

# ACTIVEBLENDZ SUPERIOR FIBER+

**white paper provided by Archmore Botanical Research Group, LLC**

**Updated April 2018**

*A Dollar Coffee  
Club product*



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## ActiveBlendz Superior Fiber+

*a Dollar Coffee Club product*

- A technical overview outlining the safety and efficacy of ActiveBlendz Fiber+, a dietary supplement designed to support digestive health and help reduce the risk for coronary heart disease (CHD) \*
- This technical white paper will include:
  - Formulation breakdown
    - Synopsis of health benefits associated with the proprietary ingredients
  - Efficacy
    - Clinical research demonstrating a reduced risk in coronary heart disease and overall digestive health
    - Research demonstrating the use of Fiber+ for weight management efforts
  - Safety
    - Human clinical evidence demonstrating the safety of ingredients in Fiber+ at the recommended levels
  - Recommended guidelines for use
    - Dosing recommendations for cardiovascular health
    - Potential adverse events and warnings

*\*These statements have not been evaluated by the Food and Drug Administration and are meant for research purposes only.*



## Overview

Cardiovascular disease means disease of the heart and circulatory system and is the primary cause of death in industrialized countries. Coronary heart disease is the most common and serious form of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. According to the Code of Federal Regulations, high blood total- and low density lipoprotein (LDL)-cholesterol levels are major modifiable risk factors in the development of coronary heart disease, with specific plant products able to modify this risk (1). In fact, it is estimated that a reduction of 1 mmol/l (38 mg/dl) of LDL cholesterol is associated with a 25% reduction in risk of developing a cardiovascular complication (2). As high cholesterol levels are often associated with overweight, losing weight is one way to lower this risk. Another is through proven dietary interventions, such as increasing fiber and plant sterol consumption. Both of these methods are accomplished through the daily use of ActiveBlendz Superior Fiber+ drink mix.

Fiber is a type of carbohydrate found in plants that is not readily digested and absorbed by the human body but still plays a critical role in our overall health. Dietary fiber is derived from the cell walls of plants, such as fruits, vegetables, and grains. There are two forms of dietary fiber: insoluble and soluble. Although they operate differently in the body, both are vital for proper body functions, namely in the digestive system. Insoluble fiber increases transit time for digestion, speeding up the passage of foods through the stomach and intestines. It also provides bulk to the stool and acts as an irritant in the bowels to stimulate mucosal secretion, softening stools for easier passage out of the body. Soluble fiber helps to lower cholesterol by aiding in its elimination from the body as waste. It also attracts water, preventing dehydration in the bowels, alleviating diarrhea and other symptoms of irritable bowels.

Although both fibers are functionally necessary, they are not consumed at the proper amounts to provide optimal health. According to the Academy of Nutrition and Dietetics, intake of dietary fiber in the United States falls far short of the recommended adequate intake for adults, as established by the American Heart Association and the Institute of Medicine. Their recommendation for adults is to consume 25 grams (adult women) to 38 grams (adult men) per day of dietary fiber. Yet in surveys from 1999-2008, fiber consumption was reported as only 15.78 grams/day across both genders and all races. Mexican Americans were higher on average, but was still only 18.0 grams/day. African Americans were the lowest, consuming only 12.5 grams/day on average. Across all races, participants with obesity



consistently reported lower fiber intake (15.0 grams/day) than those with normal weight or even overweight (3). These less than ideal figures are contributing to an increase in health complications, from high cholesterol and obesity to coronary heart disease and stroke. An increase in dietary fiber, along with a diet low in saturated fat and cholesterol, may help to offset these symptoms, reducing risks, and leading to a healthier body. It is interesting to note that the source of the fibers, be they from supplements or foods, is not important. A trial published in August 2017 demonstrated that soluble fibers from food sources and a supplement sources have the exact same benefit on plasma glucose and insulin responses. They concluded that fibers from food or nutritional supplement are recognized the same by the body, and encouraged everyone to increase their fiber intake by any means to stave off serious illnesses (4).

