



Recombinant Human Interleukin-2 (rHu IL-2)

Lyophilized (10 µg) Cat. # AK8223-0010 | Lyophilized (100 µg) Cat. # AK8223-0100 | Liquid Syringe (1 mg) Cat. #AK9844-1000
Lyophilized (22 MIU) Cat. # AR1002-0022 | Lyophilized (1 mg) Cat. # AK8223-1000 | Liquid Bag (1 MIU) Cat. #AR1045-0010

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Product Description:

Akron's Recombinant Human Interleukin-2 (rHu IL-2) products are manufactured following all relevant cGMP guidelines for ancillary materials and are supported by a Type II Master File (MF) on file with the FDA and an MF Type I on file with Health Canada which can be referenced during your drug or biologic application process. Our rHu IL-2 amino acid sequence is identical to Proleukin® (aldesleukin), and its functional similarity in T cell expansion has been evaluated and confirmed (see page 3). Akron's rHu IL-2 is a single chain, 15.3 kDa, non-glycosylated lymphokine analog expressed in *E. coli*, containing 132 amino acids.

It is purified in a pharmaceutical facility without the use of histidine tags and nickel columns. Sterile filtration with aseptic filling and lyophilization are performed in-house with Endotoxin and Sterility testing performed per USP/EP on the final product. The lyophilized product is packaged in vials and available in various aliquots as listed above, including an aliquot of 22 MIU (AR1002-0022) specifically designed to approximate the activity of Proleukin®, which allows for easy substitution within manufacturing protocols. Our liquid rHu IL-2 formulation is available in both prefilled syringes and closed system bags (ask for details).

IL-2 plays a major role in both upregulating and downregulating the body's immune response. It is critical for the homeostasis and differentiation of many immune cell types and is involved in the immune system's ability for self-tolerance. The pleiotropic nature of cytokines is especially diverse in IL-2 due to its signal being transduced by at least three different primary signaling pathways. The trimeric IL-2 receptor protein (IL-2R) shares an identical subunit with the IL-7, IL-15, and IL-21 receptor proteins and activates some of the same signal transduction mechanisms. Akron's cGMP-compliant rHu IL-2 can be used to promote the activation and proliferation of numerous immune cell types, including CAR-T cells, TCR-T cells, Tregs, TILs, NK cells, CIK cells, B cells, monocytes, and macrophages.

Product Features:

Active Substance

- Amino acid sequence identical to Proleukin® / aldesleukin
- Carrier protein-free formulation
- *E. coli* expression system
- All raw materials are compliant, controlled, and traceable under Akron's Quality Management System (QMS)

Manufacturing

- Type II eCTD MF (#026152) on file with FDA and MF Type I (#e250089) on file with Health Canada
- Tag-free pharmaceutical processing
- Gram-scale production capacity
- In-house sterile filtration with aseptic filling and lyophilization

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Quality

- Relevant cGMP guidelines used in manufacture, testing, and release
- USP <1043>, Ancillary Materials for Cell, Gene, and Tissue-Engineered Products
- EP 5.2.12, Raw Materials of Biological Origin for the Production of Cell-based and Gene Therapy Medicinal Products
- ISO 13485:2016, Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
- ISO/TS 20399-1-3:2018, Biotechnology - Ancillary Materials Present During the Production of Cellular Therapeutic Products
- High Purity, Low Endotoxin - Endotoxin and Sterility testing per USP/EP

Release Testing:

- Appearance (Visual)
- pH (Potentiometric)
- Residual Moisture (Karl Fischer)
- IL-2 Content (Lowry)
- Identification (Reducing SDS-PAGE)
- Western Blot
- Impurities (Non-reducing SDS-PAGE)
- Host Cell-derived Proteins (ELISA)
- Host Cell DNA (RT-PCR)
- Biological Activity (HT-2 Proliferation)
- Specific Activity (HT-2 Proliferation)
- Bacterial Endotoxins (USP <85> / EP 2.6.14)
- Sterility (USP <71> / EP 2.6.1)

Stability:

- 24-month shelf life
- Store at 2-8 °C
- Transport with cold packs

Reconstitution:

Reconstitute the lyophilized product with 1 mL of sterile water for injection (WFI).

