TGO Order No. 91/92

Absence of Declaration Substances

Product group: Lactose, Inhalation

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

Dear Customer,

Referring to the Therapeutic Goods Order No. 91/92 of the Australian Therapeutic Goods Administration, we herewith confirm that:

- The substances mentioned in the table below are not present in our pharmaceutical grade lactose products produced in the European Union and New Zealand, with the exception of SuperTab® 40LL which contains in addition 5% lactitol (sugar alcohol).
- All products mentioned above in the brand name section contain lactose/sugars/milk products.

Substances requiring declaration under Therapeutic Goods Order No. 91/92 of the Australian Therapeutic Goods Administration		
aspartame	antibiotics	benzoates
crustacea and crustacean products	egg, egg products	ethanol
fish and fish products	galactose	gluten
hydroxybenzoic acid esters	peanut and peanut products	phenylalanine
pollen	potassium compounds	propolis
royal jelly	saccharin	sesame seeds and sesame seed products
sodium compounds	soya beans and soya bean products	sorbic acid and sorbic acid salts
sucralose	sugar alcohols (present in SuperTab® 40LL)	sulfites
tartrazine	tree nuts and tree nut products	

For the absence of antibiotic residues in pharmaceutical grade lactose there is a separate document (PD-0738) providing more details.

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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