

Statement

Regarding: Material conformance ReadyToProcess™ columns

We hereby certify that the parts, in contact with process fluid (wetted parts), consist of the following materials and conform to the regulatory requirements listed. This information is valid for all standard and custom ReadyToProcess columns with column housing inner diameter 80-359 mm and 450-600 mm and column bed heights 50 – 250 mm.

Table 1: List of materials

| Material | Column part |
|---|--|
| Acrylic (PMMA) | Column tube for (450-600) column |
| Ethylenepropylenediene (EPDM) | TC gaskets and O-rings on (450-600) column The EPDM O-ring on 600 id. column is Parylene coated |
| Fluorocarbon rubber (FPM) | O-rings (80 to 600 column) |
| Polyetheretherketone (PEEK) | Net holder, connectors and nozzle tube (80-359 column) plug at inlet |
| Polyethylene (PE) | Sinter mesh, 20 µm (450-600 column) |
| Polyolefin (PO) | Hose (inlet tubing) and outlet tubing on 450-600 column) |
| Polypropylene (PP) | (80-359) columns: Column tube, connections, support nets, support screens, stream stoppers, connections, lids, nets (450-600 column): Distributor, bottom inlet, top outlet |
| Silicone | Welded tubing for inlet/outlet protection |
| Ultra High Molecular Weight Polyethylene (UHMWPE) | Snap Ring 450 and Snap ring 600, Sinter mesh, 10 µm (450-600 column) |

Material conformance of wetted parts

All polymeric materials in contact with process fluid:

- are in compliance with FDA 21 CFR 177 Indirect food additives: polymers
- meet USP <87> Biological reactivity tests In Vitro
- meet USP <88> Biological reactivity tests, In Vivo, Class VI
- are animal origin free or in compliance with EMA/410/01 Rev. 3

Material of concern

REACH and list of Substances of Very High Concern (SVHC)

Cytiva is aware of the REACH regulation ((EC) No 1907/2006) and is committed to meet obligations accordingly. For more information, please visit [Cytiva Quality Policies](#).


Nitrosamine, Allergens, Latex

To the best of our knowledge the above listed components are not used for the materials in ReadyToProcess column housing, nor are they intentionally added or introduced during manufacturing of the ReadyToProcess housings. Specific analytical testing for the components is not performed.

Statements concerning materials of concern for BioProcess chromatography resins are available at www.cytiva.com/regulatorystatements.

BioProcess chromatography resin products and their different pack sizes are numbered: XXXXXYY where XXXXXX refers to a specific product and YY refers to a specific pack size (typically 25 mL - 60 L).

Bulk resin with code number XXXXXX00, used in ReadyToProcess columns are equivalent to the corresponding chromatography resins XXXXXYY.

| | |
|---|---|
| Signature:  | Date: 13 October 2023 |
| Name: Liz Samuelsson | Title Sr. Regulatory Support Manager |

The information herein is provided to the best of our knowledge and belief, based on the information we have been given and the information available to us at the time that this document was issued. The information may change as additional facts come to light, or as the circumstances warrant. Your use hereof is hence at your own risk and does not relieve you of your own responsibility for checking the suitability of our products for your intended use.

Cytiva and the Drop logo are trademarks of Life Sciences IP Holdings Corp. or an affiliate.

For additional information on trademarks see cytiva.com/trademarks.

© 2022, 2023 Cytiva