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 2016, our more than 35,000 Evonik employees produced sales of €12.7 billion and an operating result (EBITDA) of €2.165 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.

60 YEARS coating experience

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EUDRAGUARD® addresses all challenges around nutraceutical coatings

BIOAVAILABILITY
Some health ingredients are best absorbed at specific locations in the GI tract with defined release profiles to boost bioavailability:

- 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:

- Acidic environment:
  - Health ingredients that can be harmed by gastric juice may require gastric resistance

- Neutral environment:
  - Health ingredients that can be harmed by neutral pH in the small intestine may require gastro retention

PROTECTION
Some health ingredients need a protection layer:

- To improve storage stability, as they may be harmed by
  - Light
  - Moisture
  - Oxygen

- To improve consumer experience by masking unpleasant taste or odor

GENTLE PROCESSING
Some health ingredients require gentle processing:

- Heat sensitive ingredients
  - Protected by very low process temperatures

- Short spraying time
  - Reduces stress on the ingredients and, thus, preserves effectiveness

Experts at Evonik have developed the EUDRAGUARD® toolbox - functional, water-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 visual and tactile experience and can be tailored to specific requirements, while facing the key objections of nutraceutical coatings.
<table>
<thead>
<tr>
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<th>FUNCTIONALITY</th>
<th>POSSIBLE APPLICATIONS</th>
<th>KEY BENEFIT</th>
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</table>
| **EUDRAGUARD® protect** | • Taste and odor masking  
• Moisture protection  
• Protection from light and oxidation | • Vitamins  
• Minerals  
• Cosmeceuticals  
• Herbal extracts  
• BCAA | • Enhanced storage stability  
• Pleasant consumption due to taste and odor masking  
• Instant release in the stomach |
| **EUDRAGUARD® natural** | • Taste and odor masking  
• Modulated release | • Herbal extracts  
• Olive oil  
• Vitamins  
• Minerals | • Natural system  
• Applicable for functional food & beverages as well as for dietary supplements |
| **EUDRAGUARD® control** | • Gastric resistance  
| | • Fish oil  
• Garlic oil | • Superior enteric protection  
• Targeted release at specific pH |
| | • Sustained release | • Vitamine C  
• Caffeine  
• Creatine | • Extended release over time in the intestine |
| **EUDRATEC® GRS** | • Gastro retention | • Anthocyanins  
• Niacin | • Release over a long time in the stomach |
| **EUDRAGUARD® biotic** | • Colonic delivery | • Prebiotics  
• Probiotics  
• L-Tryptophan | • Unique market solution for targeted colonic delivery |
targeted functionality for nut raceutical effectiveness
EUDRAGUARD®
targeted delivery systems for nutraceuticals

**EUDRAGUARD® control | Controlled delivery**

With EUDRAGUARD® control, an aqueous-based formulation, the targeted release of sensitive ingredients is based on defined pH values in the gastrointestinal tract. This means that nutraceutical substances can be shielded from the acidic environment of the stomach.

However, in addition to superior enteric protection and targeted delivery, EUDRAGUARD® control is also perfect for ingredients requiring sustained release as well as for nice and smooth surfaces.

Its gastro-retentive capabilities allow the continual delivery of ingredients that are best absorbed over a prolonged time period in the stomach. This flexible polymer is especially suited for soft shell capsules and provides a smooth and even finish.

Low process temperatures make EUDRAGUARD® control suitable for every application where controlled delivery is desired.

**EUDRAGUARD® biotic | Right to the colon**

EUDRAGUARD® biotic is the only coating solution on the market for targeted colonic delivery. It is a pH-triggered polymer that protects compounds from gastric acid in the stomach as well as bile acid in the small intestine.

EUDRAGUARD® biotic ensures that ingredients safely reach the region where they are most effective – the colon. With more polymer weight gain, the release might be modulated.

This flexible, aqueous-based formulation can be used with low process temperatures for all solid dosage forms. Quick and easy to apply, EUDRAGUARD® biotic results in a sleek, uniform, nice and smooth surface.
Our EUDRAGUARD® line of functional polymers was developed especially for use in nutritional supplements (such as powders, granules, tablets, soft shell and hard shell capsules). They make it possible to develop a range of functional coatings for nutraceutical applications including sustained and targeted release.

**EUDRAGUARD® protect | Tastes good, stores well**

While nutraceuticals have gained in popularity, many consumers are bothered by their unpleasant odors or tastes. EUDRAGUARD® protect, a pH-triggered polymer that enables instant release in the stomach, was developed to address exactly those deficiencies and thereby enhance the attractiveness of nutraceutical products.

In addition, this aqueous-based functional coating provides superior stability of ingredients. It provides advanced protection for sensitive products from environmental elements such as moisture, light or oxygen.

EUDRAGUARD® protect truly safeguards ingredients. It also boosts patient compliance thanks to an appealing, smooth and even surface.

