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1. Description

Components	≥60 nmol/peptide MACS® GMP PepTivator® HCMV pp65.
Composition	Pool of lyophilized peptides, consisting of oligopeptides (11–15-mer) with 11 amino acids overlap, covering the complete sequence of the pp65 protein of human cytomegalovirus (HCMV) strain AD169 (Swiss-Prot Acc. no. P06725).
Product format	Lyophilized synthetic peptides as trifluoroacetate salt containing stabilizer.
Identity	Individual peptides are confirmed by HPLC/mass spectrometry (ESI-MS).
Statement of origin	No animal-, human-, or virus-derived materials were used for manufacture of this product.
Purity	Pool contains peptides covering the complete HCMV pp65 amino acid sequence 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 2–8 °C.
Storage	Store lyophilized MACS GMP PepTivator HCMV pp65 at –20 °C or lower directly upon arrival. Avoid repeated freeze-thaw cycles. The use-by date is indicated on the vial label.

Quality statement

MACS GMP PepTivator HCMV pp65 is for research use and *ex vivo* cell culture processing only, and is not intended for human *in vivo* applications.

MACS GMP PepTivator HCMV pp65 is manufactured and tested under a certified ISO 9001 quality system and in compliance with relevant GMP guidelines. It is designed following the recommendations of USP <1043> on ancillary materials.

2. Applications

- MACS GMP PepTivator HCMV pp65 can be used for a variety of applications, for example, *in vitro* stimulation of pp65-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.
- ▲ For research use and *ex vivo* cell culture processing only.
- ▲ Not intended for human *in vivo* applications.
- ▲ Do not inject or infuse the product directly into a patient. Not for parenteral 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).
- (Optional) CliniMACS Cytokine Capture System (IFN-gamma) (REF 279-01).

4.1.2 Protocol

▲ Work under sterile conditions.

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 HCMV pp65-specific T cells

▲ One vial of MACS GMP PepTivator pp65 is sufficient to stimulate up to 10^9 cells.

▲ pp65-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 RPMI 1640 Medium supplemented with 10% AB serum with an usual volume of the cell sample of 100 mL and a cell density of $0.5-1 \times 10^7$ cells/cm² and 1×10^7 cells/mL in a gas-permeable culture bag.
2. Use MACS GMP PepTivator HCMV pp65 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 HCMV pp65 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 and 5–7% CO₂ between 4 and 6 hours.
6. The pp65-stimulated T cells can be enriched using the CliniMACS Cytokine Capture System (IFN-gamma) (REF 279-01).

5. Appendix: Glossary of symbols

	Order number
	Part number
	Batch code
	Manufacturer
	Use by
	Caution, consult accompanying documents
	Do not use if package is damaged

All protocols and data sheets are available at www.miltenyibiotec.com.

Warranty

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