Advanced functional coating solutions for nutraceuticals
Evonik, producer of the world-renowned EUDRAGIT® polymers, has over six decades of experience with pharmaceutical coating development (cGMP compliant), thus enabling optimized formulations with faster time-to-market. These are important success factors in today’s marketplace, where substantial challenges have arisen in the development of nutritional coating systems.

Consumers around the world have become increasingly health conscious and are aware of the relationship between diet and health. Hence they are willing to do more to ensure their own well-being and want to be sure that dietary supplements are safe, of the highest quality as well as effective where needed in the body. At the same time, regulatory standards have been heightened.

With a view of those challenges, we offer our state-of-the-art EUDRAGUARD® portfolio. EUDRAGUARD® provides tailored solutions to deliver nutraceuticals to the right place at the right time. Our pharmaceutical expertise as well as exceptional internal resources ensure the highest quality standards.

About Evonik

In 2017, our more than 36,000 Evonik employees produced sales of €14.4 billion and an operating result (EBITDA) of €2.36 billion. As a premium supplier of food ingredients and excipients, the food industry has long been part of the strategic core business of Evonik. With years of proficiency in nutrient chemistry, our global technical experts help manufacturers develop formulations to suit specific supplement requirements. That includes selecting the ideal dosage form, optimizing release profiles and conducting scale-up trials. Evonik provides cutting-edge technical capabilities, together with deep polymer know-how and broad expertise in all development stages.
EUDRAGUARD® addresses all challenges around nutraceutical coatings

BIOAVAILABILITY
Some health ingredients are best absorbed at specific sites in the GI tract via defined release profiles:

- Delivery to the right location:
  - Stomach
  - Small intestine
  - Large intestine
- Delivery at the right time:
  - Instant
  - Delayed
  - Sustained

STABILITY
Some health ingredients face stability challenges and need gastro protection or gastro retention:

- Acidic environment:
  - Health ingredients can become unstable by gastric juice
- Neutral environment:
  - Health ingredients can become unstable by neutral pH in the small intestine

PROTECTION
Some health ingredients need a protective layer:

- Protection
- Improve storage stability with light, moisture or oxygen protection
- Protect ingredient from other ingredients
- Taste or odor
- Improve user experience by taste or odor masking
- Easier to swallow, avoiding reflux

GENTLE PROCESSING
Specific health ingredients require a gentle processing:

- Heat sensitive ingredients
- Protection via low process temperatures
- Short spraying time
- Preserve effectiveness by reduced stress on ingredients

Experts at Evonik have developed the EUDRAGUARD® toolbox - functional, aqueous or solvent based coatings to enable targeted delivery of ingredients to all parts of the gastrointestinal (GI) tract. As the next generation for nutraceutical formulations, EUDRAGUARD® coatings provide an exceptional sensory experience and can be tailored to specific requirements, while addressing key challenges of nutraceutical coatings.
targeted functionality for nutraceutical effectiveness and the reliable release of health ingredients at the right time and place

<table>
<thead>
<tr>
<th>FUNCTIONALITY</th>
<th>POSSIBLE APPLICATIONS</th>
</tr>
</thead>
</table>
| **EUDRAGUARD® protect** | - Instant release  
- Taste and odor masking  
- Moisture protection  
- Protection from light and oxidation | - Vitamins  
- Minerals  
- Herbal extracts  
- BCAA |
| **EUDRAGUARD® natural** | - Modulated or immediate release  
- Taste and odor masking | - Herbal extracts  
- Natural oil  
- Vitamins  
- Minerals |
| **EUDRAGUARD® control** | - Delayed release  
- Gastric resistance | - Fish oil  
- Garlic oil  
- Vitamine C  
- Caffeine |
| **EUDRATEC® GRS**  
Technology designed with EUDRAGUARD® control | - Sustained/ extended release in the stomach  
- Gastro retention | - Anthocyanins  
- Niacin |
| **EUDRAGUARD® biotic** | - Delayed release  
- Colonic delivery | - Prebiotics  
- Probiotics |
KEY BENEFITS ACROSS ALL EUDRAGUARD® PRODUCTS:

- Pigments, flavors and fragrances can be added to the formulation
- Smooth, even finish for visual appeal and swallowability
- Low weight gain of polymer needed (mainly for synthetic polymers)
- Quick and easy suspension preparation
- Short spraying times
- Low spraying temperature
- Works on all types of oral solid dosages forms (tablets, hard shell and soft gel capsules, multiparticulates)
- No batch-to-batch variation of the polymer, reproducible results for coating
- May be used on conventional coating equipment
- Non-animal derived
EUDRAGUARD® PRODUCTS RESEMBLE A TOOLBOX: OUR EXPERTS FIND THE RIGHT COMBINATION TO ACHIEVE YOUR DESIRED RELEASE PROFILE, NO MATTER HOW SPECIFIC.

