



# CLINICALLY DOCUMENTED PROBIOTIC SPORE



## Expanding Probiotic Possibilities

### WHAT IS DE111® PROBIOTIC?

DE111® is a strain of the probiotic *Bacillus subtilis*. The *Bacillus subtilis* species of microorganism has been known for more than a century, having first been isolated and described in 1872. It is a soil-based organism and is a normal inhabitant of the gut in animals and humans.<sup>1</sup>



### SUPPORTING DIGESTIVE AND IMMUNE HEALTH

The human body carries nearly 100 trillion bacteria in the gut ... that's more than 10 times the total number of human cells in the entire body. Probiotics are those "good" bacteria that help keep the intestines healthy and assist in digestion and nutrient absorption. Researchers are also finding evidence that certain bacteria in the gut influence the development of aspects of the immune system. In fact, about 70% of the immune system is housed in the gut.<sup>2</sup>

Scientific studies of *Bacillus subtilis* DE111® have shown the strain can<sup>3</sup>:

- Affect the growth rate of several types of undesirable bacteria
- Spur normal immune reaction of intestinal cells
- Increase production of short-chain fatty acids

Further, a clinical study has shown that this strain can germinate in the small intestine, proliferate, and then re-sporulate.<sup>4</sup>

### MARKET APPLICATIONS:

- Digestive Health
- Immune Health
- Sports and Active Nutrition

### QUALIFICATIONS

- GRAS Status: FDA No-Objection Letter (US)
- QPS listed (EU)
- Health Canada approved (NPN 80077102)
- Non-Novel Food status, Health Canada
- Non-GMO Project Verified
- Kosher
- Halal

Claims and statements contained herein are based on US regulations. Local regulations must be reviewed to confirm permissibility of ingredients and claims in each region globally.

# More Applications, More Benefits

Here are some ways our innovative probiotic can deliver



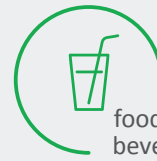
supplement capsules, tablets and bulk powder blends



stick packs



gummies



food and beverage

## STABILITY ADVANTAGE: SPORE FORMING PROBIOTICS

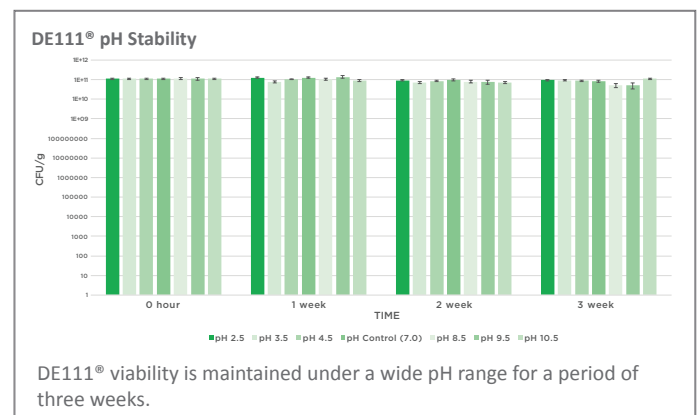
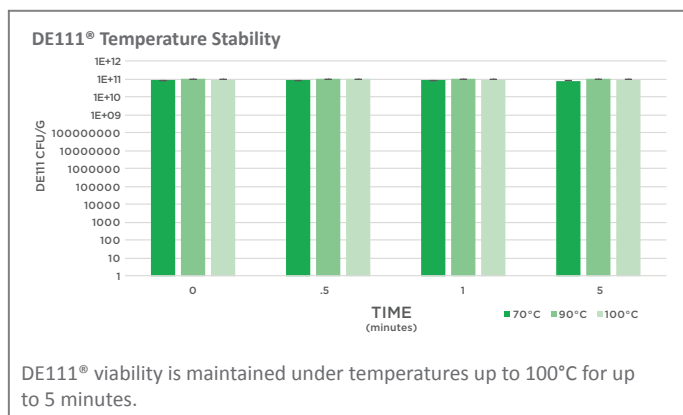
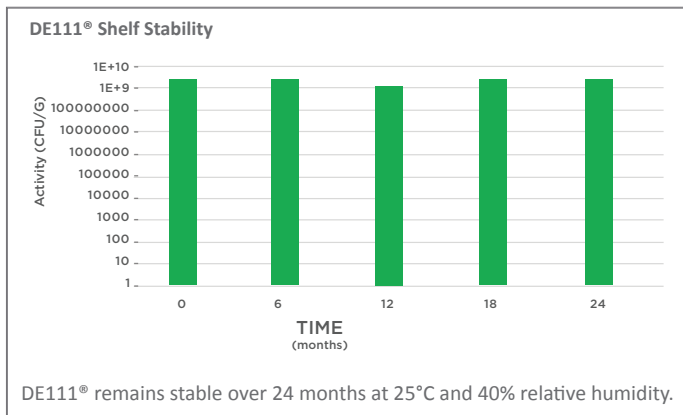
Spore forming bacteria are a diverse group of very hardy bacteria, characterized by their ability to form endospores to protect themselves in varying conditions such as high temperatures and the acidic environment of the gut.

