



Miltenyi Biotec

CliniMACS® PBS/EDTA Buffer CR/GMP

CliniMACS PBS/EDTA Buffer 1,000 mL CR/GMP

REF 220-001-827*

CliniMACS PBS/EDTA Buffer 3,000 mL CR/GMP

REF 200-070-022*

CAUTION:

The product as part of the MACS GMP family is for *ex vivo* cell processing only and it is Limited by Federal (or United States) Law to Investigational Use or under an FDA Approval. The product is not intended for human *in vivo* applications.

Contents

QTY	One bag contains:
	1,000 mL of CliniMACS PBS/EDTA Buffer CR/GMP or
	3,000 mL of CliniMACS PBS/EDTA Buffer CR/GMP

Composition

100 mL (pH 7.2) contain:	
Sodium Chloride (NaCl)	800 mg
Potassium Chloride (KCl)	19 mg
Disodium Hydrogen Phosphate (Na ₂ HPO ₄)	115 mg
Potassium Dihydrogen Phosphate (KH ₂ PO ₄)	19 mg
Edetate Disodium (Na ₂ EDTA × 2H ₂ O)	37 mg
Water for Injection (H ₂ O)	ad 100 mL
in polypropylene (PP) bag.	

Intended purpose

The CliniMACS PBS/EDTA Buffer CR/GMP is intended as wash and transport fluid for *in vitro* pre-separation or other processing of human cells from heterogeneous cell populations in combination with the CliniMACS System only, enabling further cultivation and/or genetic modification of the cells.

Side effects

Side effects have not been reported.

Precautions



The instructions for use including those described in the corresponding CliniMACS user manuals must be followed.

Further processing and use in clinical applications must be in accordance with national legislation and regulations. In the U.S., the FDA investigational use regulations must be observed.

Any clinical application of the separated cells is exclusively within the responsibility of the user.

The separation of cells using this product must be performed by trained operators only.

All materials which have come into contact with blood and blood products must be treated as infectious material. Regulations for the treatment of infectious material must be observed.

Warnings



The product is intended for *in vitro* use only. Not for intravenous infusion. Not for parenteral applications.

Drugs may be incompatible with the buffer. Do not add drugs to the buffer other than Human Serum Albumin as specified in the corresponding user manual.

Do not use the 3,000 mL Buffer with the CliniMACS Plus Instrument.



Do not use after the use-by date printed on the product label.



Do not use if package is damaged. Use buffer only if the bag is undamaged and sealed.



Do not re-use.

Storage

Store the product at a controlled room temperature of +20 °C to +25 °C (+68 °F to +77 °F). Do not freeze.

Further information

The product is tested for endotoxins.



The packaging is PVC free.



The buffer is sterilized by autoclaving.

Animal origin

The declaration of animal- or human-derived materials is given on the Certificate of Origin.

Instructions for use



If a user manual is available, additional information on specific applications involving magnetic cell labeling procedures can be found there.



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Regulatory and legal notes

Disclaimer & Quality Statement

CR/GMP products are for *ex vivo* cell processing only, and are not intended for human *in vivo* applications.

CR/GMP products are designed, manufactured and tested under an ISO 13485 quality management system and are in compliance with relevant GMP guidelines. They are designed following the recommendations of USP <1043> on ancillary materials.

Warranty

The products sold hereunder are warranted only to be free from defects in workmanship and material at the time of delivery to the customer. Miltenyi Biotec B.V. & Co. KG makes no warranty or representation, either expressed or implied, with respect to the fitness of a product for a particular purpose. There are no warranties, expressed or implied, which extend beyond the Technical Specification of the products. Miltenyi Biotec B.V. & Co. KG's liability is limited to either replacement of the products or refund of the purchase price. Miltenyi Biotec B.V. & Co. KG is not liable for any property damage, personal injury or economic loss caused by the product.

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REF 200-070-022 (previously REF 700-29)