

Product group: Lactose and Inhalation

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

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Dear Customer,

DFE Pharma GmbH & Co. KG has defined a shelf life for all of its products based on a stability testing program. DFE Pharma guarantees that its products comply with all specifications up until the end of their shelf life period (the expiry date / re-test date respectively) under the defined storage conditions. Dates of production and expiry date / re-test date respectively are printed on every packing unit and on the corresponding Certificate of Analysis.

For pharmaceutical grade lactose products the established shelf life is listed below:

| Brand Name                                                   | Shelf Life | Expressed as<br>Expiry Date / Re-test<br>Date |
|--------------------------------------------------------------|------------|-----------------------------------------------|
| Pharmatose®                                                  | 3 years    | Expiry Date                                   |
| Respitose®                                                   | 3 years    | Expiry Date                                   |
| SuperTab® AN                                                 | 2 years    | Expiry Date                                   |
| SuperTab® SD EU                                              | 2 years    | Expiry Date                                   |
| SuperTab® SD NZ                                              | 3 years    | Expiry Date                                   |
| SuperTab® GR                                                 | 3 years    | Expiry Date                                   |
| SuperTab® 24AN                                               | 2 years    | Expiry Date                                   |
| SuperTab® 40LL                                               | 3 years    | Re-test Date                                  |
| SuperTab® 50 ODT                                             | 3 years    | Re-test Date                                  |
| Lactohale® NZ                                                | 3 years    | Expiry Date                                   |
| Lactohale® 100/200 grades                                    | 3 years    | Re-test Date                                  |
| Lactohale® 300 (will be discontinued)                        | 6 months   | Re-test Date                                  |
| Lactohale® 300 micronized                                    | 1 year     | Re-test Date                                  |
| Lactohale® 400                                               | 1 year     | Re-test Date                                  |
| Lactochem®                                                   | 3 years    | Re-test Date                                  |
| Lactochem® Extra Fine Powder<br>Lactochem® Super Fine Powder | 1 year     | Re-test Date                                  |
| Lactochem® Microfine                                         | 6 months   | Re-test Date                                  |
| Lactopress® AN                                               | 2 years    | Re-test Date                                  |
| Lactopress® GR                                               | 3 years    | Expiry Date                                   |
| Lactopress® SD                                               | 3 years    | Re-test Date                                  |

SD: spray dried AN: anhydrous GR: granulated

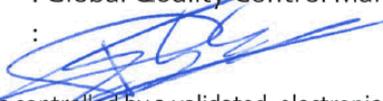
Shelf life of customized products may differ from the above list.

## Shelf Life – Statement

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The shelf life of the products as listed above is derived from results of stability studies. DFE Pharma does not perform re-testing at the end of the shelf life period. It is the customer's responsibility to determine if the product can still be used in their application after the end of the shelf life period.

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** : Peter Ebben  
**Job title** : Global Quality Control Manager  
**Signature** : 

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