



# Pharmachem Laboratories, Inc.

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phär-ma-foods®...efficacious food supplements standardized for specific potency, solubility, direct compression and disintegration characteristics...

June 21, 2006

To whom it may concern,

I, Tom Glucksman, as an appropriately qualified representative of Pharmachem Laboratories Incorporated, affirm Starch Lite™ also known as Phase 2® and Phaseolamin 2250® and Phase 2 Starch Neutralizer™, to be Generally Recognized As Safe (GRAS) for use at levels providing an upper limit of aggregate intake of 6 g of Starch Lite™ per day from qualified food, beverage and dietary supplement applications. This was based on the applicable requirements for the technical element and common knowledge element of a GRAS determination based on scientific procedures as per proposed regulation 21 CFR §170.36. An Expert Panel of independent and qualified scientific professionals was convened by Pharmachem Laboratories to evaluate the Generally Recognized as Safe (GRAS) status of the Starch Lite™. Following in-depth evaluation, the Expert Panel unanimously concurred that Starch Lite™ (meeting the product specifications and used in accordance with current Good Manufacturing Practice 21 CFR §182.1(b)) is Generally Recognized As Safe.

Starch Lite™ is a standardized extract derived from the common white bean (*Phaseolus vulgaris*) that has been shown to inhibit the activity of the digestive enzyme  $\alpha$ -amylase. Alpha-amylase is an enzyme found in plants, animals, and microorganisms that catalyzes the hydrolysis of complex carbohydrates into simpler saccharides such as maltose and glucose that can be absorbed. Inhibition of human  $\alpha$ -amylase may promote weight loss by hindering the digestion of complex carbohydrates, thereby reducing the absorption of carbohydrate-derived calories.

Starch Lite™ is manufactured by Pharmachem Laboratories, Inc. from non-genetically modified raw white kidney beans using a proprietary variation of procedures widely used in the food industry. Quality control and quality assurance standards have been implemented to ensure product quality and consistency. In addition, every lot of Starch Lite™ is tested to ensure compliance with the established standards, including  $\alpha$ -amylase-inhibiting activity of at least 3000 units per gram.

The summary basis for the conclusion of safety regarding Starch Lite™ under those conditions of intended use has been provided below:

- The source material of the Starch Lite™ aqueous extract, the common white kidney bean (*Phaseolus vulgaris*), possesses a long history of safe use in the human diet when cooked and eaten as food;

- Starch Lite™ manufacturing process is well controlled and yields consistent product quality;
- Preclinical safety data for Starch Lite™ indicates an absence of toxicity in rodents exposed to oral doses up to 2500 mg/kg/day for 28 days or 1112 mg/kg bw/day for 90 days (maximum dose tested);
- Clinical efficacy evaluations indicate an absence of adverse health effects in human subjects ingesting up to 3000 mg/day in divided doses with meals for periods from 30 days to 24 weeks;
- Starch Lite™ is currently used in amounts up to 4500 mg daily in products marketed worldwide under approximately 200 brand names, with no reports of adverse events.

The determination of GRAS status for the Starch Lite™ product by Pharmachem Laboratories was in conjunction with the evaluation of an independent review by a panel of Experts, qualified to conduct this review through scientific training and experience to evaluate the safety of food ingredients. A consensus among the Expert Panel has determined a reasonable certainty that the Starch Lite™ product would not be harmful under the intended conditions of use. This GRAS determination by Pharmachem Laboratories would therefore meet the requirements of §201(s) of the Federal Food, Drug, and Cosmetic Act; 21 CFR, §170.3 and §170.30 and the amendments to these rules proposed at 62 Fed. Reg. 18960. I, the undersigned, hereby affirm that Starch Lite™ also known as Phase 2® and Phaseolamin 2250® and Phase 2 Starch Neutralizer™, to be Generally Recognized As Safe (GRAS) for use at levels providing an upper limit of aggregate intake of 6 g of Starch Lite™ per day from qualified food, beverage and dietary supplement applications.



• Tom Glucksman

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