About Evonik

Evonik is the creative industrial group from Germany and one of the world’s leading specialty chemicals companies. Around 80 percent of Evonik sales come from market-leading positions, which we are systematically expanding. In 2013, our approximately 33,000 Evonik employees produced sales of €12.7 billion and an operating result (EBITDA) of €2 billion. Our business activities are aligned with three global megatrends: besides resource efficiency and globalization, our focus is also on the key growth sector of health and nutrition. 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.

Market focus to the power of 4

The depth and breadth of expertise in chemistry and biotechnology, and, more important, the ability to apply the knowledge acquired in both fields towards meeting the new challenges our customers face every day – that is what sets Evonik apart. That and technological capabilities enable us to keep pushing the boundaries while making processes more efficient and cost-effective.

There are four key areas making all the difference with proven, reliable and cost-competitive off-the-shelf solutions that are anything but run-of-the-mill:

**Medical Nutrition**
- Amino acids
- Amino acid derivatives
- Peptides
- Amino acid salts

**Cell Culture Ingredients**
- Superior amino acids
- Keto acids
- Peptides

**Pharmaceuticals & Intermediates**
- Generic APIs such as chlorhexidine
- Intermediates
- Phosphonium salts

**Advanced Food Ingredients**
- Amino acids
- Peptides
- Excipients
Global reach, global presence

Short response times and optimum supply security are just two aspects of customer proximity as we understand it. Our development and manufacturing sites around the world are fully cGMP (current Good Manufacturing Practice) compliant and open to agency and customer scrutiny. More than an obligation, meeting the most stringent environmental, health and safety standards is a responsibility.

Medical Nutrition

Under the Rexim® brand, we’ve earned a reputation for quality and dependability with the most comprehensive range of readily available, high-quality amino acids, amino acid derivatives and peptides for parenteral nutrition applications. Rexim® products enhance intravenous formulations for metabolic disorders, pre- and post-surgery diets and malnutrition treatments – to name but a few applications.

Cell Culture Ingredients

In biopharmaceutical research and production, users and regulatory bodies alike demand the highest quality to ensure the promised performance and a safe product. Here, Evonik non-animal-origin amino acids have emerged as the preferred choice for the preparation of chemically defined media. And for extra measure we developed a range of advanced ingredients to further increase titers and cell density.

Pharmaceuticals & Intermediates

As a supplier of generic APIs, as well as intermediates and phosphonium salts used in chemical synthesis, Evonik offers an unrivalled mix of choice, quality and availability. As a partner to the pharmaceutical industry, Evonik provides unique access to extensive experience, cutting-edge technology and global logistics, which that smoothen processes and shorten time to market.

Advanced Food Ingredients

As food manufacturers face new challenges in meeting the needs of a fast-growing global consumer base that is increasingly diverse and demanding, they are also identifying new opportunities. As a premier supplier of advanced food ingredients and excipients, Evonik opens new paths for exploring and realizing the potential for creating better and healthier foods.
Quality and product safety are as essential to us as to our customers. We’ve built our reputation on staying true to that simple and straightforward principle. At Evonik, maintaining the toughest standards, be they based on legislation or self-imposed, comes from selecting only the highest-quality raw materials and ensuring excellence in product manufacturing and supply, together with efficient and reliable order processing – and from never cutting corners.

Our customers are always welcome to our facilities to assess and verify our capabilities, as well as our commitment to quality and product safety.

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### Essential: our quality and product safety

Measuring up to the toughest standards – and more

- GMP compliance
- ISO certification 9001, 14001 and 22000
- Audits by customers and agencies (FDA and ANSM)
- HACCP implementation
- High-purity chemical grades and controlled levels of microorganisms and endotoxins
- No chlorinated solvents, preservatives, antioxidants, mycotoxins, aflatoxins, pesticides, hormones, dioxins or cytotoxic compounds
- Non-GMO products
- Kosher and halal certification
- Statements on allergens, residual solvents and BSE/TSE available
- Non-animal origin
- USP, EP, JP and FCC compliant
- Sedex audited plants
Regulatory support that shortens time to market

In addition to product and service excellence, Evonik customers can count on advice and hands-on support throughout the regulatory approval process to optimize time to market. Here, our experience provides a major head start. Besides ensuring continuous surveillance of evolving global and local legislation, as well as regulatory and cGMP requirements, our regulatory support specialists also author and maintain worldwide registration documentation.

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 (CEP)
- Consultancy in regulatory issues
- Regulatory affairs services
The Evonik technology edge

Evonik uniquely combines excellence in chemistry, biotechnology and purification technology. This enables us to provide the broadest spectrum of solutions for medical nutrition, pharmaceutical, cell culture and food applications.

