

Structure/Function Claims for Soil-Based Organisms™ Manufactured by Life Science Products, Inc., Houston, Texas

Consumer Summary

Soil-Based Organism™ (SBOs™) products consist of a mixture of eight (8) species of naturally occurring probiotic organisms embedded in a matrix of fulvic acid [the remains of ancient plants] and bacterial secretions, such as B vitamins. The bacterial species are grown in a culture containing fulvic acid, vitamins and minerals. Together, the bacteria form a stable microbial consortium, in which one type of bacteria lives off the “left-overs” or end-products of the bacteria higher up on the food chain. This method allows the bacteria to grow for an extended period of time, and thus produce the maximum amount of end products.

The species of probiotic bacteria used in these products are often found in healthy humans, but the particular strains used were originally isolated from healthy soil, and hence have not been genetically altered in any way. The trade name of the various Soil-Based Organism™ products is Body Biotics™. Body Biotics™ is sold as a dietary supplement in the form of capsules, Adult’s Chewable Body Biotics™, Children’s Chewable Body Biotics™, and Life’s Green Essentials™.

It is important to note that there are more bacterial cells in the colon, than there are cells in the human body, and each of these bacterial cells secretes end-products that may influence one or more body functions. In fact there are more than 10^{10} (10 billion) bacterial cells in each milliliter of colon contents. Therefore, it is important the right bacteria are present in the colon, and that they are producing end-products that lead to health. Unfortunately, more than 40 million Americans visit their physician each year with digestive system complaints [National Digestive Diseases Information Clearing House, Digestive Disease Statistics, 1999-2000]. Twenty-two (22) million report acute digestive conditions, such as indigestion, abdominal pain, and bowel dysfunction. One study showed that 70% of American households experienced adverse gastrointestinal symptoms within a three month period [Drossman, *et al.*, 1993]. Dysbiosis, a state in which the bacteria in the gut produce harmful effects, is associated with many common symptoms, such as flatulence, bloating, intestinal pain, cramping, constipation or diarrhea [Hawrelak, 2004].

Dysbiosis is associated with, and is one cause of a condition called increased intestinal permeability, or leaky gut syndrome. Leaky gut syndrome often goes unrecognized, and is in itself linked to a constellation of other symptoms and a number of diseases (Table 1) [Galland, 2007]. Leaky Gut Syndrome is defined as "an increase in the permeability of the intestinal mucosa to luminal macromolecules, antigens and toxins associated with inflammatory degenerative and/or atrophic mucosal damage" [Galland, 2007]. Hyperpermeability of the intestines results in many problems that affect the whole body.

Table 1

SYMPTOMS ASSOCIATED WITH INCREASED INTESTINAL PERMEABILITY				
Fatigue and malaise	Fevers of unknown origin	Diarrhea	Toxic feelings	Poor exercise tolerance
Arthralgias	Food intolerances	Skin rashes	Cognitive and memory deficits	
Myalgias	Abdominal pain	Abdominal distension	Shortness of breath	

Lactic acid bacteria have been suggested as agents to reverse the symptoms of leaky gut syndrome. Products containing *Lactobacillus sp.*, and their bioactive nonbacterial components have been shown to increase immune function and intestinal health in both children and adults. Indeed the SBOs™ contained in Body Biotics™ products have been shown to have far reaching effects in the human body. The SBOs have constant contact with the immune cells in the body, since 80% of them are located in the gut [Salminen, 1988]. The studies outlined below will serve as an example of the various effects of SBOs on gastrointestinal health.

SBOs™ Improve Gastrointestinal Health

Eleven individuals consuming SBOs™ (18 caplets per day) in a 120-day controlled pilot study demonstrated a marked improvement in their gastrointestinal system after having suffered for an average of 5.5 years with abnormal gastrointestinal-immune related function [Goldberg, 2002]. These patients were not currently taking any corticosteroid medications,

antibiotics, or other drugs that might mask the study outcome. Of these 11 subjects, 4 or 36% reported 75% or greater improvement in their gastrointestinal, joint, or respiratory function. Two subjects (18%) reported 50% or better improvement, and another 36% reported 25% or greater improvement. One subject experienced no improvement. The results of this pilot study are presented in the table below, along with each subject's perceived outcome following 120 days of SBO™ consumption [Goldberg, 2002].

