

SolarChol™ Plant Sterol & Ester

Vita-Solar Biotechnology manufactures and markets a line of plant sterol products under the brand name SolarChol™. Our products are derived from all-natural plant sources and are formulated for use in food, beverages, and dietary supplements. Based on data from scores of trials conducted on the use of plant sterols in the diet, a daily intake of at least 1.3 grams of plant sterols esters as part of a diet low in saturated fat and cholesterol is recommended to provide significant cholesterol lowering benefits. An FDA health claim may be available when plant sterols are included in two servings of foods that provide a daily total of at least 1.3 grams of vegetable oil sterols in two meals.

Introduction

Plant sterol esters are composed of vegetable oil fatty acids and plant lipids (plant sterols) that are naturally present in vegetables, fruits, and grains. SolarChol™ plant sterol esters have been developed to ease the formulation of this ingredient into vegetable oil-based and other food products¹.

Eating food products enriched with plant sterol esters helps promote healthy blood cholesterol levels. Lipase enzymes, present in the human digestive tract, cleave plant sterol esters to liberate plant sterols in the gastrointestinal tract, which then block gastrointestinal absorption of dietary and biliary cholesterol into the bloodstream, thus lowering serum cholesterol.

FDA Health Claim

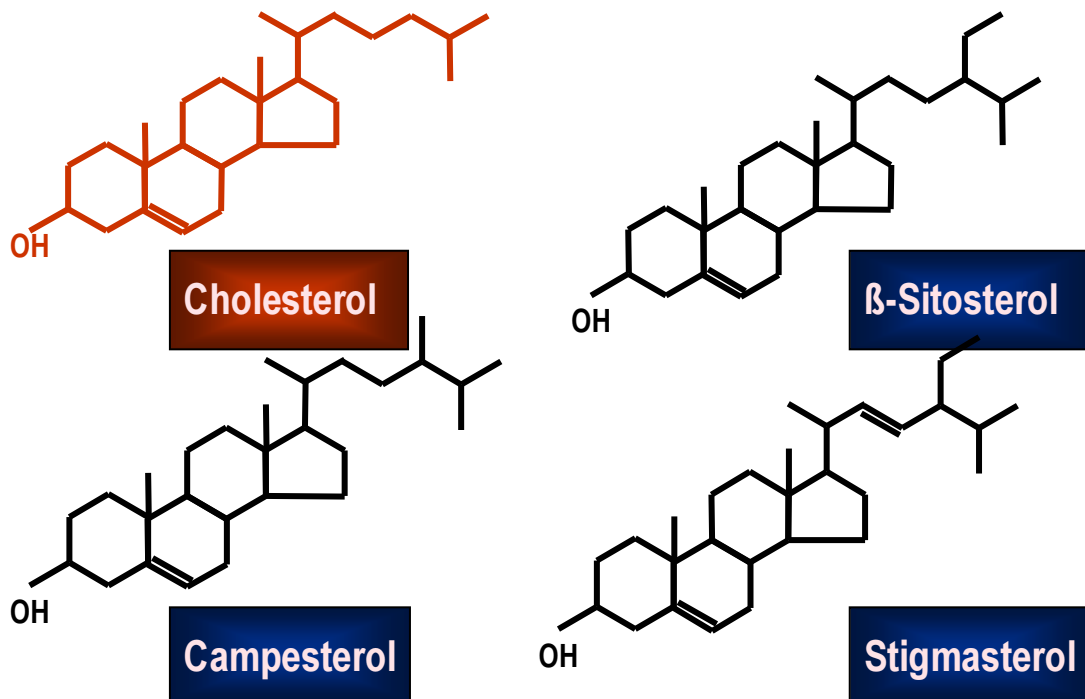
Daily consumption of at least a total of 1.3 grams of plant sterol esters in two meals may reduce the risk of heart disease when part of a diet low in fat and cholesterol. Based on a regulatory enforcement discretion letter to Cargill dated February 14, 2003, the FDA may expand the use of the plant sterol heart-health claim to a broader range of foods and beverages.

