

Change Control Notification

Uppsala, Sweden 09 June, 2020

TW401922, 401923

Regarding: Label, Certificate of Analysis and Analytical Specification update

Dear Customer,

As part of our change control program, we write to notify you of changes to labels, Certificate of Analysis and analytical specifications for the below mentioned affected products.

Affected products

The products in scope of this notification include chromatography resins, ReadyToProcess™ columns, prefilled columns, density gradient media, microcarriers and Biacore™ consumables, manufactured in Uppsala Sweden.

Change description

Labels and Certificate of Analysis are updated with the Cytiva name including logo and legal entity name. Examples of updated certificates and labels are included with this notification. The following changes are introduced:

- Change of legal entity name from GE Healthcare Bio-Sciences AB to Cytiva Sweden AB
- Change of company brand name and logo
- To align the presentation of code numbers on labels and Certificate of Analysis, code numbers on labels are now written without dashes in the same way as on Certificate of Analysis.
- Numbering of test/characteristics on Certificate of Analysis is removed (when not already implemented in earlier updates)
- Minor editorial changes (e.g. ml changed to mL)

Analytical specifications for affected products will be updated to next edition with corresponding changes.

Reason for the change

Following the Danaher Corporation's purchase of the GE Healthcare Life Sciences Biopharma business units consisting of BioProcess, Cell & Gene Therapy and Genomics & Cellular Research, our company name is now changed to Cytiva. For more information please see change control notification "GE Healthcare Life Sciences (Biopharma business) is now Cytiva" dated 1 April 2020.

Impact of change

Labels and certificates will be updated with the Cytiva name including logo, legal entity name over time. Please note that finished products in our warehouses are rotated on a regular basis using first expired, first out inventory management and will not be re-labeled. During the transition phase, documents for products or services will be

changed gradually in the coming year. For products with a longer shelf life (>2 years) the transition phase can last for several years.

Mixed branding on products (shipments with differently branded products within the same shipment and/or a product carrying both brands) will occur during the transition phase. For products with a longer shelf life (>2 years) the transition phase can last for multiple years.

Please prepare to receive certain goods with brand name and legal entity details for both Cytiva and GE Healthcare Life Sciences for a period of time. Please ensure that your warehouse and Quality Control release personnel are informed and take necessary actions.

Implementation of change

The new legal entity name is valid from 15 June 2020 and is introduced for material labeled and/or released from this date forward.

More Information

For updated information related to our transition into Cytiva, such as answers to frequently asked questions, legal entity updates and other relevant information, please visit www.cytiva.com/4customers.

Attachment

- Label and certificate examples

To receive future notifications about our products, please register and subscribe for change control notifications at our website: www.cytiva.com/rsf. We recommend the use of business-related e-mail addresses instead of personal e-mail addresses, ensuring better information sustainability (example: supplier.notifications@company.com).

While your organization is assessing the potential impact of these changes, please do not hesitate to contact your regional Customer Service team or us at RegulatorySupport@cytiva.com.

Yours sincerely,



Liz Samuelsson

Sr. Customer Regulatory Support Manager

Attachment

Certificate of Analysis layout with new legal entity and company branding

1 of 1



Certificate of Analysis

Product:

Product™

Code Number:

XXXXXXXX

Lot No:

Test/Characteristic:

Limit:

Result:

Ionic capacity

µmol H⁺ / mL resin

XXX - XXX

Function, Salt conc. in elution peak, ~~α-chymotrypsinogen~~

M NaCl

XXX - XXX

Function, Salt conc. in elution peak, Cytochrome C

M NaCl

XXX - XXX

Function, Salt conc. in elution peak, Lysozyme

M NaCl

XXX - XXX

Breakthrough capacity, Q_s at 10%

mg β-Lactoglobulin / mL resin

min. xx

Microbial contamination

Colony Forming Units / mL suspension

max. 20

Endotoxin activity

EU/mL

less than 5.0

Additional information

Column Id

N/A

Manufactured in compliance with our ISO 9001 certified quality management system.

Approval date (Year-Month-Day): YYYY-MM-DD

Expiry date (Year-Month): YYYY-MM

Manufacturing date (Year-Month): YYYY-MM

Cytiva and the Drop logo are trademarks of Global Life Sciences
IP Holdco LLC or an affiliate

Tests and limits according to AS XXXXXXXX Ed. XX

Cytiva Sweden AB
Björkgatan 30
SE-751 84 Uppsala, Sweden
T +46 (0)18 612 00 00
cytiva.com
Reg.No. SE 55 61 08 1919 01

Issued (Year-Month-Day) YYYY-MM-DD by Quality Assurance


Name

This document has been electronically produced and is valid without a signature.

DOC110861/7

Example of label with current and new legal entity and company branding


Risk information - Local language - Please open



Warning
Flammable liquid and vapour.

