

## Data Sheet

# CellGenix® GMP Recombinant Human Tumor Necrosis Factor-alpha (rh TNF- $\alpha$ )

Order No.: 1006-050 (50  $\mu$ g)

## Product Characteristics

Source	<i>E. coli</i>
Description	Human TNF-alpha, accession # P01375, Val77-Leu233 N-terminal Met Molecular mass 17.5 kDa
Formulation	Lyophilized from a 0.2 $\mu$ m-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 clinical <i>ex vivo</i> use. Not intended for human <i>in vivo</i> application.

## Quality Parameters

Identity	Confirmed by DNA-sequencing of the expression plasmid in end-of-production cells and N-terminal sequencing of the final product
Activity	20 - 80 x 10 <sup>6</sup> IU/mg calibrated against NIBSC #88/786 Measured in a cell cytotoxicity assay using a TNF- $\alpha$ -sensitive cell line, L929
Purity	$\geq$ 97 %, as determined by SDS-PAGE (under reducing and non-reducing conditions, visualized by Coomassie staining)
Product-related proteins	$\leq$ 10 % oligomers as determined by SDS-PAGE (under non-reducing conditions, visualized by Coomassie staining)
Host-cell DNA	$\leq$ 200 ng/mg, as determined with a fluorimetric assay
Host-cell protein	$\leq$ 1.0 $\mu$ g/mg, as determined by ELISA
Endotoxin	$\leq$ 50 EU/mg, as determined by LAL gel clot test according to Ph. Eur. and USP
Sterility	Sterility test according to Ph. Eur. and USP of the vial product (direct inoculation)
Mass per vial	43 - 57 $\mu$ g, as determined by spectrophotometrical measurement
Animal-derived component-free	<b>ADCF Level 2:</b> 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 <i>E. coli</i> .

## Shipment & Storage

<b>Transport</b>	Ambient temperature. Please refer to Technote ( <a href="http://www.cellgenix.com">www.cellgenix.com</a> )
<b>Expiry</b>	Minimum 6 months from date of shipping
<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.
<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

This product is manufactured, tested and released in compliance with the relevant GMP-guidelines. USP chapter <1043> has been considered in the design of this product. This product is compliant with Ph. Eur. general chapter 5.2.12.