National Heart, Lung, and Blood Institute Recommendation

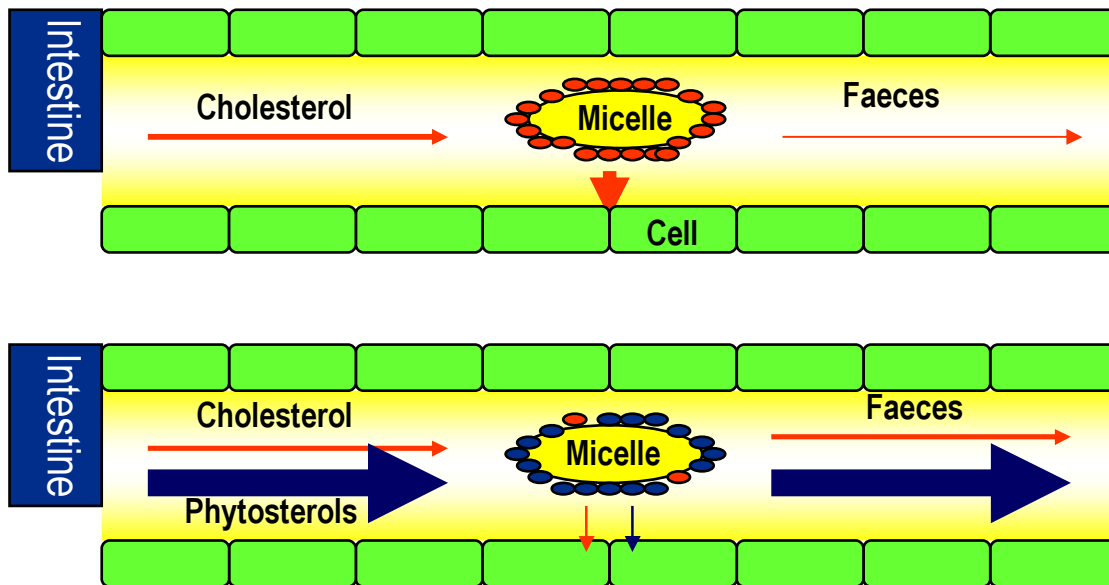
The National Cholesterol Education Program of the National Institutes of Health recommends adding plant sterols to the diet to enhance blood cholesterol reduction².

The advice was included in new guidelines issued in 2001 to help consumers reduce coronary heart disease (CHD) risk. The U.S. Food and Drug administration approved a health claim for plant sterol esters and reduced CHD risk in September of 2000. Consuming 1-2 grams of plant sterols per day typically lowers LDL cholesterol levels 5-15% within 2 to 4 weeks with no reports of significant side effects. The safety of plant sterols has been reviewed and approved for food use by government authorities in the U.S., the European Union, Australia and Japan.

Sterol Structure



Effect of Phytosterols



Properties and Typical Analysis of SolarCho™

1) Plant sterol Powder

A white or almost white powder

Total Plant Sterol 90%min.

Beta-Sitosterol 40-58%

Campesterol 20-28%

Stigmasterol 14-23%

2) Plant sterol Ester

Odorless

Creamy white translucent wax

14 °C to 28 °C melt point range

Sterol Esters 90%min.

Free sterol 8% max.

Global Regulatory Status

Regulatory authorities in various countries have authorized the use of plant sterol esters in various foods.

They include:

- The US FDA has found no objection to Cargill's GRAS determination for the use of plant sterol esters in vegetable oil spreads, salad dressings, bars and yogurt. Cargill has also completed a self-GRAS determination of a broader range of heart-healthy food applications for free and esterified sterols.
- The Food Standards Ministerial Council of Australia and New Zealand granted permission for the use of plant sterol esters in edible oil table spreads. They found that there are no public health and safety concerns associated with the use of plant sterol esters in table spreads at a maximum concentration of 13.7%.
- In Europe, the Scientific Committee on Food concluded that the use of plant sterol esters in yellow fat spreads at a maximum use level corresponding to 8% free plant sterols is safe for human use.
- The EU Standing Committee on Foodstuffs adopted a Draft Commission Decision authorizing the marketing by a specific manufacturer of "yellow fat spreads with added plant sterol esters" as a novel food ingredient under regulation (EC) No 258/97.

Packaging & Storage

- 25kg Fiber board drum & 50kg epoxy-lined steel drums
- Refrigeration recommended at 4 °C (40 °F) or lower

End Use Applications

Foods which have been formulated with plant sterol esters and commercialized include:

- Vegetable oil-based spreads
- Cooking oils
- Salad dressings
- Nutritional bars
- Yogurt-based products

Different SolarChol™ product forms

Product Code and Name	Application	Benefits
Phytosterol Powder	Limited oil solubility and completely insoluble in water.	Little to no mouth feel Minute Maid momentum Ability to blend with other dry ingredients.
Phytosterol Granular	Used to make tablets or pills.	Good flow characteristics Good compressibility
Sterol Esters	A yellowish liquid used in oil applications	Low melting point compared to sterols Dispersible in oil
Water Dispersible Sterol	An off-white powder used in aqueous applications	Dispersible in water

Why should I be concerned about my cholesterol level?

Because elevated blood cholesterol is a major risk factor for heart disease, and heart disease is responsible for 50% of all deaths in industrialized countries such as the United States. In fact, nearly 100 million Americans have elevated cholesterol (>200 mg/dL) and, oftentimes, they don't even know it. High blood cholesterol is one risk factor that can often be modified by lifestyle changes, such as eating a diet low in saturated fat and cholesterol and high in grains, fruits and vegetables. Consuming plant sterols as a regular part of a healthy diet low in saturated fat and cholesterol provides another natural option in the maintenance of cardiovascular health.

What are plant sterols?

SolarChol™ is natural compounds that can be consumed regularly as a part of a healthy diet. Foods such as fruits, vegetables, breads and other whole grain products, and most vegetable oils contain at least some plant sterols. However, it is difficult to consume enough of these foods on a daily basis to derive enough plant sterols to have a cholesterol-lowering effect. Based on data from scores of trials conducted on the use of plant sterols in the diet, a daily intake of at least 1.3 grams of plant sterol esters as part of a diet low in saturated fat and cholesterol is recommended to

provide significant cholesterol lowering benefits. Consuming foods with added plant sterols is one way to ensure that an effective daily intake is attained.

