



G M O (Modified Organisms)

Product group: Superdisintegrants
Brand name: Primellose®
Product description: Croscarmellose sodium
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Dear Customer,

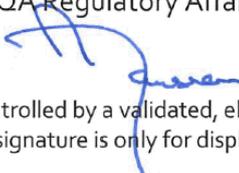
Primellose® is pharmaceutical grade Croscarmellose sodium. To meet the high quality standards from the pharmaceutical industry with respect to colour and performance of the product, cotton linters are used as starting material for Primellose®.

Cotton linters are derived from world market cotton that uses both GMO and non-GMO varieties.

DFE Pharma recommends Primellose® as a high quality ingredient in medicinal products. The use in food products may be possible depending on the local legislation. To check compliance with the local legislation is the responsibility of the user of Primellose®. Please note that the use of Primellose® in the European Union in food products is not possible because of the current stringent food legislation on the use of genetically modified organisms (GMO's) and products derived.

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 : 

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