MACS® GMP Recombinant Human GM-CSF

25 µg	Order no. 170-076-112
250 µg	Order no. 170-076-136

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1. Description

Components	MACS® GMP Recombinant Human GM-CSF: Purified recombinant human granulocyte macrophage colony-stimulating factor.
Sizes	25 µg or 250 µg
Product format	Lyophilized without carrier protein or preservatives.
Source	*E. coli.*
Specifications	For detailed specifications of MACS GMP Recombinant Human GM-CSF please refer to the respective Product Quality Certificate (PQC).
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 lyophilized MACS GMP Recombinant Human GM-CSF at –20 °C (–4 °F) or lower directly upon arrival. Avoid repeated freeze-thaw cycles.
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

- MACS GMP Recombinant Human GM-CSF can be used for a variety of *ex vivo* cell culture applications.

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

4.1 Reconstitution

- As the product contains no microbiological preservatives, the reconstituted product should be used directly. If not used directly, the user is responsible for storage time and conditions.

4.1.1 Reagent and instrument requirements

- Sterile syringe and needle
- Sterile water for injection (WFI)

4.1.2 Protocol

- Work under sterile conditions.

1. Bring the vial to room temperature. Disinfect surface of the vial before use.
2. It is recommended to reconstitute the lyophilized cytokine with 1 mL of sterile water for injection (WFI).
3. Use an appropriate sterile syringe and sterile needle to add 1 mL of sterile WFI to the lyophilized cytokine.
4. Remove the cap of the vial and disinfect the surface of the rubber plug.
5. Fill the syringe with 1 mL of sterile WFI. Puncture the rubber plug using the needle and carefully add the water from the syringe along the side wall of the vial. Avoid foam formation.

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Mix content thoroughly by carefully swaying the vial until all visible components are dissolved. This usually takes less than one minute. Do not shake or vortex.

6. Remove the reconstituted cytokine from the vial using a sterile syringe and a sterile needle.

4.2 Dilution

- For dilution with PBS or base medium a carrier protein should be included, which may have stabilizing effects.
- Dilutions should be prepared aseptically with either 0.5–1% recombinant human albumin or with 1–10% human autologous serum (HAS).

5. Glossary of symbols

	Manufacturer		Use-by date
REF	Order number		Phone
P/N	Part number		Fax
LOT	Batch code		E-mail
	Consult instruction for use		Website
	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/170-076-112** or **www.miltenyibiotec.com/170-076-136**.

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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