



**Profile for Pharma –
Formulation and Synthesis.
Together!**

Evonik. Power to create.



Evonik Industries is a globally operating industrial group with leading positions in the Chemicals, Energy, and Real Estate Business Areas. We apply our creativity daily to new, future-oriented solutions, aligning ourselves to future markets with highly promising growth dynamics, and developing essential and indispensable solutions for our customers. Evonik is active in over 100 countries around the world. In its fiscal year 2008 about 41,000 employees generated sales of about € 15.9 billion and an operating profit EBITDA of about € 2.2 billion.

Profile for Pharma – Formulation and Synthesis

Evonik Industries supports patient-friendly health care in every step of product development for the pharmaceutical industry. Specializing in synthesis and dosage form development, Evonik is a strategic partner to the industry. We offer innovative technologies for drug delivery, offering the ability for targeting and time controlled release of active ingredients.

Evonik provides its customers with know-how and expertise in custom manufacturing of starting materials and intermediates to final active pharmaceutical ingredient (API). Stringent cGMP protocol and regular FDA inspections are established for all API manufacturing sites. In addition Evonik, as a leading global catalyst supplier, can tailor and optimize heterogeneous and homogeneous metathesis catalysts to the specific needs of customers manufacturing APIs and intermediates.

Evoniks offers a broad portfolio of products and services – with focused project management, our international teams will provide timely and effective solutions designed to optimize customer's costs.



REXIM® Amino Acids

The REXIM® amino acid trademark combines perfectly regulatory compliance, highest quality, reliability and competitiveness of our products in the global market.

Our core strength is the manufacture of amino acids and their derivatives under cGMP and controlled hygiene conditions. These quality aspects enable our customers to use our products in

- parenteral nutrition, as
- active pharmaceutical ingredients or as
- versatile building blocks for chiral pharma syntheses.

At our two production sites in France and China we have established a harmonized quality system, which is ISO certified and in compliance with cGMP regulations. Moreover, for most of our products we have registered Drug Master Files in Europe and the US and we hold Certificates of Suitability for a number of them.

Our global marketing organization delivers service to the locations of our customers worldwide. To address tomorrow's needs, we drive innovation by decades of expertise in amino acid science and the R&D organization of a global leader in biotechnological and chemical processes, Evonik Industries.



rexim®

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Catalysts from Evonik – Accelerating Your Chemistry®

Evonik has been a leader in chemical catalysts for almost 40 years. Now as before, customers all over the world rely on Evonik as a competent and trustworthy partner. We have built our business models around your needs in relation to catalyst solutions. There are basically two generic business models, the product and project business model.

Product Business

We offer a specialized product portfolio of catalysts for the pharmaceutical industry:

- Precious Metal Powder Catalysts
- Activated Base Metal Catalysts
- Homogeneous Metathesis Catalysts
- Deloxan® Metal Scavengers



Learn more about the portfolio by using the interactive Catalyst Guide (www.evonik.com/catalyst-guide).

Project Business

A project is always required if a product needs to be developed or has not been produced on a commercial scale at Evonik. There are four project categories: toll manufacturing, custom manufacturing, custom design and joint development.

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Controlled Drug Release

Evonik Pharma Polymers offers a broad portfolio of products & services to meet the drug delivery challenges of the pharmaceutical industry. Our Poly(meth)acrylate-based products, worldwide known under the trade name EUDRAGIT®, are used for enteric, protective and sustained release formulations. The unique functionality and variety of EUDRAGIT® polymers provides full flexibility for your targeted drug release profiles and preferred process technologies.

Our wide range of services is adapted to meet the requirements of the pharmaceutical industry's value chain. We are able to support you in your development process to bring products safely and quickly to the market. Benefit from our knowledge and expertise – starting with EUDRAGIT® supply over technical training, feasibility testing, customer tailored formulation development to clinical batch manufacturing including scale-up and production support. Whenever required, a joint development of highly sophisticated drug release technologies can provide exclusive solutions for your drug delivery challenges.



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Innovation for Formulation and Synthesis

Solvents



DRIVERON® S, a very economic and versatile process solvent, is the brand name for our high-purity methyl-tert-butyl ether (MTBE S), which is widely used in the pharmaceutical and fine chemical industry.

Organosilanes

Organosilanes in the pharmaceutical industry are used as:

- Blocking/Protection agent
- Reducing agent
- Building block



Polymers for Medical Devices

High-performance polymers for extruding or injection molding disposable medical devices.

- CYROLITE®
- CYROLITE Med 2
- ACRYLITE® MD



Glidants and Processing Aids

Silica excipients for every formulating need:

- AEROSIL® 200 Pharma
- AEROSIL® R 972 Pharma
- AEROXIDE® 160 Pharma
- AEROPERL® 300 Pharma



Amino Acids

Products in parenteral nutrition, as active pharmaceutical ingredients or as versatile building blocks for chiral pharma syntheses.