EUDRAGUARD® protect Ready-Mix, a one-component system, is a ready-to-use mixture of the polymer plus excipients that can be augmented with pigments for a colored coating for customer convenience.

**EUDRAGUARD® natural | Natural taste & odor masking**

EUDRAGUARD® natural is a maize starch-based functional coating made from natural ingredients. It provides highly effective taste and odor masking capabilities as well as nice and smooth surfaces.

As EUDRAGUARD® natural is not a pH triggered polymer, release activation depends on the thickness of the coating.

In addition to EUDRAGUARD® natural, we provide a mixture of different excipients under the brand name EUDRAGUARD® natural match. In combination with our EUDRAGUARD® natural, a two-component system with a customized colored coating is created to offer an easy to use solution for your coating process.
EUDRAGUARD® PRODUCTS RESEMBLE A TOOLBOX: OUR EXPERTS FIND THE RIGHT COMBINATION TO ACHIEVE YOUR DESIRED RELEASE PROFILE, NO MATTER HOW SPECIFIC.

EUDRAGUARD® control

Some health ingredients are not able to unfold their effect in a way the given dose would be able to. Possible reasons for that can be instability in the acidic environment in 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.

EUDRAGUARD® biotic

In patients suffering from chronic inflammatory syndrom, the immune system is incessantly activated in different intestinal regions such as the colon.

One therapeutic approach is the administration of probiotic bacteria which are decreased in these individuals. For this, especially, bacteria of the lactobacillus species have been proven to be beneficial. These bacteria use L-Tryptophan (an essential amino acid) as an energy source. The release of L-Tryptophan in the colon might be advantageous to establish the growth of these helpful bacteria. Moreover, the majority of L-Tryptophan is catabolized into different molecules which can modulate the immune system. Many of these have been demonstrated to deactivate immune cells and thus reduce inflammation. This can lead to a positive therapeutic effect on acute and chronic inflammatory colitis.

Using EUDRAGUARD® biotic ensures that L-Tryptophan, which is marked unter the brandname REXIVA® at Evonik, is released in the colon region, where it can unfold its full benefits.
CASE STUDIES

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 a coating with an inert odor 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 final product granules were dispersed in water and the sufficient taste masking properties were evaluated within 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.
FORMULATION & TECHNICAL SERVICES
Evonik’s customers can count on access to innovative and effective coating solutions for all nutritional supplement requirements. Our strong global service network and our highly accomplished scientists ensure fully support close to our customers.

To ensure highest product quality, we implemented quality systems such as HACCP and our products are non-GMO and of non-animal origin. Kosher and Halal certification are expected soon. All our sites have ISO 9001 (quality), and 14001 (environment) certifications.

All our EUDRAGUARD® products are made in the EU.

EUDRAGUARD® products

<table>
<thead>
<tr>
<th>EUDRAGUARD® TYPE</th>
<th>E-NUMBER</th>
<th>REGULATORY STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUDRAGUARD® protect</td>
<td>E 1205</td>
<td>self affirmed GRAS</td>
</tr>
<tr>
<td>EUDRAGUARD® control</td>
<td>E 1206</td>
<td>self affirmed GRAS</td>
</tr>
<tr>
<td>EUDRAGUARD® biotic</td>
<td>E 1207</td>
<td>pending</td>
</tr>
<tr>
<td>EUDRAGUARD® natural</td>
<td>E 1420</td>
<td>21CFR</td>
</tr>
</tbody>
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REGULATORY & QUALITY
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 listed as food additives (indicated by the E number) and can be used in solid food supplements. In the US, our products have been granted GRAS status or products are registered in 21CFR as food additive.

Our services at a glance:

<table>
<thead>
<tr>
<th>FORMULATION DEVELOPMENT</th>
<th>TECHNICAL SUPPORT</th>
<th>ANALYTICAL TESTING</th>
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<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, granules, powders</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>
</tr>
<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>
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Sites & labs

WITH MORE THAN TEN FORMULATION DEVELOPMENT LABORATORIES IN MAJOR REGIONS AROUND THE GLOBE, WE ARE ALWAYS CLOSE AT HAND TO SUPPORT YOUR NEEDS.
This information and all further technical advice are based on our present knowledge and experience. However, it implies no liability or other legal responsibility on our part, including with regard to existing third party intellectual property rights, especially patent rights. In particular, no warranty, whether express or implied, or guarantee of product properties in the legal sense is intended or implied. We reserve the right to make any changes according to technological progress or further developments. The customer is not released from the obligation to conduct careful inspection and testing of incoming goods. Performance of the product described herein should be verified by testing, which should be carried out only by qualified experts in the sole responsibility of a customer. Reference to trade names used by other companies is neither a recommendation, nor does it imply that similar products could not be used.

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

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

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