

Microbiome & Overall Health

# Introduction

ButyraGen<sup>™</sup> is an innovative *next-generation prebiotic* – it is a direct butyrate generator for gut health and beyond, generating high levels of butyrate directly in the colon. This is what sets it apart from traditional prebiotics, its unique ability to generate butyrate independent of the state of the microbiome. Other prebiotics work to feed bacteria that then generate butyrate. ButyraGen<sup>™</sup> delivers benefits as a stand-alone, low-dose prebiotic, or in combination with probiotics to further enhance the health benefits of the probiotic strains. Butyrate is a key short-chain fatty acid (SCFA) postbiotic that has been shown to be a critical signaling molecule for improving gut health and for gut-related effects on other organs via the gut-brain axis.

# Features & Benefits

- Prebiotic butyrate generator for gut health
  Works well as a stand-alone, or in combination with probiotics for supporting gut health
  Can be used to increase the benefit and effectiveness of probiotic formulas targeting various health benefits
  Generates butyrate independent of the state of the microbiome diet, genetics, health, disease
  Low dose prebiotic Standard dose of 200 mg ButyraGen<sup>™</sup> 50% powder is an optimal dose and is as effective for butyrate production as 4 g of inulin or 1 g of XOS
  Standardized to <0.2 water activity which allows for easy formulation when combining with probiotics and other moisture sensitive ingredients</li>
- Clean label excipients are GRAS and acceptable for dietary supplement formulations
- Very low odor almost no smell
- Patent pending

## Product Characteristics and Formulating with ButyraGen™

ButyraGen<sup>™</sup> is an off-white – light brown free-flowing powder with a very slight odor. The active ingredient in ButyraGen<sup>™</sup>, tributyrin, is produced using a proprietary process that reduces the residual butyric acid levels (the cause of the off-odor in typical tributyrin products). ButyraGen<sup>™</sup> is a prebiotic and direct butyrate generator that can be used by itself at low doses (200 mg per day powder), or in combination with probiotics to synergistically enhance butyrate generation. It has an extremely low water activity, making it suitable for direct combination with probiotics.

- ButyraGen<sup>™</sup> can be formulated into prebiotic formulas for gut health
- ButyraGen<sup>™</sup> works well in formulas containing pre/pro-biotics (synbiotics)
- ButyraGen<sup>™</sup> will enhance any product designed to benefit the gut-organ axis including cognitive, digestive and immune health as well as anti-inflammatory formulations

### Scientific Studies

To evaluate ButyraGen<sup>™</sup> health benefits, two types of scientific studies have been conducted, the first being an ex vivo simulation of the fermentation that occurs in the colon by using human stool as a microbiome starter culture. The second study was a pre-clinical study using an animal model (*C. elegans*) to investigate reduction of oxidative stress by inducing oxidation and evaluating prevention.

The ex vivo colon simulation studies evaluated butyrate generation and other gut health parameters. Figure 1 shows that a low human equivalent dose (HED) of 200 mg ButyraGen<sup>™</sup> generates an equal amount of butyrate as 4 grams of inulin; when the HED is increased to 1,000 mg ButyraGen<sup>™</sup>, butyrate generation is significantly higher when compared to inulin.

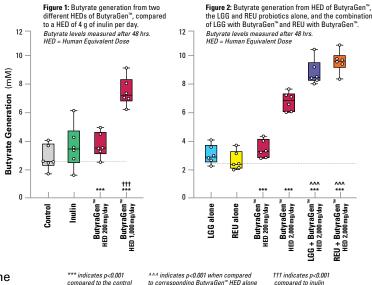


Figure 2 shows results from an additional study using the same method of ex vivo colon simulation, where butyrate generation of ButyraGen<sup>™</sup> is compared to butyrate generated

by a probiotic, *Lacticaseibacillus rhamnosus GG* (LGG) alone and in combination with ButyraGen<sup>™</sup>. A clear synergistic effect is seen when 2,000 mg of ButyraGen<sup>™</sup> is combined with the probiotic, LGG. The combination of 2,000 mg of ButyraGen<sup>™</sup> and *Limosilactobacillus reuteri* (REU) probiotic also showed synergy. Effects are also seen at lower doses. This makes ButyraGen<sup>™</sup> a great addition to probiotics to create synbiotics.

A pre-clinical animal study with *C. elegans* demonstrated the potential for ButyraGen<sup>™</sup> to reduce oxidative stress; butyrate has been associated with lower levels of oxidation. Twelve hours after addition of a potent oxidation catalyst, the percentage of animals surviving was significantly increased with ButyraGen<sup>™</sup>, including at the optimal human equivalent dose of 200 mg ButyraGen<sup>™</sup>.

#### **Mechanism of Action**

The active ingredient in ButyraGen<sup>™</sup> is tributyrin, a butyrate generator. Tributyrin is broken down in the gut by enzymes to generate high levels of the postbiotic butyrate. Butyrate is then available in the lumen. Butyrate plays an important role in intestinal barrier function and gut health, while also modulating immune and inflammatory responses. Receptors for butyrate are present in most cells in the body. Butyrate is also critical for the effects of the gut system on other organs (e.g. gut-brain axis, gut-skin axis, etc).

### Sustainable Source & Composition

ButyraGen<sup>™</sup> tributyrin is produced from sustainably sourced, RSPO Certified palm oil. The powder contains naturally sourced excipients including gum arabic, guar fiber, rosemary extract (preservative), and microcrystalline cellulose (flow agent).

### Structure/Function Claims

- Butyrate generating prebiotic
- Major signaling molecule for gut system integrity
- Modulates gut-brain and other gut-organ interactions
- ButyraGen<sup>™</sup> offers structure/function claims in many different categories including:

Gut Health • Prebiotic • Inflammation Immunity • Brain & Nervous System Support Mood & Sleep • Metabolic Syndrome Thermogenesis • Oxidative Stress • Anti-Aging plus Skin, Liver, Lung and Overall Health

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#### Applications

Dietary Supplements Functional Foods & Beverages Animal Health

### Safety & Regulatory

The active ingredient in ButyraGen<sup>™</sup>, tributyrin, is safe for human consumption and is FDA GRAS. All excipients are GRAS. ButyraGen<sup>™</sup> is an NDI (New Dietary Ingredient).



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