Miltenyi Biotec

MACS® GMP Tytonase EDTAble (20× stock solution)

Order no. 170-100-122

Contents

1. **Description**
2. **Applications**
3. **Warnings and precautions**
4. **Instructions for use**
5. **Glossary of symbols**

1. Description

Components	1×5 mL MACS® GMP Tytonase EDTAble (20× stock solution)
Composition	MACS GMP Tytonase (20× stock solution) is supplied in PBS/EDTA Buffer pH 7.2 + 0.1% poloxamer 188
Sterility	Sterility of the bottled product is tested according to Ph. Eur.
Transport	At +2 °C to +8 °C (+36 °F to +46 °F)
Storage	Store at +2 °C to +8 °C (+36 °F to +46 °F) directly upon arrival.
Shelf life	The use-by date is indicated on the vial label.

Disclaimer

MACS GMP Products are for *ex vivo* cell processing only, and are not intended for human *in vivo* applications. For regulatory status in the USA, please contact your local representative.

Quality statement

MACS 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. The manufacturing and testing of this product is in compliance with EP chapter 5.2.12 for "Raw materials of biological origin for the production of cell-based and gene therapy medicinal products".

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

2. Applications

- The final Buffer for the MACSQuant® Tyto® Cell Sorter consists of two components:

A) CliniMACS PBS/EDTA Buffer CR/GMP, # 220-001-827

B) MACS GMP Tytonase EDTAble (20× stock solution)

The preparation of the final buffer for the MACSQuant Tyto is described in detail in the instructions for use.

3. Warnings and precautions

- The instructions for use must be followed.
- Do not inject or infuse the product directly into humans. Not for human application.
- When using this product, the national legislation and regulations must be followed. Any application of *ex vivo* processed target cells is exclusively within the responsibility of the user.
- For single use only. Do not reuse.
- Use undamaged and sealed vials only.
- Do not use after the use-by date indicated on the vial label.

4. Instructions for use

- The CliniMACS PBS/EDTA Buffer CR/GMP should be supplemented with 0.5% HSA (w/v) prior to use.
- Do not vortex the MACS GMP Tytonase EDTAble (20× stock solution) but mix by inversion.

Note: Please refer to the Special Protocol 'MACS® GMP labeling of cells and preparation for cell sort on MACSQuant® Tyto® Cell Sorter using MACS GMP Tytonase EDTAble' located on the Miltenyi Biotec website for further details how to prepare samples for sorting.

To prepare the Buffer to be used in combination with the MACSQuant Tyto Cell Sorter, supplement 95 mL of CliniMACS PBS/EDTA Buffer CR/GMP with 5 mL MACS GMP Tytonase EDTAble (20× Stock solution).

210-005-196-02 | Issued: 2026-06

Miltenyi Biotec B.V. & Co. KG
Friedrich-Ebert-Straße 68, 51429 Bergisch Gladbach, Germany
+49 2204 8306-0, +49 2204 85197
macs@miltenyibiotec.de
www.miltenyibiotec.com

Miltenyi Biotec Inc.
2303 Lindbergh Street, Auburn, CA 95602, USA
800 FOR MACS, +1 866 811 4466, +1 877 591 1060
macs@miltenyibiotec.com

5. Glossary of symbols

	Manufacturer		Use-by date
REF	Order number		Do not re-use
P/N	Part number		Phone
LOT	Batch code		Fax
	Consult instruction for use		E-mail
	Do not use if package is damaged.		Website

This data sheet and corresponding information can be found under **www.miltenyibiotec.com/170-100-122**.

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 specifications 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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210-005-196-02 | Issued: 2026-06

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