

# CellGenix<sup>®</sup> Recombinant Human Tumor Necrosis Factor-alpha (rh TNF- $\alpha$ )



## Product Information

CellGenix<sup>®</sup> Recombinant Human TNF- $\alpha$  reliably stimulates the maturation of immature dendritic cells (DCs). Final manufacturing steps and QC are performed in a GMP facility. No animal- or human-derived components are present in the final product and no animal- or human-derived materials were used in production (ADCF Level 2).

## Features and Benefits

- Seamless transition from early development to clinical stages with consistent product quality & performance

## Application

Tumor necrosis factor alpha (TNF- $\alpha$ ) is a cytokine that plays a central role in inflammation, immune system development, apoptosis, and lipid metabolism. It is mainly produced by monocytes and macrophages as a response to infection, injury, or tumor burden. TNF- $\alpha$  can also be produced from a range of other cell types such as T cells, natural killer cells (NK cells) and neutrophils.

CellGenix® TNF- $\alpha$  is used in the cell and gene therapy space for the ex vivo maturation of immature DCs.

## Product Characteristics

<b>Source</b>	<i>E. coli</i>
<b>Description</b>	Human TNF- $\alpha$ accession # P01375, Val77-Leu233 N-terminal Met Molecular mass 17.5 kDa
<b>Formulation</b>	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.
<b>Intended use</b>	For preclinical ex vivo use. Not intended for therapeutic use.

## Quality Parameters

<b>Activity</b>	$\geq 20 \times 10^6$ IU/mg calibrated against current NIBSC reference standard. Measured in a cell cytotoxicity assay using a TNF $\alpha$ -sensitive cell line, L929
<b>Purity</b>	$\geq 95$ %, as determined by SDS-PAGE (under reducing and non-reducing conditions, visualized by Coomassie staining)
<b>Endotoxin</b>	$\leq 1000$ EU/mg, as determined by LAL gel clot test
<b>Sterility</b>	Sterility test of the vial product
<b>Mass per vial</b>	1406-010: 10 $\mu$ g, 1406-050: $\geq 40$ $\mu$ g
<b>Animal-derived component-free</b>	<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 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. <ul style="list-style-type: none"><li>Store a 250 <math>\mu</math>g/mL reconstituted cytokine solution for 4 weeks at 2 °C to 8 °C under sterile conditions after reconstitution. Store in the original container.</li><li>Store a 100 <math>\mu</math>g/ml reconstituted cytokine solution for 4 months at -20 °C to 80 °C under sterile conditions after reconstitution. Store in aliquots in polypropylene cryogenic vials.</li></ul> Avoid repeated freeze/thaw cycles.

## Handling Instructions

<b>Reconstitution</b>	Recommended in sterile water to a final concentration of 100 $\mu$ g/mL (for 10 $\mu$ g vials) or 250 $\mu$ g/ml (for 50 $\mu$ g 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  $\mu$ g 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 TNF- $\alpha$	50 $\mu$ g	-20 °C to -80 °C	1406-050
CellGenix® Preclinical rh TNF- $\alpha$	10 $\mu$ g	-20 °C to -80 °C	1406-010*

\*This size is no longer in production. We are offering the remaining stock while supplies last

## 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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