In addition to an increase in dietary fiber, plants contain compounds known as sterols which play a dramatic role in diminishing risk for coronary heart disease. Plant sterols are structurally similar to cholesterol but carry none of the damaging effects. By competitively inhibiting the absorption of true cholesterol, plant sterols can reduce LDL and total cholesterol levels in the body. This inhibition is so significant, showing results as great as a 14% reduction in LDL cholesterol (5). However, most individuals do not consume enough plant and vegetable products to receive the clinically effective amount of sterols. Average consumption in the US is only 150-450 mg/ day, while the clinically effective dose has been established as 650mg twice daily (6). Therefore, supplementation of plant sterols in the diet is necessary to achieve optimal results.

By combining plant sterols with the soluble fiber in ActiveBlendz Fiber+, Javita has created a uniquely powerful product. These plant-derived compounds work together to reduce cholesterol levels: first, through the competitive inhibition of cholesterol by plant sterols, and second, by flushing the cholesterol out of the body using the fiber gel matrix. This one-two punch will help to lower the risk of coronary heart disease, leading to healthier heart and circulatory systems.

In addition to heart health, Fiber+ also plays a significant role in weight management. Through the inclusion of insoluble fibers, Fiber+ can decrease appetite by increasing glucagon-like peptide-1. Simultaneously, it bulks in the digestive system, creating weight and an overall feeling of fullness. Soluble fiber also plays a role in increasing satiety through its viscosity when combined with water in the



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body. By decreasing appetite and increasing a feeling of fullness, Fiber+ can help with calorie restriction during the day, effectively becoming part of a healthy weight management program.

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## Formulation

ActiveBlendz Superior Fiber+ includes three key herbal ingredients for enhanced efficacy of the drink

- Insoluble fiber
  - Increases transit time of food through the digestive system
  - Assists in regulating the digestive and waste removal systems in the body
  - Creates a feeling of fullness in the gut
- Soluble Fiber
  - Creates a gel-like mass in the digestive system to assist in cleaning up toxins and cholesterol and pushes them out of the body with waste
  - Assists in cholesterol lowering for reduced risk of negative cardiovascular conditions
- Plant Sterols
  - Mimics cholesterol in the body to bind to receptor sites, helping reduce LDL cholesterol levels in the body
  - Reduces the risk for coronary heart disease through the competitive inhibition of cholesterol absorption



## Fiber- overview

Fiber is a plant product, usually derived from fruits, vegetables, and grain products, that is not readily absorbed by our bodies but which does play a crucial role in our health. It is derived from portions of the outer cell wall of plant matter and is classified into two types: insoluble and soluble.

Insoluble fiber is plant material that is not readily dissolved in water. This consists of bulkier plant materials usually derived from vegetables and whole grain products. Because it is not readily solubilized, it maintains its bulk through much of the stomach and intestines. This bulk creates a feeling of fullness, helping individuals consume fewer calories for weight loss. In addition, this bulky fiber pushes through the digestive tract rapidly since it is not readily absorbed, irritating the large intestines along the way. This stimulates mucous secretion which softens stools and allows for a more easy transition out of the body, eliminating waste, such as toxins, fats, and cholesterols, on a more frequent basis. By keeping the digestive system regular, insoluble fiber may also positively benefit and alleviate negative conditions of the digestive system, including constipation, hemorrhoids, and other bowel-related health problems.

Soluble fiber is similar to insoluble fiber in that it too is a carbohydrate that cannot be easily broken down and absorbed by our bodies. However, it has an affinity for water. By attracting water, soluble fiber forms a gel-like matrix as it moves through the stomach and digestive system. This matrix is able to take up compounds, such as cholesterol and sugars, and move them out as waste before they can be absorbed and negatively impact the body. Through this mechanism, soluble fiber assists in cholesterol lowering and may help stave off coronary heart disease, a condition linked to high cholesterol levels. In addition, soluble fiber, like insoluble fiber, is not easily absorbed by our bodies; therefore, it is not readily converted to glucose and does not contribute to spikes in blood sugar often seen with food consumption. This minimal absorption helps to maintain healthy blood sugar levels in those concerned with this risk, such as diabetics.

