Safety Statement

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

Product Name: Active.Lite® Hair

Code: 22045

INCI Name: Polyquaternium-80 & Water & Hydrolyzed Pea Protein & Selaginella Lepidophylla Extract

Active.Lite® Hair is manufactured by first processing (mechanical grinding/milling) *Pisum sativum* (pea) plant. The plant matter is then fermented with *Lactobacillus bulgaricus,* before filtration to isolate the protein fraction.

The *Selaginella lepidophylla* plant is simultaneously processed via grinding and/or milling followed by aqueous extraction under controlled conditions. Both plant parts are then blended together with Polyquaternium-80.

Polyquaternium-80 is a natural polymer derived from corn and coconut plants. Manufacturers of polyquaternium-80 solutions report that this product has a low irritation profile. The substance is not listed on any hazardous or carcinogenic compound databases.[1] While an official safety assessment has not yet been conducted on polyquaternium-80, there is no data available that suggests it is harmful at its typical use levels in cosmetic products.

Lactobacillus is a genus of microorganisms used to produce a variety of food products. It is a type of Lactic Acid Bacteria (LAB) and converts various sugars into lactic acid. Any existing LAB in Active.Lite® Hair is removed by filtration. Since *Lactobacillus* species are intentionally used in food, they 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]

Hydrolyzed Pea Protein is of natural origin because it is derived from the pea plant. Pea protein isolates such as, Hydrolyzed Pea Protein, are commonly used in food and nutritional wellness products like nutritional bars, ready-to-drink beverages, powders, pastas, batters, and breadings.[3] Therefore, based on the above statement, Hydrolyzed Pea Protein may be classified as GRAS according to the FDA's Federal Food, Drug and Cosmetic Act.[2]

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

Various studies have also been conducted to evaluate the safety and nutritional health benefits of *Pisum sativum* and its protein isolates. A 2006 review on legume proteins stated that peas are among the richest sources of proteins and amino acids for human and animal nutrition.[4] The edible portion of garden and protein *Pisum sativum* had a world crop production of 892 metric tons x 10^{-3}, with the biological activity of peptides from legume grains of these seeds having multiple health promoting properties such as anti-cancer, anti-obesity, and anti-inflammatory.[4]

Pisum sativum protein isolates were also investigated for use in experimental infant based formulas, as a suggested alternative to soybean formulas which commonly cause allergic reactions and intolerances.[5] In this 2001 study, iron absorption was measured in healthy non-anemic young women. The results showed increased iron availability with *Pisum sativum* protein isolate, which suggests that infant formulas based on pea-protein may be a feasible alternative to soybean based formulas.[5] This study demonstrated the safety of *Pisum sativum* protein isolate for use in nutritionally beneficial products such as infant based formulas.

There are few published reports concerning the safety of *Selaginella lepidophylla*. However, the plant was used in traditional Mexican medicines, most commonly in tea preparations.[6] Therefore it has been considered safe for use by humans for many years.

Selaginella lepidophylla is not listed on common toxic plant databases, including Poisonous Plants of North Carolina[7], Cornell University Plants Poisonous to Livestock[8], University of Pennsylvania Poisonous Plants[9], and Texas Toxic Plant Database[10].

Active.Lite® Hair was analyzed for its effect on cell viability and metabolism. The assay concluded that it is not cytotoxic and did not inhibit cell viability.

Active.Lite® Hair was tested using *in vitro* dermal and ocular irritation models. This product was found to be non-irritating in both models.

A bacterial reverse mutation study described by Ames et al. (1975) was performed to evaluate whether Active.Lite® Hair would cause mutagenic changes in the average number of reveratants for histidine-dependent *Salmonella typhimurium* strains TA98, TA100, TA1537, TA1535 and tryptophan-dependent *Escherichia coli* strain WP2uvrA in the presence and absence of Aroclor-induced rat liver S9. 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. The test article solution of Active.Lite® Hair was considered to be Non-Mutagenic to all analyzed bacterial tester strains.

Active Concepts

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

Safety Statement

Active.Lite® Hair 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.

The full reports for each safety study analyzing Active.Lite® Hair are attached for reference.

The above information supports the safety of Active.Lite® Hair in cosmetic applications at use levels referenced on the formulation guidelines. No further testing is required at this time.

1. "Safety Data Sheet- Poly Suga®Quat L-1210P". Colonial Chemical. http://www.colonialchem.com/fullpanel/uploads/files/polysugaquat-l-1210p-sds.pdf
2. Federal Food, Drug and Cosmetic Act. U.S Food and Drug Administration. www.fda.gov.
3. "US pea protein market ready to explode." FoodNavigator-USA. http://www.foodnavigator-usa.com/Markets/US-pea-protein-market-ready-to-explode
4. Duranti M. Grain legume proteins and nutraceutical properties. Filoterapia 77. 2006; 67-82.
5. Davidson L, Dimitrious T, Walczyk T, Hurrell RF. Iron absorption from experimental infant formulas based on pea (Pisum sativum)-protein isolate: the effect of phytic acid and ascorbic acid. Br J Nutr 85. 2001; 59-63. http://www.ncbi.nlm.nih.gov/pubmed/11227034
6. "Plants Used in Mexican Traditional Medicine." Armando Gonzales Stuart, PhD. http://www.herbalsafety.utep.edu/presentations/pptpresentations/Plants%20Used%20in%20Mexican%20Traditional%20Medicine-July%2004.pdf
7. "Poisonous Plants." NC Cooperative Extension Program. https://plants.ces.ncsu.edu/plants/category/poisonous-plants/
8. "Department of Animal Science - Plants Poisonous to Livestock." Cornell University College of Agriculture and Life Sciences. http://poisonousplants.ansci.cornell.edu/alphalist.html
9. "Poisonous Plants." Penn Veterinary Medicine Computer Aided Learning. http://research.vet.upenn.edu/Default.aspx?alias=research.vet.upenn.edu/poisonousplants
10. "Toxic Plants of Texas". AgriLife Extension Texas A&M System Department of Ecosystem Science and Management. http://essmextension.tamu.edu/plants/?collection=toxics