Miltenyi Biotec

MACS® GMP PepTivator® PRAME

Order no. 170-076-157

Contents

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

1. Description

Components	≥60 nmol/peptide MACS® GMP PepTivator® PRAME.
Capacity	For the stimulation of 1×10^9 cells.
Composition	Pool of lyophilized overlapping oligopeptides, (mainly 15-mer), covering the complete sequence of the Melanoma antigen preferentially expressed in tumors (PRAME) (UniProt Acc. no. P78395).
Product format	Lyophilized synthetic peptides as trifluoroacetate salt, containing stabilizer.
Identity	Individual peptides are confirmed by HPLC/mass spectometry (ESI-MS).
Purity	Pool contains peptides with a total purity of ≥90% as determined by RP-HPLC.
Endotoxin content	≤10 EU/vial as determined by kinetic Limulus Amebocyte Lysate (LAL) assay (Pharmacopoeia Europaea (Ph. Eur.)).
Residual solvents	Acetonitrile: ≤1000 ppm; counterion trifluoroacetate (TFA): ≤3% of weight, residual free TFA was not detected; water: ≤3%.
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 PepTivator PRAME 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 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.

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

2. Applications

- MACS GMP PepTivator PRAME can be used for a variety of applications, for example, *in vitro* stimulation of PRAME-specific $CD4^+$ and $CD8^+$ T cells for the enrichment of IFN-gamma–secreting T cells using the CliniMACS® Cytokine Capture System (IFN-gamma) (REF 279-01).

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 the reagent only if the vial is undamaged and sealed.
- 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.
- Work under sterile conditions.

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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, +1 530 888 8871, +1 877 591 1060
macs@miltenyibiotec.com

4.1.1 Reagent and instrument requirements

- Sterile syringe and needle
- Sterile water for injection (WFI)
- (Optional) CliniMACS Cytokine Capture System (IFN-gamma) (REF 279-01)

4.1.2 Protocol

1. Thaw the vial at room temperature. Disinfect surface of the vial before use.
2. It is recommended to reconstitute the lyophilized peptide pool with 2 mL of sterile water for injection (WFI).
3. Use an appropriate sterile syringe and sterile needle to add 2 mL of sterile WFI to the lyophilized peptide pool.
4. Remove the cap of the vial and disinfect the surface of the rubber plug.
5. Fill the syringe with 2 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. Mix content thoroughly by carefully swaying the vial until all visible components are dissolved.
6. Remove the reconstituted PepTivator from the vial using a sterile syringe and a sterile needle.

4.2 *In vitro* restimulation of PRAME–specific T cells

▲ One vial of MACS GMP PepTivator PRAME is sufficient to stimulate up to 10^9 cells.

▲ PRAME–specific T cells can be restimulated starting from leukapheresis harvest, peripheral blood mononuclear cells, or other leukocyte-containing single-cell suspensions.

1. The re-stimulation is performed using TexMACS GMP Medium (Order no. 170-076-306) with an usual volume of the cell sample of 100 mL and a cell density of $0.5–1×10^7$ cells/cm^2 and $1×10^7$ cells/mL in a gas-permeable culture bag.
2. Use MACS GMP PepTivator PRAME in a dilution of 1:50, for example, use 2 mL of the antigen solution for a 100 mL cell sample.
3. Use an appropriate sterile syringe and sterile needle to inject the appropriate amount of the antigen solution into the culture bag.
4. Mix carefully. The final concentration of MACS GMP PepTivator PRAME in the cell suspension is 0.6 nmol (approximately 1 µg) of each peptide per mL.
5. Incubate the cell culture bag at +37 °C (+99 °F) and 5–7% CO_2 between 4 and 6 hours.
6. The PRAME-stimulated T cells can be enriched using the CliniMACS Cytokine Capture System (IFN-gamma) (REF 279-01).

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/170-076-157**.

Warranty

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