


L-Leucine, USP/EP/JP

Catalog Number A37732

Pub. No. MAN0017872 Rev. 1.0

 **WARNING!** Read the Safety Data Sheets (SDSs) and follow the handling instructions. Wear appropriate protective eyewear, clothing, and gloves. Safety Data Sheets (SDSs) are available from thermofisher.com/support.

Contents and storage

Product	Catalog Number	Packaging description	Storage ^[1]
L-Leucine, USP/EP/JP	A37732	Double-bagged poly liner and rigid outer poly container	15°C to 30°C

^[1] Please reference the certificate of analysis for manufacture and expiration date of this material.

Manufacturing and supply information

Gibco™ Chemical products are produced in cGMP-compliant facilities registered with the FDA as manufacturers of medical devices, which are also certified to the ISO 13485 standard. Chemicals are qualified to ensure they meet compendia standards or are equivalent materials of high purity. The packaging process is performed in temperature and humidity controlled suites in our animal origin free facility. The suites are maintained per controlled procedure and cleaning methods that are validated.

Information	Details
Manufacturing site	Life Technologies Corporation 3175 Staley Road Grand Island, NY 14072
Manufacturing Site ISO Certifications	thermofisher.com/us/en/home/technical-resources/manufacturing-site-iso-certifications.html
Supply information	Additional supply information will be disclosed upon the signing of a confidential disclosure agreement.
Country of origin	USA

Packaging

Packaging materials are subjected to acceptance inspection in the package-testing laboratory. The materials are selected at Grand Island according to special criteria with regard to suitability for the application. In addition, the materials are inspected for physical condition upon receipt for cleanliness but not sterility.

Physical chemical information

Information	Details
CAS	61-90-5
Synonyms	(2S)-2-Amino-4-methylpentanoic acid, L-Leu
Linear formula	C ₆ H ₁₃ NO ₂
Manufacturing process	Fermentation
Manufacturing process flow	Plant (sugars) Fermentation ► Purification ► Filtration ► Crystalization ► Drying ► Filling/Packaging
Raw material origin	Plant (sugars)

Specifications

This product is tested according to the following specifications. Reference supporting certificates of analysis for specific results.

Test description	Specification limits	Units
Ammonium	≤ 0.02	%
Appearance	Acceptable	—
Appearance in solution	Acceptable	—
Arsenic (not more than)	≤ 1	PPM
Assay	≥ 99.0 to ≤ 101.0	%
Chloride (not more than)	≤ 200	PPM
Coliform	Negative	—
Elemental impurities	Acceptable	—
Endotoxin	≤ 6	EU/g
Heavy metal (not more than)	≤ 10	PPM
Identification	Acceptable	—
Infrared spectroscopy	Acceptable	—
Iron	≤ 10	PPM
Loss on drying	≤ 0.20	%
Mold	≤ 10	CFU/g
pH	≥ 5.5 to ≤ 6.5	—
Related substances	Acceptable	—
Residue on ignition	≤ 0.1	%
Specific rotation at 20°C	≥ 14.9 to ≤ 16.0	Degrees
Specific rotation at 25°C	≥ 14.9 to ≤ 17.3	Degrees
Sulfate (not more than)	≤ 200	PPM
Total microorganism	≤ 100	CFU/g

Supporting statements

Certificate of analysis

For historical batch records, review certificates of analysis found at thermofisher.com/support.

Animal origin

We certify the products are manufactured from raw materials that contain NO animal parts, products, and/or byproducts nor do they come in contact with animal parts, products, and/or by-products during the manufacturing process. This material contains no Halal or Kosher certification.

Allergen/GMO information

This product does not consist of genetically modified organisms, allergens, gluten, or latex. The manufacturing process does utilize raw materials that are derived from plants that may be genetically modified but the final product does not consist of genetically modified material. Our process does not introduce genetically modified materials, allergens, gluten or latex. All testing on the final product is shown in the specifications.

Melamine contamination

Melamine or related materials are not used as a raw material in the manufacturing of this product nor introduced or exposed to melamine or related materials during the process.

Residual solvents

The manufacturing of this product does not involve the use of residual solvents. No introduction of solvents occur in the manufacturing process.

We certify this product conforms to the USP 467 and EP and JP guidelines on residual solvent requirements.

Elemental impurities

Analysis of elemental impurities has been performed on this product. A detailed analysis can be provided upon request.

Miscellaneous product information

Date format







The dates on the Certificate of Analysis are reported as DD MMM YYYY. For example, the date for January 12, 2019, would be reported as 12 JAN 2019.

The dates on product labels are reported as YYYY-MM-DD. For example, the date January 12, 2019, would be presented as 2019-01-12.

Lot assignment format

Lot numbers are numeric, non-intelligent and are sequentially assigned by an electronic inventory management system.

Explanation of symbols

Symbol	Description	Symbol	Description	Symbol	Description
	Manufacturer		Catalog number		Batch code
	Use by		Temperature limitation		Read SDS

Limited product warranty

Life Technologies Corporation and/or its affiliate(s) warrant their products as set forth in the Life Technologies' General Terms and Conditions of Sale found on Life Technologies' website at www.thermofisher.com/us/en/home/global/terms-and-conditions.html. If you have any questions, please contact Life Technologies at www.thermofisher.com/support.



Manufacturer: Life Technologies Corporation | 3175 Staley Road | Grand Island, NY 14072

The information in this guide is subject to change without notice.

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