**EUDRAGUARD® protect**

Several nutrients feature unpleasant odor and are therefore often refused as regular supplementation. In those cases the application of an odorless coating is the best solution to increase compliance. This can be realized by using our EUDRAGUARD® protect which masks odor without slowing down the release of the nutrient from the tablet or particle. In addition odor modifying additives can be added to further design the odor.

Branched chain amino acids (BCAA) are known to suffer from unpleasant odor. The REXIVA® marked amino acid BCAA coated with EUDRAGUARD® protect show no odor. The dissolution profile shows that the release was not slowed down by the application of the coating. The BCAA are released immediately in the stomach.

**EUDRAGUARD® natural**

Bitterness is one of the most sensitive and unpleasant tastes. The reduction of ingredients’ bitterness is very important in order to provide pleasant finished products. A simple way to cover the unpleasant taste is the addition of coating materials and further taste modifying additives.

A fluidized bed coating process with EUDRAGUARD® natural was applied for a bitter tasting powder. The resulting granules were dispersed in water and the taste masking properties were evaluated for effectiveness in human taste panels. The results demonstrate heterogenous sensation amongst the individuals. This refers to the well-known large genetic variability which leads to differences in the sensory capacities for bitter taste.

In general, two independent human taste panel studies proved a very successful bitterness reduction.
**EUDRAGUARD®**

**targeted delivery systems for nutraceuticals**

<table>
<thead>
<tr>
<th>Functionality</th>
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<tbody>
<tr>
<td>• Instant release</td>
<td>• Taste &amp; odor masking</td>
<td>• Moisture protection</td>
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<tr>
<td>• Protection from light &amp; oxidation</td>
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<table>
<thead>
<tr>
<th>Possible applications</th>
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<tbody>
<tr>
<td>• Vitamins</td>
<td>• Herbal extracts</td>
<td></td>
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<tr>
<td>• Minerals</td>
<td>• BCAA</td>
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<table>
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<tr>
<th>Key benefits</th>
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<tbody>
<tr>
<td>• Enhanced storage stability</td>
<td>• Pleasant consumption (taste and odor masking)</td>
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<tr>
<td>• No release in the mouth - instant release in stomach</td>
<td>• Available in a ReadyMix version (one-component system)</td>
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<tr>
<td>• Formulation can be either aqueous or solvent based - pH dependent release</td>
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**EUDRAGUARD® natural**

**Natural taste & odor masking**

<table>
<thead>
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<th>Functionality</th>
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<tbody>
<tr>
<td>• Immediate or modulated release</td>
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<thead>
<tr>
<th>Possible applications</th>
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<tbody>
<tr>
<td>• Herbal extracts</td>
<td>• Vitamins</td>
<td></td>
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<tr>
<td>• Natural oil</td>
<td>• Minerals</td>
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<table>
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<tr>
<th>Key benefits</th>
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<tr>
<td>• Natural system (maize starch-based coating)</td>
<td>• Applicable for functional food &amp; beverages as well as for dietary supplement</td>
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<tr>
<td>• Two-component system (e.g. with a customized colored coating) under the brand name <strong>EUDRAGUARD® natural match</strong> available</td>
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</table>
EUDRAGUARD® biotic
Right to the colon

Functionality
- Delayed release
- Colonic delivery

Possible applications
- Prebiotics
- Probiotics

Key benefits
- Unique market solution for targeted colonic delivery
- Targeted release above pH 7
- Easy-to-use formulation

EUDRAGUARD® control
Controlled delivery

Functionality
- Gastric resistance
- Sustained release
- Gastro retention

Possible applications
- Fish oil
- Garlic oil
- Vitamin C
- Caffeine
- Anthocyanins
- Niacin

Key benefits
- Enteric release in combination with alginate as pore former
- Acidic protection of sensitive ingredients
- Avoid irritation of the mucosa
- Targeted release at specific pH
- Extended release over time in GI tract
- Sustained release via coating or matrix formulation
- Creation of a floating capsule in combination with a pore former
- Prolonged release in the stomach for up to 4 hours
- Flexible polymer - especially important for soft capsules
- Easy-to-use formulation
- Polymer will not dissolve but gel

EUDRATEC® GRS
Functionality
- Gastric resistance
- Sustained release
- Gastro retention

Possible applications
- Fish oil
- Garlic oil
- Vitamin C
- Caffeine
- Anthocyanins
- Niacin

Key benefits
- Enteric release in combination with alginate as pore former
- Acidic protection of sensitive ingredients
- Avoid irritation of the mucosa
- Targeted release at specific pH
- Extended release over time in GI tract
- Sustained release via coating or matrix formulation
- Creation of a floating capsule in combination with a pore former
- Prolonged release in the stomach for up to 4 hours
- Flexible polymer - especially important for soft capsules
- Easy-to-use formulation
- Polymer will not dissolve but gel
**EUDRAGUARD® control**

Some health ingredients are not able to unfold their full effectiveness if released in the stomach. A possible reason for this shortcoming is their instability in the acidic environment of the stomach. EUDRAGUARD® control can be used in a formulation with alginate as enteric coating to prevent the release of ingredients in the stomach.

