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Rexim® – amino acids from the European expert
Dear Customer,

Amino acids, amino acid derivatives, and peptides are essential components for enteral or parenteral nutrition, as components for cell culture media, as versatile building blocks for chiral synthesis, and directly as active ingredients. But what if an amino acid is not stable in a cell culture medium and cannot be taken up by the cell? Or an unique amino acid derivative is urgently needed? Or a capable producer is needed who can be entrusted with synthesizing a new peptide?

Evonik can offer the right solution to these types of problems with its Rexim® product line. Rexim® stands for a wide range of amino acids, peptides, and amino acid derivatives available in pharma, food, and highpurity cGMP grades for a comprehensive technology base that encompasses biotechnology, enzyme catalysis, and chemical synthesis, as well as backward integration into amino acids. Rexim® therefore also means supply security and expertise in regulatory matters.

At Evonik you’ll find expert, experienced partners you can trust with all your issues relating to amino acids and peptides – as this brochure will, we are confident, clearly demonstrate.

We look forward to hearing from you!

Dr Thomas Hermann
Vice President Rexim®
In 2011, our approximately 33,000 Evonik employees produced sales of €14.5 billion and an operating result (EBITDA) of €2.8 billion. More than 70 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.
We’re top performers in all disciplines: from synthesis to the formulation of active ingredients.

Evonik has defined pharmaceuticals as a strategic core business. As such, we focus much of our energy on this area – and on our customers.

For 40 years, we’ve been creating value for pharmaceutical companies by developing lasting solutions for the future: from membranes, catalysts and processing aids to pharma polymers, amino acids and custom manufacturing – all meeting the very highest quality standards.

Evonik is a trustworthy partner throughout many parts of the pharmaceutical value chain ranging from the manufacturing of active pharmaceutical ingredients (APIs) all the way to formulation. Evonik’s proven and trusted expertise enables pharmaceutical companies to concentrate on their core competences: developing and marketing of new pharmaceutical products.

Evonik products and services revolve around a partnership-driven approach and synergic technologies: solutions are developed in partnerships and services are integral part of the business model; biotechnology or catalysts are just two examples of synergic technologies which are leveraged in many products and services.

### Membranes

Membrane technology for process – efficient API manufacturing, improving yield via gentle molecular separations:
- DuraMem®
- PuraMem®

### Polymers for medical devices

High-performance polymers for advanced medical devices:
- RESOMER® (e.g. coronary stents)
- Cyrotite® (for extruding or injection molding disposable medical devices)
- VESTAKEEP® PEEK (for various medical devices; excellent biocompatibility, chemical resistance, and mechanical properties)

### Protective agents

Organosilanes for the manufacturing of APIs and intermediates:
- Blocking/protection agents
- Reducing agents
- Building blocks
Amino acids, peptides, and amino acid derivatives
Amino acids, peptides, and amino acid derivatives for parenteral nutrition, special nutrition, active pharmaceutical ingredients, flavors, cosmetics and cell culture media, or as versatile building blocks for chiral pharma syntheses.

Catalysts
Chemical catalysts for the manufacturing of APIs, intermediates, or building blocks:
- Precious Metal Powder Catalysts
- Activated Base Metal Catalysts
- Homogeneous Metathesis Catalysts
- Continuous Process Catalysts
- Magnesium ethanolate for chemical synthesis

Custom manufacturing
Custom manufacturing for advanced intermediates and APIs, from the clinical stage all the way to commercialization and along the product life cycle of the API.

Solvents
Economic and versatile solvents for API and intermediate manufacturing:
- DRIVERON® S (high-purity methyl tertiary butyl ether, MTBE)

Glidants and processing aids
Colloidal silicon dioxide excipients for improved processes and products: better powder flow, improved compact properties, tableting of liquid APIs.
- AEROSIL®
- AEROPERL®

Controlled drug release
Functional pharma polymers and formulation development services to meet the drug delivery challenges of the pharmaceutical industry:
- EUDRAGIT®
- RESOMER®
Today, Rexim® is not just the leading European supplier of pharmaceutical and food-grade amino acids, keto acids, and peptides. We’re also the only amino acid producer with both a global presence and a solid foothold in manufacturing downstream amino acid derivatives.

