



## Statement of Compliance

### Minimization of Transmission of Bovine Spongiform Encephalopathy (BSE) & Transmissible Spongiform Encephalopathy (TSE)

Pall Corporation do 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, 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 CPMP's *Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathies via human and veterinary medicinal products* (EMA410/01 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 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.

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

Please do not hesitate to contact [dossieradmin@pall.com](mailto:dossieradmin@pall.com) with any additional questions on this subject.

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