

## Data Sheet

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

Preclinical Grade - Order No.: 1426-050 (50 µg)

## Product Characteristics

Source	CAP® <sup>1</sup>
Description	Human Transforming Growth Factor-beta 1, accession # P01137, Ala279-Ser390 Molecular mass 25.6 kDa per homodimer
Formulation	Lyophilized from a 0.2 µm-filtered solution containing 1% Mannitol

## Quality Parameters

Identity	Confirmed by Immunoblot of the final product
Activity	≥ 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
Purity	≥ 90 % <sup>2</sup> , as determined by SDS-PAGE (under reducing conditions, visualized by Coomassie staining)
Endotoxin	< 10 EU/mg, as determined by LAL gel clot test
Sterility	Sterility test of the vial product (direct inoculation)
Mass per vial	50 µg
Animal-derived component-free	<b>ADCF Level 1:</b> The final product contains neither animal- nor human-derived materials.

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<sup>1</sup> The production cell line was derived from an extensively characterized human amniocyte cell line (CAP®). CAP® is a registered trademark of CEVEC Pharmaceuticals GmbH, Germany.

<sup>2</sup> May contain up to 2% of Insulin-like growth factor-binding protein 2 (IGFBP-2) as a host cell-derived impurity.

## Shipment & Storage

<b>Transport</b>	Ambient temperature. Please refer to Technote ( <a href="http://www.cellgenix.com">www.cellgenix.com</a> )
<b>Expiry</b>	3 years from date of shipment
<b>Storage &amp; 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.

## Quality Statement

Final manufacturing steps and QC are performed in a GMP facility.

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