

Melamine Compliance Statement

Regarding: Bioprocess Single-Use Consumables and Filtration Products

Background

Melamine is an organic-based chemical used in the manufacturing of plastics to give them a harder, more durable feel. Between 2007 and 2008, melamine became a concern when household pets and infants became ill due to the high amounts of this chemical in their food.

In response, the Food and Drug Administration (FDA) released a guidance document entitled "Pharmaceutical Components at Risk for Melamine Contamination" on August 6, 2009. This guidance alerted pharmaceutical manufacturers of finished products, pharmacy compounders, re-packers, and suppliers to the potential risk of melamine contamination in pharmaceutical components.

Cytiva does not manufacture Active Pharmaceutical Ingredients (APIs) or finished medicines but understands that single-use products may be used in the manufacture of finished drugs and drug products.

Statement

It is hereby stated that melamine and melamine-related components are not primary raw materials of wetted components, nor are they intentionally added or introduced during the manufacturing process of the following Cytiva bioprocess products.

Single Use Products


- ÄKTA™ ready, ready XL, readyflux™, and readyflux XL flow kits
- ReadyCircuit™ bags, sensors, jumpers, and filtration assemblies
- ReadyMate™ Disposable Aseptic Connectors (DACs)
- ReadyToProcess™ bags
- ReadyToProcess Hollow Fiber cartridges
- WAVE™ Cellbags and M*bags
- Xcellerex™ assemblies

Filtration Products

- Hollow Fiber Cartridges
- ULTA™ filters

To the best of our knowledge, melamine is not a component in the materials we purchase from our suppliers.

Cytiva appreciates the opportunity to serve our valued customers and is dedicated to improving our capabilities to manufacture and deliver products and services that meet or exceed your needs consistently.

DocuSigned by:	
Signature: 	Date: 14 OCTOBER 2021
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