



**Subject: BSE/TSE Safety (Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathy)**

**Product: Pall Food & Beverage Cartridge Filter and Sheet Based Filter Products ("W" Code)**

Pall food contact compliant ("W" code) filtration products do not knowingly contain 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:

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

Please be advised that bovine tallow-derived additives are not considered specified TSE/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 material.

Furthermore, the Committee for Proprietary Medicinal Product (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). The raw materials we purchase have been processed with these steps. Pall "W" Code filters and modules employ polymer materials of construction which are common to those used in Pall Pharmaceutical products.

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.

**Prepared by: Pall Quality Assurance and Regulatory Affairs**

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