It is interesting to note that fibers are complex carbohydrates that are not readily absorbed. Therefore they do not cause blood sugar spikes the way other carbohydrates, like simple or refined starches and sugars, would. Fibers move slowly through the gut, being poorly digested or not at all, and therefore do





not contribute to fat storage, as simple carbohydrates and sugars do. This is why they are counted in the total carbohydrate value in a Nutrition Facts label but are separated out from the sugar value.



## Plant Sterols- overview

Plant sterols, also referred to as phytosterols, are steroid compounds naturally occurring in plants. Much research is conducted on both plant sterols and plant stanols, with stanols being saturated sterols-- meaning they have no double bond in the sterol ring. Although there are over 200 known phytosterols, they differ by their carbon side chains, and are all nearly identical in structure to the well-known animal-derived compound cholesterol. Plant sterols are found in high concentrations in vegetable oils, nuts, and products made from them, but can also be found in smaller concentrations in cereals, fruits, berries, and vegetables. Because they are so similar in structure to cholesterol, they have the ability to bind to receptor sites in the body to which cholesterol would normally attach. This competition leaves the excess cholesterol vulnerable to excretion from the body as waste. Through this mechanism, plant sterols lower cholesterol levels, dramatically reducing risk for coronary heart disease.

The US FDA has established a health claim for plant sterols in relation to coronary heart disease. This claim states that foods containing at least 0.65 g (650 mg) per serving of plant sterol esters, eaten twice a day with meals, for a daily total intake of at least 1.3 g, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of Fiber+ supplies 0.75 grams (750 mg) of plant sterol esters, thus exceeding this minimum requirement.

It is not just the US that has acknowledged the immense benefit of phytosterols for cholesterol lowering, but also the European and Canadian health regulatory agencies. Both Health Canada and the European Food Safety Authority (EFSA) have approved a health claim directly relating plant sterol and stanol consumption to cholesterol lowering, with the EFSA citing a 7-10.5% reduction in cholesterol with the daily consumption of 1.5 to 2.4 grams of plant sterols and stanols. This effect was sustainable up to a minimum of 85 weeks (7,8).



## Formulation Efficacy

- Fibers- Insoluble and Soluble
  - Digestive health
    - Insoluble mechanical irritant in large intestine
    - Soluble gel-dependent water-holding capacity
  - Weight Management
    - Appetite suppression
    - Insulin sensitivity modulation
  - Cardiovascular health
    - Cholesterol lowering
    - Improved glyceemic control
- Plant Sterols
  - Competitively inhibits cholesterol absorption due to a similar chemical structure
  - Leaves cholesterol vulnerable to excretion from the body as waste
  - Reduces risk of coronary heart disease by lowering LDL cholesterol levels



## Fiber- efficacy

### Digestive Health

It is well established that fibers, both soluble and insoluble, have benefits in the digestive system. This is due in part to the bulk which insoluble fiber adds to the stool, and the increased transit time through the digestive system due to minimal absorbability. But insoluble fiber also functions as an irritant/stimulant of the colonic mucosa in the large intestines, which results in secretion of mucous and water. This then leads to larger, softer stools with faster transit through the large bowel, better regulating the waste removal process. Waste elimination can also be improved with soluble fiber due to its water-holding capacity and dehydration resistance, which softens hard stools associated with constipation (9). Soluble fiber also attenuates symptoms of irritable bowel, such as diarrhea and abdominal pain, through the water-attracting gel matrix it forms through the digestive tract (10).

### Weight Management

In a cross-sectional analysis conducted by the National Health and Nutrition Examination Survey, 23,168 men and women were assessed from 1999-2010 for risk of metabolic syndrome, inflammation and obesity associated with fiber intake. Dietary fiber was associated with lower levels of all three parameters, with the most significant differences seen among Caucasian Americans versus African Americans and Hispanic Americans (11).

