



225 Gateway Boulevard
S San Francisco CA 94080

650 780 4777 main
650 989 6700 fax

solazyme.com

September 6, 2013

National List Manager
USDA/AMS/NOP, Standard Division
1400 Independence Ave, SW
Room 2648-So., Ag Stop 0268
Washington, DC 20250-0268

RE: National List Petition for inclusion of Whole Algal Flour to 7 CFR 205.606

To Whom It May Concern,

In accordance with 72 FR 2167 (dated January 18, 2007), Solazyme, Inc. respectfully submits our petition for Whole Algal Flour to be considered for inclusion on the National Organics List under 7 CFR 205.606 – Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

There has been much debate on organisms such as algae and whether it should be considered potentially agricultural or nonagricultural. In the past, the Materials Review Board indicated that algae may be considered agricultural because they are photosynthesizing plants. However, it should be noted that algae is also a single-celled organism (microorganism) which could place it in 205.605(a) – Nonagricultural (nonorganic) substance (non-synthetic). The particular strain of algae used to make Whole Algal Flour is not cultivated in a soil-based system and is also not photosynthetic; it is a heterotrophic alga that does not use sunlight for growth but instead is cultured in fermenters. Under the suggestion of the NOP, we are submitting this petition under 205.606, however we would like the NOSB to consider placing Whole Algal Flour under 205.605 (a) based on the non-photosynthetic nature and the manufacturing process of the organism used to produce our substance.

If you have any questions, please feel free to contact me.

Regards,

Teresa Chan
Regulatory Affairs Manager
tchan@solazyme.com
Tel: 650-780-4777 x5321



Item A

- 1. Please indicate which section or sections the petitioned substance will be included on and/or removed from the National List.**

7 CFR 205.606 – Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).” However, we would like to be considered for 7 CFR 205.605(a) based on the heterotrophic nature of the algae and the manufacturing process of the organism used to produce our substance.

Item B

- 1. The substance’s chemical or material common name.**

Whole Algal Flour

- 2. The manufacturer’s or producer’s name, address and telephone number and other contact information of the manufacturer/producer of the substance listed in the petition.**

Manufacturer

Solazyme, Inc.
225 Gateway Blvd
S. San Francisco, CA 94080
Tel: 650-780-4777

Contact Person

Teresa Chan
Regulatory Affairs Manager
225 Gateway Blvd
S. San Francisco, CA 94080
Tel: 650780-4777 x 5321
tchan@solazyme.com

- 3. The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer or disinfectant. If the substance is an agricultural ingredient, the petition must provide a list of the types of product(s) (e.g., cereals, salad dressings) for which the substance will be used and a description of the substance’s function in the product(s) (e.g., ingredient, flavoring agent, emulsifier, processing aid).**



Whole Algal Flour is a whole food ingredient used as either a partial replacement for food ingredients that provide dietary fat and/or protein such as cream, milk, eggs/egg yolks, and/or butter/shortening in baked goods, beverages, dairy and egg products, sauces, gravies, margarines, salad dressings, and soups or as an added ingredient for texture and mouth feel enhancement.

- 4. A list of the crop, livestock or handling activities for which the substance will be used. If used for crops or livestock, the substance's rate and method of application must be described. If used for handling (including processing), the substance's mode of action must be described.**

Whole Algal Flour will replace a portion of cream, milk, eggs/egg yolks, and/or butter/shortening in a variety of conventional foods, including baked goods, beverages, dairy and egg products, sauces, gravies, margarines, salad dressings, and soups. As a replacement source of macronutrients and energy, the lipids, proteins, fiber and carbohydrates found in Whole Algal Flour will be digested through the same normal physiological processes by which other dried, ground plant materials common to the human diet are digested and utilized.

