

Precision Microbiome Control

Harnessing bacteriophage technology for
a balanced microbiome



INTRO

Supporting the Microbiome: An Evolving Approach



The human body is a complex ecosystem, housing ten times more bacterial cells than human cells. Maintaining the health of the beneficial resident bacteria, particularly in the gut microbiome, is important for overall health and well-being.

The human virome—consisting of an estimated 380 trillion viruses (3.8×10^{14})—is even more expansive than the gut microbiome, with viruses outnumbering gut bacteria by up to 10-fold.¹ Like bacteria, there are good viruses as well as bad viruses. PreforPro® as a “blend of bacteriophages” represents “good viruses.”

Traditionally, gut health and the gut microbiome have been supported through an additive approach: focusing on the introduction of “good” bacteria like probiotics. While probiotics can be beneficial, support for the gut microbiome—an ecosystem of bacteria, bacteriophages, and fungi—is evolving to a new strategy: **precision microbiome control**.

Precision microbiome control allows for the ability to eliminate unwanted bacteria directly, thereby balancing the gut microbiome environment. Bacteriophages, like PreforPro®, do this by functioning as precise predators of certain bacteria, selectively targeting and eliminating unwanted bacteria without negatively disrupting the gut microbiome. By shifting from an additive approach to a precision-based strategy, we can manage the gut microbiome with more accuracy.



PreforPro®

**Gut health
supplement
launches have
seen strong
growth over the
past 4 years.²**



**Over half of consumers globally link
gut health to overall health.²**

Understanding the Power of the Phage: PreforPro®

Bacteriophages, or phages, are the most abundant biological agents on earth.³ Ubiquitous in nature, they are found almost everywhere, from sea water to soil, in and on humans and in almost all foods that humans and animals consume.

Phages are composed of a nucleic acid genome encased in a shell of phage-encoded capsid proteins, which protect the genetic material and mediate its delivery into the bacterial host. Phages infect and replicate only in bacterial cells. Featuring unrivaled preciseness, phages usually only target specific strains within a bacterial species.³

As a result of their preciseness, phages like PreforPro® are incredibly safe as they are only capable of infecting bacterial cells. Many bacteriophages are classified as Generally Recognized as Safe (GRAS). PreforPro®, a cocktail of bacteriophages, has been established to be tolerable and safe for the healthy adult population.⁴

PreforPro® is the first bacteriophage available on the dietary supplement market and it selectively targets strains of *Escherichia coli*. To understand its benefits, think about a garden. If weeds are left to grow unchecked, they compete with flowers for space, sunlight and nutrients. You can add more flowers or fertilizer to promote growth, but the weeds still remain.

PreforPro® acts as the “weed killer” in the gut. By selectively targeting harmful *E. coli*, it eliminates the competition for nutrients, creating a supportive environment where beneficial bacteria can grow and confer a health benefit.

This allows PreforPro® to provide an effective prebiotic benefit by indirectly promoting the growth of beneficial bacteria and suppressing the unwanted bacteria when used in combination with select *Bifidobacterium lactis* probiotic strains.



