SARTORIUS

Product Datasheet

CellGenix® Preclinical Recombinant Human Interleukin-1 beta (rh IL-1β)

Product Information

CellGenix® Recombinant Human IL-1β reliably stimulates the maturation of immature dendritic cells (DCs). In addition, it promotes the generation of megakaryocytes derived from pluripotent stem cells (PSCs). 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

Interleukin-1 beta (IL-1β) is a proinflammatory cytokine that is mainly produced by monocytes and activated macrophages as a proprotein. Inflammatory responses are mediated by IL-1β in T cells, natural killer cells (NK cells) and B cells. It induces the production of pro-inflammatory cytokines (IL-2, IL-3, IL-6) as well as interferons. Furthermore, IL-1β modulates the secretion of cytokines by various subsets of human DCs.

CellGenix® IL-1β is used in the cell and gene therapy space for the *ex vivo* maturation of immature DCs.

Product Characteristics

Source	*E. coli*
Description	Human Interleukin-1 beta, accession # P01584, Ala117-Ser269 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	≥ 70x 10^6 IU/mg calibrated against NIBSC #86/680 Measured in a cell proliferation assay using an IL-1β-dependent cell line, D10.G4.1
Purity	≥ 95 %, as determined by SDS-PAGE (under reducing and non-reducing conditions, visualized by silver staining)
Endotoxin	≤ 1000 EU/mg, as determined by LAL gel clot test
Sterility	Sterility test of the vialed product
Mass per vial	1411-010: 10 µg, 1411-050: ≥ 40 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 and Storage

Transport	Ambient temperature. Please refer to Technical Note "Shipment of CellGenix® Preclinical and GMP Cytokines at Ambient Temperatures".
Shelf Life	3 years from date of shipment
Storage and Stability	Store lyophilized cytokine at -20 °C to -80 °C. ▪ Store a 250 µg/mL reconstituted cytokine solution for 4 weeks at 2 °C to 8 °C under sterile conditions after reconstitution. Store in the original container. ▪ Store a 100 µg/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. 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.

Packaging

CellGenix® cytokines are provided in glass vials, closed with vacuum rubber stoppers and sealed with aluminum tear off caps. The following material is used:

Glass vials
For 50 µg 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 IL-1β	50 µg	-20 °C to - 80 °C	1411-050
CellGenix® Preclinical rh IL-1β	10 µg	-20 °C to - 80 °C	1411-010*

* 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.

Germany
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49 551 308 0

Sartorius CellGenix GmbH
Am Flughafen 16
79108 Freiburg
Phone +49 761 88889 0
Fax + 49 761 88889 830
info-freiburg@sartorius.com

USA
Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178

For more information, visit
sartorius.com

Status: 09 | 2024