June 23, 2011

RE: TSE / BSE safety of Pall products

This letter is provided to address your question on the risk of TSE (and BSE) contamination in Pall part number:

ACD02M6
ACD02F6

Pall is pleased to inform you that this product does not contain materials of construction that are considered TSE risk materials according to current legislation and guidance in both Europe and the United States:

1. The European CPMP Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathies via human and veterinary medicinal products. (EMEA/410/01 Rev.2, applicable from 1st July 2004)

2. The U.S. Code of Federal Regulations, Title 9 of part 94.18, which sets forth restrictions on the geographical sourcing of products obtained from ruminants.

3. The U.S. Code of Federal Regulations, Title 21 of part 189.5, which defines specified risk materials obtained from cattle.

While none of the materials of construction of this product are of direct animal origin, trace levels of stearate materials derived from bovine tallow, are utilized in the production of polypropylene. Polypropylene is used to manufacture two of the non-fluid-contact components of the Kleenpak™ Connector, the protective cap and the thermoplastic grommets. Tallow derivatives are not considered specified BSE risk materials according to the current revision of Title 21, of the U.S. Code of Federal Regulations, part 189.5. Furthermore, the CPMP's Note for guidance (EMEA410/01) gives specific consideration to tallow derivatives and states they are unlikely to be infectious due to the rigorous processing steps used (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. Additionally, during the conversion of polypropylene resin into plastic components further high temperature steps are performed.
Please note that the polycarbonate used to manufacture the connector body does not contain any ingredients derived from bovine or animal sources.

If you should require further information, please do not hesitate to contact me.

Sincerely,

Janet Mathus
Senior Regulatory Affairs Manager
Pall Life Sciences