



Safety Statement

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Product Name: AcquaSeal® Algae

Code: 20852

INCI Name: Chlamydomonas Reinhardtii Extract

AcquaSeal® Algae is manufactured by first processing (mechanical grinding/milling) *Chlamydomonas Reinhardtii* The plant material then undergoes temperature fractionation to obtain the oil soluble components.

Chlamydomonas Reinhardtii is a common type of green microalgae. This genus is found all over the world in soil, fresh water, oceans and in snow in certain regions.¹ Microalgae have been part of the human diet for centuries. For example, species such as Chlorella and Spirulina are commonly used by people of Africa and Mexico as well as in the US as nutritional supplements and food ingredients. Over the past decades, microalgae biomass has been used almost exclusively in the health food market.²

Due to its' use in food and nutritional wellness products, microalgae derived materials such as *Chlamydomonas Reinhardtii* Extract may be classified as Generally Recognized as Safe (GRAS) according to the FDA's Federal Food, Drug and Cosmetic Act.³

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.³

AcquaSeal® Algae 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 AcquaSeal® Algae 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. AcquaSeal® Algae was considered to be nonmutagenic to the *Salmonella typhimurium* tester strains under the conditions of this assay.

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AcquaSeal® Algae 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 AcquaSeal® Algae 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, AcquaSeal® Algae is not classified and therefore not harmful to aquatic organisms.

Furthermore, AcquaSeal® Algae was assessed for ready biodegradability in an aerobic aqueous medium via the OECD 301 B Ready Biodegradability: CO₂ Evolution (Modified Sturm Test). AcquaSeal® Algae achieved 86.6% 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 AcquaSeal® Algae are attached for reference.

The above information supports the safety of AcquaSeal® Algae in cosmetic applications at use levels of 1.0 – 10.0%. No further testing is required at this time.

1. Chlamydomonas Resource Center (CRC) <https://www.chlamycollection.org/resources/about-chlamydomonas/>
2. Chacon-Lee, T.L. & Gonzalez-Marino, G.E. (2010) "Microalgae for 'Helathy' Foods-Possibilities and challenges". Comprehensive Reviews in Food Science and Food Safety. 9, 6 (1541-4337). <http://onlinelibrary.wiley.com/doi/10.1111/j.1541-4337.2010.00132.x/full>
3. Federal Food, Drug and Cosmetic Act. U.S Food and Drug Administration. www.fda.gov.

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