



TGO Order No. 91/92

Absence of Antibiotics

Product group: Lactose, Inhalation

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

Document No.: PD-0738 Page 1 of 1

Dear Customer,

Referring to the Therapeutic Goods Order No. 91/92 of the Australian Therapeutic Goods Administration, we herewith certify that there are no residues of antibiotics present in our pharmaceutical grade lactose products produced in the European Union and New Zealand. No labelling of antibiotic residues is thus required.

Lactose is isolated from milk. For milk there are stringent legal requirements for the absence of antibiotics. There is an extensive monitoring program in place to control residual antibiotic levels in milk. Furthermore, lactose is isolated from milk using a robust dual step crystallization. When lactose products are monitored for the absence of antibiotics, this absence is confirmed by not being able to detect antibiotic residues. Due to the fact that every analytical test has a limit of detection, the absence of antibiotic residues is declared as a concentration below the limit of detection. See PD-0123 Contaminants Statement – EU.

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.