



Shelf Life – Statement

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 Expiry Date / Re-test 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 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.



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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 :

A blue ink facsimile signature of Peter Ebben, written in a cursive style.

This document is controlled by a validated, electronic system and is valid without signature.
The above facsimile signature is only for display.