



Miltenyi Biotec

MACS® GMP Nuclease A

100 KU
1 MU
4×1 MU

Order no. 170-100-127
Order no. 170-100-124
Order no. 170-100-126

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1. Description

| | |
|----------------------------|---|
| Components | MACS GMP Nuclease A |
| Sizes | 100 KU, 1 MU, or 4×1 MU |
| Composition | MACS GMP Nuclease A is supplied in 20 mM Tris-HCl (pH 8.0), 2 mM MgCl ₂ , 20 mM NaCl, 50% (v/v) glycerol |
| Endotoxin content | ≤ 0.25 EU / 1000 U as determined by kinetic Limulus Amebocyte Lysate (LAL) assay (Pharmacopoeia Europaea (Ph. Eur.)). |
| Functionality assay | ≥ 250 U/μL |
| Source | <i>E. coli</i> |
| Specifications | For detailed specifications of MACS GMP Nuclease A 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 MACS GMP Nuclease A at -20 °C (-4 °F) 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 designed, manufactured and tested under an ISO 13485 quality management system 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 in compliance with EP chapter 5.2.12 for “Raw materials of biological origin for the production of cell-based and gene therapy medicinal products”.

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












2. Applications

MACS GMP Nuclease A is intended as an enzymatic component for *in vitro* degradation of residual nucleic acids. It can be used for viral vector, biologics and vaccine production, sample preparation in electrophoresis and chromatography and prevention of cell clumping and viscosity.

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.
- ▲ The product is intended to be used by trained operators and in a GMP environment for clinical applications.

4. Glossary of symbols

| | | | |
|---|-----------------------------------|---|-------------|
|  | Manufacturer |  | Use-by date |
|  | Order number |  | Phone |
|  | Part number |  | Fax |
|  | 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/170-100-127, www.miltenyibiotec.com/170-100-124 and www.miltenyibiotec.com/170-100-126.

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 B.V. & Co. KG 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 B.V. & Co. KG's liability is limited to either replacement of the products or refund of the purchase price. Miltenyi Biotec B.V. & Co. KG is not liable for any property damage, personal injury or economic loss caused by the product.

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