Catalysts

Catalysts for the pharmaceutical industry:

- Precious Metal Powder Catalysts
- Activated Base Metal Catalysts
- Homogeneous Metathesis Catalysts
- Deloxan® Metal Scavengers



Controlled Drug Release

Products & services to meet the drug delivery challenges of the pharmaceutical industry:

- EUDRAGIT® – Acrylic Drug Delivery Excipients



Exclusive Synthesis

Evonik Exclusive Synthesis can meet your needs for advanced intermediates and APIs, from the clinical stage all the way to commercialization.



Exclusive Synthesis

Evonik Exclusive Synthesis can meet your needs for advanced intermediates and APIs, from the clinical stage all the way to commercialization.

Global in scope and entrepreneurial in approach, our organization takes pride in being fast, responsive and flexible in meeting your project needs. We believe that open communication and transparency between you and us are key factors for the success of your projects. Our innovative and experienced chemists and

engineers will work with you and your technical staff to achieve the right solutions for your project. Once implementation is completed, we help optimize commercial processes, keeping you competitive.

We have outstanding cGMP capabilities at several FDA-inspected sites. With sites located in Europe and Asia, we can grow with your project through its life-cycle. We take an active role in meeting or exceeding regulatory requirements and in cooperating with your QA specialists.

Our goal is to provide you, our customer and contract manufacturing partner, a superior level of service. Your challenge is our passion.



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Glidants and Processing Aids

Evonik offers a broad range of silica excipients for every formulating need:

AEROSIL® 200 Pharma is an excellent glidant as well as an efficient rheological aid for viscosity control in gels and suppositories.

AEROSIL® R 972 Pharma has a chemically-treated hydrophobic surface. As a glidant it is especially suitable for short and/or low-shear mixing processes. It may also be used for stabilizing emulsions.

AEROXIDE® 160 Pharma has the same high glidant performance as the AEROSIL® products, but its higher tapped density makes it less dusty and thus easier to handle, weigh, and sieve.

AEROPERL® 300 Pharma is high-purity granulated colloidal silica with excellent carrier properties.

AEROSIL®, AEROXIDE® and AEROPERL® are characterized by their high purity and chemical inertness. All are supplied with a certificate of analysis stating that the product has been tested according to and meets the standards of the most recent pharmacopoeia.



AEROPERL®
AEROSIL®
AEROXIDE®

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Polymers for Medical Devices

Evonik offers a range of high-performance polymers for extruding or injection molding disposable medical devices.

CYROLITE® acrylic-based multipolymer compounds are transparent, impact-modified compounds offering exceptional chemical resistance, high heat deflection temperature, outstanding impact strength, and simple processing. Ideal for lipid-based drug delivery solutions, these polymers deliver the highest level of sterilization stability in the industry and are engineered for applications where gamma or E-beam sterilization is required.

CYROLITE® Med 2 compound is the world's only alcohol and lipid resistant acrylic polymer for applications involving IPA swabbing. ACRYLITE® MD acrylic polymers are pure PMMA with the highest optical clarity, transparency and UV transmission for medical diagnostic applications including cuvettes, test packs, rotors and crystallography trays. VuStat® static dissipative acrylic multipolymer compound is used for dry powder inhalers to ensure consistent dosage.



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Organosilanes

As market leader in organosilanes Evonik Degussa offers products for the pharmaceutical industry which are designed to meet the industry's demand for innovation, reliability, and quality.

Dynasytan® Organosilanes can act in a large variety of ways but in pharmaceutical industry they are used as:

- Blocking/Protective agent to improve reaction selectivity, solubility in solvents and stability during distillation
 - Dynasytan® HMDS
 - Dynasytan® BSA
- Reducing agent to enable a selective chemical reduction
 - Dynasytan® TES
- Chemical building block as useful precursor to various intermediates including amino alcohols
 - Dynasytan® TMSCN



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Solvents

DRIVERON® S is our high-purity methyl-tert.-butyl ether (MTBE S), which is widely used in the pharmaceutical and fine chemical industry as a very economic and versatile process solvent for extractions, crystallisations, chromatography as well as an alkylating agent or entrainer for drying of alcohols.



DRIVERON® S is miscible with all customary hydrocarbons and organic solvents, but only slightly soluble in water, separating from aqueous phases.

DRIVERON® S shows excellent oxidative stability resisting the formation of dangerous peroxides without adding any inhibitors, thus helping to improve the purity of the product and allowing repeated recycling of DRIVERON® S by distillation.

DRIVERON® S has a shelf-life of five years, if stored under ambient temperature, even in contact with air and contains very few water.

DRIVERON® S is resistant to weak acids and alkalis and has a moderate low boiling point (+55 °C), a high self-ignition temperature (+460 °C) and a very low freezing point (−109 °C). The flash point is −28 °C.

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EVONIK
INDUSTRIES

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Evonik. Power to create.