- 5. The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product.**

Whole Algal Flour is a whole food product made from a family of algae long consumed in other cultures globally. Microalgae, such as *Chlorella* spp., have been an accepted part of the human diet for hundreds of years, especially among the populations of Asia and sub-Saharan Africa.¹

Whole Algal Flour is manufactured by fermenting and harvesting cultures of a non-toxicogenic strain of *Chlorella protothecoides*. A pure, clonally isolated culture is initially used to prepare a master seed bank from which working seed vials are prepared. Three samples from the master and each working seed bank are characterized by molecular genotyping to demonstrate that they are genetically identical (*i.e.*, 100% homology between the six chromosomal footprints and 100% homology between their 23S ribosomal deoxyribonucleic acid (DNA) sequences).² For a production lot, a cryo-preserved working seed vial is thawed and the contents used to inoculate a flask culture, which is transferred into larger flasks at mid-log phase, and then to standard, industrial seed fermenters. Throughout the fermentation process, pH, temperature, agitation and aeration rates are controlled, and glucose or sucrose and nutrients are added. Lipid production is induced by limiting inorganic nitrogen during the fermentation process. Currently, production is done in the United States. Following completion of

¹ (Kay, 1991; Ravishankar *et al.*, 2006).

² When tested, the six 23S ribosomal DNA sequences also demonstrated 100% identity to the 23S reference sequence for the original *C. protothecoides* S106 isolate.



fermentation, the cells are inactivated by pasteurization, and separated from the culture broth by centrifugation. The separated cells are washed with water to remove the medium and other non-biomass related material and concentrated. The pH is adjusted to neutral with caustic material such as potassium hydroxide or sodium hydroxide.

At this step, the material can be provided without additional ingredients, but for some customers, food-grade antioxidants (e.g., mixed tocopherols) may be necessary to keep the product suitable for incorporation in end products. The antioxidants would be present at insignificant levels and are unlikely to have any technical effect in the final formulation. They could be considered processing aids for the end-user's application. The end user must make that determination. Our use of antioxidants is to meet customer commitments and can be provided without them to customers who request it.

The biomass is then homogenized, dried and packaged. If needed, food grade flow agents may be added to assist processing through drying and packaging; at present the use of such agents is not part of the standard process. All ingredients used during manufacture are safe and suitable.

The final product, Whole Algal Flour, is available in quantities of 15 – 25 kg packed in a bag-in-box arrangement and stored at temperatures < 25 °C.

6. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance.

Whole Algal Flour has been self- affirmed as generally recognized as safe (GRAS). The determination that Whole Algal Flour is GRAS is on the basis of scientific procedures as a Food Ingredient. There is consensus among experts, qualified by scientific training and experience to evaluate the safety of substances added to food, that Whole Algal Flour is GRAS under the intended conditions of use.

7. Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers.

A GRAS Notification was submitted to FDA (GRN 469) and a No Questions Letter from FDA was received on June 7, 2013.³

8. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance.

Whole Algal Flour does not have a CAS number. See Appendix I for a copy of the label.

³ <<http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm361155.htm>>; site accessed June 17, 2013



9. The substance’s physical properties and chemical mode of action including:

Whole Algal Flour is a golden yellow high lipid powder composed of the dried biomass of the green microalgae *Chlorella protothecoides*. Whole Algal Flour is a mixture of fiber, ash, protein, fat, and sucrose and acts as a source of macronutrients as partial replacement for cream, milk, egg/egg yolks, and/or butter/shortening. It is digested through the same normal physiological processes by which other dried, ground plant materials common to the human diet are digested and utilized. Table 1 shows the physical and chemical properties of Whole Algal Flour.

Characteristic	Value
Synonyms	High lipid Algal flour (HLAF), Algal flour, Algal flour
Appearance	Golden yellow powder
Moisture Content	≤ 10 %
Fiber Content	10 – 50 %
Ash Content	< 10 %
Protein Content	2 – 15 %
Fat Content	40 – 70 %
Lead (ppm)	< 0.5
Arsenic (ppm)	< 0.2
Mercury (ppm)	< 0.1
Cadmium (ppm)	< 0.1
Chromium (ppm)	< 2

Table 1. Physical and chemical properties of Whole Algal Flour

a) Chemical interactions with other substances, especially substances used in organic production;

Whole Algal Flour is not known to have any chemical interactions with other substances.

b) Toxicity and environmental persistence;

Whole Algal Flour is derived from natural microalgae, which is inherently biodegradable.

c) Environmental impacts from its use and/ or manufacture;

There are no known adverse environmental impacts from the intended use or manufacture of Whole Algal Flour. Whole Algal Flour is manufactured in closed



fermentation systems that meet EPA and OSHA requirements. Food grade Good Manufacturing Practices (GMP) is in place and we are unaware of any environmental issues associated with the manufacture of this product.

d) Effects on human health;

The safety of Whole Algal Flour as a food ingredient is supported by publicly available information including, but not limited to, 13-week toxicity, pathogenicity, and genotoxicity studies (Szabo *et al.*, 2012), as well as a human allergenicity trial with Whole Algal Flour (Szabo *et al.*, 2012) and a 28-day repeated dose study on the similarly composed ground yellow high-lipid *C. protothecoides* biomass (Day *et al.*, 2009; FDA, 2011).

e) Effects on soil, organisms, crops, or livestock.

