Colony Forming Units:
At the time of manufacture, there are approximately 30-42 billion Colony Forming Units per capsule. Ortho Molecular puts this average in to ensure label claim at time of expiration.

Product Rationale:
Supply live probiotic organisms to the gastrointestinal tract for both supplemental and therapeutic benefits.

Probiotics:
Over 300 different strains of bacteria compete for the environment within the lower gastrointestinal tract. Strains that promote health (probiotic), as well as those that cause disease compete for space and nutrients. Most of these probiotic organisms come from either the Lactobacillus or Bifidobacterium genus of bacteria. When there is a healthy balance (eubiosis), few symptoms exist. On the other hand, dysbiosis occurs when fewer than normal probiotic organisms and an over abundance of potentially harmful bacteria, yeast or parasitic organisms prevail. Dysbiosis often results in a number of gastrointestinal symptoms like diarrhea, constipation, gas, bloating, “leaky gut” and more.

Dysbiosis
Events that often trigger dysbiosis include:
• Antibiotic use
• Foods contaminated with parasites
• Foods with bacterial overgrowth
• Abdominal irradiation
• Use of NSAIDs and other drugs
• Foods that lead to gut inflammation
• Abuse of strong gut irritants (alcohol, caffeine)

Research Findings

Antimicrobial activity/ Correcting dysbiosis
• Indirect (passive) activity due to competition for attachment sites and nutrients, against strains such as E. coli, Salmonella, and Yersinia.
• Altering pH environment, reducing bacterial growth such as H. pylori, and Salmonella.
• Active secretion of anti-microbial and anti-yeast components that inhibit organisms like Shigella, Staph. Aureus, Listeria, Salmonella, Klebsiella, Pseudomonas and Enterobacter.

Immune Enhancing Properties
• Increased mucosal immunity
• Increased immune cell phagocytosis
• Increased NK cell activity after ingesting L. rhamnosus

Other Benefits:
• Protection from carcinogens
• Potential cholesterol lowering activity
• Increased production of Short-Chained Fatty Acids for energy along gut mucosa.
**Lactobacillus acidophilus** 19:
- L. acidophilus protects human epithelial cells from invasion of E. coli.
- L. acidophilus decreases bacterial enzymes implicated in colon carcinogenesis.
- L. acidophilus, fed by means of a fermented milk product, was shown to increase phagocytic and lymphocytic activity in mice.
- Found in the human intestinal tract.

**Lactobacillus paracasei:**
- L. acidophilus in combination with L. paracasei reduce diarrheal duration and vomiting in children (6-24 months) suffering from persistent diarrhea (19).

**Bifidobacterium bifidum** 20:
- B. bifidum has a high tolerance against stomach acids.
- B. bifidum can effectively inhibit E. coli and Staphylococcus aureus.

**Bifidobacterium lactis** 21:
- Predominantly found in the colon.
- In an in vitro study, Bifidobacterium strains were able to inhibit gastrointestinal pathogen adhesion on and/or invasion in human intestinal cells.
- Studies show that B. lactis may help prevent allergies in infants.

**Lactobacillus plantarum** 22:
- Consumption of L. plantarum dramatically increases Lactobacillus counts on the jejunal mucosa.
- L. plantarum has been shown to prevent increased gut permeability induced by E. coli.
- L. plantarum has a protective effect by down regulating IL-8 secretion (a pro-inflammatory cytokine).
- A double-blind placebo controlled study containing 60 people with IBS, showed L. plantarum reduced flatulence and maintained a better overall GI function than in the placebo group.

**Lactobacillus rhamnosus:**
- L. rhamnosus has a high acid tolerance (23).
- Used in the prevention and treatment of diarrhea, primarily in children (28).
- L. rhamnosus GG has been found to inhibit the adhesion of Salmonella to Caco-2 cells via a pH effect (28).

**Saccharomyces boulardii:**
- S. boulardii is a brewer's yeast. It has been approved in Germany for the treatment of chronic acne, boils, acute and traveler's diarrhea (24).
- 200 children with acute diarrhea were randomly given 250 mg/day S. boulardii or placebo. Stool frequency, duration of diarrhea, and hospital stay were all greatly improved in the group that received the S. boulardii (25).
- S. boulardii stimulates PPAR-gamma expression and reduces response of human colon cells to pro-inflammatory cytokines (26).
- 269 children (6 mo-14yrs) with otitis media and/or respiratory tract infections were given either antibiotic treatment plus 250 mg/twice per day of S. boulardii or placebo. Children receiving the S. boulardii had lower prevalence of diarrhea. S. boulardii also reduced the risk of anti-biotic associated diarrhea (27).

**Formula Synergy:**
It is the intention of this product to enhance the probiotic environment to give the preferential individual strains (from the diet) an advantage within the gastrointestinal tract, as opposed to the intention of reseeding only these 7 strains.

**Product Viability**
In order to maximize strain viability at room temperature the following manufacturing parameters are followed:
- Strains are frozen under nitrogen before shipment to O MPI
- After thawing, product is encapsulated and bottled in one production cycle to minimize exposure to moisture and air.
- Product is packed with desiccant to prevent moisture damage to product.
- Product is manufactured fresh at intervals averaging 3 weeks (10 month expiration).
**Dose**
1 capsule per day.

**Contraindications, Adverse or Other reactions:**
Probiotics are considered very safe with no known adverse affects. Some changes in the stool may be noted and occasionally some people notice a temporary increase in digestive gas.

**References:**
23. Danisco. Lactobacillus rhamnosus Lr-32 technical information.