



STATEMENT

Absence of Melamine and Cyanuric Acid

Product group: Lactose
Brand name: Lactochem®, Lactohale®,
Lactopress®, Pharmatose®,
Respitose®, SuperTab®
Document No.: PD-0543 Page 1 of 2

Dear Customer,

Herewith we declare that in all pharmaceutical grade lactose products sold and marketed by DFE Pharma GmbH & Co.KG Melamine and Cyanuric Acid are absent.

Historical perspective;

In 2008/2009 melamine was found as an adulteration in dairy products produced from Chinese cow's milk.

A Melamine* testing program was conducted in 2008 and 2009 on product samples utilizing independent accredited laboratories in Europe (TNO, The Netherlands) and in New Zealand (ASUREQuality, New Zealand). This testing has been undertaken using the following method: Liquid Chromatograph Tandem Mass Spectrometry (LC-MS/MS).

Both laboratories reported that in pharmaceutical grade lactose batches no melamine* was found at the current highest sensitivity level of 50 ppb.

Risk assessment;

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 DFE Pharma manufacturing process.

For dairy based raw materials sourced outside DFE Pharma, documentation from the supplier is requested on the absence of melamine and cyanuric acid.

Please note: Melamine* is water soluble. Pharmaceutical grade lactose is physically extracted from (cheese) whey / whey permeate by crystallization and by further washing and refining steps. If raw milk would be contaminated with 1 ppb of melamine* this would result into 0.02 ppb in the lactose fraction.

*: Melamine and related analogs (e.g. melamine and cyanuric acid)

Monitoring;

In the countries where the milk and whey for production of DFE Pharma lactose is sampled, no instances of adulteration with melamine* have occurred. Monitoring is in place to confirm the safety of the produced dairy products including lactose. DFE Pharma does not test individual batches of its lactose products for the absence of melamine*. Monitoring is part of the testing for raw milk. Furthermore, there is a monitoring program in place including raw materials (whey) and dairy based end products (lactose).



STATEMENT

Absence of Melamine and Cyanuric Acid

Product group: Lactose

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

Document No.: PD-0543 Page 2 of 2

This statement substitutes all previous statements with the subject "Absence of Melamine and Cyanuric Acid" issued for the brand names mentioned above.

We trust that by this document, which is made up to the best of our knowledge, we have informed you sufficiently. In case of any question please don't hesitate to contact your sales representative.

Yours truly,

Name : Armand M. Janssen
Job title : QA Regulatory Affairs Officer
Signature : 

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