Product Name: ACB Wakame Bioferment Advanced

Code: 20024

INCI Name: Undaria Pinnatifida Cell Culture Extract

ACB Wakame Bioferment Advanced is manufactured by first growing Undaria pinnatifida in cell culture, then macerating and fermenting the plant with Lactobacillus. The ferment then undergoes filtration to purify the plant culture extract.

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 ACB Wakame Bioferment Advanced 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

Undaria pinnatifida, or wakame seaweed, is widely used in both food/beverage and medicinal applications. In traditional Oriental medicine, Undaria pinnatifida has been used for blood purification, intestinal strength, skin, hair, reproductive organs and menstrual regularity. In Asia and Europe, it is commonly used in Miso soup and salads or often as a side dish to tofu. Many women also consume wakame during pregnancy and after giving birth as it contains a high content of minerals and nutrients that are important for the nutrition of nursing mothers.² Due to its wide use in the food and food-related industries, Wakame and the cell culture extract derived from Undaria pinnatifida plant cells, may be considered GRAS according to the FDA.¹

Undaria pinnatifida is part of the brown seaweed family.² The FDA Select Committee on GRAS Substances (SCOGS) investigated the safety of various species of seaweed, including brown algae. The biological information available with respect to algae, dulse, kelp and certain species derived from the like, came from studies involving several animal species that revealed no evidence of adverse health effects from the ingestion of algal species tested or from their derived products. The SCOGS concluded that there is no evidence to demonstrate or suggest reasonable grounds to suspect a hazard to the public safety or health when these plants are used at current levels or at reasonable expected levels in the future.³

¹ This information is presented in good faith but is not warranted as to accuracy of results. Also, freedom from patent infringement is not implied. This information is offered solely for your investigation, verification, and consideration.
ACB Wakame Bioferment Advanced was analyzed for its effect on cell viability and metabolism. The assay concluded that it is not cytotoxic and increased cell viability and metabolism.

ACB Wakame Bioferment Advanced was tested using *in vitro* dermal and ocular irritation models, including phototoxicity irritation (EpiDerm™ EPI-200-SIT). This product was found to be non-irritating in all models, including non-phototoxic for the *in vitro* dermal model. The full reports are attached for reference.

A *Salmonella typhimurium* reverse mutation standard plate incorporation study was conducted to evaluate whether ACB Wakame Bioferment Advanced would cause mutagenic changes in the average number of revertants for histidine-dependent *Salmonella typhimurium* strains 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. ACB Wakame Bioferment Advanced was considered to be nonmutagenic to the *Salmonella typhimurium* tester strains under the conditions of this assay.

ACB Wakame Bioferment Advanced 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.

An OECD 202 *Daphnia spp.* Acute Immobilization Test was conducted to determine the toxicity of ACB Wakame Bioferment Advanced by exposing *Daphnia spp.* to the test substance for 48 hours and measuring the immobilization rate against the control. Under the conditions of this assay according to the EU Directive 93/67/EEC, ACB Wakame Bioferment Advanced is not classified and therefore not harmful to aquatic organisms.

Furthermore, ACB Wakame Bioferment Advanced was assessed for ready biodegradability in an aerobic aqueous medium via the OECD 301 B Ready Biodegradability: CO2 Evolution (Modified Sturm Test). ACB Wakame Bioferment Advanced achieved 91.0% biodegradation after 28 days of testing, indicating that the product meets method requirements for the Ready Biodegradable classifications.

The full reports for each safety study analyzing ACB Wakame Bioferment Advanced are attached for reference.

The above information supports the safety of ACB Wakame Bioferment Advanced in cosmetic applications at use levels of 0.5 – 2.0%. No further testing is required at this time.

3. FDA’s Database of Select Committee on GRAS Substances (SCOGS) Reviews.

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