific-guideline
- 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.
- The lactose manufacturing process is 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. https://www.ema.europa.eu/en/risk-regulatory-assessment-lactose-other-products-prepared-using-calf-rennet-scientific-guideline
- The applicable TGA self-assessment requirements for pharmaceutical grade lactose as mentioned in https://www.tga.gov.au/resources/guidance/transmissible-spongiform-encephalopathies-tse-tga-approach-minimising-risk-exposure are met. The assessment is supported by the following scientific documents:

  1. "The safety of animal rennet in regard to risks from animal TSE and BSE in particular" (2002), Scientific Steering Committee of the European Union. (https://food.ec.europa.eu/document/download/b5a75fbc-7fe9-487d-9312-152883c7dee2_en?filename=sci-com_ssc_out265_en.pdf&prefLang=ga)
  2. EMA public statement, "Lactose prepared using calf rennet: risk assessment in relation to bovine spongiform encephalopathies (BSE)" (https://www.ema.europa.eu/en/documents/public-statement/public-statement-lactose-prepared-using-calf-rennet-risk-assessment-relationship-bovine-spongiform-encephalopathies-bse_en.pdf)
- 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.

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- 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 : Lorina Bisharat
Job title : Regulatory Affairs Manager
Signature :

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