Rexim® – amino acids from the European expert

Rexim® is the leading European expert, with global reach, in pharmaceutical and food-grade amino acids, amino acid derivatives, and peptides.

It is because amino acids play such a fundamental role in our lives – they make up the proteins that in turn make up much of human and animal tissue, and they are key to ensuring cell growth, repair, and maintenance – that we at Rexim® value quality above all, in our products and processes, in our services, and in the relationship we build with our customers.

In more than five decades of specialization, we have acquired a broad and deep understanding of the building blocks of life that is unparalleled in the industry. Here, our extensive experience in chemistry and also biotechnology and purification technology enables us to meet any product challenge. At the same time, together with our customers, we are continuously pushing the frontier in research, analytics, and technology to realize the potential of amino acids and their derivatives for improving health and productivity.
Performance through partnership

Our processes have been honed over decades of manufacturing and logistics, by collaborating with our customers to deliver the right product at the right price – and in the right place at the right time. A global presence combined with local proximity makes us more effective in understanding where our customers are coming from and helping them get where they want to go when it comes to their amino-acid-related needs.

Ultimately, it’s about giving our customers the peace of mind that comes from being able to plan ahead – not just in terms of supply reliability, but also with regard to growing their business for the long term. Customers can plan with and rely on Rexim®. This strategic and dependable approach facilitates long-term partnerships with customers, which Rexim® focuses on.
Parenteral nutrition is not only dependent on highly soluble amino acid forms, but also on microbiological purity, including strict tolerances for endotoxins. As products for these applications effectively perform as APIs, Rexim® ensures compliance with cGMP (current Good Manufacturing Practice) and provides all relevant documentation, e.g., Certificates of Suitability or Drug Master Files.

- L-amino acids
- Acetylated amino acids
- Peptides
- Customized pre-mixes

Applications include infant formulas and medical diet products that address metabolic ailments, allergies, malnutrition or intense physical stress. Rexim® products can be designed to help meet the specific nutritional requirements of the elderly, or to boost performance and muscle recovery in athletes, for instance. The majority of our products are also certified kosher and halal to adhere to religions law.

- Single L-amino acids and pre-mixes
- L-Lysine and L-Arginine salts
- Keto acids

The Maillard reaction, for example, which is based on amino acids and sugars, is at the core of the aroma and flavor industry. It is crucial in the preparation or presentation of many types of food – the type of amino acid effectively determines the aroma. Rexim® amino acids manufactured by fermentation meet regulatory requirements for the production of natural aromas, as well as those for kosher and halal certification.

- L-Proline
- L-Methionine
Amino acids act as valuable compounds for precursors for chiral substances, particularly in the pharmaceutical industry. Rexim® offers extensive know-how in the manufacture and purification of derivatives of readily available L-amino acids.

- Racemic DL and enantiopure D-amino acids
- L-tert-Leucine
- Isoserine, L-Homoserine
- L-Norvaline
- MOC-, BOC-, CBZ-protected L- and D-amino acids
- MOC-, BOC-, CBZ-protected L- and D-amino acid derivatives
- Oligopeptides

Amino acids are natural constituents of skin and hair and thus readily absorbed in topical formulations to repair damaged cells or as a protective barrier against environmental factors, e.g., UV radiation. Advances in nutrition science and proven positive effects of amino-acid-containing cosmetics are opening new possibilities for cosmetics applications based on Rexim® non-animal amino acids.

- Amino acid mixtures and pre-mixes
- Oligopeptides

Biotechnology is one of the fastest-growing industries, churning out innovations almost on a daily basis, from biofuel production to biopharmaceuticals. Highly purified and microbiologically stabilized Rexim® amino acids, have become the preferred choice for creating the cell culture media necessary to raise the microorganisms or mammalian cells that create the target biomolecules.

- Cell culture media

Amino acids for a variety of applications
Quality and product safety are essential in our markets. Rexim® stands for the very high quality and product safety. Our quality standards are based on the selection of high-quality raw materials and excellence in product manufacturing and supply, together with efficient and reliable order processing.

We welcome the customers to visit our facilities so that they can see and assess our commitment to very high quality and product safety.

