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## 1. Description

Components	0.2 mg in 1 mL MACS GMP CD3 pure or 1 mg in 1 mL MACS GMP CD3 pure.
Product format	Antibodies are supplied in phosphate-buffered saline (PBS), pH 7.5, with 200 ppm polysorbate 80.
Clone	OKT3 (isotype: mouse IgG2a)
Identity	Mass of light chain is confirmed by mass spectometry (ESI-MS).
Source	Mouse hybridoma cells.
Purity	≥95% as determined by chip electrophores is.
Endotoxin content	<2 EU/vial as determined by kinetic Limulus Amebocyte Lysate (LAL) assay (Pharmacopoeia Europaea (Ph. Eur.)).
Residual host cell DNA content	$\leq$ 100 pg DNA/mg IgG as determined by quantitative PCR specific for mouse genomic DNA.
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 CD3 pure at +2 °C to +8 °C (+36 °F to +46 °F) directly upon arrival.
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".

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# MACS® GMP CD3 pure

 0.2 mg in 1 mL
 Order no. 170-076-124

 1 mg in 1 mL
 Order no. 170-076-116

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

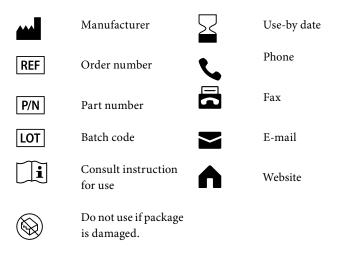
## 2. Applications

• MACS GMP CD3 pure 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. Glossary of symbols



This data sheet and corresponding information as well as special protocols can be found under www.miltenyibiotec.com/170-076-124 or www.miltenyibiotec.com/170-076-116.

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#### Warranty

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