Data Sheet

CellGenix® Recombinant Human Tumor Necrosis Factor-alpha (rh TNF-α)

Preclinical Grade - Order No.: 1406-010 (10 µg), 1406-050 (50 µg)

Product Characteristics

Source	*E. coli*
Description	Human TNF-α accession # P01375, Val77-Leu233 N-terminal Met Molecular mass 17.5 kDa
Formulation	Lyophilized from a 0.2 µm-filtered solution containing 1.5 mM potassium phosphate, 8.1 mM sodium phosphate, 2.7 mM potassium chloride, and 137 mM sodium chloride, pH 7.5.
Intended use	For preclinical *ex vivo* use. Not intended for therapeutic use.

Quality Parameters

Activity	≥ 20 x 10^6 IU/mg calibrated against NIBSC #88/786 Measured in a cell cytotoxicity assay using a TNFα-sensitive cell line, L929
Purity	≥ 95 %, as determined by SDS-PAGE (under reducing and non-reducing conditions, visualized by Coomassie staining)
Endotoxin	< 1000 EU/mg, as determined by LAL gel clot test
Sterility	Sterility test of the vialed product (direct inoculation)
Mass per vial	1406-010: 10 µg, 1406-050: 50 µg
Animal-derived component-free	**ADCF Level 2:** The final product contains neither animal- nor human-derived materials. ADCF Level 2 cytokines are produced in our dedicated animal-free facility. No animal-derived components are used throughout the complete production process. All ADCF Level 2 cytokines are produced in *E. coli*.

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. Store a 100 µg/ml reconstituted cytokine solution: • 4 weeks at 2°C to 8°C under sterile conditions after reconstitution. Store in the original container. • 4 months at -20°C to -80°C under sterile conditions after reconstitution. Store in 80 µl aliquots in polypropylene cryogenic vials. Avoid repeated freeze/thaw cycles.

Handling Instructions

Reconstitution	Recommended in sterile water to a final concentration of 100 µg/ml (for 10 µg vials) or 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.

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