

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

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