One well-known mechanism for assisting in this weight loss is through appetite reduction and increased satiety. When the appetite is suppressed, less calories should be consumed, so less sugars will be available to be stored as fat. Satiety measurements have historically been through qualitative analysis, through questionnaires and other subjective means. Studies such as these have produced significant results, showing insoluble fibers decreasing appetite immediately after consumption up to 180 minutes, the standard duration of the postprandial test phase (12). However, researchers have identified quantifiable compounds to determine if appetite suppression has reached statistically significant levels. One of these compounds is glucagon-like peptide-1 (GLP-1). In a double-blind, randomized, controlled trial on healthy individuals, GLP-1 was significantly higher after subjects received a diet high in insoluble



fiber. This rise in GLP-1 was observed immediately after fiber intake, continuing through 180 minutes post consumption (13). To determine if this rise in GLP-1 does indeed affect calorie consumption, individuals were provided a specific amount of food along with the insoluble fiber at breakfast for 5 weeks. After this initial period, they continued taking the fiber supplement at breakfast but were allowed to consume their own foods at their discretion. A significant reduction in the amount of calories consumed was observed when participants were allowed to choose foods based on appetite following the fiber supplementation. Researchers concluded that due to the satiating effects of insoluble fiber, subjects consumed fewer calories, which will have a positive impact on weight loss (14).

A statistically significant decrease in calories consumed and weight loss has also been observed by obese individuals consuming high fiber diets more so than lean individuals consuming high fiber diets. In a trial testing this phenomenon, researchers concluded that this was due to higher levels of satiation and appetite control in the obese individuals, yet the underlying cause for this variation has yet to be discovered. An interesting discovery in this trial was that satiety and reduced calorie intake occurred regardless of the form in which the fiber was dosed (15). For example, individuals being given high fiber supplements saw the same increase in satiety and reduction in calorie consumption as did those individuals receiving fiber from all food sources. The conclusion was made that it is best for individuals to get their fiber in whatever form they can for optimal health benefits.

Soluble fiber may also play a role in appetite reduction. In a review of available studies involving soluble fiber and satiety, researchers observed that viscosity of edible compounds (such as fiber) interferes with the mixing process in the small intestine, impeding digestion and absorption of nutrients, which precipitates satiety signals. Soluble fiber was measured to be highly viscous, although a standardized method for measuring viscosity and the inherent nature of appetite have made it difficult for researchers to quantify the amount of satiety achieved. That being said, it was concluded that soluble fibers do have a positive effect on perceptions of satiety at varying levels because of its viscous nature (16).

In a comparative study assessing the effects of soluble versus insoluble fibers on satiety and calorie intake, subjects were found to eat less and be less hungry after a high insoluble fiber breakfast than soluble fiber. Yet interestingly, those who consumed the soluble fiber breakfast were found to be less hungry later in the day than those consuming the insoluble fiber breakfast. These results suggest that



the different types of fibers affect appetite control at different times due to their varying transit times through the digestive system; therefore, a combination of the two might be ideal for affecting the total energy intake throughout the day (17).

In a study involving 40 healthy men, researchers wanted to see if low-fiber-high-protein meals had similar effects on satiety and appetite compared to high-fiber-high-protein meals. Satiety and fullness increased 11% and 13% in the high-fiber meals, respectively; while hunger and prospective intake decreased 17% and 15%, compared with the Low-fiber meal ( $P < 0.01$ ). Hormonal and metabolic responses did not differ between the meals. They concluded it is the fiber providing the appetite control and that these diets could be used for weight management (18).

An interesting study stemming from this research in appetite suppression shows that the benefits of fiber can be felt long after the fiber is initially consumed. In this clinical trial, subjects were remained in the lab for 150 min following the consumption of 20g fiber beverage, during which time appetite and hunger were assessed. Although there were no significant reductions in either parameter immediately after fiber consumption, significant reductions were measured in real world data collected during the day after subjects went about their usual activities outside of the lab. Researchers want to attempt further review to determine if the lab setting may have had a confounding variable effect, but the results were positive for appetite control for longer periods of time following fiber consumption (19).

Soluble fiber can also assist in weight management by directly affecting measures of fatness as well as insulin sensitivity. This was demonstrated in a randomized, controlled crossover, single-blind dietary intervention study performed on 30 healthy non-obese non-diabetic subjects over the course of 8 weeks. Subjects were evaluated for weight and BMI (body mass index) as well as insulin resistance, estimated with the Homeostasis Model Assessment Index as well as the Lipid Accumulation Product Index, both being standards of measure for this type of analysis. It was determined that soluble fiber significantly lowered total weight and BMI and improved insulin resistance. These results were so significant that researchers hypothesized similar results would be found in subjects with metabolic abnormalities (20).

