Safety Statement

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Product Name: ProCutiGen® Bond

Code: 20829

INCI Name: Salvia Hispanica Seed Extract

ProCutiGen® Bond is manufactured by first processing (mechanical grinding/milling) *Salvia hispanica* Seeds. The plant is then extracted in water and filtered.

Salvia hispanica, more commonly known as chia, has been consumed as a traditional grain in central and southern America for centuries. Chia initially started as the major food crop of the indigenous people of Mexico and Guatemala and is now widely cultivated and commercialized throughout the world. Chia seeds and its oil are used in multiple food industry applications in the US, Canada, Chile, Australia, New Zealand, and Mexico. It has been widely used to make bread, oil, breakfast cereals, bars, cookie snacks, fruit juices, yogurt, and cake.[1]

Due to its' use in food and nutritional wellness products, *Salvia hispanica* derived materials such as Salvia hispanica Seed Extract may be classified as Generally Recognized as Safe (GRAS) according to the FDA's Federal Food, Drug and Cosmetic Act.[2]

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.[2]

ProCutiGen® Bond 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® Bond 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® Bond was considered to be nonmutagenic to the *Salmonella typhimurium* tester strains under the conditions of this assay.

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ProCutiGen® Bond 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® Bond 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® Bond is not classified and therefore not harmful to aquatic organisms.

Furthermore, ProCutiGen® Bond was assessed for ready biodegradability in an aerobic aqueous medium via the OECD 301 B Ready Biodegradability: CO2 Evolution (Modified Sturm Test). ProCutiGen™ Bond achieved 91.8% 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® Bond are attached for reference.

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

1. Mohd Ali, N., Yeap, S. K., Ho, W. Y., Beh, B. K., Tan, S. W., & Tan, S. G. (2012). The Promising Future of Chia, Salvia hispanica L. Journal of Biomedicine and Biotechnology. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3518271/
2. Federal Food, Drug and Cosmetic Act. U.S Food and Drug Administration. www.fda.gov.