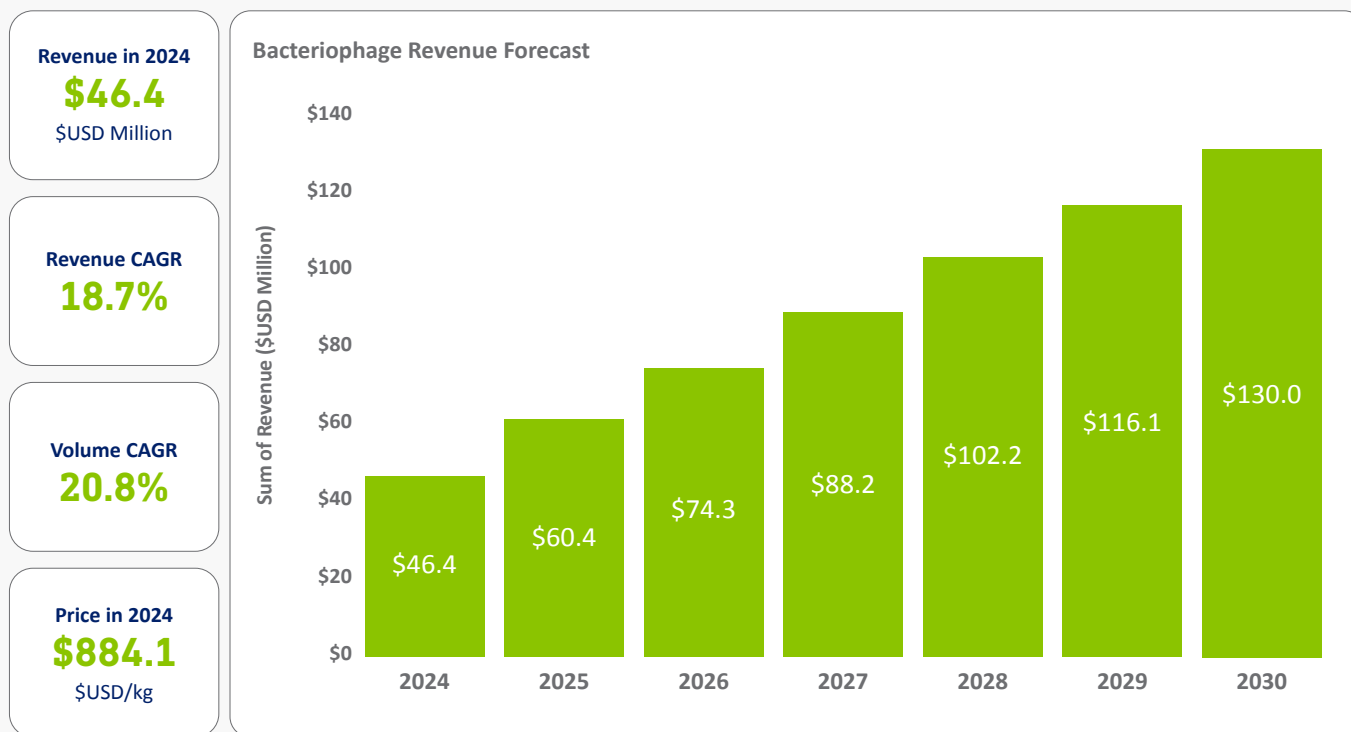
OPPORTUNITY AND CONSUMER EDUCATION

The Phage Opportunity

This shift towards precision microbiome control is aligned with an increasing consumer interest in more targeted, efficient wellness solutions. While the “additive” probiotic market has become mainstream, there is a growth in supplement options that offer additional and more specific results, like phages.



Global Microbiome Ingredients Growth Opportunity Engine, 2024 - 2032



All figures are rounded. Source: Frost & Sullivan

Consumer education on bacteriophages is key to unlocking adoption and driving predicted market growth. While 36% of supplement users say they are familiar with bacteriophages, their receptivity is high once they understand the science. When educated on bacteriophages:⁵



86%
found
bacteriophages
appealing



85%
reported
believability



87%
said they are
likely to try
bacteriophages

MECHANISM OF ACTION

Mechanism of Action: The Science of Precision

PreforPro® phages function via a safe and predictable lytic cycle, whereby host bacteria are neutralized.

