



# Safety Statement

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Product Name: AC Plant Keratin PF

Code: 20624PF

INCI Name: Hydrolyzed Corn Protein & Hydrolyzed Wheat Protein & Hydrolyzed Soy Protein

AC Plant Keratin PF is manufactured by enzymatic hydrolysis of corn, wheat, and soy proteins under controlled conditions. The hydrolysates are then filtered.

The Cosmetic Ingredient Review (CIR) conducted a safety assessment of cosmetic ingredients derived from corn (*Zea mays*), including hydrolyzed corn protein. The study included irritation, genotoxicity, carcinogenicity, and reproductive and developmental toxicity assays, mostly conducted on corn oil and corn extracts. While there is not specific safety data available on all of the ingredients tested, the Panel considered that the chemical characterization of each ingredient for which data was available was sufficient to apply the data to ingredients with similar composition. The Panel concluded that hydrolyzed corn protein is safe as presently used in cosmetic applications.<sup>1</sup>

The CIR conducted a safety assessment of hydrolyzed wheat protein and hydrolyzed wheat gluten as used in cosmetics. The proteins used in the study ranged from approximately 500 Da to greater than 30 kDa. The molecular weight range of AC Plant Keratin PF is 2-4 kDa. Peptides greater than 30 amino acids in length can precipitate Type I hypersensitivity reactions in individuals sensitized to either wheat or gluten hydrolysates. However, AC Plant Keratin PF does not exceed 30 amino acids, so it is not a risk factor for this hypersensitivity.<sup>2</sup>

The CIR also found that mice subjected to tape-stripping tests demonstrated sensitivity to hydrolyzed wheat proteins, but only at a size from about 40 kDa to 50 kDa, much larger than that of AC Plant Keratin PF. However, a variety of hydrolyzed wheat protein sizes were used to test sensitivity in the eye area, and the CIR concluded that, at this time, hydrolyzed wheat proteins should not be used on damaged skin or on mucous membranes in cosmetic products. These ingredients should also not be used in products that may be inhaled.<sup>2</sup>

The CIR found that hydrolyzed wheat protein and hydrolyzed wheat gluten are safe as used in cosmetics as long as they are formulated to minimize peptide lengths greater than 30 amino acids.<sup>2</sup>

While the CIR has not reviewed the safety of hydrolyzed soy protein, they did conduct a study regarding safety of hydrolyzed soy starch. The conclusion of the hydrolyzed soy starch report states that it is safe as presently used in cosmetics, based on toxicology testing of it and related compounds.<sup>3</sup>

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Soy protein isolate, a purified/refined form of soy protein, is on the FDA's Generally Recognized as Safe (GRAS) list. It underwent extensive safety and toxicology testing before it was declared as safe for use in food preparations.<sup>4</sup>

Active Concepts, LLC certifies that AC Plant Keratin PF is free of intact gluten.

AC Plant Keratin PF was tested using *in vitro* dermal and ocular irritation models. This product was found to be non-irritating in both models. The full report is attached for reference.

AC Plant Keratin PF was also tested for its effect on cell viability. The assay proved that AC Plant Keratin PF is capable of increasing cellular metabolism and viability.

The above information supports the safety of AC Plant Keratin PF in cosmetic applications at use levels of 1.0 – 5.0%. No further testing is required at this time.

1. "Final Report on the Safety Assessment of Cosmetic Ingredients Derived from Zea Mays (Corn)". Cosmetic Ingredient Review. <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr282.pdf>
2. "Safety Assessment of Hydrolyzed Wheat Protein and Hydrolyzed Wheat Gluten as Used in Cosmetics". Cosmetic Ingredient Review. <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/TR624.pdf>
3. "Safety Assessment of Plant Polysaccharide Gums as Used in Cosmetics". Cosmetic Ingredient Review. <http://online.personalcarecouncil.org/ctfa-static/>
4. "Soy Protein Isolate". GRAS Substances Database. U.S. Food and Drug Administration. <http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/SCOGS/ucm261441.htm>

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