Contaminants -Statement (NZ)

Product group: Lactose

Brand name: Lactohale®,Pharmatose® & SuperTab®

Produced in New Zealand

Dear Customer,

DFE Pharma supplies pharmaceutical grade lactose from production sites located in Europe and in New Zealand.

We hereby certify that all our pharmaceutical grade lactose qualities produced in New Zealand are sourced solely from the milk of New Zealand dairy cows.
The sourcing and processing of the milk in New Zealand is constantly, officially supervised by competent authorities.

The milk used for lactose production:

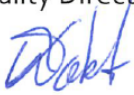
- does not contain any pesticides exceeding the limits specified in the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards regulated by the Ministry for Primary Industries (MPI-formerly **NZFSA**/MAF). [link 1]
- conforms to the requirements of NZFSA and does not contain any penicillin or equivalent/ml exceeding the limits specified in Approved Criteria for General Dairy Processing DPC1, DPC2. [link 1]

In addition we confirm that no hormones are used in the production process of our pharmaceutical grade lactose.
This includes the non-use of any amount of Estrogens (including Estron, Estradiol, Estriol), Progesterone and Testosterone.

Pharmaceutical grade lactose as produced in New Zealand is suitable for human use in oral solid dosage forms.

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.

Name : Wilbert van de Rakt
Job title : Quality Director
Signature :



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The above facsimile signature is only for display.

Link 1: http://www.foodsafety.govt.nz/elibrary/industry/register-list-mrl-agricultural-compounds.htm

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