Viral Safety-Statement

Product group: Lactose and Inhalation

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

Document No.: PD-0116

Dear Customer,

The aforementioned DFE Pharma lactose products are pharmaceutical grade lactose products made from cow's milk (cow= Bos primigenius taurus).

As defined in Note for Guidance CPMP/BWP/268/95 (Validation of virus removal and inactivation procedures), virus validation studies are only necessary for the following types of products:

- products derived from in vitro cell lines of human and animal origin,
- products derived from in vivo culture of cell lines or from organs or tissues of human or animal origin,
- products derived from blood or urine or other biological fluids of human or animal origin.

In chapter 2 of the Note for Guidance, some cases of sources of viral contamination are mentioned. None of the contamination sources applies to milk as the source material for lactose.

Furthermore, the milk used for the manufacture of lactose complies with the current health regulations in the EU. This means that the milk is derived from healthy cows and that it is fit for human consumption. The sourcing and processing of the milk is constantly, and officially supervised by competent authorities.

For the manufacture of lactose no virus validation studies have been performed, because:

- The source material milk is not considered to be an (important) source of viruses, and is fit for human consumption,
- Virus validation studies could compromise the safety of our manufacturing equipment,
- All milk undergoes pasteurization by a treatment involving a high temperature for a short time (at least 72 °C for 15 seconds) in accordance with Regulation (EC) No 853/2004, Annex III, Section IX, Chapter II, II.1(a).
- In addition, our lactose is subject to a second heat treatment which exceeds the minimum pasteurization condition (at least 72 °C for 15 seconds), whereby the product is kept at:
  - at least 95°C for on average 30 minutes in Europe
  - at least 90°C for at least 15 minutes in New Zealand
- It is a well-known fact that double pasteurization (15 seconds at 72 °C) is a recognized risk-mitigating treatment and provides sufficient guarantees with regard to the destruction of, for example, Foot-and-Mouth Disease virus in milk and milk products, in accordance with Delegated Regulation (EU) 2020/687. Many studies have been performed on this subject.

Based on the information above, there is no credible risk of viral contamination associated with the manufacture of lactose.

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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