Table 2 Effect of SBOs™ on Persistent Gastrointestinal – Immune Malfunction

Subject	Subjective Outcome
1.	C
2.	C
3.	A
4.	A
5.	C
6.	C
7.	B
8.	A
9.	D
10.	A
11.	B

A=75% or greater subjective improvement

B=50% or greater subjective improvement

C=25% or greater subjective improvement

D=No improvement

E=Worsening of symptoms

A second human study published in *Progress in Nutrition* studied the effect of SBOs™ on 70 subjects with chronic digestive disorders. All the qualified subjects reported on-going painful spastic intestinal contractions, persistent alternating diarrhea and constipation for a minimum of nine months. All the subjects were observed to have elevated white blood counts, immune system imbalances, mineral and enzyme deficiencies. The subjects were of both sexes between 25 and 60 years old [Rothschild, *et al.*, 2002]. Further, these individuals had not been treated with tranquilizers, anti-depressants, steroids and/or chemotherapeutic drugs for at least 3 months prior to the beginning of the study.

The subjects were divided into a control and a test group. Each group contained 35 subjects, and each test subject consumed 18-1100 mg SBO™ caplets daily (where the SBO™ Blend was 350 mg and the balance was fulvic acid-containing matrix and fermented plant material). This dose

was divided into 6 caplets 3 times daily 30 minutes before meals. This regimen was continued for 30 days followed by taking 12 caplets per day (4 caplets 3 times per day) 30 minutes before meals for a 60 day period. The control group received a placebo on the same dosing schedule.

Approximately 52% of the participating test subjects did achieve complete regeneration of their normal gastrointestinal functioning by the conclusion of the study. The remaining subjects experienced varying but still significant degrees of balance and normalcy. The visual analog scale below presents the subject's subjective scores [Rothschild, *et al.*, 2002]. Interestingly, 21 of the original 35 subjects in the control group dropped out of the study because they did not experience any change in gastrointestinal function.

Clinical Study N°0712/02 SBO™ Caplets

GRADATION

<u>A</u>	<u>B</u>	<u>C</u>	<u>D</u>	<u>E</u>	<u>Dropouts</u>	<u>Total</u>
16	10	5	0	0	4	35

Test group population at the beginning of the study: 35 adults.

Test group population at the conclusion of the study: 31 adults.

The final test results were defined by the following gradation: Full remission = A; Partial remission (symptom palliation with objective proof) = B; Moderate palliation = C; Unchanged condition = D; Worsened condition = E.

Clinical Study N°0712/02 Control Group (Placebo caplets)

GRADATION

<u>A</u>	<u>B</u>	<u>C</u>	<u>D</u>	<u>E</u>	<u>Dropouts</u>	<u>Total</u>
0	0	0	8	6	21	35

Control group population at the beginning of the study: 35 adults

Control group population at the conclusion of the study: 14

It has been said that all health begins in the gut. SBOs™ provide a comprehensive dietary supplement that effectively delivers positive changes for a high percentage of individuals who have endured poor digestive/immune function for long periods of time.

Dosage

The manufacturer recommends 1 caplet (500 mg each) per day of this dietary supplement for week 1 followed by 2 caplets (500 mg each) per day during week 2. During the 3rd week the dosage may be increased to 4 caplets (500 mg each)

per day. This dosage may then be increased to 6 or 8 caplets per day for several months. A maintenance dose of 2-4 caplets per day may be taken for life.

According to the manufacturer, this product is best consumed with water or juice 20-30 minutes before meals. Multiple caplets may be dispensed before each meal, such as 2 caplets before breakfast, 1 before lunch and then 1 before dinner.

Safety

To ensure the safety of its products, the manufacturer of SBOs™, Life Science Products, Inc. has included only species of probiotics with a long history of safe use in foods. Further, the company has relied on the results of both human and animal studies sponsored by Life Science Products, Inc. and by others who have included SBOs as major components of their commercial products.

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