



Miltenyi Biotec

MACS® GMP Recombinant Human IL-2

25 µg

Order no. 170-076-148

100 µg

Order no. 170-076-146

500 µg

Order no. 170-076-147

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1. Description

Components	MACS® GMP Recombinant Human IL-2: Purified recombinant human interleukin 2
Sizes	25 µg, 100 µg, or 500 µg
Product format	Lyophilized without carrier protein or preservatives.
Biological activity	The specific activity* is at least 1.0×10^6 IU/mg. The biological activity of the specific lot is indicated on the Certificate of Analysis.
Identity/ Molecular mass	15400 Da, determined by mass spectrometry. This corresponds to the mature form of human IL-2 with a cysteine-to-serine substitution at amino acid sequence position 125 (133 amino acids).
Source	<i>E. coli</i> .
Purity	≥95 % as determined by chip electrophoresis
Endotoxin content	25 µg: <2.5 EU/vial 100 µg: <10 EU/vial 500 µg: <50 EU/vial as determined by kinetic Limulus Amoebocyte Lysate (LAL) assay (Pharmacopoeia Europaea (Ph. Eur.)).
Residual host cell DNA content	25 µg size: <5 ng DNA/vial 100 µg size: <20 ng DNA/vial 500 µg size: <100 ng DNA/vial as determined by quantitative PCR specific for <i>E. coli</i> genomic DNA.
Residual host cell protein content	25 µg size: <25 ng host cell protein/vial 100 µg size: <100 ng host cell protein/vial 500 µg size: <500 ng host cell protein/vial as determined by <i>E. coli</i> HCP ELISA.

* The specific activity is determined by proliferation assay according to Gearing and Bird¹ using CTLL-2 cells. The proliferation assay was calibrated with the 2nd international standard for human IL-2 (NIBSC code 86/500) provided by the National Institute for Biological Standards and Control.

Sterility

Sterility of the bottled product is tested according to Ph. Eur.

Transport

At 2–8 °C

Storage

Store MACS GMP Recombinant Human IL-2 at –20 °C 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 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- or human-derived materials were used for the manufacture of this product, unless otherwise stated in the respective Certificate of Origin.

2. Applications

MACS GMP Recombinant Human IL-2 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.

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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. 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. References

1. Gearing, A.J.H. and C.B. Bird (1987) in *Lymphokines and Interferons, A Practical Approach*. Clemens, M.J. *et al.* (eds): IRL Press. 295.

6. Glossary of symbols



Manufacturer



Order number



Part number



Batch code



Use-by date



Consult instruction for use.



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/170-076-146, www.miltenyibiotec.com/170-076-147, or www.miltenyibiotec.com/170-076-148.

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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