- GMP compliance
- ISO certified
- Inspected by customers and agencies (FDA, AFSSaPS)
- HACCP implemented
- High-purity chemical grades and controlled levels of microorganisms and endotoxins
- Free of chlorinated solvents, preservatives, antioxidants, mycotoxins, aflatoxins, pesticides, hormones, dioxins, and cytotoxic compounds
- GMO-free products
- Kosher and halal certification
- Statements on allergens, residual solvents, and BSE/TSE available
The Rexim® technology edge

Rexim® combines excellence in chemistry, biotechnology, and purification technology in a way that is unique for the industry. Consequently, Rexim® stands for a broad variety of amino acids and amino acid derivatives.

As a unit of Evonik, we can also combine this extensive portfolio of products, services, and expertise with a comprehensive organic chemistry toolbox available to us from other units – we can offer a range of non-natural amino acids and derivatives not available from any other major amino acid supplier. More importantly, Rexim® continuously reaffirms its commitment to innovation, particularly in biotechnology, by actively supporting internal and external research programs.

Rexim® offers three different quality grades to meet the varying degrees of purity requirements of our different customers: our GMP-grade products, which comply with good manufacturing practice, can be used as active pharmaceutical ingredients or as ingredients for parenteral nutrition; nutraceutical grade products destined for human medical nutrition or food applications; and pure-grade products, most commonly used as versatile building blocks for chiral synthesis.

The ability to calibrate the degree of purity to match customer requirements not only makes us a one-stop shop for the broadest spectrum of applications, but also gives our customers the benefit of cost-effective solutions to meet needs specific to their industry and their processes.

Special technologies
- Mixing of solids under cGMP conditions
- Micronization technology
- Milling and sieving under cGMP
- Chromatographic purification services
- Broad amino acid derivative technology
- Fermentation technology
- Biocatalytic processes
- Enzymatic synthesis

GMP = Good Manufacturing Practice grade
NG = Nutraceutical grade
PG = Pure grade
How chemistry, biotechnology, and purification technology work together at Rexim®

The ability to combine and compare processes and technologies across different areas, and also to share and learn from experiences across different disciplines, enables us to make new, unexpected connections in the problem-solving process. The unique mix of advanced purification technology and expertise in organic synthesis, for example, enables us to manufacture various amino acid derivatives and specialties to GMP standards. Along with manufacturing sites around the globe, we have a large-scale fermentation capacity to produce crude amino acids at a very competitive cost point as well. And our broad and deep expertise in biotechnology is pivotal in the development of extremely efficient processes, for manufacturing D-tryptophan.

At Rexim® we understand that finding the solution to a specific problem requires both specialized knowledge and a holistic approach. And because something that works also has to be practical, any potential solution also has to be thoroughly validated from the process perspective. This we achieve with a broad technical setup that ranges from the lab environment to the pilot plant to industrial-scale production facilities for fermentation, chromatography, crystallization, and organic synthesis.

Rexim® purification technology

Rexim® uses ion exchange chromatography for the purification of amino acids. We have 0.5 to 25 m³ columns resulting in more than several hundred cubic meter. With our equipment we can purify amino acids on any scale.

Ion exchange chromatography columns for the separation of amino acid mixtures on a large scale
Rexim® is the expert in amino acid derivatives

Due to the unique combination of chemistry, biotechnology, and purification technology, Rexim® also provides a broad variety of amino acid derivatives, which are used as building blocks in pharmaceutical synthesis. In addition to the standard amino acid derivatives, Rexim® also delivers custom-made derivatives.

Our customers benefit twofold from Rexim®: firstly, the unique combination of chemistry, biotechnology and purification technology leads to a broad variety of amino acid derivatives and makes custom-made derivatives possible. Secondly: the Rexim® deep backward integration, which is unique in the industry, gives high supply security.

Deep backward integration ensures high supply security of Rexim® products

From the production of crude amino acids to chemical derivatization, all the way to GMP-grade purification – each step is performed in-house. The entire supply chain is similarly in one hand. By controlling all the inputs, we’re able to achieve not only consistent product quality at the highest levels and ensure optimum supply reliability, but also to offer a degree of accountability that is rare in the industry. This unique combination of backward integration and supply chain control also creates the best conditions for continuous process optimization. In addition to lower costs and higher efficiencies, our customers benefit from increased regulatory safety as well – all the data is harmonized and under one roof, which facilitates the evaluation process, speeds up the approval process, and shortens time to market.
Customers benefit from our innovative services far beyond amino acids

Rexim® stands for a unique combination of extensive experience, innovative drive, and dedicated customer service that has continuously grown with and adapted to evolving customer and market needs. Today, after more than fifty years in the industry, Rexim® can offer product and service solutions that reach far beyond amino acids in driving our customers’ businesses forward.

