# Origin of Milk-Statement

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

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

We hereby certify that all our pharmaceutical grade lactose qualities produced in Europe, with the exception of Lactohale® 300 (Article code: 1217617), are made from cow's milk (cow= *Bos primigenius taurus*) that is, according to our quality procedures, exclusively sourced from The Netherlands, Belgium and Germany. Lactohale® 300 (Article code: 1217617) produced in Europe is made from cow's milk sourced in New Zealand. All our pharmaceutical grade lactose qualities produced in New Zealand is sourced solely from the milk of New Zealand dairy cows.

For all production sites in Europe and New Zealand the milk is sourced from healthy bovine animals in the same condition as milk collected for human consumption. The average lifespan of cows producing the milk from which our pharmaceutical grade lactose is produced is 6 years.

The sourcing and processing of the milk is constantly, and officially supervised by competent authorities.

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 Estrone, Estradiol, Estriol), Progesterone, Testosterone and rBST (recombinant bovine somatotrophin).

Pharmaceutical grade lactose as manufactured by DFE Pharma is suitable for human use in solid doses and inhalation devices (Respitose®, Lactohale®).

This statement substitutes all previous versions issued for the brand names mentioned above.

We trust that this information, which is made up to the best of our knowledge, will be helpful to you.

**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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