



UNIQUE ATTRIBUTES OF SLENDESTA® POTATO EXTRACT

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KEY CONCLUSIONS

- *Slendesta® is a unique ingredient developed to support VDS and Food & Beverage customers to create products specifically designed to promote satiety and weight management.*
- *Scientific evidence substantiates that proteinase inhibitor II (PI2), the active component of Slendesta, safely promotes satiety and weight management.*
- *Slendesta is recommended for use by people who wish to manage their weight through healthy dieting and exercise.*
- *Kemin's patent position and other Intellectual Property protection offer an important competitive edge for Slendesta.*
- *Slendesta is a quality guaranteed nutritional ingredient with suitable regulatory status for use in conventional foods and food supplements in many countries.*
- *The small effective dose and different delivery systems for Slendesta make it an optimal ingredient for use in a range of functional foods and food supplements.*

INTRODUCTION

Dedicated to improving health and wellness worldwide, Kemin Health, L.C has developed Slendesta® Potato Extract (Slendesta) to offer an innovative approach to enhancing satiety and helping address one of the key health issues in the industrialized world—weight control. Slendesta is a proprietary, natural standardized potato extract derived from white potatoes, one of the most safe and commonly consumed foods. The active component of this extract, potato proteinase inhibitor II (PI2), is a naturally occurring, well-studied protein commonly found in some plants including tomato plant leaves and potatoes. Slendesta is recommended for use by people who wish to manage their weight through healthy dieting and exercise.

SCIENTIFIC SUPPORT

PI2 is a proteinase inhibitor from potatoes that has been shown to increase intestinal cholecystokinin (CCK) release via inhibiting digestive trypsin and chymotrypsin through luminal feedback regulation mechanism (1, 8). CCK is one of the best known satiety regulatory hormones and has shown its effects on slowing gastric emptying, suppressing appetite, and reducing food intake in humans and various animal models (15, 16, 17). Scientific evidence including the knowledge on PI2's mode of action, as well as the findings of numerous clinical trials, supports the efficacy and safety of Kemin's Slendesta Potato Extract in promoting CCK release and satiety as well as healthy weight loss (4, 10).

- Clinical studies reported in the literature have collectively demonstrated that administration of various doses of PI2 (as the PI2 contained in Slendesta) resulted in increased CCK release and a delay of gastric emptying, which in turn lowered post-prandial glucose spike (6, 9, 11-14).
- Kemin's proprietary and unpublished clinical studies further substantiate that a 300 mg dose of Slendesta (providing 15 mg active PI2 at 5% standardization), taken one hour before a meal, enhanced CCK release, effectively modulating appetite (measured as fullness, hunger, desire to eat, and prospective food consumption), and when taken before the two largest meals, supported people in their effort to manage weight (ISU study, RTL Study, Heartland Study, Hill Top Research Study) (2, 3, 5, 7).
- Independent reviews by external scientific experts further validate that scientific evidence supports Slendesta's efficacy in human appetite control and weight management, producing placebo adjusted weight loss and/or weight loss from baseline, and promoting CCK release as well as the appetite suppression mediated by CCK.



- The scientifically supported Slendesta has been recognized with three different awards in 2008: the Silver Award for the Best Innovation Ingredient at HI Europe and Fi South America, and the “Most Innovative Ingredient” at Slimming Ingredients Spain.
- A critical benefit of Slendesta is that it has no known side effects when used as directed. The safety of this extract has been established through a combination of the history of consumption of potato components in the human diet, as well as animal toxicity studies and clinical trials conducted with nearly 700 individuals consuming Slendesta.
- The general safety of Slendesta is validated by its Generally Recognized as Safe (GRAS) status for the intended food applications in the US. GRAS status was concluded by an independent Expert Panel of qualified scientists upon critical review and evaluation of the information pertaining specifically to the safety of Slendesta, including the background of the ingredient, history of use, method of manufacture, product quality specifications, analytical data, intended use levels in specified food products, consumption estimates for all intended uses, safety information, and toxicological studies.

