

# Statement

## Regarding: Melamine contamination in chromatography resins

A guidance document entitled Pharmaceutical Components at Risk for Melamine Contamination was issued by the US Food and Drug Administration (FDA) on August 6, 2009. This guidance is intended to alert pharmaceutical manufacturers of finished products, pharmacy compounders, re-packers, and suppliers to the potential risk of melamine contamination in pharmaceutical components. In response to this guidance, a risk assessment has been performed by Cytiva and the outcome is summarized below.

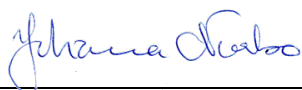
**Purchasing controls:** Cytiva assures that purchases of materials conform to specified requirements and are acquired from qualified suppliers. This is achieved through a robust qualification process and through a supplier monitoring process, which includes conducting supplier audits for materials essential to function.

**Site security:** The site is closed off to the outside with a secure perimeter fence. Closed circuit television is in place which allows security personnel to monitor entrances, gates, and perimeter fences. A passage card in combination with a personal code is required to gain access to the site. Each building is closed off allowing only people with access to enter. A passage card is required to gain access to individual buildings.

**Design and manufacture:** Cytiva do not design-in or add melamine or melamine-related materials during the manufacture of chromatography resins. Specific analytical testing for detection of melamine contamination is not performed on the product/s.

**Distribution chain:** Tamper-proof sealing is used for all distributed bioprocess resins. Attempts to alter the product during and after distribution will be indicated by the broken seal. Cytiva advises customers not to use products that arrive with broken seals.

**Overall summary and conclusions:** Chromatographic resins are used as process aids. They are not used as ingredients and are not part of finished pharmaceutical products. The overall risk for melamine contamination in bioprocess chromatography resins is considered low.

Signature: 	Date: 20 October, 2022
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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.

**Attachment**

Product/Part name	Product code
6-AKS Sepharose™ 4 Fast Flow	17310004
AH Sepharose 4B	17047003
Amino Sepharose 6 Fast Flow	17309202, 17309209
ANX Sepharose 4 Fast Flow	17128601, 17128604
ANX Sepharose 4 Fast Flow (High Sub)	17128701, 17128704, 17128705, 17128710, 17128760
AVB Sepharose High Performance	28411201, 28411202, 28411203, 28411204, 28411210
Benzamidine Sepharose 4 Fast Flow (High Sub)	17512301, 17512302, 17512303, 17512310
Benzamidine Sepharose 4 Fast Flow (Low Sub)	28410801, 28410802, 28410803, 28410810
Benzamidine Sepharose 6B	17056801, 17056802, 17056804
Blue Sepharose 6 Fast Flow	17094801, 17094802, 17094803, 17094804
Butyl Sepharose 4 Fast Flow	17098001, 17098002, 17098004, 17098005, 17098010
Butyl Sepharose 4B	17096003, 17096004, 17096098
Butyl Sepharose High Performance	17543201, 17543202, 17543203, 17543204, 17543260
Butyl Sepharose High Performance (High Sub)	17543303, 17543304
Butyl-S Sepharose 6 Fast Flow	17097802, 17097803, 17097804, 17097810
Capto™ adhere	17544401, 17544403, 17544404, 17544405, 17544410, 17544460
Capto adhere ImpRes	17371501, 17371502, 17371503, 17371504, 17371505
Capto AVB	17372201, 17372202, 17372203, 17372204
Capto Blue	17544801, 17544802, 17544804, 17544805, 17544860
Capto Blue High Sub	17545201, 17545202, 17545204, 17545205
Capto Butyl	17545901, 17545902, 17545903, 17545904, 17545905
Capto Butyl ImpRes	17371901, 17371902, 17371903, 17371904
Capto Butyl-S	17549701, 17549702, 17549703, 17549704, 17549723, 17549724
Capto Chelating	17548501, 17548502, 17548503, 17548504, 17548505
Capto Core 400	17372401, 17372402, 17372403, 17372404
Capto Core 700	17548101, 17548102, 17548103, 17548104
Capto DEAE	17544301, 17544303, 17544304, 17544305, 17544310, 17544360
Capto DeVirS	17546601, 17546602, 17546603, 17546604
Capto Heparin	17546201, 17546202, 17546203, 17546204
Capto L	17547801, 17547802, 17547803, 17547804, 17547805, 17547806
Capto Lentil Lectin	17548901, 17548902, 17548903, 17548904
Capto MMC	17531702, 17531703, 17531704, 17531705, 17531710, 17531760
Capto MMC ImpRes	17371601, 17371602, 17371603, 17371604, 17371605
Capto Octyl	17546501, 17546502, 17546503, 17546504
Capto Phenyl High Sub	17545101, 17545102, 17545103, 17545104, 17545105, 17545160
Capto Phenyl ImpRes	17548401, 17548402, 17548403, 17548404
Capto PlasmidSelect	17549901, 17549902, 17549903, 17549904
Capto Q	17531602, 17531603, 17531604, 17531605, 17531610, 17531660
Capto Q ImpRes	17547002, 17547003, 17547004, 17547005, 17547010
Capto Q XP	17547301, 17547302, 17547303, 17547304
Capto S	17544101, 17544103, 17544104, 17544105, 17544110, 17544160