Customers benefit from our ability to enhance this extensive portfolio of products, services and expertise with the comprehensive organic chemistry toolbox available to us from other units. It puts us in the position to offer a range of functional ingredients and derivatives not available from any other major amino acid supplier. Just as importantly, we consistently push innovation, particularly in biotechnology, by actively supporting internal and external research programs.

In addition, the ability to finely calibrate the degree of purity to match market and customer requirements not only makes us a one-stop shop for a wide universe of applications, but also gives our customers the benefit of cost-effective solutions to meet needs that are specific to their industry and their processes.

Beyond ingredients, Evonik also offers excipients and formulation development services that allow our customers to create more differentiated products to address their markets.

Process integration of the sensible kind
Deep backward integration for more control and supply security

From the production of basic amino acids to chemical derivatization, all the way to GMP-grade purification – each step is performed in-house. The same applies to our supply chain. Having full control over all the inputs enables us to do more than achieve consistent product quality at the highest levels and ensure optimum supply reliability. It also means we can offer a degree of accountability that is rare in the industry.

This depth of backward integration also extends to monomers for our EUDRAGUARD® range of polymer coatings developed specifically for the food supplement market.

Our unique ability to combine upstream and downstream integration with total supply chain control also creates the best conditions for continuous process optimization. In addition to lower costs and greater efficiencies, our customers benefit directly from increased regulatory certainty as well. All product and process data are harmonized and kept under one roof. And that facilitates evaluations, speeds up approvals and shortens time to market.

Supply security you can trust:

Our decades of operating a global manufacturing and logistics network save you headaches and give you better planning visibility.
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, 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.

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 over the long term. Customers can plan with and rely on Evonik. Being dependable to facilitate long-term partnerships with our customers is more than a strategy – it’s a commitment.
Your Evonik edge

- Global reach, global presence
- Unique combination of chemistry, biotechnology and purification technology.
- Highest quality and product safety
- Broad platform of process technologies
- Innovative value-adding services
- Formulation expertise
- Know-how in regulatory aspects
- Deep backward integration for high supply security
- EUDRAGUARD®
Medical Nutrition

Enhancing efficacy and efficiency with Rexim® nutrients

With a global reach, Evonik is the leading European expert in pharmaceutical amino acids, amino acid derivatives and peptides. Amino acids play such a fundamental role in our lives – they make up the proteins that in turn compose much of human and animal tissue, and they are key to ensuring cell growth, repair and maintenance. For this reason, we at Evonik 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’ve acquired a broad and deep understanding of the building blocks of life that is unparalleled in the industry. Here, our extensive experience in chemistry, 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.

Our partners who specialize in parenteral nutrition have come to count on us for more than just essential nutrient compounds that meet the highest product quality specifications and regulatory standards. That is because we view reliable supply coupled with comprehensive added value services as being part of the product, too.

At the core of our offering is the unique combination of chemistry, biotechnology and purification technology. It allows us to provide not only a broad array of amino acids, but also the complete spectrum of standard derivatives, as well as custom-designed compounds.
Parenteral nutrition

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, we ensure compliance with cGMP and provides all relevant documentation, such as Certificates of Suitability or Drug Master Files.

Enteral nutrition

For solutions delivered directly into the gastrointestinal tract, our products can be fine-tuned to meet specific needs across the entire patient age spectrum, from infancy to old age.

From newborn formulas to medical diet products that address metabolic ailments, allergies, malnutrition or intense physical stress to nutritional formulas targeted at the elderly – Rexim® amino acids and derivatives deliver the consistent quality that enteral feeding depends on. In addition, most of our enteral products are also certified kosher and halal.

Special technologies

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

Special services

- Particle design
- On-demand amino acid derivatives
- Robust peptides platform
- On-demand labeled amino acids (13C, 15N)
- Analytical services
- Customized pre-mixes
- Customer-specific process development
- Purification services

Product information

You will find our product data sheets at the back of this brochure.
Pharmaceuticals & Intermediates

One-stop shopping for quality key ingredients

Over decades we’ve built our reputation as a dependable source of generic APIs such as chlorhexidine, intermediates – many of which are based on amino acids – and phosphonium salts.

All our manufacturing facilities implement uniform Western standards and have been audited by the FDA and other independent organizations and public authorities. We rigorously follow cGMP guidelines and meet the most stringent environmental, health and safety standards.

As a reliable partner, we deliver the grades and quantities you require – in full and on time. But our responsibility doesn’t end at your receiving dock.

Besides the supply security you can count on, we offer technical services to address any issues you may encounter after delivery – from optimizing handling and processing at your site to aspects as far downstream as hands-on support in obtaining regulatory approvals.

Generic APIs

When it comes to generic APIs, quality is a top priority. So is minimizing your risks.

