

TGO Order No. 91/92

Absence of Allergens

Product group:

Lactose, Inhalation

Brand name:

Pharmatose®, SuperTab®,

Lactopress®, Lactochem®

Respitose®, Lactohale®

Document No.:

PD-0737

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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 the substances mentioned in the table below are not present in our pharmaceutical grade lactose products produced in the European Union and New Zealand. There are two exceptions;

- All products mentioned above contain lactose/sugars/milk products;
- SuperTab® 4oLL contains in addition 5% lactitol (sugar alcohol).

Allergens according Therapeutic Goods Order No. 91 of the Australian Therapeutic Goods		
Administration		
aspartame	antibiotics	benzoates
crustacea and crustacean	egg, egg products	ethanol
products		
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	sorbic acid and sorbic acid salts
	products	
sucralose	sugar alcohols (present in	sulfites
	SuperTab [®] 4oLL)	
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

: 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.