Particle design

Give our experts a track to run on and we will tailor particle size, shape, and crystalline structure to meet the desired property or combination of properties, for example purity, bioavailability, particle size distribution (PSD), compaction behavior, caking behavior, and bulk density. In addition to the industrial equipment for mixing, milling, and sieving,

our customers also benefit from our lab capacities for characterizing crystalline structures and optimizing crystallization parameters, including phase diagram determination, in situ PSD determination, hot-stage stereomicroscopy, X-ray diffraction, and electron microscopy, to name only the main ones.

On-demand amino acid derivatives

The combination of decades of process experience and extensive scientific expertise we bring to the table gives our customers a head start when it comes to on-demand amino acid derivatives, such as acetyl, ester, amide, DL- and D-amino acids and protected amino acids. And the advanced technology at our disposal cuts the time between request and delivery even further.

Robust peptides platform

The same approach we take to customizing particle design is also applied to the development of processes for synthesizing dipeptides and polypeptides as per customer requirements. Here, too, our manufacturing facilities can handle peptide demand on a multiton scale, creating efficiencies on several levels for our customers.

On-demand labeled amino acids ($^{13}$C, $^{15}$N)

Rexim® also offers the full line of $^{13}$C and $^{15}$N labeled amino acids and derivatives in minute quantities for research purposes and for diverse applications, such as labeled protein and polypeptide production or media supplementation. Complete process integration ensures consistent, high-quality products in the shortest time.
Regulatory support

In addition to providing product and service excellence, Rexim® gives the full benefit of a strong reputation, built over more than five decades, in helping our customers obtain regulatory approval – and shortening time to market.

**Regulatory services:**
- REACH registration
- Expertise in registration processes worldwide
- Know-how in regional regulatory specifics
- Proactive implementation of new regulatory requirements
- Creation of Drug Master Files (DMF)
- Creation and maintenance of Certificates of Suitability
- Consultancy in regulatory issues
- Regulatory affairs services

Analytical services

Highly purified products desire the best available analytical services. Rexim® offers analytical support for your amino acid, amino acid derivative or peptide challenge. You would like to know the precise composition of an amino acid mixture or the by-product composition of an amino acid derivative? We can offer you our in house analytical services.

**Analytical services**

- REACH registration
- Expertise in registration processes worldwide
- Know-how in regional regulatory specifics
- Proactive implementation of new regulatory requirements
- Creation of Drug Master Files (DMF)
- Creation and maintenance of Certificates of Suitability
- Consultancy in regulatory issues
- Regulatory affairs services

Customized pre-mixes

Using amino acid mixtures are getting more and more usual in pharma and food applications. Due to our technological expertise and experience in formulation of customized pre-mixes we offer you support in mixing, milling and sieving.

**Customized pre-mixes**

- REACH registration
- Expertise in registration processes worldwide
- Know-how in regional regulatory specifics
- Proactive implementation of new regulatory requirements
- Creation of Drug Master Files (DMF)
- Creation and maintenance of Certificates of Suitability
- Consultancy in regulatory issues
- Regulatory affairs services

Customer specific process development

Do you need an amino acid derivative you cannot get elsewhere? Or do you need it in an unusual specification or grade? Challenge us and our expertise in amino acid and amino acid derivative manufacturing and participate in our technological network.

**Customer specific process development**

- REACH registration
- Expertise in registration processes worldwide
- Know-how in regional regulatory specifics
- Proactive implementation of new regulatory requirements
- Creation of Drug Master Files (DMF)
- Creation and maintenance of Certificates of Suitability
- Consultancy in regulatory issues
- Regulatory affairs services

Purification services

We have several decades experience in purification of natural materials by applying chromatographic technologies. Contact us in case you have a specific request for a separation job.

