

DESCRIPTION

Source	<i>E. coli</i> -derived Glu26-Ala189, with an N-terminal Met Accession # P21583.1 Produced using non-animal reagents in an animal-free laboratory. Manufactured and tested under cGMP guidelines.
N-terminal Sequence Analysis	Met-Glu ₂₆ -Gly-Ile-(Cys)-Arg-Asn-Arg-Val-Thr
Predicted Molecular Mass	18.6 kDa

SPECIFICATIONS

SDS-PAGE	19 kDa, reducing conditions
Activity	Measured in a cell proliferation assay using TF-1 human erythroleukemic cells. Kitamura, T. <i>et al.</i> (1989) J. Cell Physiol. 140 :323. The ED ₅₀ for this effect is 1-5 ng/mL. The specific activity of recombinant human SCF is approximately 564 units/μg, which is calibrated against recombinant human SCF WHO Standard (NIBSC code: 91/682).
Endotoxin Level	<0.10 EU per 1 μg of the protein by the LAL method.
Purity	>97%, by SDS-PAGE with silver staining, under reducing conditions.
Mass Spectrometry	Intact mass analysis of recombinant human SCF confirms the predicted molecular mass of 18589 Da.
Host Cell Protein	<0.5 ng per μg of protein when tested by ELISA.
Mycoplasma	Negative when tested in a ribosomal RNA hybridization assay.
Formulation	Lyophilized from a 0.2 μm filtered solution in PBS. See Certificate of Analysis for details.

PREPARATION AND STORAGE

Reconstitution	Reconstitute at 100 μg/mL in PBS.
Shipping	The product is shipped at ambient temperature. Upon receipt, store it immediately at the temperature recommended below.
Stability & Storage	Use a manual defrost freezer and avoid repeated freeze-thaw cycles. <ul style="list-style-type: none"> • A minimum of 12 months when stored at ≤ -20 °C as supplied. Refer to lot specific COA for the Use by Date. • 1 month, 2 to 8 °C under sterile conditions after reconstitution. • 3 months, ≤ -20 °C under sterile conditions after reconstitution.

DATA

<p>Bioactivity</p> <p>Mean RFU</p> <p>Recombinant Human SCF GMP (ng/mL)</p> <p>GMP-grade Recombinant Human SCF/c-kit Ligand (Catalog # 255-GMP) stimulates cell proliferation of the TF-1 human erythroleukemic cell line. The ED₅₀ for this effect is 1-5 ng/mL.</p>	<p>SDS-PAGE</p> <p>1 μg/lane of GMP-grade Recombinant Human SCF/c-kit Ligand (Catalog # 255-GMP) was resolved with SDS-PAGE under reducing (R) conditions and visualized by silver staining, showing a single band at 19 kDa.</p>
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BACKGROUND

Stem cell factor (SCF), also known as c-kit ligand (KL), mast cell growth factor (MGF), and steel factor (SLF), is a widely expressed 28-40 kDa type I transmembrane glycoprotein (1). It promotes the survival, differentiation, and mobilization of multiple cell types including myeloid, erythroid, megakaryocytic, lymphoid, germ cell, and melanocyte progenitors (1-7). SCF is a primary growth and activation factor for mast cells and eosinophils (8). Mature human SCF consists of a 189 amino acid (aa) extracellular domain (ECD), a 23 aa transmembrane segment, and a 36 aa cytoplasmic tail (9). The ECD shows both N-linked and O-linked glycosylation (10). Proteolytic cleavage at two alternate sites in the extracellular juxtamembrane region releases a 25 kDa soluble molecule which is comparable to the only form produced by Steel-dickie mutant mice (11, 12). An alternately spliced isoform of human SCF lacks 28 aa that encompasses the primary proteolytic recognition site (13). Within the ECD of the long isoform (corresponding to this recombinant protein), human SCF shares 79%-87% aa sequence identity with canine, feline, mouse, and rat SCF. Rat SCF is active on mouse and human cells, but human SCF is only weakly active on mouse cells (9). Noncovalent dimers of transmembrane or soluble SCF interact with the receptor tyrosine kinase SCF R/c-kit to trigger receptor dimerization and signaling (14). SCF assists in the recovery of cardiac function following myocardial infarction by increasing the number of cardiomyocytes and vascular channels (15).