Our generic APIs, such as chlorhexidine come with an unrivalled track record for quality, reliability and safety. With Evonik as your source, there is an additional benefit: consistency.

This kind of added value only comes from decades of experience, advanced manufacturing capabilities and a global network.

And our approach to safety is just as thorough and comprehensive: All production stages not only comply with national and international regulations, but must also meet our own high self-imposed standards. The result is the ultimate in product quality and product safety. And that means smoother processes, more certainty and less risk. Because our goal is your peace of mind.
With Evonik, you will benefit from extensive experience in the manufacture of quaternary phosphonium compounds on commercial and pilot scale. This also includes high-purity stable phosphoranes in salt-free form. We have a long track record of custom manufacturing from small quantities (for development, testing, etc) to multiple tons. Our portfolio comprises the following classes of compounds:

- Alkyltriphenylphosphonium halides (Cl, Br, I)
- Alkyltriphenylphosphonium salts (-hydroxides, -acetates, -phosphates)
- Carboxyalkyltriphenylphosphonium halides
- Carboxyalkoxytriphenylphosphonium halides
- Stable phosphoranes (ylides) derived from c or d.

**Product in focus: L-Ornithine-L-Aspartate (LOLA)**

A body in good health will metabolize ammonia and evacuate it via the urea cycle. A malfunctioning liver may slow down this process dramatically, however, allowing ammonia to reach toxic levels and even induce coma. L-Ornithine-L-Aspartate (LOLA) provides an effective treatment of this liver disease by facilitating the conversion of ammonia into neutral urea.

- High purity
- Well-defined particle size distribution (other particle size distributions on request)
- Individual particles with pure crystalline structure
- Superior product stability
- Low methanol content
- Low endotoxin content, high microbiological quality
- Customer specification on request
- Standard packaging: 25 kg drums (5 drums per pallet)

**Intermediates**

The stepping stones to systematic success – intermediates from Evonik

Evonik proposes a broad array of intermediates for the pharmaceutical industry with a unique added value. Many of our intermediates are based on amino acids, which act as valuable precursor compounds for chiral substances, and on benzophenones. We offer 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
- MOC-L-tert-Leucin
- BOC-L-tert-Leucin
- Tbc-L-tert-Leucin
- Z-L-tert-Leucin DCHA
- L-Homoserine
- L-Norvaline
- L-Serine
- MOC-, BOC-, Z-protected L- and D-amino acids
- MOC-, BOC-, Z-protected L- and D-amino acid derivatives
- Oligopeptides

In addition, we can offer a range of non-natural amino acids and derivatives not available from any other major amino acid supplier.

**Phosphonium salts**

**Quaternary phosphonium compounds and their derivatives**

With Evonik, you will benefit from extensive experience in the manufacture of quaternary phosphonium compounds on commercial and pilot scale. This also includes high-purity stable phosphoranes in salt-free form. We have a long track record of custom manufacturing from small quantities (for development, testing, etc) to multiple tons. Our portfolio comprises the following classes of compounds:

**Product information**

You will find our product data sheets at the back of this brochure.
We’ve come a long way since we started producing DL-Methionine in 1948. Over the following six decades, we’ve acquired a knowledge of the building blocks of life that remains unparalleled in its depth and breadth. Our extensive experience in chemistry, biotechnology and purification technology enables us to meet any cell culture product challenge – from amino acids and their derivatives to keto acids and dipeptides of all types. All these years of experience in the key disciplines are put to good use when it comes to developing new products and processes. And when it comes to unlocking the full potential of our products for our customers, we aim to be at the forefront of research, analytics and technology.

The progress we’ve made translates into better reagents that can be made available to you faster and in the quantities you need – reliably, consistently and cost-effectively. What’s the purpose of experience if not to make things easier?

Cell Culture Ingredients

Bringing superior products and services together

Biotechnology is in our DNA

Amino acids

The solid foundation

Our partners in the pharma and biotech industries value our ability to meet precise purity standards and fulfill key requirements for cell culture research, development and production:

- High and consistent quality standards
- Non-animal origin
- Cell culture mediatested
- cGMP quality
- Low microbiological burden
- Low endotoxin level < 6 EU/g

In addition to proteinogenic L-amino acids, we also offer the gamut of D-, DL- and non-proteinogenic amino acids. Please contact us with your exact requirements.
**Boosters**

**The next step in improved performance**

**Keto acids**

If ammonia concentration is critical to your process, we also offer a comprehensive range of keto acids and their derivatives as an alternative to amino acids.

Specific keto acids have distinct functions in the cell. α-Ketoglutarate (AKG), for example, is a key intermediate in the metabolism. Supplementation of AKG as part of the basal medium or feed can lead to higher cell viability, product titer and product quality.