How do plant sterols lower cholesterol levels in the blood?

Because plant sterols are structurally similar to cholesterol, they compete with the cholesterol we ingest for absorption through the small intestine. To a point, the more plant sterol present in the intestine following a meal, the less cholesterol absorption will occur. Further, the plant sterols we consume are not absorbed themselves to any appreciable extent. So, when you consume plant sterols you not only inhibit the uptake of cholesterol by the body, but you "flush" the plant sterols through the system without absorbing them as well. The overall effect is an average "bad" (LDL) cholesterol decline of 8-15%, with no observed adverse effects.

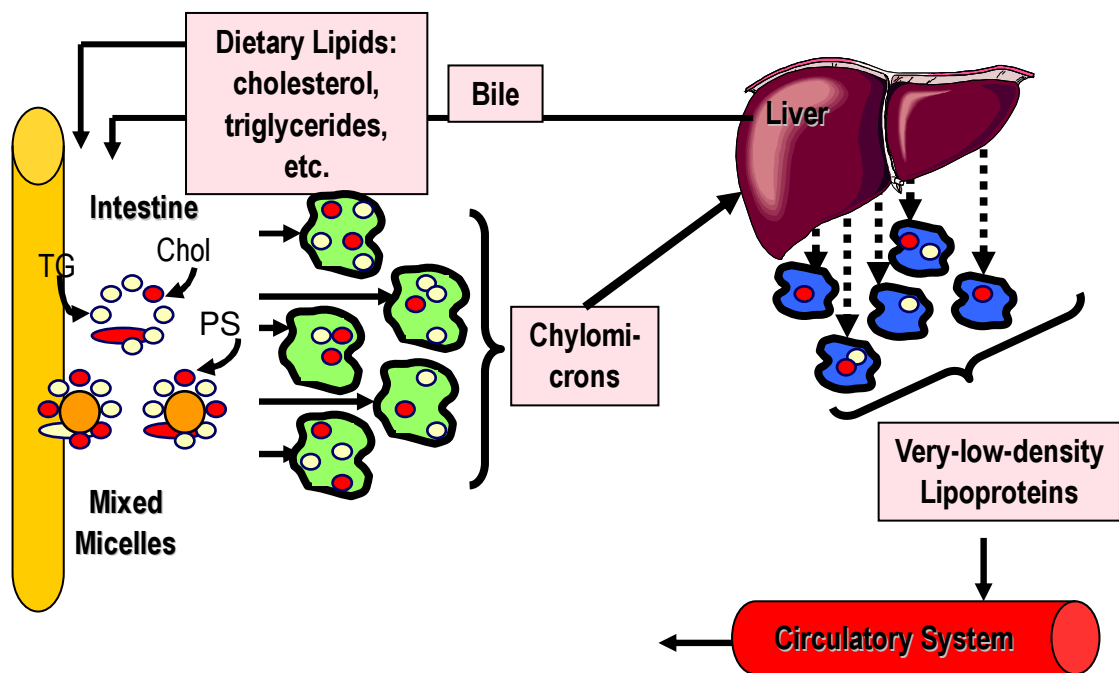


Figure 1. Cholesterol Digestion & Absorption

Figure 2. phytosterol and sterol ester reduces total cholesterol concentrations of hypercholesterolemic men

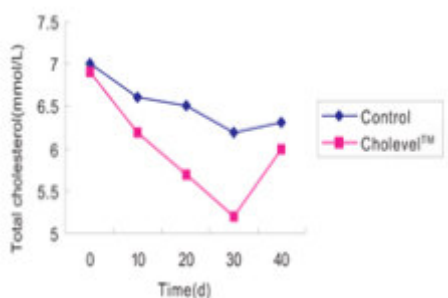
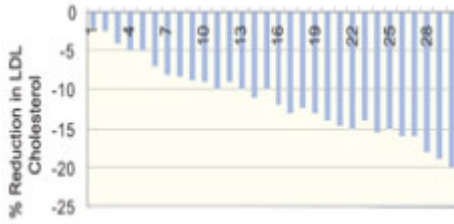


Figure 3. LDL Cholesterol Clinical Data of Phytosterols and sterol ester



Are plant sterols safe?

Yes. Scores of human studies with plant sterols have shown no adverse effects. Some studies have found that large doses of plant sterols reduce the absorption of the pre-vitamin beta-carotene. However, clinical trials have demonstrated that even in the face of rather large daily intakes of plant sterols, serum fat-soluble vitamin levels, including vitamin A, remained well within normal ranges. There is no reason not to consume and enjoy plant sterol-containing products on an ongoing basis.

How can people consume more plant sterols?

Vita-Solar Biotechnology is working with a number of food companies that plan to incorporate plant sterols into new and existing products. Plant sterols have proven successful in a wide range of products worldwide, including spreads, yogurt and milk. Clinically shown to lower cholesterol, plant sterols can serve as an important part of a heart-healthy diet.