

## MATERIAL COMPLIANCE SUMMARY

Pall Pharmaceutical-grade Emflon® HTPFR Filters  
Reference Part Numbers: AB\*HTPFR\*PV\*

### Biological Safety

Representative components used in Emflon HTPFR filters have met the requirements for biological reactivity, *in vivo*, under USP <88> (for Class VI - 121°C plastics) and *in vitro*, under USP <87> (Elution Test). This includes the Systemic Toxicity Test, the Intracutaneous Test, Implantation Test and the Minimum Essential Medium (MEM) Elution Cytotoxicity Test.

### Conformance with CFR 21 Parts 170 – 199

Emflon HTPFR filters are manufactured from materials of construction which are listed in Title 21 of the U.S. **Code of Federal Regulations** (21 CFR) parts 170 - 199.

### TSE / BSE Safety (Conformance to EMA/410/01 and U.S. Code of Federal Regulations Title 21 Part 189.5 Subpart B)

Emflon HTPFR filters do not contain animal materials (i.e. animal parts, tissues, or body fluids) and hence may be designated “animal component free” under many classification systems. However, plastics resins used to manufacture some filter components may contain trace ingredients (additives) which are produced from bovine tallow as a starting substance. Please be advised that neither tallow nor tallow-derived materials are specified BSE risk materials according to the current revision of the U.S. Code of Federal Regulations, Title 21 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 (EMA/410/01) gives specific consideration to tallow derivatives and states 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). Any animal-derived ingredients contained in plastic resins that are employed in our filter construction have experienced conditions at least as rigorous.

### Melamine Declaration

Pall does not utilize melamine or any of the “at-risk” components for melamine contamination identified in FDA's *Guidance for Industry – Pharmaceutical Components at Risk for Melamine Contamination* (Aug 2009) in the manufacturing process of this product. It is also our understanding that melamine is not used as an ingredient or additive in the materials we purchase to manufacture these products. Therefore we do not expect that melamine is present in these products.

### **Latex Declaration**

Please be informed that these products are not made with natural rubber latex. Please note that Pall does not test the final product for the absence of specific compounds related to natural rubber latex allergies.

### **Shelf Life and Storage Recommendation**

Pall recommends a shelf life of 5-years for Emflon HTPFR filters from the date of manufacture (located on the product label or certificate).

To achieve satisfactory performance, filters should be stored in their original packaging at a temperature between 0°C - 30°C, and kept away from direct sunlight and other sources of heat radiation. Exercise care during filter handling and storage to avoid physical damage. Inspection and, where appropriate, integrity testing is recommended prior to use.

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

**Issued: April 2017**

To the best of our knowledge this information is accurate as of the date of issue. However, these statements are subject to change as new information becomes available. We therefore recommend that users periodically confirm this information. Please also be advised that Pall may not perform testing on finished products to confirm exclusion of specific referenced substances.