

Subject: BSE/TSE Safety

Product: Pall Pharmaceutical-grade Disposable Filter Cartridges and Capsules

Pall pharmaceutical-grade products do not contain animal materials (i.e. animal parts, tissues, or body fluids) and hence may be designated “animal free” under many customer classification systems. However, to assist our biopharmaceutical customers in performing a BSE/TSE risk assessment, we are pleased to provide the following information.

Certain plastics, such as polypropylene, are known to contain trace levels of additive (e.g. calcium stearate) which are manufactured from bovine tallow. Pall pharmaceutical-grade disposable filters may utilize components in the fluid pathway which are fabricated from plastic resins containing bovine-derived additives at trace levels.

Please be advised that tallow-derived additives are not considered specified BSE risk materials according to the current revision of the U.S. **Code of Federal Regulations**, Title 21 of part 189.5, which defines specified risk materials obtained from cattle. Furthermore, the CPMP's *Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathies via human and veterinary medicinal products* (EMA410/01 rev 3) gives specific consideration to tallow derivatives and states they are unlikely to be infectious due to the rigorous processing steps used during their manufacture (an example of which is transesterification, or hydrolysis, at not less than 200°C under pressure for not less than 20 minutes).

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 and to confirm specific sourcing and processing details, where applicable.

We hope you will find this information satisfactory. Please do not hesitate to contact your Pall Representative if you should have any additional questions on this subject.

Prepared by: Pall Corporation Quality Assurance and Regulatory Affairs

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To the best of our knowledge this information is accurate as of the date of issuance. However, these statements are subject to change as new information becomes available. We recommend that you periodically confirm this information.

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