Nano Materials

Product group: MCC, Starch, Biopharma, Lactose, Inhalation & Superdisintegrants

Brand name: Pharmacel®, Solani Amylum, Prejel PA5 PH, Lactochem®, Lactohale®, Lactopress®, Lactose HMS Impalpable®, Pharmatose®, Respitose®, SuperTab®, Primojel®, Primellose®, BioHale® Sucrose and BioHale® Trehalose Dihydrate

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Dear Customer,

There is ongoing discussion on definitions for nanomaterials, particularly in the European Union. The challenge is that the definition should be as broad to include all nanomaterials and at the same time be as small to avoid that non nanomaterials fall into the definition. An overview of the definitions can be found in the following article:
https://www.sciencedirect.com/science/article/pii/S0273230015300088

Some critical aspects of the definitions are:

- Size limits: e.g., 100 nm
- Percentage of total particles that are in the nano range; in most cases 50% is used
- Intentional manufacturing at nano scale.

The mentioned DFE Pharma products are not intentionally manufactured to be in the nanoscale. The particle size distribution of our products can be found in the related product specification and on our website, where applicable (https://www.dfepharma.com/excipients).

From this, it is clear that our excipients do not meet any of the following definitions:

- Novel food regulation: Regulation (EU) 2015/2283
- Food Labelling; Regulation (EC) 1169/2011
- Commission Recommendation 2022/C229/01
- USP-NF General Chapter ⟨1153⟩ Drug Products Containing Nanomaterials

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.

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