References:

1. Ashman, L.K. (1999) *Int. J. Biochem. Cell Biol.* **31**:1037.
2. Sette, C. *et al.* (2000) *Int. J. Dev. Biol.* **44**:599.
3. Yoshida, H. *et al.* (2001) *J. Invest. Dermatol. Symp. Proc.* **6**:1.
4. Erlandsson, A. *et al.* (2004) *Exp. Cell Res.* **301**:201.
5. Kapur, R. *et al.* (2002) *Blood* **100**:1287.
6. Wang, C.-H. *et al.* (2007) *Arterioscler. Thromb. Vasc. Biol.* **27**:540.
7. Bashamboo, A. *et al.* (2006) *J. Cell Sci.* **119**:3039.
8. Reber, L. *et al.* (2006) *Eur. J. Pharmacol.* **533**:327.
9. Martin, F.H. *et al.* (1990) *Cell* **63**:203.
10. Arakawa, T. *et al.* (1991) *J. Biol. Chem.* **266**:18942.
11. Majumdar, M.K. *et al.* (1994) *J. Biol. Chem.* **269**:1237.
12. Brannan, C.I. *et al.* (1991) *Proc. Natl. Acad. Sci.* **88**:4671.
13. Anderson, D.M. *et al.* (1991) *Cell Growth Differ.* **2**:373.
14. Lemmon, M.A. *et al.* (1997) *J. Biol. Chem.* **272**:6311.
15. Kanellakis, P. *et al.* (2006) *Cardiovasc. Res.* **70**:117.

MANUFACTURING SPECIFICATIONS

GMP Proteins

R&D Systems, a Bio-Techne Brand's GMP proteins are produced according to relevant sections of the following documents: WHO TRS, No. 822, 1992 Annex 1, Good Manufacturing Practices for Biological Products; USP Chapter 1043, Ancillary Materials for Cell, Gene and Tissue-Engineered Products and USP Chapter 92, Growth Factors and Cytokines Used in Cell Therapy Manufacturing.

R&D Systems' quality focus includes:

- Manufactured and tested under an ISO 9001:2015 and ISO 13485:2016 certified quality system
- Documented processes and QA control of documentation and process changes
- Personnel training programs
- Raw material testing and vendor qualification/monitoring
- Fully validated equipment, processes and test methods
- Equipment calibration schedules using a computerized calibration program
- Facility maintenance, safety programs and pest control
- Material review process for variances
- Monitoring of stability over product shelf-life

R&D Systems strives to provide our customers with the analytical characteristics of each product so that customers may determine whether our products are appropriate for their research. The Certificate of Analysis provided contains the following lot specific information:

- N-terminal amino acid analysis, SDS-PAGE analysis, and endotoxin level (as determined by LAL assay) performed on each bulk QC lot, not on individual bottlings of each QC lot
- Post-bottling lot-specific bioassay results (compliance with an established range) and results of microbial bioburden testing (using broth culture, Sabourand's dextrose and blood agar plates with results reported at 3 days and at 7 days)
- Host Cell Protein testing performed by ELISA
- Mycoplasma testing by ribosomal RNA hybridization assay

Additional testing and documentation requested by the customer can be arranged at an additional cost. Testing may include, but is not limited to, USP <61> bioburden testing, positive identity testing, testing for adventitious agents and testing for residual host cell content.

Production records and facilities are available for examination by appropriate personnel on-site at R&D Systems in Minneapolis, Minnesota USA.

R&D Systems sells its GMP grade recombinant protein products for research use or further manufacturing use in *ex vivo* cell therapy applications. They are not for *in vivo* use or for use as therapeutic or other drugs, biologic products or devices. Please read the following End User Terms prior to using this product.

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Production

- All molecular biology procedures use animal-free media and dedicated labware.
- Dedicated fermentors are utilized in committed animal-free areas.

Purification

- Protein purification columns are animal-free.
- Bulk proteins are filtered using animal-free filters.
- Purified proteins are stored in animal-free containers in a dedicated cold storage room.

Quality Assurance

- Low Endotoxin Level.
- No impairment of biological activity.
- High quality product obtained under stringent conditions.
- For *ex vivo* research or bioproduction, [additional documentation](#) can be provided.

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