TGO Order No. 91/92

Absence of Antibiotics

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

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

The absence of antibiotic residues in lactose products is supported by monitoring of the raw milk. 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, based on raw milk monitoring data. 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 : Lorina Bisharat
Job title : Regulatory Affairs Manager
Signature :

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The above facsimile signature is only for display.

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