

Ortho Biotic

Product #527, 528

Supplement Facts		
Serving Size 1 Capsule or 1 Scoop		
	Amount Per Serving	% Daily Value
1 capsule contains:		
Proprietary Blend	20 billion CFU**	*
Lactobacillus acidophilus		
Lactobacillus paracasei		
Bifidobacterium bifidum		
Bifidobacterium lactis		
Lactobacillus plantarum		
Lactobacillus rhamnosus		
Saccharomyces boulardii	2 billion CFU**	*
* % Daily Value not established		

DOSE FORM AND DOSAGE:

Vegetable capsule or powder. One capsule or 1 scoop 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.

PRODUCT RATIONALE:

It is the intention of this product to 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 disturbances compete for space and nutrients.

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.

DYSBIOSIS:

Events that often trigger dysbiosis include:

- Antibiotic use
- Abdominal irradiation
- Foods that lead to gut inflammation
- Foods contaminated with parasites and bacteria
- Use of NSAIDs and other drugs

BENEFITS:

- Indirect (passive) activity due to competition for attachment sites and nutrients, against strains such as E. coli, Salmonella, and Yersinia (1-3).
- Alters pH environment.
- Active secretion of anti-microbial and anti-yeast components that inhibit non-beneficial organisms.
- Increased mucosal immunity (4,5)
- Increased immune cell phagocytosis (6)
- Increased NK cell activity after ingesting L. rhamnosus (7)
- Protection from carcinogens (8-10)
- Potential cholesterol lowering activity (11)
- Increased production of Short-Chain Fatty Acids for energy along gut mucosa (12)

PROBIOTIC STRAINS:

Lactobacillus acidophilus (13):

- Protects human epithelial cells from invasion of E. coli.
- 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.

Lactobacillus paracasei:

- L. acidophilus in combination with L. paracasei reduce diarrheal duration and vomiting in children (6-24 months) suffering from persistent diarrhea (13).

Bifidobacterium bifidum (14):

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

Bifidobacterium lactis (15):

- 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 (16):

- 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 :

- Increased NK cell activity after ingesting L. rhamnosus (7).
- Used in the prevention and treatment of diarrhea, primarily in children (20).
- Specific strains of Lactobacillus rhamnosus have been found to inhibit the adhesion of Salmonella to Caco-2 cells via a pH effect (20).

Saccharomyces boulardii:

- S. boulardii is a brewers yeast. It has been approved in Germany for the treatment of chronic acne, boils, acute and traveler's diarrhea (17).
- 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 (18).
- S. boulardii stimulates PPAR-gamma expression and reduces response of human colon cells to pro-inflammatory cytokines (19).

PRODUCT VIABILITY:

In order to maximize strain viability at room temperature the following manufacturing parameters are followed:

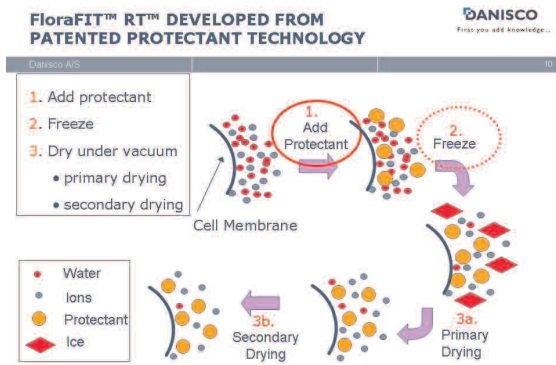
- The organisms are produced under a unique process called FloraFit to maximize room temperature stability (See below).
- Strains are frozen under nitrogen before shipment to Ortho Molecular Products

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease. The information provided here is intended to help health care professionals make informed decisions about recommending this product safely and effectively.

- 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.

Colony Forming Units:

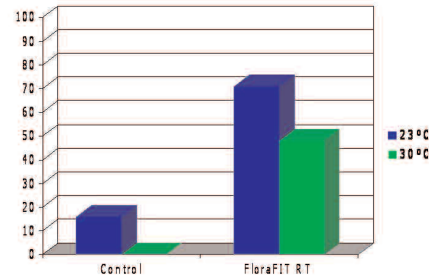
At the time of manufacture, there are approximately 30-42 billion Colony Forming Units per capsule. Ortho Molecular puts this overage in to ensure 20 billion CFU's at the time of expiration (1 year after manufacturing).



