

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® ¹
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
Intended use	For preclinical <i>ex vivo</i> use. Not intended for therapeutic use.

Quality Parameters

Identity	Confirmed by Immunoblot of the final product
Activity	≥ 9 x 10 ⁶ 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 % ² , 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	ADCF Level 1: The final product contains neither animal- nor human-derived materials.

¹ 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.

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

Shipment & Storage

Transport	Ambient temperature. Please refer to Technote (www.cellgenix.com)
Expiry	3 years from date of shipment
Storage & Stability	Store lyophilized cytokine at -20°C to -80 °C. Avoid repeated freeze/thaw cycles.

Handling Instructions

Reconstitution	Recommended in sterile water to a final concentration of 250 µg/ml (for 50 µg vials).
Dilution	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.