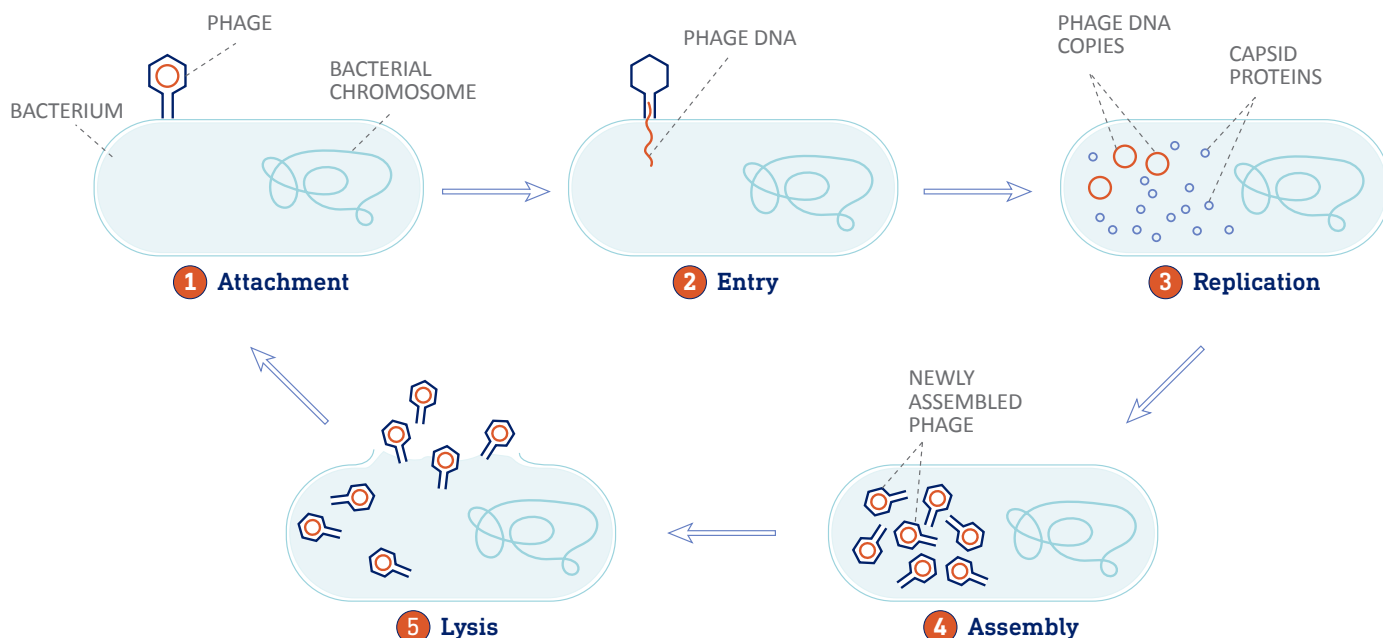
91%

of supplement users
say they need to
understand how
ingredients work.⁵

THE LYTIC CYCLE⁶

- 1 Attachment:** Unique proteins found within bacteriophages work by binding to a specific receptor on the surface of targeted unwanted bacterial cell walls.
- 2 Entry:** Bacteriophage injects its DNA into the bacteria.
- 3 Replication:** Bacteriophage DNA is copied and genes are expressed to make key proteins.
- 4 Assembly:** Newly synthesized phage proteins are assembled into fully formed bacteriophages particles.
- 5 Lysis:** Bacteriophage produces an enzyme that digests the bacterial cell wall from the inside out, resulting in the cell bursting, or lysis. This releases newly formed bacteriophages, which can seek, target and infect other harmful bacteria nearby.

The Lytic Cycle



IN VIVO DATA

Clinically Backed PreforPro®

PreforPro® is a groundbreaking development in gut health technology. Unlike traditional prebiotics, PreforPro® begins exerting its **effects within hours (not days)** and has been proven effective at a low 15mg dose.

PreforPro® is the market-leading bacteriophage backed by gold-standard clinical science. Three human clinical trials demonstrate it is safe for consumption and its precision microbiome control and compatibility with probiotics.

SAFETY

In a randomized double-blind placebo-controlled, cross-over design clinical trial, the **tolerability of 15mg of PreforPro®** was assessed among 43 healthy participants with mild to moderate gastrointestinal distress.⁴ The supplementation period lasted 28 days with a 2-week washout period.

Among the 32 completers, no adverse effects of the supplement were observed based on metabolic panel outcomes. Levels of aspartate aminotransferase, a liver injury marker significantly decreased from baseline among participants when they consumed PreforPro® but not when they consumed the placebo.

PRECISION MICROBIOME CONTROL

In a randomized double-blind placebo-controlled, cross-over design trial, the gut microbiota composition and intestinal inflammatory markers were assessed among 43 normal to overweight adults supplemented with either 15mg of PreforPro® or placebo control.^{4,7} The supplementation period lasted 28 days with a 2-week washout period.

Among the 32 completers, **a reduction in fecal *E. coli* was observed with PreforPro® consumption**, but not with placebo. In addition, supplementation with PreforPro® led to an increase in select microbiota of the butyrate-producing genera, *Eubacterium*, and a decrease in the select taxa most closely related to *Clostridium perfringens*. A significant decrease in circulating interleukin-4 (IL-4) from baseline was also observed when subjects consumed PreforPro®.