*Bacillus subtilis* has the ability to form spores that protect the microbes from harsh conditions until they enter an environment ripe for germination, such as

the GI tract. This means that DE111<sup>®</sup> remains viable under a wide temperature range, and doesn't require refrigeration. It also survives passage through the acidic environment of the stomach<sup>3,4</sup>. While all spores are hardy, different strains thrive under varying conditions, and at different rates of growth. *Bacillus subtilis* grows quickly under physiological conditions, while some other spores grow best in temperatures below that of human body.

Because DE111<sup>®</sup> remains viable under a wide temperature and pH range, the probiotic is ideal for use in supplements, foods and beverages. In stability testing, DE111<sup>®</sup> experienced virtually no loss of colony forming units (CFU) over 24 months, when stored at room temperature (25°C).

DE111<sup>®</sup> can also stand up to many food and beverage processing and storage conditions.





## Clinical Results: Safety and Efficacy

More than 30 studies have been performed to confirm safety and investigate efficacy of *Bacillus subtilis* DE111®.

A full genome sequencing confirmed the strain contained no plasmids, antibiotic resistant or deleterious genes.

The genome sequence of DE111® has been uploaded to GenBank, the National Institutes of Health genetic sequence database.

Multiple human clinical studies have shown effects on digestive and immune health parameters, and ADM is committed to conducting further studies. All studies are IRB-approved, double-blind, randomized and placebo controlled.

### DIGESTION

A clinical study evaluating the effect of DE111® (5 billion CFU) on digestive health demonstrated DE111® was able to maintain healthy levels of cholesterol, glucose and triglycerides, indicating that DE111® may be involved in normal breakdown of complex carbohydrates, sugars and fats.<sup>5</sup>

### IMMUNE FUNCTION

In a study involving 44 participants aged 20-62, researchers observed after four weeks of daily consumption of the probiotic DE111® at 1 billion CFU, a significant decrease from baseline in the basal levels of several immune cell populations, including CD3+ T cells and NKT cells. Moreover, the probiotic group showed an increased immune response in cells with an induced inflammation (*ex vivo*). The results indicate that DE111® may modulate the immune system through action on both innate (rapid response) and adaptive (slow response) immune cell types.<sup>6</sup>

### REGULARITY

A clinical study showed an improvement in stool quality for participants taking DE111® (1 billion CFU) when compared to participants taking the placebo. Over the course of the study, the proportion of

normal stools increased from 37% to 43% in the DE111® group, while remaining the same in the placebo group.<sup>7</sup>

### CHILDREN'S HEALTH

In a study involving 91 children aged 2 to 6, researchers found that daily consumption of the probiotic DE111® positively modulated “the gut microbiome profile without changing the overall microbiome equilibrium.” After 8 weeks of daily consumption at 1 billion CFU, the researchers observed an “increase in alpha-diversity at the phylum level, suggesting an expanded functional diversity of the microbiome” compared to that of the children in the placebo group. Specifically, the study authors report, there were nine differentially abundant taxa at the genus level found in the probiotic group, six (of the phylum *bacteroidetes*) grew in abundance while three (of the phylum *firmicutes*) were reduced. This modulation of the *firmicutes/bacteroidetes* ratio of the microbiome in children taking *B. subtilis* DE111® may be a positive indication for healthy gut function.<sup>8</sup>

In a study involving 81 children aged 2 to 6, researchers found that children taking DE111® had improvements in measures of gastrointestinal wellness compared to the placebo group.<sup>9</sup>





## BODY COMPOSITION AND RECOVERY

In a study involving female collegiate athletes during offseason training, researchers found that DE111® (1 billion CFU), in conjunction with a protein drink supplement, was associated with changed body composition with strength training. The results of the study showed that compared to the placebo, the probiotic DE111® produced statistically significant reduction of body fat percentage.<sup>10</sup>

In a study involving male collegiate athletes during offseason training, researchers found that supplementation with DE111® (1 billion CFU), in conjunction with adequate post-workout nutrition, was associated with a statistically significant reduction of tumor necrosis factor alpha (TNF- $\alpha$ ), a cytokine that indicates inflammatory response.<sup>11</sup>

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### References:

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