Mutagenic Impurities

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

Brand name: Lactochem®, Lactohale®, Lactopress®, Nutracel®, Pharmacel®, Pharmatose®, Pharmacel® sMCC 90, Prejel PA5 PH, Primellose®, Respitose®, Solani Amylum, SuperStarch 200, SuperTab®, BioHale® Sucrose, BioHale® Trehalose Dihydrate,

Dear Customer,

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

Our products have a long history of safe use as pharmaceutical excipients. In line with ICH M7 (R2) "Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals for Human Use", it is noted that this guideline is not intended for excipients used in existing marketed products.

Nevertheless, DFE Pharma confirms that substances that can cause DNA damage leading to mutations and therefore potentially causing cancer, i.e. DNA-reactive (mutagenic) substances, are not used in the manufacturing process of our pharmaceutical excipients.

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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