An unfortunate side effect of metabolic syndrome and the increased risk for blood sugar irregularities, is that weight loss becomes more difficult. In a clinical review that followed (Sept 2017-) over 3000



individuals with a high risk for developing type 2 diabetes, researchers evaluated their ability to lose weight one year after diagnosis of risk. Those individuals who followed a high fiber, high carbohydrate, low fat diet were more likely to lose weight and had a significant risk reduction for contracting diabetes than those individuals who were not following a high fiber low fat diet (21).

Weight loss maintenance is also an important area of interest for researchers, not just the initial weight loss. A recent publication summarized the impact of carbohydrates such as fiber on three weight maintenance parameters: energy efficiency, partitioning weight regain as fat versus lean mass, and appetite control. The evidence suggests that diets with low-glycemic index foods and slowly digestible, poorly absorbable carbohydrates (dietary fibers) may improve these three aspects of weight-loss maintenance. They hypothesized that these fibers modify gastrointestinal peptides involved in appetite and metabolic regulation and exert prebiotic effects, thus helping the body maintain the weight loss previously achieved (22).

## Cardiovascular Health

Dietary fiber has been well-documented to reduce the risk of cardiovascular disease and associated risk factors. According to the Code of Federal Regulations established by the FDA, individuals with healthier eating habits, that include diets high in fruits, vegetables, and grains and specifically plant foods with high fiber contents, have lower blood cholesterol levels, leading to a lower incidence of coronary heart disease (23). In a pooled analysis of cohort studies analyzing data from over 91,000 men and 245,000 women over 6-10 years, researchers assessed the direct relationship between dietary fiber intake and risk of coronary heart disease. After adjusting for demographics, BMI, and lifestyle factors, total dietary fiber was associated with a 14% decrease in risk of all coronary events and a 27% decrease in risk for coronary death (24).

These results were echoed in a prospective cohort study conducted by the NIH and AARP. Here, researchers evaluated the risk of death from various biological conditions and compared this to dietary fiber intake. Using data from more than 31,000 individuals, they concluded that dietary fiber may reduce the risk of death not only from cardiovascular disease, but also from infectious and respiratory diseases (25).



High blood pressure is known as the “silent killer” due to its ability to damage arteries, heart and other organs without any symptoms. It can lead to heart attack, heart disease, congestive heart failure, aortic dissection, atherosclerosis, and other detrimental conditions of the cardiovascular system. In a meta-analysis of 25 randomized controlled trials, the relationship between blood pressure and dietary fiber intake was assessed. These trials used only fiber intake as the intervention between the active and control groups; therefore, there were no confounding variables. Results indicated that the increase of dietary fiber significantly reduces blood pressure in patients with hypertension, with optimal results occurring after 8 weeks (26). These results suggest using dietary fiber as a natural alternative and/or additive to classical medical interventions for cardiovascular protection.

Recently another mechanism of action was discovered for fiber and its ability to prevent cardiovascular disease. Using an animal model, researchers demonstrated that high fiber diets assisted in conditions of hypertension and heart failure by directly changing the microbiotic content of the intestine. By creating a more healthy environment, microbiota that assist with lowering blood pressure were able to thrive. If reproducible in humans, this could prove another useful means for preventing cardiovascular disease (27).





## Plant Sterols-efficacy

Mechanism of Action: Competitively inhibits cholesterol absorption due to a similar chemical structure

Phytosterols, or plant sterols, are triterpenes, a subgroup of steroids, which are found in plant membranes. They serve to stabilize phospholipid bilayers in plant cell membranes, just as cholesterol does in animal cell membranes. As they are closely related, plant sterols and cholesterol are chemically similar, differing only in the structure of the side chain off the sterol ring. This minor difference, however, has major impacts in the human body. The body will recognize a plant sterol as cholesterol and allow it to bind to receptors normally used by cholesterol to be absorbed by the body. This prevents cholesterol itself from being absorbed and allows it to be excreted as waste. However, because plant sterols differ in structure from cholesterol, they do not pose the same debilitating effects as does the accumulation of cholesterol, specifically LDL cholesterol (28).