Warning, Внимание, Atención, Varovani, Advarsel, Achtung, Holatus, Προσοχή, Attention, Attenzione, Uzmanību, Atsargai, Figyelem, Waarschuwing, Uwaga, Atenção, Atenție, Pozor, Varoitus, Varning, Upozorenje

Label No 04005704-ED




17-5316-04
5 l
Lot 20121217
Expiry 2012-12

Store at +4 to +30°C

MADE IN SWEDEN


GE Healthcare Bio-Sciences AB
SE-751 84 Uppsala, Sweden
+46 18 612 00 00
www.gelifesciences.com

GE Healthcare



Capto™ Q

contains 20% ethanol as preservative



www.gelifesciences.com/Instructions

Risk information - Local language - Please open



Warning
Flammable liquid and vapour.

Warning, Внимание, Atención, Varovani, Advarsel, Achtung, Holatus, Προσοχή, Attention, Attenzione, Uzmanību, Atsargai, Figyelem, Waarschuwing, Uwaga, Atenção, Atenție, Pozor, Varoitus, Varning, Upozorenje

Label No 04005704-EE



17531604
5 L
Lot 20200527
Expiry 2020-05

Store at +4 to +30°C

MADE IN SWEDEN

Cytiva Sweden AB
SE-751 84 Uppsala, Sweden
+46 18 612 00 00
cytiva.com

cytiva


Capto™ Q

contains 20% ethanol as preservative



cytiva.com/Instructions

Label No 71502133-EF




17-0033-07
40 kg
Lot 20130531
Pack 201305
Expiry 2013-05

Store at +4 to +30°C
MADE IN SWEDEN

GE Healthcare Bio-Sciences AB
SE-751 84 Uppsala, Sweden
+46 18 612 00 00
www.gelifesciences.com

GE Healthcare



**Sephadex™ G-25
Medium**

Label No 71502133-EG



17003307
40 kg
Lot 20200320
Pack 20200320
Expiry 2020-03

Store at +4 to +30°C
MADE IN SWEDEN

Cytiva Sweden AB
SE-751 84 Uppsala, Sweden
+46 18 612 00 00
cytiva.com

cytiva

**Sephadex™ G-25
Medium**

Label No 28931985-AD

GE Healthcare

**ReadyToProcess™
Q Sepharose™ FF
10 L (251/200)**

10 L column

Lot 20170815
Expiry 2017-08
Id No. 20170815

Store at +4 to +30°C
MADE IN SWEDEN

GE Healthcare Bio-Sciences AB
SE-751 84 Uppsala, Sweden
+46 18 612 00 00
www.gelifsciences.com

contains 20% ethanol as preservative

Max Operating Pressure: 4 Bar
Max Operating Temperature: 30°C

* for research and further manufacturing use only

Flammable liquid and vapour. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Wear protective gloves and eye or face protection. Keep cool. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.

Warning 

Label No 28921005-AE

cytiva

**ReadyToProcess™
Q Sepharose™ FF
10 L (251/200)**

10 L column

28929079

Lot 20200330
Expiry 2020-03
Id No. 20200330

Store at +4 to +30°C
MADE IN SWEDEN


Cytiva Sweden AB
SE-751 84 Uppsala, Sweden
+46 18 612 00 00
cytiva.com

contains 20% ethanol as preservative

Max Operating Pressure: 4 Bar
Max Operating Temperature: 30°C

* for research and further manufacturing use only

Flammable liquid and vapour. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Wear protective gloves and eye or face protection. Keep cool. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.

Warning 

Label No 29107200-AA

GE Healthcare

**Series S
Sensor Chip CM3**

Pack of 1

Lot 20140414
Expiry 2014-04

Store at +2 to +8°C
MADE IN SWEDEN

GE Healthcare Bio-Sciences AB
SE-751 84 Uppsala, Sweden
+46 18 612 00 00
www.gelifsciences.com

Label No 29107200-AB

cytiva

**Series S
Sensor Chip CM3**

Pack of 1

29104990

Lot 20200428
Expiry 2020-04

Store at +2 to +8°C
MADE IN SWEDEN

Cytiva Sweden AB
SE-751 84 Uppsala, Sweden
+46 18 612 00 00
cytiva.com

Label No 14004040-AP

GE Healthcare

**Ficoll-Paque™ PREMIUM
sterile solution**

500 ml
(sold as 6x500 ml)

Lot 20130219
Expiry 2013-02

protect from direct light
Store at +4 to +30°C
MADE IN SWEDEN

GE Healthcare Bio-Sciences AB
SE-751 84 Uppsala, Sweden
+46 18 612 00 00
www.gelifsciences.com

density 1.077 ±0.001 g/ml (+20°C)

mononuclear cell preparation
endotoxin tested (<0.12 EU/ml)

Manufactured under a Quality Management System
certified to ISO 13485

For Research Use Only
Not for use in diagnostic procedures

Label No 14004040-AG

cytiva

**Ficoll-Paque™ PREMIUM
sterile solution**

500 mL
(sold as 6x500 mL)

Lot 20200508
Expiry 2020-05

protect from direct light
Store at +4 to +30°C
MADE IN SWEDEN

Cytiva Sweden AB
SE-751 84 Uppsala, Sweden
+46 18 612 00 00
cytiva.com

density 1.077 ±0.001 g/mL (+20°C)

mononuclear cell preparation
endotoxin tested (<0.12 EU/mL)

Manufactured under a Quality Management System
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