STATEMENT

Melamine and Cyanuric Acid

Product group: Lactose, inhalation
Brand name: Lactochem®, Lactohale®, Lactopress®,Pharmatose®, Respitose®, SuperTab®

Dear Customer,

Herewith we declare that Melamine and Cyanuric Acid are not detected in any pharmaceutical grade lactose products sold and marketed by DFE Pharma GmbH & Co.KG.

These products are not covered by the definition of "at-risk component" as referenced in footnote 3 of the FDA Guidance for Industry: Pharmaceutical Components at Risk for Melamine Contamination. However, lactose is listed as an example of "at-risk pharmaceutical component" as the sourced starting material can be derived from milk.

In the countries supplying milk and whey for the production of DFE Pharma lactose, no cases of adulteration with melamine have occurred. Monitoring is part of the testing for raw milk carried out by national authorities.

Additionally, a risk assessment was performed on raw material, contact material and production equipment to identify if there could be any in-process contamination risk. As melamine is not used as an ingredient, processing aid and additive, or in any other way, there is no possibility of contamination in the manufacturing process.

Nevertheless, monitoring is in place to confirm the safety of lactose products. Monitoring is performed by our CMO (production site of finished lactose products and raw material (lactose) supplier) at the raw material level (testing of raw milk) and/ or through testing of lactose products. DFE Pharma does not perform additional testing of its lactose products for melamine. However, based on the reasons outlined above, there is no risk of melamine contamination in the production process at DFE Pharma.

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 : 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.

DFE Pharma GmbH & Co. KG
Klever Strasse 187, 47574 Goch, Germany, P.O. Box 20 21 20, 47568 Goch, Germany, T. +49 2823 9288 770, F. +49 2823 9288 7799

The document is an uncontrolled copy and is valid only at the time of distribution. Timestamp: 08-11-2026; 16:56 UTC

Release date: 12-05-2026