Whole Algal Flour is not intended for use on soil, organisms, crops, or livestock. The source organism is not genetically modified or pathogenic. The fermentation is produced under closed systems.

10. Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies.

A substance report from the National Institute of Environmental Health Studies does not exist. See Appendix II for a copy of the Material Safety Data Sheet.

11. Research information about the substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List. For petitions to include non-organic agricultural substances onto the National List, this information item should include research concerning why the substance should be permitted in the production or handling of an organic product, including the availability of organic alternatives. Commercial availability does not depend upon geographic location or local market conditions.

See Appendix III for a list of References. Please note, no references were found on contrasting positions on inclusion of Whole Algal Flour in foods or in organic labeled foods.

Whole Algal Flour is a whole food product made from a family of algae long consumed in other cultures globally, but now offered in the US as a new food ingredient. This ingredient is considered GRAS by FDA. FDA has issued a No Questions Letter for



Whole Algal Flour (GRN 469) on June 7, 2013⁴. FDA has also issued a No Questions letter to a GRAS Notification for Algal oil made from *Chlorella protothecoides* (GRN 384)⁵, the same algal strain used for Whole Algal Flour.

Microalgae, such as *Chlorella* spp., have been an accepted part of the human diet for hundreds of years, especially among the populations of Asia and sub-Saharan Africa.⁶ Currently, wild stocks of various microalgae are harvested as food sources not only in Asia (*e.g.*, China, Japan, Burma, Thailand, India, Mongolia, and Siberia), but also in Central and South America (*e.g.*, Mexico, Bolivia, Ecuador, and Peru), Pacific island nations such as Fiji and Hawaii.⁷

Of the microalgae that are commercially cultured, those most popular in the U.S., include, but are not limited to, the green microalgae *Chlorella* spp. and *Scenedesmus* spp., and the cyanobacteria *Spirulina* spp. and *Aphanizomenon flos-aquae* spp.⁸ In the early 1970s, U.S. companies cultivating microalgae for human and animal use included Earthrise Farms⁹ in California, Cell Tech¹⁰ in Oregon and Cyanotech Corporation¹¹ in Washington¹².

Internationally, Sun Chlorella¹³ in Japan and SOSA Texcoco/Spirulina Mexicana¹⁴ in Mexico also grew microalgae during this same period.¹⁵ Consumption is not as high in the U.S. as it is among the major consuming populations of China, Korea, and Japan, *Chlorella* spp. are still widely available in U.S. markets as dietary supplements¹⁶. At least twelve different brands of chlorella products are available in forms that include powder, tablet and capsule with recommended dosages ranging from 200 mg up to 10 g/day¹⁷. National retailers Vitamin Shoppe¹⁸ and GNC¹⁹ both carry chlorella products.

⁴ <<http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm361155.htm>>; site accessed June 17, 2013

⁵ <<http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm308520.htm>>; site accessed June 17, 2013

⁶ (Kay, 1991; Ravishankar *et al.*, 2006).

⁷ (Kay, 1991).

⁸ (Kay, 1991).

⁹ <<http://www.earthrise.com/farm.html>>; site accessed February 1, 2012.

¹⁰ Currently SimpleXity Health, Inc. (<<http://www.simplexityhealth.com>>; site accessed February 1, 2012).

¹¹ <<http://www.cyanotech.com>>; site accessed February 1, 2012).

¹² (Kay, 1991).

¹³ <<http://www.sunchlorella.com>>; site accessed February 1, 2012.

