Miltenyi Biotec

# MACS® GMP PepTivator® WT1

Order no. 170-076-123

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## 1. Description

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|---|---|
| **Components** | ≥60 nmol/peptide MACS® GMP PepTivator® WT1. |
| **Capacity** | For the stimulation of $1\times10^9$ cells. |
| **Composition** | Pool of lyophilized overlapping oligopeptides, (mainly 15-mer), covering the complete sequence of the Wilms tumor protein (WT1) (Swiss-Prot Acc. no. P19544). |
| **Product format** | Lyophilized synthetic peptides as trifluoro-acetate salt containing stabilizer. |
| **Identity** | Individual peptides are confirmed by HPLC/ mass spectometry (ESI-MS). |
| **Purity** | Pool contains peptides covering the complete WT1 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 trifluoro-acetate (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 WT1 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 WT1 can be used for a variety of applications, for example, *in vitro* stimulation of WT1-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 a 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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#### 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. Bring the vial to 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 WT1–specific T cells

▲ One vial of MACS GMP PepTivator WT1 is sufficient to stimulate up to $10^9$ cells.

▲ WT1-specific T cells can be restimulated starting from leukapheresis harvest, peripheral blood mononuclear cells, or other leukocyte-containing single-cell suspensions.

▲ WT1-specific T cells are expected to be present only in certain individuals. Their frequency may be very low compared to T cells with other specificities. The given protocol for *in vitro* T cell stimulation thus may only serve as a recommendation and is based on experiences using other MACS GMP PepTivator products, for example, MACS GMP PepTivator HCMV pp65.

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×$10^7$ cells/$cm^2$ and 1×$10^7$ cells/mL in a gas-permeable culture bag.

2 Use MACS GMP PepTivator WT1 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 WT1 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 WT1-stimulated T cells can be enriched using the CliniMACS Cytokine Capture System (IFN-gamma) (REF 279-01).

## 5. Glossary of symbols

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|---|---|---|---|
| | 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/170-076-123**.

#### Warranty

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