In a ground breaking clinical trial published in the New England Journal of Medicine, researchers studied the effects of a readily used plant sterol on cholesterol absorption. One hundred fifty three healthy participants with mild hypercholesterolemia were used in this randomized, double-blind, placebo controlled year-long trial. Both tolerability and cholesterol lowering were observed throughout the trial. A significant decrease of 14% in LDL cholesterol was observed in the plant sterol group versus only a 1% decrease in the control group. Plant sterols were shown to have no effect on HDL cholesterol, also known as the “good cholesterol”. Serum campesterol, a dietary plant sterol whose levels reflect cholesterol absorption, was decreased by 36 percent in the plant sterol group, and the reduction was directly correlated with the reduction in total cholesterol. Researchers concluded that the dietary intake of plant sterols is effective in lowering serum cholesterol and LDL cholesterol (29).

This early publication has since led to dozens of trials corroborating the results. Among these is a meta-analysis by the Mayo Clinic in 2003 evaluating 41 different clinical trials. This analysis showed an average decrease in LDL cholesterol levels of 10% at recommended doses of plant sterols, and that this benefit may be as high as 20% when combined with a diet low in saturated fat and cholesterol. They also found that combining sterols with statins was more effective for reducing LDL cholesterol levels than doubling the statin dose (30).



In a trial published in the American Journal of Clinical Nutrition, researchers addressed the question of whether it truly is the phytosterols lowering the cholesterol or simply the consumption of healthy plant products. They dosed subjects with two types of wheat germ: one with a high content of plant sterols and one with no sterols. They then measured cholesterol absorption, finding that those with phytosterol-rich wheat germ had far lower cholesterol absorption levels than the control. They concluded that it is indeed the phytosterols that are competitively inhibiting cholesterol absorption, independent of other healthy nutrients found in the plant products (31).

Another interesting question has been raised by researchers. Since plant sterols are increased in the plasma following a sterol treatment regimen, does this increase one's risk for atherosclerosis? Throughout these 41 well-designed clinical trials, researchers noted that the increase in plasma sterol levels did not increase the risk for atherosclerosis. They went so far as to determine that the small increase in plasma sterol levels was more than offset by the decrease in plasma LDL and thereby still decreased the risk of atherosclerosis significantly (32).

Future research continues to explore the potential benefits of plant sterols on cholesterol-lowering. A study conducted at the end of 2015 evaluated the genetic predisposition of individuals to positively respond to phytosterol treatment for cholesterol lowering. Geneticists have been able to identify a candidate single-nucleotide polymorphism and apolipoprotein isoform using a genotyping assay to determine the extent of reduction in circulating LDL cholesterol levels in response to phytosterol supplementation. This could serve as a potential predictive genetic marker to identify individuals who would derive the maximum LDL cholesterol lowering benefits from plant sterols (33). This has value for future medical research, as it may lead to strategies that recommend phytosterol treatment over statin treatment as a first line of defense in genetically hyper-responsive individuals.



## Safety

ActiveBlendz Superior Fiber+ was designed to be safe and effective for everyday consumption by healthy individuals as well as those concerned with weight management and heart health.

Following the recommendations established by the scientific and medical communities, Fiber+ is to be consumed twice daily with the two largest meals. At this dosage, safety of the ingredients was evaluated.

- Fiber+ was designed such that two doses daily would meet the minimum requirements for heart health while maintaining safety parameters
- All safety studies outlined below are relevant to the dosages recommended for Fiber+
- Any available adverse safety and toxicity trials are also reviewed



## Fiber- safety

Dietary fiber is a non-digestible complex carbohydrate derived from plants that is necessary for optimal digestive health and nutrition in humans. The blend used in Fiber+ contains both insoluble and soluble fiber from non-GMO plant sources. According to medical doctors at the Mayo Clinic, there is no evidence that daily consumption of fiber supplements is harmful, and is actually beneficial due to the minimal amounts of fiber consumed as food by the average individual. Fiber is recognized as having beneficial effects on health when consumed at the recommended levels of 25 g/day for adult women and 38 g/day for adult men; however, the US population consumes on average only 15 g/day of dietary fiber (34). As Fiber+ contains 5 grams of total fiber, this falls below the daily recommended allotment. Therefore, two daily doses of Fiber+ will not over-supply ones daily fiber intake but rather will bridge the gap between what is being consumed through food and what is recommended for optimal health.