¹⁴ The world's first large plant for processing microalgae (*Spirulina* spp.) was built on Lake Texacoco in the 1970s. Although Mexican *Spirulina* was first imported into the U.S. for use in health food products in 1979, in 1982 importation was blocked by U.S. authorities due to quality concerns related to pollution of the lake system. In addition to health food products, *Spirulina* was also used in animal and aquaculture feeds. *Spirulina Mexicana* has been closed for several years (<<http://www.spirulinasource.com/earthfoodch6c.html>>; site accessed February 1, 2012).

¹⁵ (Kay, 1991).

¹⁶ (Day *et al.*, 2009)

¹⁷ (Hendler and D. Rorvik, 2008; FDA, 2011)

¹⁸ <<http://www.vitaminshoppe.com>>; site accessed February 1, 2012.

¹⁹ <<http://www.gnc.com>>; site accessed February 1, 2012.



12. A “Petition Justification Statement” which provides justification for any of the following actions requested in the petition: *G. Inclusion of a Non-Organically Produced Agricultural Substance Onto the National List, § 205.606*
Provide a comparative description on why the non-organic form of the substance is necessary for use in organic handling.

Solazyme, Inc. is unaware of any commercially available, organic-certified ingredient that can be a partial replacement for dietary fat. Whole Algal Flour is a high lipid (40-70% fat) algal flour composed of the dried biomass of the microalgae *Chlorella protothecoides*. Unlike many other synthetic and non-synthetic ingredients, no GMOs, chemical modification or solvents are used in the production process. Whole Algal Flour will be used as partial replacement for cream, milk, eggs/egg yolks, and/or butter/shortening in baked goods, beverages, dairy and egg products, sauces, gravies, margarines, salad dressings, and soups. It can improve organic product nutrition without taste or texture compromise. It can be used to reduce fat in finished goods or used in smaller quantities to add indulgence or mouthfeel. Organic product producers can simplify their ingredient use and labeling with a better ingredient. Many companies use a combination of starch, gums, hydrocolloids, and fiber to try and achieve lower fat or more indulgent products. Whole Algal Flour can achieve this in one multi-component food ingredient, and create better mouthfeel without increasing viscosity. Unhealthy fats can be reduced by use of this whole food alternative.

There are no other solutions that match the functional and nutritional benefits of Whole Algal Flour in one ingredient. To achieve the same result as Whole Algal Flour, organic producers would have to use more non-synthetic or synthetic ingredients in their products. Whole Algal Flour also has the benefit of reducing the fat content in organic products without compromising taste or texture.

Whole Algal Flour is a vegan, natural, non-GMO, and gluten free product. Whole Algal Flour is a whole food and therefore no solvents are used or byproducts wasted. It is sustainably produced in food grade cGMP fermentation process with the ability to use a variety of simple sugar sources (corn, sugarcane, etc.) to create a higher order food ingredient. No sewage sludge or ionizing radiation is used in the production process. Whole Algal Flour provides an alternative to eggs, butter and other such ingredients that may be allergens to some Organic customers, and not suitable for others, such as strict Vegans. It also allows for lower fat content without sacrificing flavor, texture, and other important attributes.

Provide current and historical industry information/research/evidence that explains how or why the substance cannot be obtained organically in the *appropriate form, appropriate quality, and appropriate quantity* to fulfill an essential function in a system of organic handling.



According to Quality Assurance International (QAI), an organic certifying body, there are 57 *Chlorella* products (6 processors and 4 distributors) that have been certified organic.²⁰ However, these *Chlorella* products are dietary supplements and are not of the same composition, form or quality of Whole Algal Flour.

Appropriate form

The algal strain used in Whole Algal Flour is *Chlorella protothecoides*. We could not find any organic certified *Chlorella protothecoides* derived products. The algal strains used in Organic-certified *Chlorella* products and other (non-organic) commercially available *Chlorella* products are *Chlorella pyrenoidosa*^{21,22} and *Chlorella vulgaris*^{23,24}. The products made from these species will have different compositions of lipids and triglycerides (TAG) and therefore are not a suitable replacement for making Whole Algal Flour. A comparison of the lipid and TAG content from the different organisms are described in a paper by A. Assmann, et. al., titled, “The Potential for Micro-Algae and other ‘Micro-Crops’ to produce Sustainable Biofuels”²⁵ and include in Table 2, below. While this paper is about emerging technologies for producing biofuels, the same yield information is applicable. We could not find evidence of organically, or even non-organically, produced *Chlorella protothecoides* used as a food/food additive or dietary supplement product.

