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Home a Drug Can Get®

June 13, 2022

Subject: Bovine Spongiform Encephalopathy (BSE) / Transmissible Spongiform Encephalopathy (TSE) Safety Statement for SaniSure Assembly Products

To Whom It May Concern:

This letter is provided to address your request on the risk of TSE and BSE specific to Fluid Path Raw Materials for SaniSure's Raw Material(s) and/or Final Product(s). SaniSure makes every effort to source raw materials that are free of animal origin. However the use of animal-derived materials is unavoidable; therefore SaniSure relies on and evaluates animal origin content information provided by our Suppliers/Sub-Suppliers. SaniSure does not test for the presence of animal origin materials and does not add any during the manufacturing process. SaniSure believes that the information provided by our Suppliers and/or Sub-Suppliers to be constructed of true and accurate information. 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 and polycarbonate, are known to contain trace levels of additives which are manufactured from bovine tallow. These products (fatty acids, fatty alcohols, metallic soaps, fatty amines, fatty amides, fatty acid esters, glycerin, etc.) are incorporated into plastics as lubricants, slip agents, anti-static agents as well as emulsifiers, anti-oxidants or corrosion inhibitors. They are primarily extracted from tissues of bovine origin. SaniSure assembly products may utilize components or materials (e.g. filters, tubing, connectors, carboys, bags) that are in the fluid pathway, and which are fabricated from plastic resins containing the tallow-derived additives.

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 **Committee for Proprietary Medicinal Products (CPMP)** and the ***Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathies via human and veterinary medicinal products (EMA 410/01 rev. 3)*** give specific consideration to tallow derivatives and state they are unlikely to be infectious due to the rigorous processing steps used during their manufacture.

SaniSure 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 Company Representative if you have any additional questions on this subject.