Although fiber itself poses little to no safety risk for the majority of individuals, increasing ones daily fiber intake may have minor short-term side effects. These include gastrointestinal distress such as cramping, bloating, and gas. Most of these negative side effects have been observed with 50 grams or more of low digestible carbohydrate (dietary fiber) in a single dose, which is far less than the 5 grams per dose provided with Fiber+ (35). Therefore, Fiber+ should not distress the digestive system. However, should GI distress occur, it is recommended to reduce the initial dose of Fiber+ for several days, and gradually increase the dose once GI distress is alleviated.

The specific type of fibers used in Fiber+ are derived from non-GMO plant products and are designated as dietary fibers, a classification consistent with the American Association of Cereal Chemists, the Food and Nutrition Board of the National Academy of Science, and the Institute of Medicine. It has been certified as “digestion resistant” by the formally approved analytical methodology of the AOAC using a combination testing method of enzyme-gravimetric and liquid chromatograph. The fibers in Fiber+ have been recognized as GRAS (generally recognized as safe) by the FDA and are certified Kosher and Pareve by the Orthodox Union.



## **Plant Sterols (phytosterols)- safety**

Phytosterols have been widely studied for their effectiveness in cholesterol lowering. Therefore, much research has been conducted in terms of safety, both in short term and long term use. In a clinical trial evaluating the long-term consumption of sterol esters, 185 healthy volunteers consumed 1.6 g/day of plant sterols for a full year. All standard safety parameters were measured at critical points during the study. These include hormone levels, red blood cell deformability, and clinical chemical and hematological parameters. Researchers reported all points unaffected by phytosterol consumption. In addition, the reported adverse events were not different between the test subjects and the control group. Researchers concluded that long term consumption of plant sterols is safe.

In a recent review of available literature through 2014, researchers evaluated the effectiveness and tolerability of nutritional compounds such as plant sterols for cholesterol lowering. In particular, they were determining the additive effects of sterols with classical statin therapies in middle to low risk cardiovascular subjects. Plant sterols were found to be well-tolerated in these individuals and were actually found to be useful for patients experiencing unwanted side effects from classical therapies (36).

The plant sterols utilized in Fiber+ are non-GMO and are certified GRAS (generally recognized as safe).



## Usage Guidelines

According to the Mayo Clinic, there is no evidence that the daily use of fiber supplements, such as Fiber+, poses any harm to the body. In fact, the daily intake of a fiber supplement such as this provides more health benefits than risks. The same has been confirmed for the long-term use of plant sterols. However, since fiber bulks up the stool and affects the digestive system, some gastrointestinal distress (i.e. bloating, cramping, gas, etc.) may be experienced in a few individuals, particularly those with very low fiber intakes initially. For these individuals, a half dosage should be consumed initially, gradually increasing the dosage over time to the full recommended amount.

Fiber modifies the transit time of food and other consumables, including supplements and medicines, and may have negative effects on timely absorption. This is especially true for medications that reduce blood sugar levels, as timeliness is key. Therefore, discuss any medications you are taking with your health care professional prior to starting a fiber regimen. For standard nutritional supplements, it is advisable to consume them 30 minutes prior to or two hours following the consumption of Fiber+ to allow for optimal absorption of these supplements.

The fibers and plant sterols included in Fiber+ do not contain any known allergens. However, because they are derived from plant products including corn, it is possible that sensitivity may occur in some individuals. Should you experience symptoms of sensitivity, discontinue use and consult your healthcare professional.

Although the components of Fiber+ are considered safe, it is advisable that pregnant and lactating women consult their doctor prior to starting any nutritional program. This same advice applies to children and those under a physician's care.



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