

TSE (transmissible spongiform encephalopathy) and BSE (bovine spongiform encephalopathy) Statement

Pall pharmaceutical-grade filters, TFF cassettes, and biotechnology single-use systems are assembled from components using polymeric resin materials and elastomeric materials. While some of the materials may contain chemicals produced from animal material substances, they are not considered a TSE/BSE risk based on their source (sourcing takes into consideration animal species, tissue and country of origin) and/or exposure to processing conditions known to inactivate infectious agents associated with TSE/BSE diseases. See below for further information on polymeric chemical additives produced from ‘tallow’.

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 not considered risk material for TSE/BSE according to the current revision of the U.S. Code of Federal Regulations, Title 21 Part 189.5 *Prohibited cattle material*. 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 current version), and other international guidelines, gives specific consideration to tallow-derivatives and states that they are unlikely to be infectious due to the rigorous processing steps used during their manufacture (for example, transesterification or hydrolysis, at not less than 200°C under pressure for not less than 20 minutes). Our suppliers have stated that these raw materials have been processed under conditions at least as rigorous as these.

The above information reflects Pall’s current knowledge based on supplier’s information and Pall process controls. The statements provided in this letter are subject to change as new information from our suppliers becomes available. Pall will notify customers if any new information is received that would impact TSE/BSE safety; however, we also recommend that users periodically confirm this information.

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