**Purification services**

- REACH registration
- Expertise in registration processes worldwide
- Know-how in regional regulatory specifics
- Proactive implementation of new regulatory requirements
- Creation of Drug Master Files (DMF)
- Creation and maintenance of Certificates of Suitability
- Consultancy in regulatory issues
- Regulatory affairs services

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**Rexim® is the expert at your side in amino acids and their derivatives**

**Customers benefit from:**

- Highest quality and product safety
- The Rexim® global reach
- The Rexim® expertise both in chemistry and biotechnology
- A broad range of process technologies
- High supply security due to backward integration
- The Rexim® know-how in regulatory needs
- Innovative complementary services
### Amino acids

<table>
<thead>
<tr>
<th>Amino acid</th>
<th>CAS No.</th>
<th>GMP grade</th>
<th>Nutraceutical grade</th>
<th>Pure grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>L-Alanine</td>
<td>56-41-7</td>
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<tr>
<td>L-Asparagine</td>
<td>5794-13-8</td>
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<tr>
<td>L-Aspartic acid</td>
<td>56-84-8</td>
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<tr>
<td>L-Glutamic acid</td>
<td>56-86-0</td>
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<tr>
<td>Glycine</td>
<td>56-40-6</td>
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<td>L-Isoleucine</td>
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<td>L-Leucine</td>
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<td>L-Lysine monohydrate</td>
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<td>L-Lysine 50% solution</td>
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<td>L-Methionine</td>
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<td>DL-Alanine</td>
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### Amino acid salts

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<th>Amino acid salts</th>
<th>CAS No.</th>
<th>GMP grade</th>
<th>Nutraceutical grade</th>
<th>Pure grade</th>
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<tr>
<td>L-Arginine-L-aspartate</td>
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<td>L-Arginine-L-glutamate</td>
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<tr>
<td>L-Arginine-L-pyroglutamate</td>
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<td>L-Lysine acetate</td>
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<td>L-Lysine-L-aspartate</td>
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<td>L-Lysine hydrochloride</td>
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<tr>
<td>L-Lysine-L-glutamate dihydrate</td>
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<td>L-Lysine-L-malate</td>
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<tr>
<td>L-Ornithine-L-aspartate</td>
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### Peptides

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<th>Peptides</th>
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<th>GMP grade</th>
<th>Nutraceutical grade</th>
<th>Pure grade</th>
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<td>L-Alanyl-L-glutamine</td>
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<td>Glycyl-L-glutamine monohydrate</td>
<td>13115-71-4</td>
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<tr>
<td>Glycyl-L-tyrosine dihydrate</td>
<td>658-79-7</td>
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<tr>
<td>N-Acetyl-L-alanyl-L-glutamine</td>
<td>121574-43-4</td>
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<tr>
<td>(L-Alanyl-L-Cytine) dimer</td>
<td>750-08-5</td>
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### Peptides

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<th>Peptides</th>
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<td>L-Alanyl-L-prolin</td>
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</tr>
<tr>
<td>L-Alanyl-L-tyrosine</td>
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### Keto acids and their salts

<table>
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<tr>
<th>Keto acids and their salts</th>
<th>CAS No.</th>
<th>GMP grade</th>
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<tbody>
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<td>L-Arginine-α-ketoglutarate</td>
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<td>α-Ketoglutaric acid</td>
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<td>Di-L-Ornithine-α-ketoglutarate dihydrate</td>
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<td>Ketoleucine Ca-salt</td>
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<td>Calcium (S)-3-Methyl-2-oxovaleric acid</td>
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### Standard derivatives

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<td>L-Serine methyl ester hydrochloride</td>
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<td>N-Acetyl-L-methionine</td>
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<tr>
<td>N-Acetyl-DL-methionine</td>
<td>1115-47-5</td>
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<td>N-Acetyl-DL-tryptophan</td>
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### Other specialties

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<th>Other specialties</th>
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<tr>
<td>L-Homoserine</td>
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<td>L-Isoserine</td>
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<td>L-Norvaline</td>
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<td>L-tert-Leucine</td>
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<td>DL-Isoserine</td>
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<tr>
<td>5-(Hydroxy-methyl)-furfural</td>
<td>67-47-0</td>
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</tbody>
</table>

Other products and amino acid derivatives available on request