



## L-Methionine Applications and Manufacturing Network

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## About Evonik

In 2013, our approximately 33,000 Evonik employees produced sales of € 12.7 billion and an operating result (EBITDA) of € 2.0 billion. Around 76 percent of sales are generated outside Germany, providing convincing evidence that our business is global. Our business activities are aligned with three global mega-trends: besides resource efficiency and globalization, our focus is also on the key growth sector of health and nutrition. Here, the pharma industry is part of the strategic core business of Evonik, and it has been for several decades. As Evonik and Degussa, our track record builds on 40 years of experience in the production of pharmaceutical-grade products. Our Health Care Business Line is firmly embedded within the Evonik Group, enabling us to promise our customers stability and staying power – essential for building long-term partnerships.

## L-Methionine Applications and Manufacturing Network

L-Methionine is one of two essential proteinogenic sulfur-containing amino acids. Since L-Methionine can not be synthesized by the body, humans must obtain L-Methionine or Methionine-containing proteins from their diet.

Evonik Industries has produced L-Methionine in commercial quantities

for many decades utilizing its proprietary manufacturing process. Evonik's L-Methionine is used in:

- Parenteral nutrition
- Enteral nutrition
- Pharmaceuticals
- Cell culture media preparation (product is cell culture media tested)

## Product Specification (using GMP grade specification)

Characteristics: White crystals or crystalline powder, weak, characteristic odour

Specifications	Limits	Unit
Assay	99.0/101.0	% *
Specific rotation $[\alpha]^{20}_D$ (2 g/100 ml HCl 6N)	+22.5/+24.0	° *
Specific rotation $[\alpha]^{25}_D$ (2 g/100 ml HCl 6N)	+22.6/+24.1	° *
Transmittance (10 g/100 ml HCl 2N)	≥ 98.0	%
pH (2.5% H <sub>2</sub> O, 25 °C)	5.6/6.1	
Loss on drying (3 h, 105 °C)	≤ 0.20	%
Residue on ignition (sulphated ash)	≤ 0.10	%
Chloride	≤ 200	ppm
Sulfate	≤ 200	ppm
Ammonium	≤ 200	ppm
Heavy Metals (as lead)	≤ 5	ppm
Iron	≤ 10	ppm
Arsenic	≤ 1	ppm
<b>TLC</b> related substances	≤ 0.5	%
Bacterial endotoxins test	≤ 6	EU/g
<b>Microbiology</b>		
Total microbial count	≤ 100	CFU/g
Yeasts and moulds	≤ 10	CFU/g
Escherichia coli	0	CFU/g
Salmonella species	0	CFU/10g
Staphylococcus aureus	0	CFU/g
Pseudomonas aeruginosa	0	CFU/g

\* calculated for anhydrous substance

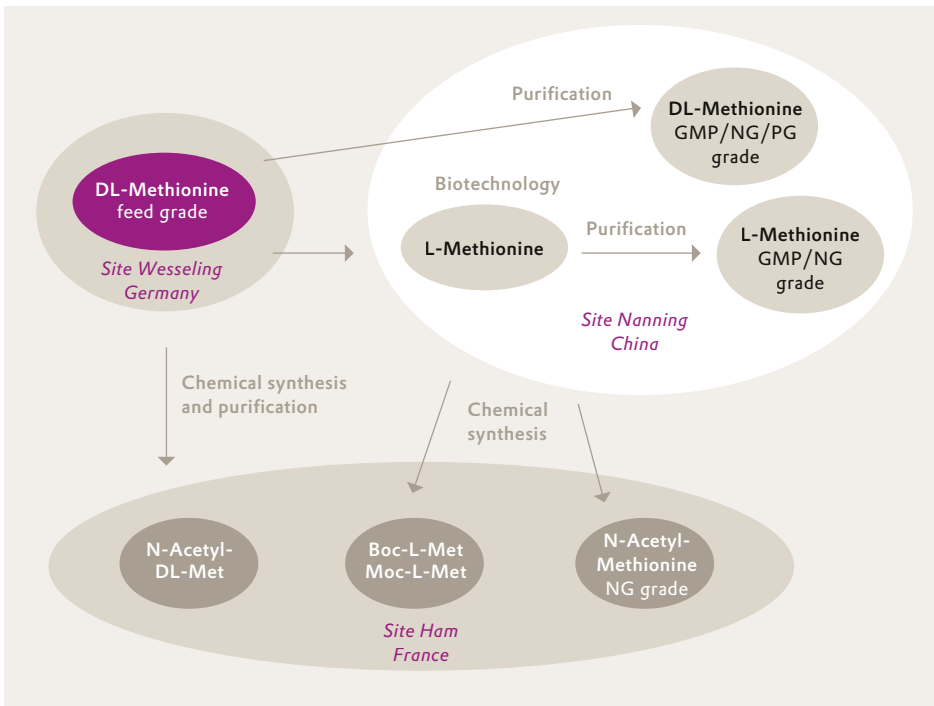
Product is in accordance with the EP, JP, USP and FCC monographs

Evonik's L-Methionine is subject to the highest quality control standards and meets strict regulatory requirements such as:

- United States Pharmacopoeia (USP)
- European Pharmacopoeia (CEP)
- Japanese Pharmacopoeia (JP)

Evonik also hold drug master files (DMF) based on L-Methionine in both the US and Europe. The product is considered HACCP, Kosher and Halal certified. The manufacturing plant is routinely audited by the U. S. FDA, the French Health authority (ANSM), as well as customers with audit requirements.

For our chemical synthesis feedstock, DL-Methionine is produced in Evonik's world scale D,L-Methionine production plant for Feed Additives located in Wesseling (Germany) following ISO 9001/14001 and strict animal feed regulations (see fig. 1). The complete backward integration of L-Methionine is considered one of Evonik's core competencies and further guarantees consistent quality and supply security to our customers.



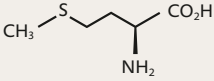
**Figure 1**

## Technical data

### 1 Nomenclature

International Non-Proprietary Name	L-Methionine
Chemical name /IUPAC	L-2-Amino-4-(methylthio)-butyric acid (S)-2-Amino-4-(methylthio)-butanoic acid
Chemical Abstract N°	[63-68-3]
EINECS N°	200-562-9

### 2 Description

Molecular formula	C <sub>5</sub> H <sub>11</sub> NO <sub>2</sub> S
Structural formula	
Molecular weight	149.21
Chirality levorotatory	(S) absolute configuration

### 3 Characteristics

Physical form	White crystals or crystalline powder. Weak, characteristic odour
Solubility	5.3 g/100 g H <sub>2</sub> O (20 °C)

### Storage and stability

The retest date of this product is 4 years, starting from the date of manufacture, provided that the product remains in its original packaging (i. e. unopened) and has been stored under recommended conditions (dry, dark, preserve in well-closed containers).

### Packaging

25 kg fibre drum (12 drums per pallet), 300 kg per pallet

### Residual solvents

The product is in agreement with ICH guideline:  
"Impurities: Residual solvents", the European Pharmacopoeia  
General test 5.4: "Residual solvents" and United States  
Pharmacopoeia General test <467>: "Residual solvents"

Solvent used: Methanol, class 2, content: ≤ 3000 ppm

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