

2000 mL bag	Order no. 170-076-306
1000 mL bottle	Order no. 170-076-307
1000 mL bottle (Phenol Red)	Order no. 170-076-309

Contents

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

1. Description

Components	2000 mL TexMACS™ GMP Medium 1000 mL TexMACS GMP Medium 1000 mL (Phenol Red) TexMACS GMP Medium
Main components	Salts, amino acids, fatty acids, vitamins, buffers.
Human Proteins	Contains human albumin (pharmaceutical grade).
Specifications	Osmolality: 280–340 mOsmol/kg pH: 6.9–7.3 Endotoxin: ≤0.5 EU/mL (Pharmacopoeia Europaea (Ph. Eur.)) Functionality assay: <i>Ex vivo</i> expansion of human T cells. Appearance: clear
Sterility	The medium is 0.1 µm filtered. Tested for sterility.
Transport	At room temperature
Storage	Store TexMACS GMP Medium protected from light at 2–8 °C. Do not freeze.
Shelf life	The use-by date is indicated on the bag/bottle label.

Disclaimer

MACS GMP Products are for research use and *ex vivo* cell culture 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 manufactured and tested under a quality management system (ISO 13485) and are in compliance with relevant GMP guidelines. They are designed following the recommendations of USP <1043> on ancillary materials.

No animal-derived components were used for manufacture of this product.

2. Applications

- TexMACS GMP Medium has been developed for the cultivation and expansion of human T cells and optimized for the use in combination with the CliniMACS® Cytokine Capture System (IFN-gamma).

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 bags and sealed bottles only.
- ▲ Do not use after the use-by date indicated on the label.

4. Instructions for use

TexMACS GMP Medium filled in bags can be supplemented, for example, with cytokines or growth factors. Injection and sampling ports, including female luer locks and a tube for sterile welding maintain an aseptic workflow, to allow easy and convenient sampling.

- ▲ Cultures should be maintained protected from light at 37°C in a 5% CO₂ atmosphere.
- ▲ For additional technical information, such as certificate of analysis (CoA), please visit our website at www.macsgmp.com/certificates.

5. Glossary of symbols



Manufacturer



Order number



Part number



Batch code



Use-by date



Consult instruction for use.



Keep away from sunlight



Do not use if package is damaged.

This data sheet and corresponding information as well as special protocols can be found under www.miltenyibiotec.com/170-076-306, www.miltenyibiotec.com/170-076-307 and www.miltenyibiotec.com/170-076-309.

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 GmbH 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 GmbH's liability is limited to either replacement of the products or refund of the purchase price. Miltenyi Biotec GmbH is not liable for any property damage, personal injury or economic loss caused by the product.

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