Besides the standard products, we also offer additional keto acids and salts on request. Our reagents come with the assurance of consistently precise composition, longer shelf life and environmentally responsible manufacturing processes.

**Peptides**

Peptides afford better solubility in water and help stabilize sensitive amino acids. They also prevent ammonia build-up, which is toxic to most cell cultures and negatively impacts glycosylation patterns. These features make peptides an ideal supplement to optimize cell viability, product titer and product quality.

Our existing peptide line-up already tackles some of the most common problems. We offer various L-glutamine-containing peptides such as L-alanyl-L-glutamine or glycyl-L-glutamine to provide a stable source of this essential amino acid. In addition, we also manufacture a modified form: N-acetyl-L-alanyl-L-glutamine. Another known issue is the low solubility of tyrosine. Our glycyl-L-tyrosine effectively addresses it by increasing solubility more than tenfold at a neutral pH.

But there’s even more: our chemical processes combined with proprietary technology enable us to manufacture virtually any di-, tri- or oligopeptide—and all this under controlled conditions up to ton scale.

**Services**

**Designed to support your application**

With technical services that range from milling and blending under cGMP conditions to analytics for verifying end-product purity, we can assist our customers at every stage on the path to market. Customized solutions extend from special products, such as peptides for scientific development of cell culture media, to special packaging (even 1kg bags are possible).

**Technical services**

**Milling**
- Pin mill
- Hosokawa / jet mill

**Mixing / Blending**
- Paddle dryer
- Cone dryer
- Vacuum mixing dryer
- Slanting dryer

**Packaging**
- To customer requirements

**Analytical services**

- Amino acid analyses
- Malvern particle size measurements
- Microbiological measurements
- Cell culture media testing
- Mass spectrometry

**Product information**

You will find our product data sheets at the back of this brochure.
Advanced Food Ingredients
Paving the way to better and healthier foods

What Evonik brings to the table: experience in addressing the evolving need for better quality, performance and value in nutritional products with amino acids and related compounds.

As the European supplier of advanced food ingredients and excipients, Evonik had become the food industry’s preferred partner for realizing the potential for creating better and healthier foods to meet the demands of a fast-growing global consumer base that is increasingly diverse and demanding consumer base.

Infant nutrition
Where standard cow’s milk or soy-based infant formulas fall short, amino-acid-enriched formulas consistently prove effective in addressing specific newborn needs or concerns. Indications include food allergies and intolerances, growth support and immune system development, brain and eye health and amino acid salt deficiencies.

Flavors
While amino acids can add or intensify food flavors, the actual reaction of supplemented amino acids with foods during cooking – the Maillard reaction – is what amplifies the flavoring effect. In particular, amino acids manufactured by fermentation are commonly used for the production of natural aromas and flavors.

Dietary supplements
Our key ingredients for dietary supplements – amino acids and their derivatives, as well as keto acids – serve to support and enhance physical and mental performance or detoxify the body. We also offer dedicated products for addressing metabolic disorders.

We provide the excipients for solid dosage forms that will mask unpleasant tastes or odors, protect actives until they reach the area in the body where they can unfold maximum benefits, and supply formulators with targeted release options.
Product in focus: EUDRAGUARD®

Our many decades of experience with excipients and formulation services for the pharmaceutical industry not only give food manufacturers the assurance of meeting the toughest product quality and regulatory standards, but they also widen the horizon for designing new and enhanced supplements. The EUDRAGUARD® range of solid oral dosage form excipients for supplements, for instance, specifically addresses the challenges of this niche in the food industry. By adding key properties – such as moisture protection, taste and odor masking, gastric fluid protection and targeted release – our excipients can make supplements more appealing and more nutritious. And more efficient, too, by ensuring they unfold their full potential where it counts.

- **EUDRAGUARD® control**
  for sustained-release and gastric-resistant formulations

- **EUDRAGUARD® protect**
  for taste and odor masking, as well as moisture protection

Sports nutrition

Advanced food ingredients from Evonik help active people and athletes keep their batteries charged and help their bodies derive greater benefits from physical activity, while preventing damage.

In addition, our excipients enable formulations for protecting nutrients until they reach a specific target area and releasing them according to a pre-defined time profile.

Our solid oral dosage form excipients are especially effective in masking any unpleasant taste or odor an ingredient may have. This ensures great-tasting sports nutrition formulations and opens more possibilities for product differentiation.

Product information

You will find our product data sheets at the back of this brochure.
Product information sheets

Medical Nutrition
Pharmaceuticals & Intermediates
Cell Culture Ingredients
Advanced Food Ingredients
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Contact
We look forward to showing you the value we can add to your business.
For a personal consultation, please contact our global sales support team:

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You can also contact us with your questions and enquiries via our website:

www.evonik.com/pharma-food-ingredients

There you will find details of your local contact.