

Statement

Regarding: Animal origin information for ReadyToProcess™ columns

Chromatography resins

Based on statements from our suppliers of raw materials, chromatography resins are animal and human origin free or meet the guidelines outlined in EMA/410/01, rev. 3. To the best of our knowledge, the BSE/TSE issue does not concern these products.

Statements concerning non-animal origin for BioProcess chromatography resins are available at www.cytiva.com/regulatorystatements. Information regarding non-animal origin for chromatography resins can also be found in Certificate of Analysis, available at www.cytiva.com/certificates.

Statements concerning BioProcess chromatography resins manufactured using animal derived raw materials are available upon request.

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 XXXXXXYY.

Column wetted parts

Based on statements from our suppliers, the fluid path components of the products are either animal origin free or meet the guidelines outlined in EMA/410/01, rev. 3. For material in compliance with EMA 410/01 the polymeric material is in accordance with the conditions for tallow derivatives in the Note for Guidance (EMA/410/01) and therefore BSE/TSE contamination is unlikely. Cytiva does not intentionally add animal or human origin materials during our manufacturing processes.

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.

Signature:	Date: 07 September 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.

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