Safety Statement

info@activeconceptsllc.com • Phone: +1-704-276-7100 • Fax: +1-704-276-7101

Product Name: ProCutiGen™ Hold
Code: 20831
INCI Name: Phyllostachys Bambusoides Extract

ProCutiGen™ Hold is manufactured by first processing (mechanical grinding/milling) *Phyllostachys bambusoides.* The plant is then extracted in water and filtered.

Phyllostachys bambusoides, more commonly known as bamboo, has a long history of consumption as a traditional food throughout the United States and Asia (China, India, and Japan). Bamboo is widely used in the food industry, with young shoots being cooked as a fresh, fermented, or canned vegetable. Bamboo fiber is a common ingredient in cereals, fruit juices, bakery and meat products, sauces, cheeses, pastas, desserts and snacks. This plant contains high amounts of fiber and phyto-nutrients, categorizing it as a nutraceutical in addition to an edible food-stuff. Additionally, the shoots are free from residual toxicity and grow without the application of fertilizers or pesticides. [1,2]

Due to its' use in food and nutritional wellness products, *Phyllostachys bambusoides* derived materials such as Phyllostachys Bambusoides Extract may be classified as Generally Recognized as Safe (GRAS) according to the FDA's Federal Food, Drug and Cosmetic Act.[3]

The act states:

> Any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive.[3]

ProCutiGen™ Hold was tested using *in vitro* dermal and ocular irritation models, including phototoxicity irritation (EpiDerm™ EPI-200-SIT). This product was found to be non-irritating in all models, including non-photoxic for the *in vitro* dermal model. The full reports are attached for reference.

A *Salmonella typhimurium* reverse mutation standard plate incorporation study was conducted to evaluate whether ProCutiGen™ Hold would cause mutagenic changes in the average number of revertants for histidine-dependent *Salmonella typhimurium* strains in the presence and absence of S9 metabolic activation. This study was conducted to satisfy, in part, the Genotoxicity requirement of the International Organization for Standardization: Biological Evaluation of Medical Devices, Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity. ProCutiGen™ Hold was considered to be nonmutagenic to the *Salmonella typhimurium* tester strains under the conditions of this assay.

ProCutiGen™ Hold was also tested via the OECD TG 442C Direct Peptide Reactivity and OECD TG 442D In Vitro Skin Sensitization Assays in accordance with the EURL ECVAM and UN GHS guidelines. This product was determined to be a non-skin sensitizer in both *in chemico* and *in vitro* models.

An OECD 202 *Daphnia* spp. Acute Immobilization Test was conducted to determine the toxicity of ProCutiGen™ Hold by exposing *Daphnia* spp. to the test substance for 48 hours and measuring the immobilization rate against the control. Under the conditions of this assay according to the EU Directive 93/67/EEC, ProCutiGen™ Hold is not classified and therefore not harmful to aquatic organisms.

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Furthermore, ProCutiGen™ Hold was assessed for ready biodegradability in an aerobic aqueous medium via the OECD 301 B Ready Biodegradability: CO2 Evolution (Modified Sturm Test). ProCutiGen™ Hold achieved 91.2% biodegradation after 28 days of testing, indicating that the product meets method requirements for the Ready Biodegradable classifications.

The full reports for each safety study analyzing ProCutiGen™ Hold are attached for reference.

The above information supports the safety of ProCutiGen™ Hold in cosmetic applications at use levels of 1.0 – 10.0%. No further testing is required at this time.

1. Plants for a Future, Phyllostachys bambusoides - Siebold.&Zucc, http://www.pfaf.org/USER/Plant.aspx?LatinName=Phyllostachys+bambusoides
2. Chongtham, N., Bisht, M. S. and Haorongbam, S. (2011), Nutritional Properties of Bamboo Shoots: Potential and Prospects for Utilization as a Health Food. Comprehensive Reviews in Food Science and Food Safety, 10: 153–168
3. Federal Food, Drug and Cosmetic Act. U.S Food and Drug Administration. www.fda.gov.