

## Spore-based probiotic to support intestinal health & microbial balance\*

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ProbioSpore™ is a broad-spectrum, spore-based probiotic used to optimize gastrointestinal health.\* Spore-based, aerobic, gram-positive strands such as *Bacillus* are vital to the food chain as they have the intrinsic ability to produce a multitude of enzymes, secretory proteins, antimicrobial compounds, vitamins, and carotenoids.<sup>1</sup> Moreover, *Bacillus* strains possess antioxidant, immunomodulatory, and pathogen-exclusion abilities.<sup>1</sup>

ProbioSpore™ is an evidence-supported diverse combination of 5 different bacillus strains, including:

- 5 billion CFU *Bacillus subtilis* (DE111®)
- 2 billion CFU *Bacillus coagulans* (Lactospore®)
- 1 Billion CFU *Bacillus coagulans* (SNZ1969)
- 100 million CFU *Bacillus coagulans* (Lacris-15)
- 2 billion CFU *Bacillus clausii* (CSI-08)

These spore-forming bacilli are resistant to heat and ambient humidity, thus no refrigeration is required. The spores are also resistant to ultraviolet radiation, solvents, hydrogen peroxide, and enzymes. While these beneficial spore-forming *bacilli* lie dormant in the bottle, they revert to growing bacteria once they reach the intestines. As a result, spore-based probiotics offer high acid tolerance and resist being destroyed by the gastric environment, making them ideal for supporting gut microflora balance.

### Viability

*Bacillus subtilis*, DE111®, is a probiotic spore that works to improve immune function and digestive stability by controlling microbial populations. It also has a unique ability to form spores that protect the microbes from harsh conditions while in transit to the large intestine where they can propagate robustly. Its spore-forming action ensures it remains viable in a wide range of pH and temperatures, ensuring its efficacy and stability as a dietary supplement.

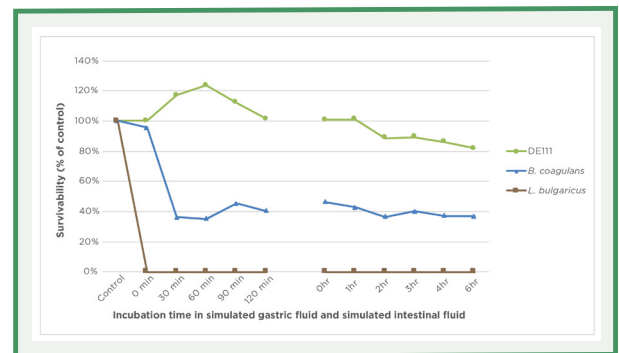
According to an in vitro study comparing *Bacillus*- and *Lactobacillus*-based strains, *Bacillus coagulans* showed double the survival rate over that of *Lactobacillus bulgaricus*, while DE111 *B. subtilis* exhibited over ten times greater survivability when placed in simulated gastric and intestinal fluids similar to those of humans.<sup>2</sup> Additionally, *B. coagulans* spores showed a significant tolerance to simulated digestive processes as well as adherence to two human colonic cell lines.<sup>3</sup> The enhanced survivability of DE111® *B. subtilis* under hostile environments makes it ideal for inclusion in ProbioSpore™.<sup>4</sup>

### Gut Function & Microflora Balance

It is well established that the short-chain fatty acids (SCFA) acetate, propionate, and butyrate, are metabolically the most valuable end-products from the microbial fermentation process of dietary carbohydrates. In clinical trials, DE111® *B. subtilis* was able to successfully proliferate under normal physiological conditions of the human GI tract, and furthermore, the strain has shown the ability to effectively produce propionic and butyric acid.<sup>2</sup> Butyric acid is the preferred fuel source for colonocytes and has been shown to play a protective role against colon cancer and ulcerative colitis, as it affects colonic cellular differentiation, proliferation, and apoptosis. SCFAs have been shown to improve gut barrier function through stimulating the formation of mucin, antimicrobial peptides, and tight-junction proteins. *Bacillus* interacts with the immune system, has anti-inflammatory effects, stimulates the absorption of water and sodium, and reduces reactive oxygen species within the colon.<sup>2</sup>

### Benefits\*:

- Antimicrobial activity
- Anti-inflammatory properties
- Cytoprotective
- Immunomodulatory
- Promotes bowel regularity
- Supports a healthy microbial balance



A comprehensive review demonstrated how intestinal Bacilli are natural guards against pathogens through their ability to secrete bacteriocins, lipopeptides and other compounds that possess antimicrobial and antiviral actions.<sup>5</sup> The review further explained that Bacilli secrete hydrolytic enzymes that can decompose food polymers and demonstrate direct antimicrobial activity by inhibiting and disrupting biofilm formation.<sup>5</sup>

