Absence of Melamine

Product group: MCC, Starch, Biopharma and Superdisintegrants

Brand name: Pharmacel®, Solani Amylum, Prejel PA5 PH, Primellose®, Primojel®, BioHale® Sucrose, BioHale® Trehalose Dihydrate, and Pharmacel® sMCC

Dear Customer,

DFE Pharma GmbH & Co. KG is a global excipient supplier with production sites located in Europe, New Zealand and India.

Herewith we confirm that no melamine is used in manufacturing of our products.
To the best of our knowledge **no melamine is present in**:

- Primojel® (Sodium Starch Glycolate type A),
- Primellose® (Croscarmellose Sodium),
- Pharmacel® (Microcrystalline Cellulose),
- Pharmacel® sMCC (Silicified Microcrystalline Cellulose)
- Solani Amylum (Native potato starch),
- Prejel PA5 PH (Pregelatinized potato starch).
- BioHale® Sucrose (Sucrose)
- BioHale® Trehalose Dihydrate (Trehalose Dihydrate)

Our products listed above do not fall into the scope of "*at-risk component for melamine contamination*" as laid down in FDA Guidance for Industry - Pharmaceutical Components at Risk for Melamine Contamination, August 2009.

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
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