Natural Products Insider
Phaseolamin 2250™

The Zone. The Atkins Diet. Carbohydrate Addicts. One of the hottest weight loss and diet trends over the past decade has been the low-carb movement. Designed to control blood glucose levels by minimizing intake of starchy carbohydrates, which are easily converted to sugar, these diets emphasize slower-metabolized foods such as proteins and fats. However, it can be difficult to change in the long term, particularly when traveling or when faced with a plate of pasta or freshly baked bread.

As early as the 1940s, scientists discovered that some plants, particularly wheat and beans, contained specific inhibitors of animal alpha amylases, the enzyme that helps turn starch to sugar. Researchers theorized that use of these inhibitors could help improve carbohydrate tolerance in diabetics and aid in weight control. It wasn't until the early 1970s that studies were conducted to determine the specific starch neutralizing ability of the plants. In 1974, J. John Marshall and Carmen Lauda purified a proteinaceious inhibitor of alpha-amylase from kidney beans (*Phaseolus vulgaris*), which they named Phaseolamin. A study they conducted on Phaseolamin found that it was a specific alpha amylase inhibitor (*J Biol Chem*, 250(20):8030-8037, 1975).

The research launched an array of crude bean amylase inhibitor preparations for weight control. They were marketed as "starch blockers" that claimed to reduce starch digestion by inhibiting intraluminal amylase activity. Unfortunately, in July 1982, the Food and Drug Administration (FDA) suspended sale of these "starch blockers" after several clinical studies showed that most products failed to deliver on their promised benefits.

The concept was still intriguing, and a group of researchers at the Mayo Clinic and Foundation in Rochester, Minn., launched a study to determine why the commercial preparations were ineffective in vivo in spite of their activity in vitro. In the study (*Gastroenterology*, 88(6):1895-1902, 1985), Peter Layer, Gerald Carlson and Eugene DiMagno used a purification procedure to concentrate the bean-derived alpha-amylase inhibitor. "Compared with a commercial preparation and crude bean extract, this partially purified inhibitor inactivated intraduodenal, intraileal and salivary amylase in vitro faster and more completely," they wrote. "Commercial amylase inhibitors failed to decrease starch digestion in vivo mainly because they have insufficient antiamylase activity. However, a partially purified inhibitor with increased specific activity is stable in human gastrointestinal secretions, slows dietary starch digestion in vitro, rapidly inactivates amylase in the human intestinal lumen and ... may decrease intraluminal digestion of starch in humans."

A follow up in vivo study by Layer (*Gastroenterology*, 91(1):41-48, 1986) found similar results. The researchers used four volunteers to investigate the effects of decreased intraluminal amylase activity on digestion of starch and postprandial gastrointestinal and hormonal responses. The results showed that more than 95-percent inhibition of amylase reduced dietary starch digestion within the small intestine and uptake of dietary starch from the small intestine. In addition, they found that the amylase inhibitor decreased postprandial release of insulin.

Using these studies as a basis for investigation and product development, Pharmachem Laboratories recently introduced Phaseolamin 2250™. The ingredient is a standardized, all-natural, non-stimulant starch neutralizer, extracted from a portion of the white kidney bean, which Pharmachem stated is similar to the extract studied by the Mayo Clinic.

The name comes from an independent in vitro test conducted by Lycoming Laboratories for Pharmachem. Using a modified U.S. Pharmacopoeia (USP) test method, Lycoming Laboratories found that Phaseolamin has approximately 5,000 alpha amylase inhibiting units (aaiu) per gram. Pharmachem then applied its proprietary conversion factor based on USP literature to convert the aaiu/gram to calories/gram. Its findings--that Phaseolamin neutralized 2,250 starch calories, or the equivalent of more than one pound of spaghetti.

Pharmachem manufactures the ingredient from a non-genetically modified plant source. Phaseolamin contains no stimulants and is generally recognized as safe (GRAS). To further its research basis, Pharmachem launched two additional studies. The first, "In Vivo Effectiveness of a Starch Absorption Blocker in a Double-Blind, Placebo-Controlled Study with Normal Human Subjects," is being conducted by Joe Vinson and Donna Shuta at the University of Scranton, Pa. Pharmachem planned to present preliminary results at Natural Products Expo East in Washington, D.C., in October 2001. The second study is a human study on weight loss associated with a starch neutralizer, and is being conducted in Italy. The results of that study should be released before the end of 2001.

Due to its GRAS status, Phaseolamin can be used in a variety of product applications. Among those being promoted are tablets, capsules, chewables, powdered drinks, chewing gums, functional foods and baking mixes. Doses range from 250 to 1,000 mg/person, depending on needs and the degree of starch in the meal.