*Bacillus spp.* probiotics have shown protective effects against cytotoxins. In an in vitro study *Bacillus clausii* strain O/C was able to counteract the toxic effects of two cytotoxic pathogens, *Clostridium difficile* and *Bacillus cereus*.<sup>5</sup> The cytoprotective effects of *B. clausii* were due to its ability to secrete a serine protease that inhibited the toxicogenic bacterial strain; demonstrating that this strain could potentially be an effective probiotic treatment for antibiotic-associated diarrhea.<sup>6</sup> In an animal study, *Bacillus subtilis* strains were shown to ameliorate dysbiosis and intestinal inflammation by way of rebalancing the gut microflora toward beneficial microbial populations and anti-inflammatory mediators, which ultimately helped ameliorate gut mucosal damage caused by ulcerative colitis.<sup>7</sup>

## Bowel Regularity

Bacilli promote regularity and normal bowel movements, helping to protect against occasional constipation or diarrhea. A randomized, double-blind, placebo-controlled human clinical trial showed that subjects who received 5 billion CFU *B. subtilis* DE111<sup>®</sup> probiotic in capsule form for an average of 20 days significantly increased the average number of bowel movements per day, and significantly reduced fasting blood glucose levels compared to the placebo group.<sup>8</sup> In another clinical trial, after 105 days of supplementation, healthy subjects from the bacillus subtilis DE111<sup>®</sup> probiotic group moved to a notably healthier bowel index according to the Bristol Stool Chart and digestive health questionnaires compared to healthy controls.<sup>9</sup> A double-blind randomized placebo-controlled human trial showed that 2 billion CFU per day dose of *Bacillus coagulans* Lactospore<sup>®</sup> for 90 days significantly improved symptoms associated with diarrhea-predominant irritable bowel syndrome (IBS-D), including bloating, vomiting, diarrhea, stool frequency, and abdominal pain.<sup>10</sup> Moreover, the same *Bacillus coagulans sp.* significantly improved quality of life for IBS patients with major depressive disorder by decreasing clinical symptoms of both conditions, correlating with research showing how intestinal bacteria affects depression-like and anxiety-like behaviors due to the link between the brain and the GI tract.<sup>11</sup>

## Immune Function

A positive effect of *Bacillus spp.* to cells beyond the GI tract, such as immune cells, has been established in research. *Bacillus subtilis* was shown to modulate the release of cytokines on human immunocompetent peripheral blood mononuclear cells, activating significant levels of anti-inflammatory IL-10 and very low levels of pro-inflammatory IL-12, TNF- $\alpha$ , and IFN- $\gamma$ .<sup>1</sup> In an animal model, oral administration of a combination of probiotic *B. coagulans* and prebiotic inulin improved markers of rheumatoid arthritis, significantly reducing pro-inflammatory cytokine, fibrinogen, and serum amyloid A levels.<sup>12</sup>

A comprehensive human clinical study observed that consumption of *B. clausii* modulated genes of the small intestines that are involved in inflammation, immune response, defense response, intestinal permeability, cellular adhesion, differentiation, growth, and signaling, as well as apoptosis, signal transcription and transduction.<sup>1</sup> Data from a novel in vitro study suggests that Bacillus-based spore-form probiotics may improve digestive health by reinforcing the intestinal barrier and limiting response by pro-inflammatory mediators. The *Bacillus subtilis* strain used in this study blunted pro-inflammatory signals and was able to greatly reduce the production of IL-8 in all stress conditions, as well as the upregulation of intestinal nitric oxide (iNOS) protein levels, compared to the control cells further demonstrating intestinal anti-inflammatory potential.<sup>13</sup> In a double-blind, randomized, placebo-controlled trial of college athletes undergoing rigorous off-season training, those who received 1 billion CFU DE111<sup>®</sup> probiotic for 12 weeks attenuated the increases in the circulating pro-inflammatory cytokine, TNF- $\alpha$ , that were observed in the control group.<sup>14</sup>

## Supplement Facts

Serving Size 1 capsule

Amount Per Serving	% Daily Value
<i>Bacillus coagulans</i> (Lactospore <sup>®</sup> )	25 mg (2 billion CFU) *
<i>Bacillus subtilis</i> (DE111 <sup>®</sup> )	20.8 mg (5 billion CFU) *
<i>Bacillus coagulans</i> (SNZ1969)	12.5 mg (1 billion CFU) *
<i>Bacillus coagulans</i> (Lacris-15)	8.3 mg (100 million CFU) *
<i>Bacillus clausii</i> (CSI-08)	8.3 mg (2 billion CFU) *

\*Daily Value not established.

**Other Ingredients:** Microcrystalline cellulose, capsule (hypromellose, water), medium chain triglycerides, silicon dioxide.

Formulated with 12.6 billion CFU at time of manufacture

### Recommended Use:

As a dietary supplement, take 1 capsule per day with a meal, or as directed by your healthcare practitioner.

For enhanced gastrointestinal health, ProBioSpore<sup>™</sup> may be coupled with other Designs for Health prebiotic and probiotic formulas such as ProBioMed<sup>™</sup> 50, 100, or 250, PreBioMed<sup>™</sup> XOS, FloraMyces<sup>™</sup>, ProBioPhage DF<sup>™</sup>, Probiotic Synergy<sup>™</sup>, or Probiotic Supreme DF<sup>™</sup>.



For a list of references cited in this document, please visit:

<https://www.designsforhealth.com/techsheet-references/probiospore-references.pdf>

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