



BSE/TSE - Statement

Product group: Superdisintegrants
Brand name: Primojel®, Primellose®
Document No.: PD-0306 Page 1 of 1

Dear Customer,

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

Primojel® (Sodium Starch Glycolate) and Primellose® (Croscarmellose Sodium) don't fall into the scope of the requirements laid down in Note for Guidance EMA/410/01 rev 3*.

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

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

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

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.

*For more detailed information regarding the Note for Guidance as mentioned above you are kindly requested to refer to the following internet site:

<http://www.ema.europa.eu>