

Lactose IID Statement

Product group: Lactose and Inhalation
Brand name: SuperTab®, Pharmatose®,
Respitose®, Lactochem®,
Lactohale®, Lactopress®
Product description: lactose monohydrate,
anhydrous and granulated
Document No.: PD-0580 Page 1 of 1

Dear Customer,

SuperTab®, Lactochem®, Lactohale®, Lactopress®, Pharmatose® and Respitose® are brand names for DFE's pharmaceutical grade lactose. It complies with the requirements of the current version of the USP-NF, Ph. Eur. and JP monographs.

Lactose and Lactitol are safe ingredients and are accepted by FDA as exemplified by the number of applications where lactose is used as a filler/binder. Furthermore, lactose is mentioned in 21 CFR168.122 which implies that it is Generally Recognized as Safe (GRAS).

Limits in the inactive substance database (IID) are mentioned for the excipients as written by applicants "as it is" in their filing e.g. anhydrous lactose, monohydrate or only lactose, and lactitol. After application both lactose and lactose anhydrous will dissolve and have exactly the same biological properties.

We trust this information, which is made up to the best of our knowledge, will be helpful to you.

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.