

DESCRIPTION

Source	<i>E. coli</i> -derived Accession # P40933 Produced using non-animal reagents in an animal-free laboratory. Manufactured and tested under cGMP guidelines.
N-terminal Sequence Analysis	Asn-Trp-Val-Asn-Val-Ile-Ser-Asp-Leu-Lys
Predicted Molecular Mass	12.5 kDa

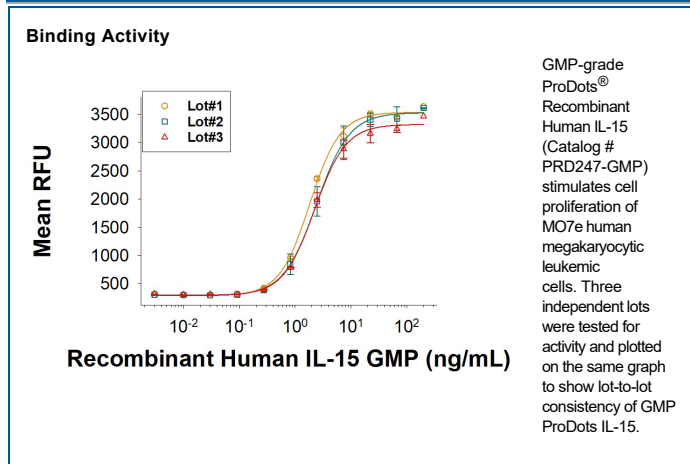
SPECIFICATIONS

Activity	Measured in a cell proliferation assay using MO7e human megakaryocytic leukemic cells. The ED ₅₀ for this effect is 0.3-2.6 ng/mL. The specific activity of ProDots Recombinant Human IL-15 GMP is >2.0 x 10 ⁸ units/mg, which is calibrated against the human IL-15 reference standard (NIBSC code: 95/554).
Endotoxin Level	<0.10 EU per 1 µg of the protein by the LAL method.
Purity	>97%, by SDS-PAGE with silver staining.
Host Cell Protein	< 0.5 ng per µg of protein when tested by ELISA.
Mycoplasma	Negative when tested in a ribosomal RNA hybridization assay.
Host Cell DNA	< 0.010 ng per µg of protein when tested by PCR.
Formulation	Lyophilized from an phosphate buffered saline-based formulation using proprietary excipients. See Certificate of Analysis for details.

PREPARATION AND STORAGE

Reconstitution	Reconstitute with cell culture media immediately prior to use.
Shipping	The product is shipped with polar packs. Upon receipt, store it immediately at the temperature recommended below.
Stability & Storage	Store material as supplied, unopened, and unconstituted at 2-8 °C until use. Stability is a minimum of 8 weeks when stored at 2-8 °C as supplied. Refer to lot specific COA for the Use by Date. The foil pouch is used for shipping and storage only and is not terminally sterilized. GMP ProDots within the weldable bag are prepared under GMP-controlled conditions and protein content is tested to USP <71> guidelines.

DATA



BACKGROUND

Interleukin 15 (IL-15) is a widely expressed 14 kDa cytokine that is structurally and functionally related to IL-2 and plays an important role in many immunological diseases (1, 2). Mature human IL-15 shares 70% amino acid sequence identity with mouse and rat IL-15. Alternative splicing generates isoforms of IL-15 with either a long or short signal peptide (LSP or SSP), and the SSP isoform is retained intracellularly (3). IL-15 binds with high affinity to IL-15 R α (4). It binds with lower affinity to a complex of IL-2 R β and the common gamma chain (γ c) which are also subunits of the IL-2 receptor complex (5). IL-15 associates with IL-15 R α in the endoplasmic reticulum, and this complex is expressed on the cell surface (6). The dominant mechanism of IL-15 action is known as transpresentation in which IL-15 and IL-15 R α are coordinately expressed on the surface of one cell and interact with complexes of IL-2 R β / γ c on adjacent cells (7). This enables cells to respond to IL-15 even if they do not express IL-15 R α (6). In human and mouse, soluble IL-15-binding forms of IL-15 R α can be generated by proteolytic shedding and bind up nearly all the IL-15 in circulation (8-10). Soluble IL-15 R α functions as an inhibitor that limits IL-15 action (4, 9). Ligation of membrane-associated IL-15/IL-15 R α complexes also induces reverse signaling that promotes activation of the IL-15/IL-15 R α expressing cells (11). IL-15 induces or enhances the differentiation, maintenance, or activation of multiple T cell subsets including NK, NKT, Th17, Treg, and CD8⁺ memory cells (12 - 16). An important component of these functions is the ability of IL-15 to induce dendritic cell differentiation and inflammatory activation (11, 14). IL-15 exhibits anti-tumor activity independent of its actions on NK cells or CD8⁺ T cells (17). It also inhibits the deposition of lipid in adipocytes, and its circulating levels are decreased in obesity (18).

References:

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PRODUCT SPECIFIC NOTICES

The GMP ProDot bag(s) should be used after proper inspection. Assess the bags after media is added to the bag either through the weldable port or needless valve. Inspect the bag to ensure complete dissolution of the GMP ProDot, and visually inspect seals and corners for a complete seal.

GMP ProDots are fragile. Please handle with care. If breakage of a ProDot is observed, there is no integrity lost, and can be used as indicated.

SDS-PAGE Purity, Host Cell DNA, and Host Cell Protein testing were completed on protein prior to lyophilization.

The End User is aware that R&D Systems, Inc. sells GMP products for preclinical or clinical *ex vivo* use and not for *in vivo* use. The End User Terms of Use of Product may be found at: RnDSystems.com/legal-information.