Active Concepts

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

Safety Statement

Product Name: AC CytoPure PF

Code: 20757PF

INCI Name: Crypthecodinium Cohnii Extract

AC CytoPure PF is manufactured by first fermenting *Crypthecodinium cohnii* using sulfur rich growth media. The plant matter is then filtered.

Crypthecodinium cohnii extract is derived from a non-toxigenic strain of the microalgae species *Crypthecodinium cohnii*. *Crypthecodinium cohnii* is a non-pathogenic organism, and derivatives of such have been used in food and nutritional wellness products such as dietary supplements and infant formulas.[1]

Due to the manufacturing process of AC CytoPure PF, the material does not contain viable cells of the marine dinoflagellate organism itself. Therefore, *Crypthecodinium cohnii* derived materials such as *Crypthecodinium cohnii* 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]

In vitro dermal and ocular irritation studies were conducted to evaluate whether AC CytoPure PF would induce dermal or ocular irriation in the EpiDerm™ and EpiOcular™ model assays. This product was found to be non-irritating in both models. Test substances were applied to the tissue inserts and incubated. Cell viability was measured by dehydrogenase conversion of MTT, present in cell mitochondria, into blue formazan salt that is measured after extraction from the tissue. The irritation potential of the test chemical was dictated by the reduction in tissue viability of exposed tissues compared to the negative control. Under conditions of this assay, the test article was considered to be nonirritating in both models. The substances used in these assays were undiluted. The full report is attached for reference.

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A Salmonella typhimurium reverse mutation standard plate incorporation study was conducted to evaluate whether AC CytoPure PF would cause mutagenic changes in the average number of revertants for histidine-dependent *Salmonella typhimurium* strains TA98, TA100, TA1537, TA1535 and WP2uvrA 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. Under the conditions of this assay, the test article solution was considered to be nonmutagenic to Salmonella typhimurium tester strains TA98, TA100, TA1537, TA1535 and WP2uvrA. The product was tested undiluted and the negative and positive controls performed as anticipated.

AC CytoPure PF 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 AC CytoPure PF are attached for reference.

In summary, several toxicological, irritation, and sensitization data sets exist for AC CytoPure PF, which performed with favorable results for each assay.

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

1. CFSAN/Office of Premarket Approval. http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm154126.htm
2. Federal Food, Drug and Cosmetic Act. U.S Food and Drug Administration. www.fda.gov.