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

<table>
<thead>
<tr>
<th>Specifications</th>
<th>Limits</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assay</td>
<td>99.0 / 101.0</td>
<td>%</td>
</tr>
<tr>
<td>Specific rotation $[\alpha]^{20\circ}$ (2 g / 100 ml HCl 6N)</td>
<td>+22.5 / +24.0</td>
<td>°  *</td>
</tr>
<tr>
<td>Specific rotation $[\alpha]^{25\circ}$ (2 g / 100 ml HCl 6N)</td>
<td>+22.6 / +24.1</td>
<td>°  *</td>
</tr>
<tr>
<td>Transmittance (10 g / 100 ml HCl 2N)</td>
<td>≥ 98.0</td>
<td>%</td>
</tr>
<tr>
<td>pH (2.5 % $H_2O$, 25 °C)</td>
<td>5.6 / 6.1</td>
<td></td>
</tr>
<tr>
<td>Loss on drying (3 h, 105 °C)</td>
<td>≤ 0.20</td>
<td>%</td>
</tr>
<tr>
<td>Residue on ignition (sulphated ash)</td>
<td>≤ 0.10</td>
<td>%</td>
</tr>
<tr>
<td>Chloride</td>
<td>≤ 200</td>
<td>ppm</td>
</tr>
<tr>
<td>Sulfate</td>
<td>≤ 200</td>
<td>ppm</td>
</tr>
<tr>
<td>Ammonium</td>
<td>≤ 200</td>
<td>ppm</td>
</tr>
<tr>
<td>Heavy Metals (as lead)</td>
<td>≤ 5</td>
<td>ppm</td>
</tr>
<tr>
<td>Iron</td>
<td>≤ 10</td>
<td>ppm</td>
</tr>
<tr>
<td>Arsenic</td>
<td>≤ 1</td>
<td>ppm</td>
</tr>
<tr>
<td><strong>TLC</strong> related substances</td>
<td>≤ 0.5</td>
<td>%</td>
</tr>
<tr>
<td><strong>Bacterial endotoxins test</strong></td>
<td>≤ 6</td>
<td>EU / g</td>
</tr>
</tbody>
</table>

**Microbiology**

<table>
<thead>
<tr>
<th></th>
<th>Limits</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total microbial count</td>
<td>≤ 100</td>
<td>CFU / g</td>
</tr>
<tr>
<td>Yeasts and moulds</td>
<td>≤ 10</td>
<td>CFU / g</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>0</td>
<td>CFU / g</td>
</tr>
<tr>
<td>Salmonella species</td>
<td>0</td>
<td>CFU / 10 g</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>0</td>
<td>CFU / g</td>
</tr>
<tr>
<td>Pseudomonas acruginosa</td>
<td>0</td>
<td>CFU / g</td>
</tr>
</tbody>
</table>

* 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.
## Technical data

### 1 Nomenclature

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

### 2 Description

<table>
<thead>
<tr>
<th>Molecular formula</th>
<th>C₅H₁₁NO₂S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Structural formula</td>
<td><img src="image" alt="Structural formula" /></td>
</tr>
<tr>
<td>Molecular weight</td>
<td>149.21</td>
</tr>
<tr>
<td>Chirality levorotary</td>
<td>(S) absolute configuration</td>
</tr>
</tbody>
</table>

### 3 Characteristics

<table>
<thead>
<tr>
<th>Physical form</th>
<th>White crystals or crystalline powder. Weak, characteristic odour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solubility</td>
<td>5.3 g / 100 g H₂O (20 °C)</td>
</tr>
</tbody>
</table>

### 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
North America  
Evonik Degussa Corporation  
299 Jefferson Road  
Parsippany, NJ 07054-0677  
USA  
PHONE +1 973 929-8175  
FAX +1 973 929-8160

Latin America  
(except for Brazil, Mexico)  
Evonik Degussa Argentina S.A.  
Darragueira 38  
B1609HDB San Isidro  
Buenos Aires  
Argentina  
PHONE +54 11 4708-2070  
FAX +54 11 4708-2001

Brazil  
Evonik Degussa Brasil Ltda.  
Alameda Campinas, 579  
São Paulo–SP  
01404-000 – Jardim Paulista  
Brazil  
PHONE +55 11 3146-4143  
FAX +55 11 3146-4199

Mexico  
Evonik Industries AG  
Kirschenallee 45  
64293 Darmstadt  
Germany  
PHONE +49 6151 18 3517  
FAX +49 6151 18-3520

Argentina  
Evonik Degussa Argentina S.A.  
Darragueira 38  
B1609HDB San Isidro  
Buenos Aires  
Argentina  
PHONE +54 11 4708-2070  
FAX +54 11 4708-2001

India, Bangladesh, Pakistan  
Evonik Degussa India Pvt. Ltd.  
Krislon House, Opp. Marwha Centre,  
Saki Vihar Road, Saki Naka, Andheri  
Mumbai 400 072  
India  
PHONE +91 22 6991-6993  
FAX +91 22 6991-6996

China  
Evonik Degussa China Co., Ltd.  
55 Chundong Road  
Xinzhuang Industry Park  
Shanghai 201 108  
People’s Republic of China  
PHONE +86 21 6119-1032  
FAX +86 21 6119-3612

Japan, South Korea, Taiwan  
Evonik Degussa Japan Co., Ltd.  
Shinjuku Monolith 12F  
2-3-1, Nishi-Shinjuku  
Shinjuku-ku  
Tokyo 163-0938  
Japan  
PHONE +81 3 5323-7357  
FAX +81 3 5323-8789

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Evonik Industries AG  
Rodenbacher Chaussee 4  
63457 Hanau  
Germany  
www.evonik.com  
www.evonik.com/pharmaceutical-amino-acids  
rexim@evonik.com

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