



Biotech

Statement of Compliance

Nitrosamine Compounds

This statement is intended to assist customer efforts in evaluating the risk of nitrosamine impurities in the manufacturing processes.

Nitrosamines are compounds of toxicologic concern, which have been known to result from biological reactions and/or manufacturing processes involving reaction of nitrites (or nitrates) with amines. While recent regulatory guidance mainly focuses on chemically synthesized active ingredients as a source of nitrosamine contamination, polymeric materials manufactured with nitrosation-reactive functional groups and amines or produced on manufacturing lines involving these substances, warrant risk assessment as to the likelihood these compounds being present.

Pall has performed a risk assessment for the possible presence of nitrosamine compounds in our pharmaceutical grade filters and Allegro™ single-use systems, which includes assessment of materials of construction, Pall manufacturing processes, and our global material purchasing specifications related to disallowed and controlled substances (which specifically identifies N-nitrosamines compounds as substances of concern to Pall, see <https://www.pall.com/content/dam/pall/pall-corp/literature-library/non-gated/E962.pdf>); and selected extractables testing of Pall Biotech products.

For the purpose of this assessment we considered representative Pall sterilizing grade filters and prefilters, virus filters, TFF devices, continuous chromatography consumables, aseptic connectors, biocontainers and mixer materials, and other components typical of single-use systems. Materials such as non-silicone o-rings and Mustang® chromatography products were excluded from the risk assessment, as although we have strong supplier statements, we have either limited extractables data or knowledge of the manufacturing process to support an equivalently robust assessment.

Based on this assessment, the risk of Pall pharmaceutical-grade filters and Allegro single-use systems being a contributing source of nitrosamine impurities is low.

Please be advised that Pall does not routinely analyze products for the presence of these compounds.

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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