SLENDESTA IS A WORLD FRIENDLY™ INGREDIENT

- World-friendly regulatory status provides customers the ability to quickly enter key global markets with a single formulation.
 - Slendesta is a dietary ingredient for use in dietary supplements in the US. Slendesta is also affirmed as GRAS, which allows manufacturers to add Slendesta to a variety of conventional food products at the intended inclusion levels in the US market.
 - Slendesta can be used in food supplements and conventional foods in the European Union, and is not considered as a Novel Food ingredient when used in food and/or food supplement as officially confirmed by the Belgian and French authorities. Food supplements containing Slendesta have been commercialized in different European Member States for more than two years. Notifications to appropriate authorities of these food supplements were realized prior to their introduction on the market without receiving any objection from the authorities.
 - Slendesta has successfully achieved product specific food status in Japan, Taiwan, Chile, Argentina, and Colombia and can be used in conventional foods as well as food supplements in these markets.
 - Slendesta has obtained product specific regulatory clearance for use in supplement products in Canada and Australia.
 - Regulatory dossier materials have been developed that can be adapted for registration of Slendesta or Slendesta-containing products in other countries of customer interest.
- Kemin's international patent portfolio and other intellectual property protection for Slendesta support its uniqueness for our customers/partners and provide an important competitive edge for products using the ingredient.
 - The manufacturing process for Slendesta is protected by patents either exclusively licensed to or owned by Kemin. PI2 and its manufacturing process are protected under a number of patents in the US and their counterparts in Europe. Kemin also has patents pending for the use of the PI2 molecule or the composition containing PI2 for blood glucose control and satiety regulation in a number of countries.
 - Slendesta's proprietary data supports product claims that are specific to Slendesta. With Slendesta's unique, patent -protected manufacturing process, potential competitors who wish to make similar claims for their plant extracts with proteinase inhibitors generally should be conducting their own safety and efficacy studies to support the marketing of their products.
 - The Slendesta Trademark is registered in a number of countries worldwide, and its use can be licensed to customers. Kemin is dedicated to protecting and enhancing the value of its mark by allowing only the authorized use of the Slendesta logo.



- Slendesta is backed by an uncompromised quality guarantee.
 - Slendesta is of US origin and manufactured in an ISO 9001:2000 certified facility with implemented HACCP controls. The manufacturing processes are compliant with US FDA's current Food Good Manufacturing Practices (cGMPs) (21 C.F.R §110). The facility has consistently received superior ratings from a third-party auditing firm that conducts yearly unannounced inspections.
 - All incoming raw materials used in the manufacturing process are inspected to ensure they meet Kemin's quality and safety standards. Kemin has complete supplier certification processes and full traceability of all lots of Slendesta from incoming potatoes to the finished product. All outgoing finished Slendesta products are tested in order to ensure compliance with Kemin's established quality standards.
 - Slendesta is obtained through a patented gentle aqueous extraction process of a commercially available variety of non-GMO potatoes (*Solanum tuberosum*) grown in the US. The active component, PI2, is not chemically altered during such production process, and is identical to that naturally found in potatoes.
 - Slendesta Potato Extract has a unique compositional fingerprint, and PI2 is the main proteinase inhibitor of the extract.
 - Slendesta is absent of allergens, and is BSE/TSE, preservative, and irradiation free.
 - Slendesta is Kosher/Halal certified and is suitable for use by a range of consumers.
 - Available in three different formulations, Slendesta is suitable for inclusion in different types of functional foods and food supplement formulations. The small effective dose of this standardized potato extract (300 mg) provides advantages over some other satiety ingredients, allowing its use as a stand-alone product or in a blend with other ingredients.
 - Slendesta has a confirmed stability and shelf life, a critical factor to quality. Stability analysis ensures Slendesta Potato Extract 5% Powder meets label claim throughout its 3 year shelf life. Slendesta WD Potato Extract 5% Powder, Slendesta Potato Extract 10% Powder and Slendesta SG Potato Extract 5% Powder have a 2 year shelf life and are currently under evaluation to extend their shelf life to 3 years.

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