Cytiva
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USA

Nitrosamine Compliance Statement

Regarding: Bioprocess single-use consumables and filtration products

Background

According to the World Health Organization (WHO), nitrosamines are any compound containing a nitroso (NO) functional group. These compounds are of concern because they are potential carcinogens. Nitrosamine is formed when secondary or tertiary amines react with a nitrosating agent, such as nitrous acid. The most common source of nitrosating agents is sodium nitrite.

The European Medicines Agency (EMA) finalized a review under Article 5(3) of Regulation (EC) No 726/2004 in June 2020 to provide guidance to marketing authorization holders (MAH) on how to avoid presence of nitrosamine impurities in human medicines. Assessment report EMA/369136/2020 "Nitrosamine impurities in human medicinal products" was published on 25 June 2020 and adopted by the Committee for Medicinal Products for Human Use (CHMP).

The U.S. Food and Drug Administration (FDA) Guidance for Industry, entitled "Control of Nitrosamine Impurities in Human Drugs" and published in February 2021, recommends steps manufacturers of active pharmaceutical ingredients (APIs) and drug products should take to detect and prevent unacceptable levels of nitrosamine impurities in pharmaceutical products.

Cytiva does not manufacture 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 nitrosamines 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. To the best of our knowledge, nitrosamine is not a component in the materials we purchase from our suppliers. Extractables studies are available on the Customer Regulatory Support website, *www.cytiva.com/rsf*.

Single Use Products

- ÄKTA ready™, ÄKTA ready XL, ÄKTA ready 450, ÄKTA readyflux™, and ÄKTA readyflux XL flow kits
- ReadyCircuit™ bags, sensors, jumpers, and filtration assemblies
- ReadyMate™ Disposable Aseptic Connectors (DACs)
- ReadyToProcess™ bags
- WAVE™ Cellbags™ and M*bags
- Xcellerex™ assemblies (including XDR, XDM, and X-platform bags)

Filtration Products

- ULTA™ filters

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General statements, including this one, are available on the Customer Regulatory Support website at www.cytiva.com/rsf. See "Download without a subscription" then "Statements."