



Product group: MCC, Starch, Lactose, Inhalation and Superdisintegrants

All products manufactured by DMV-Fonterra Excipients GmbH & Co. KG

To whom it may concern

Our Reference: IL15009
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Subject: Genotoxic Impurities

Dear Customer,

DFE Pharma (legal name: DMV-Fonterra Excipients GmbH & Co. KG) is a global excipient supplier with production sites located in Europe, New Zealand and India.

We, DFE Pharma, herewith declare that no substances are used which are capable of altering DNA, thereby causing cancer or mutation ("Genotoxic Impurities") in the manufacture of any of our pharmaceutical excipients.

This statement substitutes all previous statements with the subject "Genotoxic Impurities" issued for all products manufactured by DMV-Fonterra Excipients GmbH & Co. KG.

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 sincerely,

Armand M. Janssen
Manager Regulatory Affairs

The information given in this document is based on our current knowledge and experience, however without any obligation and without any assumption of liability on our part. The information may be used at your discretion and risk. The statement was provided as an answer to a specific question at a specific time. It is not a controlled document and will not be updated, reflecting changes in DFE Pharma controlled documents or scientific evidence. It is in the responsibility of the users of the statement to convince them of the actuality.

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All offers for the sale and purchase of products by DMV-Fonterra Excipients GmbH & Co. KG, and all agreements with respect thereto, are subject to the general conditions of DMV-Fonterra Excipients GmbH & Co. KG. A copy of these conditions will be sent upon request and can be consulted at www.dfepharma.com