

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 a lot of discussion on definitions for nanomaterials, especially in the European Union. The issue 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.

For all DFE Pharma products the intention is not to produce nano particles.

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 none of our excipients fall in any of the definitions used in the European Union.

Nano materials are referred to in the European Union food legislation in:

- Novel food regulation: Regulation (EC) 2015/2283
- Food Labelling; Regulation (EC) 1169/2011
- Commission Recommendation 2011/696/EU

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.