Product/Part name	Product code
Capto S ImpAct	17371701, 17371702, 17371703, 17371704, 17371705
Capto SP ImpRes	17546802, 17546803, 17546804, 17546805, 17546810, 17546860
Capto STI	17549001, 17549002, 17549003, 17549004, 17549005
Chelating Sepharose Big Beads	17527203, 17527205
Chelating Sepharose Fast Flow	17057501, 17057502, 17057504
CM Sephadex™ C-25	17021001, 17021002, 17021003, 17021007
CM Sephadex C-50	17022001, 17022002, 17022003, 17022007
CM Sepharose Fast Flow	17071901, 17071905, 17071910, 17071960, 17071922, 17071923, 17071924
CM Sepharose High Performance	17127701, 17127703, 17127705
CNBr Activated Sepharose 4 Fast Flow	17098101, 17098103, 17098105
CNBr Activated Sepharose 4B	17043001, 17043002, 17043003
Con A Sepharose 4B	17044001, 17044002, 17044003, 17044004
DEAE Sephacel™	17050001, 17050005
DEAE Sephadex A-25	17017001, 17017002, 17017003, 17017007
DEAE Sephadex A-50	17018001, 17018002, 17018003, 17018007
DEAE Sephadex A-50 Special grade	17018103
DEAE Sepharose CL-6B	17071001, 17071005
DEAE Sepharose Fast Flow	17070901, 17070905, 17070910, 17070960
ECH Lysine Sepharose 4 Fast Flow	17090202, 17090204
GCSFSelect	17548301, 17548302, 17548303, 17548304
Gelatin Sepharose 4 Fast Flow	17097603, 17097604
Gelatin Sepharose 4B	17095601, 17095603, 17095604
Glutathione Sepharose 4B	17075601, 17075604, 17075605
Glutathione Sepharose 4 Fast Flow	17513201, 17513202, 17513203
Heparin Sepharose 6 Fast Flow	17099801, 17099803, 17099804, 17099825
Heparin Sepharose CL-6B	17055202, 17055204, 17055298, 17046701, 17046709
IgSelect	28411301, 28411302, 28411303
IMAC Sepharose 6 Fast Flow	17092107, 17092108, 17092109, 17092110
IXSelect	17371401, 17371402, 17371403, 17371404
KappaSelect	17545801, 17545802, 17545803, 17545804
LambdaFabSelect	17548201, 17548202, 17548203, 17548204
Lentil Lectin Sepharose 4B	17044401, 17044403
MabSelect™ PrismA	17549801, 17549802, 17549803, 17549804, 17549805, 17549806
MabSelect SuRe™	17543801, 17543802, 17543803, 17543804, 17543805, 17543821, 17543822, 17543823
MabSelect SuRe LX	17547401, 17547402, 17547403, 17547404, 17547405, 17547421, 17547422, 17547423
MabSelect SuRe pcc	17549101, 17549102, 17549103, 17549104, 17549105
MabSelect VL	17542001, 17542002, 17542003, 17542004, 17542005, 17542023, 17542024, 17542025
MabSelect Xtra™	17526902, 17526903, 17526904, 17526905, 17526906, 17526907
MabSelect	17519901, 17519902, 17519903, 17519904, 17519906, 17519921, 17519922
MacroCap™ Q	17546901, 17546902, 17546904
MacroCap SP	17544001, 17544002, 17544003, 17544005, 17544010
NHS-activated Sepharose 4 Fast Flow	17090601, 17090602, 17090604, 17090607
Ni Sepharose excel	17371201, 17371202, 17371203, 17371213

