

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.
- All polymeric materials in contact with process fluid meet USP <87> Biological reactivity tests In Vitro.
- All polymeric materials in contact with process fluid meet USP <88> Biological reactivity tests, In Vivo, Class VI.
- All polymeric materials in contact with process fluid are animal origin free or in compliance with EMA/410/01 Rev. 3.

Material of concern

Melamine, 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 the above listed materials 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: 29 April 2022
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