

# CellGenix® Preclinical Recombinant Human Transforming Growth Factor-beta 1 (rh TGF-β1)



## Product Information

CellGenix® Recombinant Human TGF-β1 reliably promotes the expansion of induced pluripotent stem cells (iPSC), embryonic stem cells (ESC), mesenchymal stem cells (MSC) as well as regulatory T cells (Tregs). It also stimulates the differentiation of T cells into Tregs.

CellGenix® Recombinant Human TGF-β1 is produced using a human amniocyte cell line (CAP®). By using the CAP® technology we are able to produce this difficult to express glyco-protein with authentic human post-translational modifications. These human post-translational modifications are not accessible by bacterial expression.

Final manufacturing steps and QC are performed in a GMP facility. No animal or human-derived components are present in the final product, and with the exception of the production cell line, no animal or human-derived materials were used in production (ADCF Level 1). The production cell line was derived from a human amniocyte cell line (CAP®) and was characterized following ICH Guidelines Q5A and Q5D. For the originating CAP® cell bank a Biologics Master File (BB-MF) was submitted to the U.S. Food and Drug Administration (FDA).

## Features and Benefits

- Native folding & glycosylation: expressed in human CAP® cells
- Safe and ADCF: CAP® cell line extensively characterized and tested for viruses
- Seamless transition from early development to clinical stages with consistent product quality & performance

## Application

Transforming Growth Factor-beta 1 (TGF-β1) is a member of the growth factor beta superfamily and plays a role in various cellular functions like cell differentiation, proliferation and apoptosis. It is secreted by most immune cells and especially interacts with T cells, B cells, macrophages and monocytes. TGF-β1 is used in the cell and gene therapy space to promote expansion of iPSC, ESC, MSC and Tregs.

## Product Characteristics

<b>Source</b>	Human amniocyte cell line (CAP®)
<b>Description</b>	Human Transforming Growth Factor-beta 1, accession # P01137, Ala279-Ser390 Molecular mass 25.6 kDa per homodimer
<b>Formulation</b>	Lyophilized from a 0.2 µm-filtered solution containing 1% Mannitol
<b>Intended use</b>	For preclinical <i>ex vivo</i> use. Not intended for therapeutic use.

<sup>1</sup>CAP® is a registered trademark of CEVEC Pharmaceuticals GmbH, Germany.

## Quality Parameters

<b>Identity</b>	Confirmed by Immunoblot of the final product
<b>Activity</b>	≥ 9 x 10 <sup>6</sup> IU/mg calibrated against NIBSC #89/514 Measured in a cell proliferation assay using a TGF-β1-dependent cell line, HT2 clone A5E
<b>Purity</b>	≥ 95 %, as determined by SDS-PAGE (under reducing conditions, visualized by Coomassie staining)
<b>Endotoxin</b>	≤ 10 EU/mg, as determined by LAL gel clot test
<b>Sterility</b>	Sterility test of the vial product
<b>Mass per vial</b>	≥ 40 µg
<b>Animal-derived component-free</b>	<b>ADCF Level 1:</b> The final product contains neither animal- nor human-derived materials. Please refer to Technical Note "Animal-Derived Component-Free Policy CellGenix® Preclinical and GMP Cytokines".

## Shipment and Storage

<b>Transport</b>	Ambient temperature. Please refer to Technical Note "Shipment of CellGenix® Preclinical and GMP Cytokines at Ambient Temperatures".
<b>Shelf Life</b>	3 years from date of shipment
<b>Storage and Stability</b>	Store lyophilized cytokine at -20°C to -80°C. Avoid repeated freeze/thaw cycles.

## Handling Instructions

<b>Reconstitution</b>	Recommended in sterile water to a final concentration of 250 µg/mL (for 50 µg vials).
<b>Dilution</b>	Recommended in CellGenix® serum-free media. For dilution with protein free medium, a carrier protein (0.1-1% albumin or 1-10% appropriate serum) has to be included. Failure to dilute product according to these instructions may result in loss of activity.

## Packaging

CellGenix® cytokines are provided in glass vials, closed with vacuum rubber stoppers and sealed with aluminum tear off caps. The following materials are used:

### Glass vials

For 50 µg vials: Glass vials (2 mL; colorless; 35.00 x 13.75 mm) with DIN Crimp Neck N13-2 made from borosilicate glass hydrolytic type I (in compliance with Ph. Eur. 3.2.1 and USP <660> glass containers for pharmaceutical use).

### Vacuum rubber stoppers, Type I butyl rubber

The formulation is 4023/50/grey. This corresponds to bromobutyl rubber with a hardness of 50 (hardness measured in shore A). This is compliant with Ph. Eur. 3.2.9 Type 1 and with the physicochemical tests as described in USP General Chapter <381> "Elastomeric Closures for Injections".

### Aluminum tear off caps

Aluminum tear off caps (13 mm; gold) are produced in accordance to valid quality criteria for metal caps.

The container closure has been validated after a storage period of up to 5 years at -80 °C by verification of sterility. In addition, the container closure has been demonstrated according to USP <671>.

## Ordering Information

Product Description	Size & Package	Storage	Cat. No.
CellGenix® Preclinical rh TGF-β1	50 µg	-20°C to -80°C	1426-050

## Sartorius is Your Reliable Supply Partner

High-quality raw materials are essential to ensure safety, efficacy and batch-to-batch consistency. We propose premium-grade raw materials suitable from preclinical development to the manufacturing of the therapy. Our GMP grade products allow for the safe use in clinical trials and commercial manufacturing.

Our GMP cytokines include documented evidence of lot specific sterility, activity, and shelf-life. Our experts will help simplify your raw material qualification and validation efforts. We provide customized solutions to your enquiries, as well as quality control services to ensure the quality of our products. Our regulatory expertise guarantees a suited service to your regulatory procedures, ensuring an extensive support every step of the process.

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