



Safety Statement

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Product Name: AC Rice Curl Complex PF

Code: 20650PF

INCI Name: Water & Lactobacillus/Tomato Fruit Ferment Extract & Oryza Sativa (Rice) Extract & Keratin Amino Acids & Acyl Coenzyme A Desaturase

AC Rice Curl Complex PF is manufactured by first macerating and fermenting *Solanum lycopersicum* (tomato) with *Lactobacillus*, followed by filtration. The *Oryza sativa* (rice) and Keratin undergo separate enzymatic hydrolysis for a specific duration at an elevated temperature, and are then filtered. All materials are blended with acyl coenzyme A desaturase, then filtered.

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 AC Rice Curl Complex PF 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.¹

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.¹

Solanum lycopersicum, or tomato fruit, is widely used in both food and nutritional wellness products. The fruit leaf and vine of *Solanum lycopersicum* are also commonly used to make medicine that may help treat cancer.² Due to its wide use in the food and food-related industries, *Solanum lycopersicum* derived materials may be considered GRAS according to the FDA.¹

Since both components of *Lactobacillus*/tomato fruit ferment extract are GRAS, one can reasonably infer that the ferment produced by combining the two under specified manufacturing conditions is also GRAS.

Oryza sativa is also of natural origin and commonly used in food and nutritional wellness products.³ Therefore *Oryza sativa* derived materials may be classified as GRAS.¹

The Cosmetic Ingredient Review (CIR) conducted a safety assessment of various types of *Oryza sativa* (rice) products, including the extract, oil, bran, germ, and starch, among others. The report concluded that all types of *Oryza sativa* forms studied are safe for use in cosmetic preparations.⁴

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The CIR conducted a safety assessment of plant- and animal-derived amino acids as used in cosmetics, such as the keratin amino acids used in AC Rice Curl Complex PF. Keratin amino acids are naturally derived from sheep's wool. The conclusion of the safety assessment was that all of the amino acids tested, including keratin amino acids, are safe as currently used in cosmetics. This conclusion was based on irritation, sensitization, toxicology, and phototoxicity studies.⁵

Acyl coenzyme A desaturase is a naturally derived enzyme from *Saccharomyces cerevisiae* (yeast). Enzymes are proteins that act as catalysts in all living organisms. Along with microorganisms such as yeast, enzymes extracted from edible plants and animal tissues have been used in food manufacturing industries for centuries.⁶ Enzyme preparations are used in various food processing techniques such as processing starch into high fructose corn syrup or in the production of baked goods, such bread-making.⁷ Since yeast and yeast derived materials or enzymes are intentionally used in food, they may be classified as GRAS.

AC Rice Curl Complex 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 Rice Curl Complex PF was also tested for its effect on cell viability and metabolism. The assay concluded that it is not cytotoxic and increases cell metabolism which indicates it can safely be used in cosmetic materials, especially those suitable for applications designed to increase cell viability and metabolism. The full irritation and viability reports are attached for reference.

The above information supports the safety of AC Rice Curl Complex PF in cosmetic applications at use levels of 1.0 – 10.0%. No further testing is required at this time.

1. Federal Food, Drug and Cosmetic Act. U.S Food and Drug Administration. www.fda.gov.
2. "Tomato". Natural Medicines Comprehensive Database Consumer Version. © Therapeutic Research Faculty 2009. <http://www.webmd.com/vitamins-supplements/ingredientmono-900-tomato.aspx?activeingredientid=900&activeingredientname=tomato>
3. Begun, R., "A Global Grain: The Health Benefits and Culinary Uses of Rice." Food & Nutrition Magazine (2013). <http://www.foodandnutrition.org/May-2013/A-Global-Grain-The-Health-Benefits-and-Culinary-Uses-of-Rice/>
4. "Amended Final Report on the Safety Assessment of Oryza Sativa (Rice) Bran Oil, Oryza Sativa (Rice) Germ Oil, Rice Bran Acid, Oryza Sativa (Rice) Bran Wax, Hydrogenated Rice Bran Wax, Oryza Sativa (Rice) Bran Extract, Oryza Sativa (Rice) Extract, Oryza Sativa (Rice) Germ Powder, Oryza Sativa (Rice) Starch, Oryza Sativa (Rice) Bran, Hydrolyzed Rice Bran Extract, Hydrolyzed Rice Bran Protein, Hydrolyzed Rice Bran Extract, and Hydrolyzed Rice Protein". Cosmetic Ingredient Review. <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr403.pdf>
5. "Safety Assessment of Animal- and Plant-Derived Amion Acids as Used in Cosmetics". Cosmetic Ingredient Review. <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/FR625.pdf>
6. "Enzymes used in Food Processing". Food and Nutrition. Health Canada. http://www.hc-sc.gc.ca/fn-an/securit/addit/food_enzymes-eng.php
7. "Guidance for Industry: Enzyme Preparations: Recommendations for Submission of Chemical and Technological Data for Food Additive Petitions and GRAS Notices". Food and Drug Administration. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm217685.htm>

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