Miltenyi Biotec

MACS® GMP T Cell TransAct™ - Large Scale CR/GMP

Order no. 200-076-204

CAUTION:
The product as part of the MACS GMP family is for *ex vivo* cell processing only and it is Limited by Federal (or United States) Law to Investigational Use or under an FDA Approval. The product is not intended for human *in vivo* applications.

Contents

1. **Description**
2. **Intended purpose**
3. **Warnings and precautions**
4. **Instructions for use**
5. **Glossary of symbols**

1. Description

Components	One vial containing 4 mL MACS® GMP T Cell TransAct™ – Large Scale CR/GMP
Capacity	The reagent is sufficient to activate and expand up to 4×10^8 enriched $CD3^+$ T cells in a maximal volume of 210 mL, when used at recommended titer of 1:52.5.
Product format	Polymeric nanomatrix conjugated to humanized CD3 and CD28 agonist supplied in phosphate buffered-saline (PBS), containing 0.03% poloxamer 188 and 5 g/L recombinant human serum albumin, pH 7.3–7.9
Endotoxin content	≤2 EU/vial as determined by kinetic Limulus Amebocyte Lysate (LAL) assay (Pharmacopoeia Europaea (Ph. Eur.)).
T cell proliferation assay	≥ 20% CD25/CD69 co-expression on day 2 ≥ 80% proliferating T cells on day 7
Sterility	Sterility is tested according to Ph. Eur.
Transport	At +2 °C to +8 °C (+36 °F to +46 °F)
Storage	Store protected from light at +2 °C to +8 °C (+36 °F to +46 °F). Do not freeze.
Shelf life	The use-by date is indicated on the vial label.

Disclaimer

CR/GMP products are for *ex vivo* cell processing only, and are not intended for human *in vivo* applications.

Quality statement

CR/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.

Background information

The MACS GMP T Cell TransAct – Large Scale CR/GMP has been designed to activate and expand enriched T cell populations, and is provided in a format directly applicable to the CliniMACS® Prodigy. Polyclonal T cell expansion can be used when increased numbers of effector cells are required or when T cells are activated to enable gene modification.

Due to the nanoscale structure of the MACS GMP T Cell TransAct – Large Scale CR/GMP, it can be sterile filtered and excess reagent can be removed by centrifugation and following conventional supernatant replacement. This reagent is suitable for the use in automated culture Systems, such as the CliniMACS Prodigy.

2. Intended purpose

- The MACS GMP T Cell TransAct – Large Scale CR/GMP is intended for the *in vitro* stimulation and expansion of human T cells from hematological cell populations (e.g. PBMC or CD4 and CD8 enriched T cells).

3. Warnings and precautions

- The instructions for use must be followed.
- Do not inject or infuse the product directly into humans. Not for human applications.
- 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 re-use.
- Use only if vials are undamaged and sealed.
- Do not use after the use-by date indicated on the vial label.

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4. Instructions for use

4.1 Reagents and materials required

Product	Order No
CliniMACS® Prodigy TS 620 (CR)	170-076-620
MACS GMP® T Cell TransAct™ – Large Scale CR/GMP	200-076-204
TexMACS™ GMP Medium – 2000mL	170-076-306
MACS® GMP Recombinant Human IL-2, or equivalent	170-076-148
MACS® GMP Recombinant Human IL-7, or equivalent	170-076-111
MACS® GMP Recombinant Human IL-15, or equivalent	170-076-114

4.2 General notes

- Excess MACS GMP T Cell TransAct – Large Scale CR/GMP is removed by a washing step, e.g. centrifugation (at least 10-fold reduction) 2-3 days after initial stimulation. Performing a washing step earlier may result in reduced T cell proliferation.
- MACS GMP T Cell TransAct – Large Scale CR/GMP has been developed in combination with TexMACS™ GMP Medium and IL-7 + IL-15 or IL-2.
- MACS GMP T Cell TransAct – Large Scale CR/GMP can be used in combination with lentiviral transduction. It is recommended to transduce T cells with lentiviral vector one day after stimulation.
- Presence of residual EDTA (e.g. when using CliniMACS buffer) will hamper T cell stimulation. Ensure removal (i.e. over 200-fold reduction) of EDTA prior to T cell stimulation with MACS GMP T Cell TransAct – Large Scale CR/GMP e.g. via a washing step.

4.3 Protocol

4.3.1 Fresh or Frozen cell product with CliniMACS Prodigy System

For automated stimulation of fresh CD4 and CD8 enriched T cells with MACS GMP T Cell TransAct- Large Scale CR/GMP, a final dilution of 1:52.5 is recommended. Cells should be cultured at a concentration of 1.9×10^6 cells/mL. Stimulation of frozen cell product can be performed after thaw and automatic DMSO removal prior to CD4 and CD8 enrichment by the CliniMACS Prodigy T Cell Transduction - Large Scale process. Refer to CliniMACS Prodigy T Cell Transduction - Large Scale User manual for more information.

4.3.2 Manual preparation of fresh or frozen cell product

For stimulation of CD4 and CD8 enriched T cells from fresh or thawed cell product with MACS GMP T Cell TransAct – Large Scale CR/GMP, a final dilution of 1:52.5 is recommended. Cells should be cultured at a concentration of 1.0×10^6 cells/mL. When working with frozen material, it is recommended (before further downstream activities) to rapidly thaw the cells, wash away the freezing solution containing DMSO, resuspend the cells in culture medium at densities below 5×10^6 cells/mL and rest the cells overnight at +37 °C (+99 °F) and 5% CO_2, in culture medium.

5. Glossary of symbols

	Manufacturer		Use-by date
REF	Order number		Do not reuse
P/N	Part number	+2 °C +8 °C	Temperature limit
LOT	Batch code		Phone
	Consult instruction for use		Fax
	Do not use if package is damaged.		E-mail
	Caution		Website

This data sheet and corresponding information as well as special protocols can be found under **www.miltenyibiotec.com/200-076-204.**

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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