

## Data Sheet

### CellGenix® GMP Recombinant Human Interleukin-21 (rh IL-21)

Order No.: 1019-050 (50 µg)

#### Product Characteristics

Source	<i>E. coli</i>
Description	Human Interleukin-21, accession # Q9HBE4, Gln25-Ser155 N-terminal Met Molecular mass 15.4 kDa
Formulation	Lyophilized from a 0.2 µm-filtered solution containing 15 mM sodium acetate and 45 mM sodium chloride, pH 5.5
Intended use	For further manufacturing use.

#### 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	0.5 – 1.6 x 10 <sup>6</sup> U/mg calibrated against the internal standard "IL-21 RS1" Measured in a cell proliferation assay using an IL-21-dependent cell line, mouse hybridoma B-cells (B9)
Purity	≥ 97 %, as determined by SDS-PAGE (under reducing and non-reducing conditions, visualized by Coomassie staining)
Product-related proteins	≤ 5 % oligomers, as determined by SDS-PAGE (under non-reducing conditions, visualized by Coomassie staining)
Host-cell DNA	≤ 200 ng/mg, as determined with a fluorimetric assay
Host-cell protein	≤ 1.0 µg/mg, as determined by ELISA
Endotoxin	≤ 25 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 vialled product
Mass per vial	43 – 57 µg, 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>Shelf life</b>	Minimum 6 months from date of shipping
<b>Storage &amp; Stability</b>	Store lyophilized cytokine at -20 °C to -80 °C. Store a 100 µg/ml reconstituted cytokine solution: <ul style="list-style-type: none"><li>• 4 weeks at 2 °C to 8 °C under sterile conditions after reconstitution. Store in the original container.</li><li>• 4 months at -20 °C to -80 °C under sterile conditions after reconstitution. Store in 80 µl 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 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. 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). USP chapter <1043> has been considered in the design of this product. This product is compliant with Ph. Eur. general chapter 5.2.12 and ISO Technical Standard 20399.