TERUMOBCT

40814

Anticoagulant Citrate Dextrose Solution Ph Eur (ACD) Solution A 500 mL

40818

Anticoagulant Citrate Dextrose Solution Ph Eur (ACD) Solution A 750 mL

Ingredient Information

Component	Percent (%w/v)	grams/100 mL	CAS Number
Citric Acid Monohydrate (Acidum Citricum Monohydricum Ph Eur)	0.80%	0.80 g	5949-29-1
Sodium Citrate Dihydrate (Natrii Citras Dihydricum Ph Eur)	2.20%	2.20 g	6132-04-3
Dextrose Monohydrate (Glucosum Monohydricum Ph Eur)	2.45%	2.45 g	14431-43-7
Water for Injection (Aqua ad Injectabilia Ph Eur)	_	_	_

General Specifications

Catalog Numbers	40814, 40818 Terumo BCT, Inc., Lakewood, CO		
Legal Manufacturer			
Manufacturing Location	Larne, UK		
Declaration of Conformity	The conformity assessment was done in conformance with the procedures set out in Annex II, Section 3.2, Full Quality Assurance System of the Council Directive 93/42/EEC as amended, under the supervision of BSI.		
Referenced Standards	See applicable standards document. EN ISO 10993-1:2009; 10993-2:2006; 10993-3:2003/(R)2009; 10993-4:2009; 10993-5:2009; 10993-10:2010; 10993-11:2009; 10993-12:2009;10993-17:2002; 10993-18:2005 EN ISO 13485:2003 EN ISO 14971:2012 EN ISO 15223-1:2012 EN ISO 17665-1:2006		
Notified Body Within the European Union	BSI		
GMDN Code	46812, Blood Storage Solution, Anticoagulant		

Packaging Specifications

Quantity of Bags Per Case	500 mL bags:	18
	750 mL bags:	12

External Case Dimension	385 mm × 300 mm	385 mm × 300 mm × 240 mm (15.16 in × 11.81 in × 9.45 in) (L × W × H)		
Case Weight	500 mL bags:	Containing bags: 10.31 kg (22.73 lb)		
	750 mL bags:	Containing bags: 10.90 kg (24.03 lb)		
Bag Primary Packaging	500 mL bags:	220 mm × 135 mm (8.66 in × 5.31 in)		
Dimension	750 mL bags:	290 mm × 135 mm (11.42 in × 5.31 in)		
Recycling	25 PP	Bag overwrap: plastic (0.015 kg, 0.03 lb)		
	Box: cardboard (0.60 kg, 1.32 lb)			
	IFU/Insert: paper (variable)			
Lot Number and Expiry Date	Refer to the Terumo BCT Support Center (TERUMOBCT.COM) for certificates of analysis.			
Location	LOT	Users can find the lot number adjacent to this symbol in the following locations on the packaging: box label, bag label.		
	\geq	Users can find the expiration date adjacent to this symbol in the following locations on the packaging: box label, bag label.		

Technical Specifications

Sterilization	STERILE Indicates that the product is sterilized using steam or dry heat. This product is steam sterilized.		
	Indicates that the product should not be reused.		
	Indicates that the product is non-pyrogenic.		
Expiry Date	24 months from the date of manufacture. Refer to product labeling for Expiry Date. No special shipping conditions required.		
Shipping Conditions			
Bag Storage Conditions	Indicates the temperature limitations for product storage when accompanied by temperature(s).		
	Store at up to 25 °C.		
	Protect from freezing.		
	Avoid excessive heat.		

Bag Specifications

Bag Composition	Bag: Polyolefin Connectivity: Luer (made of polycarbonate) with a frangible connector Injection port: polycarbonate, polypropylene and elastomer
	Not made with natural rubber latex, PVC, or Di (2-ethylhexyl) phthalate (DEHP).



Terumo BCT, Inc. 10811 W. Collins Avenue Lakewood, Colorado 80215 USA USA Phone: +1.877.339.4228

Phone: +1.303.231.4357 USA Fax: +1.866.715.6768 Fax: +1.303.542.5215



Terumo BCT Europe N.V. Ikaroslaan 41 1930 Zaventem Belgium Phone: +32.2.715.05.90

Fax: +32.2.721.07.70

TERUMOBCT.COM

2015-08 ©2015 Terumo BCT, Inc. Part No. 777020-370