



Technical Literature

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Safety of Slendesta™ Potato Protein Extract 5% Powder

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Key Conclusions

- **Slendesta Potato Protein Extract 5% Powder is standardized to contain 5% proteinase inhibitors (PI2), naturally occurring proteins present in white potatoes**
- **Clinical trials report that no serious adverse events occur when Slendesta Potato Protein Extract 5% Powder is taken as directed**
- **Slendesta Potato Protein Extract 5% Powder is produced in accordance with FDA's Current Good Manufacturing Practices**

Introduction

Safety of weight management products is one of the top concerns among consumers (3). Of the many over-the-counter and prescription weight loss products available today, many are associated with unwanted side effects. Certain appetite suppressants, thermogenic formulas, fat blockers, and other weight loss products contain ingredients known to cause adverse effects or interact adversely with certain medications(5, 10, 11, 18). For example, fiber supplements aid in energy and weight regulation(7, 13), but can result in unwanted side effects such as nausea, diarrhea, and abdominal bloating(15, 16). These effects are simple annoyances, but the effects of other products can be quite severe, unsafe, and constitute severe safety concerns, jeopardizing public health in some cases(4). Kemin Health has developed Slendesta™ Potato Protein Extract 5% Powder (Slendesta) as a safe approach to weight loss. Slendesta is standardized to contain 5% potato proteinase inhibitors (PI2), naturally occurring proteins present in white potatoes(6), a food commonly consumed by humans.

Kemin Health (KH) is committed to providing uncompromising quality in Slendesta. This commitment starts with ensuring that the product is safe for its intended use. KH has undertaken considerable efforts to apply science-based principles to the evaluation of the safety of Slendesta. These ongoing efforts include understanding the historical consumption of potatoes, researching scientific articles, and conducting human and animal studies.

Safety

Initial studies examined the effects of relatively high doses of the active constituent of Slendesta, PI2 (1500 mg(12, 19) and 1000 mg(17)). These doses were effective, inducing feelings of fullness and satiety while not causing side effects. In subsequent research, a much lower dosage of PI2 was shown to provide significant effects on both satiety and weight loss in humans, with no side effects observed (21, 23). Subjects who ingested 30 mg PI2 (600 mg Slendesta) in a drink formulation

twice daily for four weeks lost an average of 4 pounds (1.8 kg), with no adverse effects observed (21). Another study showed that doses of 15 and 30 mg PI2 (300 and 600 mg Slendesta, respectively) significantly reduced post-prandial blood sugar levels in healthy adult subjects. No serious side effects were observed (22). Kemin Health has also performed a randomized, double-blind study in conjunction with Research Testing Laboratories(14) in order to assess the safety and efficacy of Slendesta when taken according to recommended levels. In this study, 240 overweight to obese subjects were supplemented with 0, 15, or 30 mg PI2 (0, 300, 600 mg Slendesta, respectively) in a controlled trial performed at two separate sites in New York state. These subjects consumed PI2 treatments 60 minutes before their two largest meals of the day for 12 weeks. Safety was assessed through the recording of the occurrence of adverse experiences: adverse events were first classified by body system and clinical symptoms, and then rated according to severity and relatedness to treatment. Over the three months of the study, adverse events were not significantly different among groups and no serious adverse events were observed in any treatment group. Finally, an open label study conducted by Heartland Vascular Medicine & Surgery in Des Moines, IA supplemented 28 subjects with 30-60 mg PI2/day (300-600 mg Slendesta/day) for 12 weeks(8). Seventeen of these subjects voluntarily continued PI2 treatment daily for an additional 8 weeks for a total of 20 weeks daily PI2 consumption(9). No serious side effects associated with consumption of PI2 supplied by Slendesta were observed.

These safety results are supported by a study in animals administered levels of PI2 much higher than the recommended daily dose (~300 mg PI2 equal to 6000 mg Slendesta). This study was conducted in conjunction with Veterinary Resources, Inc. and Iowa State University as a toxicity test in an animal model. Results revealed no adverse effects on the histopathology of several organs, select clinical chemistries, and hematologic variables evaluated. These effects were not seen in any of the treatment groups(20). Therefore, according to the research data gathered to date, PI2 supplied by Slendesta exerts no known toxic or negative side effects.

Slendesta, with minimal dietary fiber, does not present side effects associated with some fiber supplements

Some supplements for weight management contain fiber since the unique properties of fiber have been shown to aid in induction of satiety, helping to reduce food intake and contribute to weight loss (7, 13). However, undesirable effects such as nausea, diarrhea, abdominal bloating, and gas may occur with ingestion of fiber contained in these supplements(15, 16). Slendesta contains less than 3% by weight of total dietary fiber (2). Therefore, side effects such as bloating, attributable to the dietary fiber, are not expected.

Potatoes provide a safe source of Slendesta

Slendesta, standardized to the active constituent proteinase inhibitors (PI2), is produced using commercially available Russet potatoes. Potatoes are among the foods most commonly consumed by Americans. The per capita intake of potatoes is approximately 180 g potato products consumed per person per day in the United States(1). Research shows that PI2 such as that in Slendesta, remains intact and stable in potatoes even after heating and cooking. This indicates that PI2 is present in the

food supply and that people ingest PI2 on a regular basis when consuming potatoes and certain potato products. In other words, PI2 has been part of the typical diet for as long as potatoes have been consumed by humans. Combined with the fact that there are no reports that consumption of cooked potatoes by humans in general is associated with any negative side effects, this and the data discussed above suggest that PI2 supplied by Slendesta has no harmful or deleterious effects.

Manufacturing

KH produces Slendesta from commercially available Russet potatoes. All potatoes are subject to normal USDA inspection and certification prior to shipment and are also inspected by KH staff upon delivery. During manufacturing, KH adheres to formally approved procedures and quality checks in accordance with the United States Food and Drug Administration's current Food Good Manufacturing Practices (21 C.F.R.§110(2005)). Multiple tests and procedures are in place throughout the manufacturing process to ensure that raw materials, in-process product, and final product released to customers meet KH's stringent quality requirements. Potential physical, chemical, and microbiological hazards associated with the manufacture of KH's products have been studied and addressed in Hazard Analysis and Critical Control Point (HACCP) plans. Slendesta is properly considered to be a safe dietary ingredient that complies fully with the laws and regulations governing dietary supplements when taken as directed for its intended use.

Conclusions

Slendesta Potato Protein Extract 5% Powder is a dietary ingredient as defined by the Dietary Supplement Health and Education Act of 1994, and is safe for use as a dietary supplement when taken as directed. PI2 as supplied by Slendesta Potato Protein Extract 5% Powder remains intact and stable in cooked potatoes, a food frequently consumed by humans. Side effects that may be associated with the use of fiber supplements such as abdominal bloating are not expected with use of Slendesta, as it does not contain appreciable amounts of dietary fiber when taken as directed. Current clinical and toxicological data and scientific literature report there are no serious side effects associated with the use of Slendesta Potato Protein Extract 5% Powder.

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