Process of adding the protectant to the probiotic.

FloraFIT™ RT™ PROVIDES SUPERIOR PROBIOTIC STABILITY

18 Month *L. acidophilus* Viability in a low Aw carrier (Aw = 0.05)



REFERENCES:

1. Bernet MF, Brassart D, Neeser JR, Servin AL. Adhesion of human bifidobacterial strains to cultured human intestinal epithelial cells and inhibition of enteropathogen-cell interactions. *Appl Environ Microbiol* 1993; 59(12):4121-8
2. Bernet MF, Brassart D, Neeser JR, Servin AL. *Lactobacillus acidophilus* LA 1 binds to cultured human intestinal cell lines and inhibits cell attachment and cell invasion by enterovirulent bacteria. *Gut* 1994; 35(4):483-9
3. Coconnier MH, Bernet MF, Kerneis S, et al. Inhibition of adhesion of enteroinvasive pathogens to human intestinal Caco-2 cells by *Lactobacillus acidophilus* strain LB decreases bacterial invasion. *FEMS Microbiol Lett* 1993; 110(3):299-305
4. Majamaa H, Isolauri E, Saxelin M, Vesikari T. Lactic acid bacteria in the treatment of acute rotavirus gastroenteritis. *J Pediatr Gastroenterol Nutr* 1995; 20(3):333-8
5. De Simone C, Ciardi A, Grassi A, et al. Effect of *Bifidobacterium bifidum* and *Lactobacillus acidophilus* on gut mucosa and peripheral blood B lymphocytes. *Immunopharmacol Immunotoxicol* 1992; 14(1-2):331-40
6. Schiffrin EJ, Brassart D, Servin AL, et al. Immune modulation of blood leukocytes in humans by lactic acid bacteria: criteria for strain selection. *Am J Clin Nutr* 1997; 66(2):515S-520S.
7. Sheih YH, Chiang BL, Wang LH, Liao CK, Gill HS Systemic immunity-enhancing effects in healthy subjects following dietary consumption of the lactic acid bacterium *Lactobacillus rhamnosus* HN001 *J Am Coll Nutr* 2001; 20(2 Suppl):149-56
8. Hayatsu H, Hayatsu T. Suppressing effect of *Lactobacillus casei* administration on the urinary mutagenicity arising from ingestion of fried ground beef in the human. *Cancer Lett* 1993; 73(2-3):173-9
9. Orrhage K, Sillerstrom E, Gustafsson JA, et al. Binding of mutagenic heterocyclic amines by intestinal and lactic acid bacteria. *Mutat Res* 1994; 311(2):239-48
10. Reddy BS, Rivenson A. Inhibitory effect of *Bifidobacterium longum* on colon, mammary, and liver carcinogenesis induced by 2-amino-3-methylimidazo[4,5-f]quinoline, a food mutagen. *Cancer Res* 1993; 53(17):3914-8
11. Klaver FA, van der Meer R. The assumed assimilation of cholesterol by *Lactobacilli* and *Bifidobacterium bifidum* is due to their bile salt-conjugating activity. *Appl Environ Microbiol* 1993; 59(4):1120-4
12. Holzapfel WH, Haberer P, Snel J, et al. Overview of gut flora and probiotics. *Int J Food Microbiol* 1998; 41:85-101
13. Danisco. *Lactobacillus acidophilus* La-14 probiotic identity card.
14. Danisco. *Bifidobacterium bifidum* Bb-02 technical information.
15. Danisco. *Bifidobacterium lactis* BI-04 probiotic identity card.
16. Danisco. *Lactobacillus plantarum* Lp-115 probiotic identity card.
17. American Botanical Council. Yeast, Brewer's/Hansen CBS 5926. <http://www.herbalgram.org>
18. Kurugol Z, Koturoglu G. Effects of *Saccharomyces boulardii* in children with acute diarrhea. *Acta Paediatr*. 2005; 94(1):44-47.
19. Lee SK, et al. *Saccharomyces boulardii* activates expression of peroxisome proliferators-activated receptor-gamma in HT-29 cells. *Korean J Gastroenterol*. 2005; 45(5):328-334.
20. Guilliams, T. Healthy Microbial Organisms HMOs You Can Really Count On. *The Standard*. 1999; 2(2).

