

## Data Sheet

### CellGenix® GMP Recombinant Human Interleukin-2 (rh IL-2)

Order No.: 1020-050 (50 µg), 1020-1000 (1000 µg)

#### Product Characteristics

Source	<i>E. coli</i>
Description	Human Interleukin-2 with a substitution of cysteine-125 by serine, accession # P60568, Pro22-Thr153 N-terminal Met and C-terminal 6xHis-tag Molecular mass 16.3 kDa With the exception of the added C-terminal 6xHis-tag, the amino acid sequence corresponds to that of Aldesleukin.
Formulation	Lyophilized from a 0.2 µm-filtered solution containing 25 mM sodium acetate and 50 mM sodium chloride, pH 5.0.
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	8 - 32 x 10 <sup>6</sup> IU /mg calibrated against internal reference standard*. Measured in a cell proliferation assay using an IL-2-dependent cell line, CTLL-2. *The internal reference standard was calibrated against Proleukin®. Proleukin® is a registered trademark of Novartis AG.
Purity	≥ 97 %, as determined by SDS-PAGE (under reducing and non-reducing conditions, visualized by Coomassie staining) and RP-HPLC
Product-related proteins	≤ 5 % oligomers as determined by SDS-PAGE (under non-reducing conditions, visualized by Coomassie staining) and ≤ 5 % oxidized IL-2 species as determined by RP-HPLC
Host-cell DNA	≤ 200 ng/mg, as determined with Pico Green®
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 vial product
Mass per vial	50 µg: 43 - 57 µg, 1000 µg: 900 - 1100 µg as determined by spectrophotometrical measurement
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 <i>E. coli</i> .

## Shipment & Storage

Transport	Ambient temperature. Please refer to Technote ( <a href="http://www.cellgenix.com">www.cellgenix.com</a> )
Shelf life	Minimum 6 months from date of shipping
Storage & Stability	Store lyophilized cytokine at -20 °C to -80 °C. Store a 250 µg/ml 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 60 µl aliquots in polypropylene cryogenic vials.</li></ul> Avoid repeated freeze/thaw cycles.

## Handling Instructions

Reconstitution	Recommended in 0.2 % acetic acid to a final concentration of 250 µg/ml for 50 µg vials or 500 µg/ml for 1000 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

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 20399:2022.