Product/Part name	Product code
Ni Sepharose 6 Fast Flow	17531801, 17531802, 17531803, 17531804, 17531805, 17531806
Ni Sepharose High Performance	17526801, 17526802, 17526804
nProtein A Sepharose 4 Fast Flow	17528001, 17528002, 17528003, 17528004, 17528005, 17528006
Octyl Sepharose 4 Fast Flow	17094602, 17094603, 17094604, 17094610
Octyl Sepharose 6 Fast Flow	17372001, 17372002, 17372003, 17372004, 17372005
Octyl Sepharose CL-4B	17079001, 17079005
Phenyl Sepharose 6 Fast flow (High Sub)	17097303, 17097304, 17097305, 17097306, 17097310
Phenyl Sepharose 6 Fast flow (Low Sub)	17096503, 17096504, 17096505, 17096510
Phenyl Sepharose Big Beads	17509803, 17509805
Phenyl Sepharose CL-4B	17081001, 17081005
Phenyl Sepharose High Performance	171082-01, 17108203, 17108204, 17108260
PlasmidSelect Xtra	28402401, 28402402, 28402403, 28402404
Plasminogen Removal Gel	28410903
Protein A Sepharose 6 Fast Flow	17097002, 17097003
Protein A Sepharose CL-4B	17096302, 17096303, 17078001, 17078003, 17078004
Protein G Sepharose 4 Fast Flow	17061801, 17061802, 17061804, 17061805, 17061806
Q Sepharose High Performance	17101401, 17101403, 17101404, 17101405
Q Sepharose Big Beads	17098903, 17098905, 17098960
Q Sepharose Fast Flow	17051001, 17051004, 17051005, 17051010, 17051011, 17051060, 17051022, 17051023, 17051024
Q Sepharose XL	17507201, 17507204, 17507205, 17507260
QAE Sephadex A-25	17019001, 17019003
QAE Sephadex A-50	17020001, 17020003
rmpProtein A Sepharose Fast Flow	17513801, 17513802, 17513803, 17513804, 17513805
rProtein A Sepharose Fast Flow	17127901, 17127902, 17127903, 17127904, 17127905, 17127906, 17127907
S Sepharose Fast Flow	17051104, 17051105, 17051160
Sephacryl™ S-100 HR	17061201, 17061205, 17061210
Sephacryl S-300 HR	17059901, 17059905, 17059910
Sephacryl S-400 HR	17060901, 17060905, 17060910
Sephacryl S-500 HR	17061301, 17061305, 17061310
Sephacryl S-200 HR	17058401, 17058405, 17058410
Sephadex G-10	17001001, 17001002, 17001003
Sephadex G-100	17006001, 17006003, 17006015
Sephadex G-100 SF	17006101, 17006133
Sephadex G-15	17002001, 17002003, 17002005, 17002007
Sephadex G-25 Coarse	17003401, 17003402, 17003403, 17003407
Sephadex G-25 Fine	17003201, 17003202, 17003203
Sephadex G-25 Medium	17003301, 17003302, 17003303, 17003307
Sephadex G-25 Superfine	17003101, 17003102, 17003103
Sephadex G-50 Fine	17004201, 17004202, 17004203
Sephadex G-50 Medium	17004301, 17004302, 17004303
Sephadex G-50 Superfine	17004101, 17004103
Sephadex G-75	17005001, 17005003
Sephadex G-75 Superfine	17005101, 17005103
Sephadex LH-20	17009001, 17009002, 17009003, 17009010
Sepharose 4 Fast Flow	17014901, 17014905, 17014960
Sepharose 4B	17012001, 17012005

Product/Part name	Product code
Sepharose 6 Fast Flow	17015901, 17015905
Sepharose 6B	17011001, 17011005
Sepharose CL-2B	17014001, 17014005
Sepharose CL-4B	17015001, 17015005
Sepharose CL-6B	17016001, 17016005
SOURCE™ 15S	17094401, 17094402, 17094403, 17094405, 17094410
SOURCE 15ISO	17014801, 17014802, 17014804
SOURCE 15PHE	17014701, 17014702, 17014704, 17014705
SOURCE 15RPC	17072702, 17072703, 17072704, 17072705, 17072720
SOURCE 30RPC	17512002, 17512003, 17512004, 17512005, 17512020
SOURCE 30Q	17127501, 17127502, 17127503, 17127504
SOURCE 30S	17127301, 17127302, 17127303, 17127304, 17127330, 17127335, 17127340, 17127345
SOURCE 15Q	17094701, 17094702, 17094703, 17094704, 17094705, 17094720
SP Sepharose Big Beads	17065703, 17065705, 17065760
SP Sepharose Fast Flow	17072901, 17072904, 17072905, 17072910, 17072960, 17072922, 17072923, 17072924
SP Sepharose High Performance	17108701, 17108703, 17108704, 17108705, 17108708
SP Sepharose XL	17507301, 17507304, 17507305, 17507360
STREAMLINE™ Chelating	17128001, 17128002
STREAMLINE DEAE	17099401, 17099402, 17099405
STREAMLINE PHENYL	17512101, 17512102, 17512103, 17512104
STREAMLINE Q XL	17507501, 17507502, 17507505
STREAMLINE SP	17099301, 17099302, 17099305
STREAMLINE SP XL	17507601, 17507602, 17507605
Superdex™ 75 Prep Grade	17104401, 17104402, 17104404
Superdex 30 Prep Grade	17090501, 17090503, 17090504
Superdex 200 Prep Grade	17104301, 17104302, 17104304, 17104305, 17104306
Superose™ 12 Prep Grade	17053601, 17053603, 17053604
Superose 6 Prep Grade	17048901, 17048903, 17048904
VIISelect	17545001, 17545002, 17545004
VIISelect	17547701, 17547702, 17547703, 17547704