BIOTECH

Statement of Compliance

USTR 3803

Minimization of Transmission of Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE)

Pall Corporation does not knowingly employ materials of direct animal origin i.e. animal parts, tissues, or body fluids. However, to assist our customers in performing a TSE/BSE risk assessment, we are pleased to provide the following information.

Disposable pharmaceutical-grade filters, tangential flow filtration (TFF) cassettes, and single-use systems (SUS) are assembled from components using polymeric resin materials that may contain trace ingredients that are derived from materials of animal origin. These materials do not present a risk of TSE/BSE based on their source (sourcing considers animal species, tissue and country of origin) and/or exposure to processing conditions known to inactivate infectious agents associated with TSE/BSE diseases.

Tallow-Derivatives:

Some polymeric resin manufacturers employ trace levels of additives in the resin formulation. These additives may be manufactured using animal tallow as a starting substance ("tallow-derivatives"). The tallow may have been sourced from bovine species or, less commonly, from non-TSE relevant species. Please be advised that bovine tallow-derivatives are considered low risk material for TSE/BSE according to the current revision of the U.S. Code of Federal Regulations, Title 21 Part 189.5 Substances Prohibited from Use in Human Food; Sub part B: Prohibited Cattle Material: Paragraph a7. Furthermore, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) 'Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products' (EMA/410/01 Rev 3, 2011), and other international guidelines, gives specific consideration to tallow-derivatives and states that they are unlikely to be infectious if rigorously processed during their manufacture (for example, hydrolysis or transesterification, at not less than 200 °C under pressure for not less than 20 minutes). Our suppliers have stated that their raw materials have been processed under conditions at least as rigorous as these.

Pall Corporation continuously works to assure the safety of our products with respect to potential BSE/TSE transmission by working through our supply chain to obtain information regarding the possible use of animal-based material.

Please do not hesitate to contact dossieradmin@pall.com with any additional questions on this subject.

Please check the Pall website regularly for changes or updates. This statement is correct at the time of preparation, however, customers should routinely consult the Pall Corporation website for changes or updates. All products shall be used in accordance with the Instructions for Use (IFU).

Prepared by Pall Quality Assurance and Regulatory Affairs for Biotechnology

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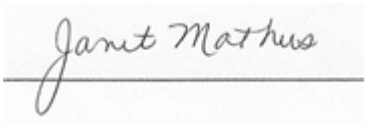
Signature:	

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