For Use Statement:

For research use or further manufacturing use in *ex vivo* cell therapy applications. This product is not intended for direct *in vivo* use or for direct clinical use as a drug, therapeutic, biologic, or medical device.

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Related Products:

Catalog Number	Product Name	Size
AK9984-1000	Recombinant Human Interleukin-2 (rHu IL-2) Prefilled Syringe (1 mg/mL)	1 mL
AK9842-0040	Recombinant Human Interleukin-7 (rHu IL-7)	40 µg
AK9823-0040	Recombinant Human Interleukin-15 (rHu IL-15)	40 µg
AK9833-0040	Recombinant Human Interleukin-21 (rHu IL-21)	40 µg
AK9995-0020	Recombinant Human Interleukin-12 (rHu IL-12)	20 µg
AK9999-0025	Recombinant Human Interleukin-18 (rHu IL-18)	25 µg

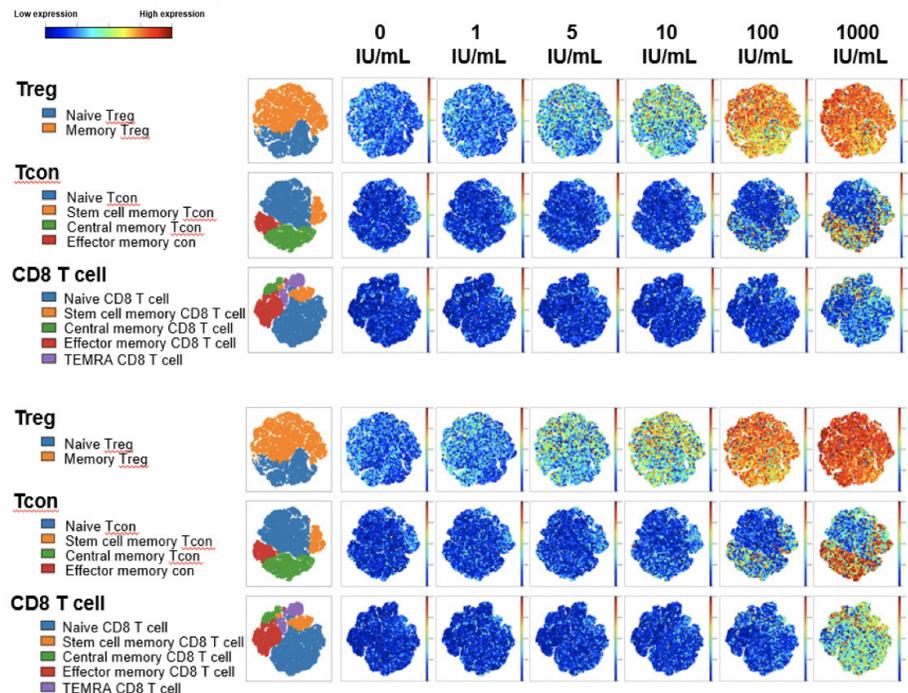
Functionality Data:

Figure 1: To examine IL-2 signaling, freshly isolated PBMC from healthy donors were stained with surface antibodies targeting 21 different protein markers prior to in vitro stimulation with IL-2. Single mass cell cytometry was used to compare the effect of Akron's rHu IL-2 (above) against Proleukin® (below) on the expression of pSTAT5, pSTAT3, & pSTAT1 in T cell subsets. (pSTAT5 example shown to right).

When results were summarized for 6 healthy donors, T cell stimulation in vitro by Proleukin® and Akron rHu IL-2 were indistinguishable.

This study was done in collaboration with the Dana-Farber Cancer Institute; study and poster available upon request.

Akron rHu IL-2 vs Proleukin® - pSTAT5 Expression



For more information on our available products or for technical assistance, see contact info below.
 For contract orders under master supply agreement, please inquire.