PROBIOTIC COMPATIBILITY

In a randomized double-blind placebo-controlled, parallel design trial, a combination of PreforPro® and *Bifidobacterium animalis* subsp. *lactis* (*B. lactis*) was assessed for its effects on gastrointestinal (GI) parameters based on a self-assessment using a GI health questionnaire, a daily stool log and fecal 16s rRNA analysis.⁸ In the study, 68 healthy participants were randomized to 3 different groups and supplemented for 4 weeks.

The combination of the probiotic and PreforPro® led to **a significant improvement in gastrointestinal inflammation** versus baseline (an effect not observed with the probiotic alone) and a trending **improvement in colon pain** versus baseline. Microbiome analysis showed an increase in *Lactobacillus* and short-chain fatty acid-producing microbial taxa among participants taking PreforPro® in combination with *B. lactis* versus baseline.

Participants reported significant improvements in several symptoms of gastrointestinal distress in both supplementation arms. In addition, PreforPro® was safe and tolerable in this target human population.



Overall, these results suggest the addition of PreforPro® to a probiotic supplement may provide more benefits than the probiotic alone.



Connecting PreforPro®'s Science to Its Benefits

The clinical data demonstrate how PreforPro® seeks and infects unwanted bacteria, restoring microbiome balance and allowing beneficial microflora to flourish, resulting in a healthier microbiome.

The clinical results translate to PreforPro®'s gut microbiome benefits:

- Support for a healthy GI tract and stomach comfort*
- Positive modulation of the gut microbiome
- Displacement of unwanted bacteria within the gut, clearing space for beneficial bacteria to proliferate and grow
- Support for the beneficial effects of select probiotics*
- Works in hours, not days**

*When used in combination with select *B. lactis* probiotic strains

***in-vitro* data suggests

Supplement Consumers' Top Priorities⁵

93%

demand fast-acting solutions

91%

need to understand how ingredients work

91%

require scientific/clinical validation

90%

value supplement compatibility

The PreforPro® Advantage

PreforPro® is a patent-pending and market-leading bacteriophage solution that offers precision and speed, backed by gold-standard science. Its demonstrated prebiotic activity enhances the growth of beneficial bacteria in the gut microbiome.

Nearly every other microbiome ingredient in the market simply adds. PreforPro® is the ideal microbiome ingredient as it precisely modulates the gut microbiome by seeking out and infecting harmful *E. coli*. This targeted bacterial attack positively affects the gut microbiota.



FOR FORMULATORS, PREFORPRO® OFFERS DISTINCT ADVANTAGES:

- ✓ Fast acting (based on *in-vitro* data)
- ✓ Compatible with probiotics
- ✓ Patent pending
- ✓ High efficacy at a low dosage: 15mg vs. 5-40g for traditional fiber prebiotics
- ✓ Flexibility in supplement applications
 - Capsules, Tablets, Sachets, Stick packs
- ✓ Certifications
 - Non-GMO Project verified
 - Kosher
 - Gluten free
 - Lactose free

Strategic Tips when formulating bacteriophage supplements:

- 1 Education is key: Brief exposure drives appeal, believability and trial intent.
- 2 Lead with performance claims: Speed, support for comfort and consistency are keys to belief.
- 3 Position PreforPro® in your supplement as containing an ingredient—the first in its kind—that works unlike traditional prebiotics and is the one thing consumers haven't tried yet that will make them feel great.
- 4 Probiotic compatibility is a core advantage in multi-benefit supplements in a complex gut microbiome ecosystem.
- 5 Clinical validation is table stakes: Consumers want scientific proof.

Mass retail readiness is essential: Purchase intent is most common through larger channels.

From Lab to Life: ADM Microbiome Solutions

ADM drives innovation. From the science behind the ingredients to real-world applications in food, beverage and dietary supplements, ADM delivers future-forward nutrition fueled by science, with a complete range of solutions from pre-, pro- and postbiotics to bacteriophages and enzymes, all clinically documented to deliver health & wellness benefits.

Success with ADM

Bacteriophage technology is a proven, commercially available reality that will be used for more future-forward nutrition fueled by science. PreforPro® is the leading commercialized bacteriophage solution and an integral part of ADM's premier and comprehensive line of microbiome modulating solutions, all clinically documented to deliver health and wellness benefits.

ADM's vertically integrated supply chain ensures the reliability and availability of high-quality products. Combined with ADM's dependable customer service, you get industry-leading quality solutions to ensure your success.

SOURCES

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