BSE/TSE - Statement

Product group: Superdisintegrants
Brand name: Primojel®, Primellose®
Document No.: PD-0306

Dear Customer,

We, DFE Pharma GmbH & Co. KG, hereby certify the following:

Primojel® (Sodium Starch Glycolate) and Primellose® (Croscarmellose Sodium) do not fall into the scope of the requirements laid down in the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products (EMA/410/01 rev 3) [1].

Both products are manufactured exclusively from non-animal derived substances and there is no risk of contamination with any animal-derived substance.

The equipment and facilities used to manufacture Primojel® and Primellose® are not shared with products of animal-origin.

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.

Reference:
[1] Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 Rev. 3), Official Journal of the European Union, C73, 5 March 2011, p. 1-18.

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