

MACS® GMP Recombinant Human IL-12

5 μg Order no. 170-076-173 25 μg Order no. 170-076-174 100 μg Order no. 170-076-175

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

2. Applications

MACS GMP Recombinant Human IL-12 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.
- 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.

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1. Description

Components MACS® GMP Recombinant Human IL-12:

Purified recombinant human interleukin 12.

Sizes 5 μg, 25 μg or 100 μg

Product format Lyophilized without carrier protein or

preservatives.

Source CHO cells

Specifications For detailed specifications of MACS GMP

Recombinant Human IL-12 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 IL-12 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

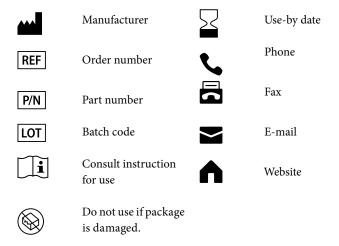
MACS GMP Products are manufactured and tested under a quality management system (ISO 13485) and are in compliance with relevant GMP guidelines. They are designed following the recommendations of USP <1043> on ancillary materials. The manufacturing and testing of this product is compliant with the requirements laid down in the Ph. Eur. Chapter 5.2.12.

- 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. Glossary of symbols



This data sheet and corresponding information as well as special protocols can be found under www.miltenyibiotec.com/170-076-173, www.miltenyibiotec.com/170-076-174 and www.miltenyibiotec.com/170-076-175.

Warranty

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