Active Concepts

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

Safety Statement

Product Name: AC Kerazyme®

Code: 16594

INCI Name: Hydrolyzed Keratin & Trametes Versicolor Extract

The manufacturing process for AC Kerazyme® takes place in two parts. The first part is the processing, via mechanical grinding or milling, of Trametes versicolor. The plant is then extracted in water under controlled conditions and filtered. Meanwhile, keratin derived from sheep's wool undergoes an enzymatic hydrolysis, after which heat treatment accomplishes enzyme denaturation. After filtration of that component, the hydrolyzed keratin and Trametes versicolor extract are blended.

There is not a specific safety data report for hydrolyzed keratin in cosmetic preparations. However, keratin, with a molecular weight of 2-4 kDa, is functionally similar to collagen. Therefore, collagen hydrolysate data may be extrapolated for keratin hydrolysates. Collagen hydrolysates are classified by the Cosmetic Ingredient Review (CIR) as Hydrolyzed Animal Protein and are safe to use up to 20.0%. The recommended use level for AC Kerazyme®, which contains 23% hydrolyzed keratin, is 1-10%. Hydrolyzed collagen, as reported by the CIR's safety assessment, is nontoxic using both oral and topical administration routes. It was minimally irritating in an ocular study at full strength, and a 50% aqueous solution of hydrolyzed collagen was only mildly irritating dermally. Studies conducted on formulations containing 2% hydrolyzed collagen were negative for systemic toxicity in animals. Clinical studies proved hydrolyzed collagen causes no skin irritation, and there was no significant evidence of sensitization.[1]

The CIR also conducted a safety assessment of animal- and plant-derived amino acids, including keratin. Keratin amino acids were not irritating in dermal or ocular studies. The CIR concluded that all 21 amino acids tested were safe for use in cosmetics.[2]

Trametes versicolor is a type of mushroom traditionally used in Chinese herbal medicines. Polysaccharide-K, a compound isolated from the fruitbody of the mushroom, has been studied by the American Cancer Society for its anti-cancer properties.[3] The Federal Food & Drug Administration (FDA) approved *Trametes versicolor* for clinical cancer trials in 2012.[4] Phase one of a clinical trial in breast cancer patients proved that orally administered *Trametes versicolor* preparations were well tolerated by patients, with up to 9 grams per day being considered safe and tolerable.[5] While topical safety data is lacking, there have been no significant adverse effects reported in ongoing trials involving this species of mushroom.

AC Kerazyme® 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.

Safety Statement

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

The above information supports the safety of AC Kerazyme® in cosmetic applications at use levels of 1-10%. No further testing is required at this time.

1. "Final Report on the Safety Assessment of Hydrolyzed Collagen". Cosmetic Ingredient Review. http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr192.pdf
2. "Safety Assessment of Animal- and Plant-Derived Amino Acids as Used in Cosmetics". Cosmetic Ingredient Review. http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/FR625.pdf
3. "Coriolus Versicolor". American Cancer Society. http://www.cancer.org/treatment/treatmentsandsideeffects/complementaryandalternativemedicine/dietandnutrition/coriolus-versicolor
4. "FDA Approves Bastyr Turkey Tail Trial for Cancer Patients". Bastyr University. http://www.bastyr.edu/news/general-news/2012/11/fda-approves-bastyr-turkey-tail-trial-cancer-patients?utm_campaign=Bastyr%2BNews%2BDecember%2B2012&utm_medium=email&utm_source=newsletter&utm_content=Full%20 Article
5. Torkelson, et. al. "Phase 1 Clinical Trial of Trametes versicolor in Women with Breast Cancer". ISRN Oncology. 2012: 251632. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3369477/