



GMO (Modified Organisms)

Product group: Lactose and Inhalation
Brand name: Lactochem®, Lactohale®,
Lactopress®,
Pharmatose®, Respitose®
and SuperTab®

Product description: Lactose monohydrate and
anhydrous lactose

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Dear Customer,

Herewith we confirm to you that we do not use genetically modified organisms (GMO's) or GMO derived products in the production of our pharmaceutical grade lactose qualities.

Referring to the current legislation in the European Union* the products referenced above in section "Brand names" do not have to be labeled as GMO or GMO derived.

* Relevant EU legislation:

Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed

Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC

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 : Armand M. Janssen
Job title : QA Regulatory Affairs Officer
Signature : A handwritten signature in blue ink, appearing to read 'Janssen'.

This document is controlled by a validated, electronic system and is valid without signature.
The above facsimile signature is only for display.