Fish oil capsules are well-known and established in the nutraceutical market. However, they can cause common side effects like the irritation of the gastric mucosa and fishy burps. The application of an enteric coating is a valuable key to overcome those unpleasant side effects. The release of the fish oil is delayed and happens in the small intestine in order to prevent side effects occurring in the stomach.

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**EUDRAGUARD® biotic**

Oral administration of live bacteria in form of probiotics is a preferred approach to improve gut health and support the prevention of certain diseases.

However, the application is challenging, as a sufficiently high dose of live and metabolically active microorganism in the target region is crucial for an appropriate health response. For many bacterial strains the target is the colon. Typically, the number of active probiotics is already highly affected by manufacturing processes such as drying steps and might be further reduced during the gastrointestinal pathway due to low pH values in the gastric juice, enzymes and bile salts. Gentle process conditions during formulation and targeted release to the colonic regions are therefore mandatory prerequisites for an appropriate health effect.

Formulations with EUDRAGUARD® biotic as targeted release agent benefit from the combination of gentle process conditions (as low process temperature and short spraying time) and a safe and targeted colonic delivery.
Evonik has gained its reputation based on excellent quality and product safety. We maintain the highest standards, both voluntarily and by strict adherence to legislation. Selecting only the highest quality raw materials and ensuring excellence in product manufacturing and supply are a matter of course.

In the European Union, all EUDRAGUARD® products are approved as food additives. In the US, they are GRAS (or pending, see table below) or listed in 21CFR as food additive.

EUDRAGUARD® natural is approved for use in many food categories, usually without quantity limits.

EUDRAGUARD® biotic, protect and control have been evaluated and legally approved solely for use as glazing agent for pre-dosed solid dietary/food supplements within the allowed quantity limits as defined by EFSA and listed in the product specification. It is neither evaluated nor legally approved for any other application, including but not limited to conventional human food or any application for animals.

Evonik assumes no liability whatsoever for any improper use for any application other than pre-dosed solid dietary/food supplements.

To ensure highest product quality, we implemented quality systems such as HACCP, and our products are non-GMO and of non-animal origin. EUDRAGUARD® biotic, protect and control have been certified as Halal. All EUDRAGUARD® production sites have ISO 9001 certification.

All our EUDRAGUARD® products are made in the EU.

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**EUDRAGUARD® may be used in the following countries**

<table>
<thead>
<tr>
<th></th>
<th>EUDRAGUARD® protect</th>
<th>EUDRAGUARD® control</th>
<th>EUDRAGUARD® biotic</th>
<th>EUDRAGUARD® natural</th>
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<tbody>
<tr>
<td>EU</td>
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<td>US</td>
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<td>China</td>
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<td>India</td>
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<td>Mexico</td>
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<td>Codex alimentarius / JECFA</td>
<td>under evaluation</td>
<td>under evaluation</td>
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</table>

*other countries on request*
FORMULATION & TECHNICAL SERVICES
With our expertise in formulation development, our experts support you to differentiate your product and may help to shorten the time-to-market for your product development.

Our services at a glance

<table>
<thead>
<tr>
<th>FORMULATION DEVELOPMENT</th>
<th>TECHNICAL SUPPORT</th>
<th>ANALYTICAL TESTING</th>
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</thead>
<tbody>
<tr>
<td>Different technologies available, for example drum or fluid bed coating</td>
<td>Comprehensive support of individual formulation development – fast and flexible</td>
<td>Characterization of formulation via disintegration test or dissolution</td>
</tr>
<tr>
<td>Coating on different delivery forms: soft or hard capsules, tablets, multiparticulates</td>
<td>Scale up and production support at customer or CMO site</td>
<td>Microscopical evaluation (for example via scanning electron microscopy)</td>
</tr>
<tr>
<td>Technical or HACCP compliant samples available</td>
<td>In-house-training</td>
<td>Taste property testing via electronic tongue or taste panel</td>
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<tr>
<td>Preparation of delivery forms: tableting, capsule filling, granulation</td>
<td>Workshops</td>
<td>Analysis of PSD, Assay, Impurity, additional complex analytical tools available upon request</td>
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</tbody>
</table>
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EUDRAGUARD® – reg. trademark of Evonik Industries AG and its subsidiaries

REXIVA® – reg. trademark of Evonik Industries AG and its subsidiaries