



Biotech

Statement of Compliance

Use of Melamine in Pharmaceutical-Grade Filters

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 processes of pharmaceutical-grade filters. Additionally, to the best of our knowledge melamine is not a component in the materials we purchase to manufacture our Biotech products. Therefore, we do not expect that melamine would be a potential leachable from our pharmaceutical-grade filters.

Please do not hesitate to contact Pall Biotech at dossieradmin@pall.com should you have any additional questions on this subject.

Other Information/References:

1. Guidance for Industry – Pharmaceutical Components at Risk for Melamine Contamination, U.S Food and Drug Administration, August 2009.

Please check the Pall website regularly for changes or updates. This statement is correct at the time of preparation, however customers should routinely consult the Pall Biotech website for changes or updates. All products shall be used in accordance with the Instructions for Use (IFU).

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