

**BSE-TSE STATEMENT**

According to Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agent via Medicinal Products and Veterinary Medicinal Products (EMA/410/01 current revision)

**1616 REAGENT FEHLINF B QUANTITATIVE**

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We hereby confirm that the product referenced above does NOT contain substances of animal origin.

No substances of animal origin, or any of its derivatives, are intentionally added to the product during the manufacturing process. Furthermore, based on our current knowledge of the raw materials and our processes, no contamination with substances of animal origin is expected, therefore the product is not expected to contain BSE-TSE contamination either.

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Esparreguera, September 12th 2025

**Laia Galitó**  
Regulatory Affairs Specialist