²⁰ <http://www.qai-inc.com/listings/listings_results.asp?KeyWords=chlorella&SearchType=QUICK&ShowCompany=N>; site accessed June 17, 2013

²¹ <http://www.starwest-botanicals.com/organic-chlorella_powder.html>; site accessed June 17, 2013

²² <<http://www.sunchlorella.com/product-info/whats-chlorella.html>>; site accessed June 17, 2013

²³ <http://www.npnutra.com/chlorella_details.html>; site accessed June 17, 2013

²⁴ <<http://www.algomed.de/index.php?op=produkte>>; site accessed June 17, 2013

²⁵ <<http://deepblue.lib.umich.edu/bitstream/2027.42/83511/1/April%2018%20Final%20Draft.pdf>>; site accessed June 17, 2013

Organism	System A: Autotrophic Cultivation		System B ^A : Heterotrophic Cultivation in bioreactors
	Photobioreactor (Seed Production)	Open Raceway Pond (Lipid Production)	
	<i>Chlorella vulgaris</i>	<i>Chlorella Vulgaris</i>	<i>Chlorella Protothecoides</i>
Biomass Density ^{C,G,D,S} (kg/m ³)	2.5	0.5	3 – 15
Lipid Content ^{G, T, D, F, U}	14%	35%	45% – 58%
Volume Productivity ^{C,G,D,S} (kg biomass/m ³ .day)	0.60	0.07	14.71
TAG Content ^{Q,U,E}	20%	85%	80%
Area ^{J,B,L,M} (m ²)	22	1344	6.7
Volume ^{J,B,L,M} (m ³)	1.6	324	20
Length ^{J,B,L,M} (m)	193	100	3
Breadth/Diameter ^{J,B,L,M} (m)	0.11	10	3
Depth ^{J,B,L,M} (m)	N/A	0.3	N/A
Hydraulic residence time (days)	5	5	1
Water Source	Brackish (Aquifer)	Brackish (Aquifer)	Fresh
Water Recycling	No	Yes	No
Location	Southwest	Southwest	Urban/Suburban
Energy Source	Sunlight	Sunlight	Acetate
Carbon Source	Atmospheric CO ₂	Atmospheric CO ₂	Acetate
Nitrogen source		Urea	
Phosphorus source		Super Phosphate	
Potassium		Potash Fertilizer	
Harvest Efficiency ^N	N/A.	87	90
Lipid Extraction Efficiency ^O	N/A.	70	70
TAG Refining Efficiency ^{P,Q}	N/A	80	80
Transesterification Efficiency ^R	N/A	97	97
Evaporation (per month)	No	25% -100%	No
Pesticides	No	Yes	No
GMO		Yes	Yes
Waste Management		On-site Storage	Wastewater Treatment Plant

A: O'Grady & Morgan (2011), B: Clarens et al. (2010), C: Lee (2011), D: Jorquera et al. (2009), E: Chisti (2007), F: Singh & Gu (2010), G: Brennan & Owende (2010), H: Demirbas (2009), I: Lundquist et al. (2010), J: Collet et al. (2011), L: Lardon et al. (2009), M: Sheehan et al. (1998), N: Yang (2010), O: Lee et al. (2010), P: Greenwell et al. (2009), Q: Chinnasamy et al. (2010), R: Ban et al. (2002), S: Amin (2009), T: Mata (2010), U: Hu (2008)

Table 2: System specification from A. Assmann, et. al., page 16



Appropriate quality

The manufacturing process of the Organic certified *Chlorella* products will also affect the appropriate form and quality of the substance. Algae production from the companies producing Organic and non-organic *Chlorella* is done by a photosynthetic process in open ponds or in photobioreactors.^{26,27,28} Whole Algal Flour uses a heterotrophic algae, which does not require sunlight, in a fermentation process.

Current Good Manufacturing Practices (cGMP) for Organic *Chlorella* products should be manufactured in accordance with 21 CFR 111 for dietary supplements since they are being marketed and sold as dietary supplements. Whole Algal Flour is made in accordance with 21 CFR 110 for food (and food additives). The differences in GMPs affect the quality of the product and suitability for its end use. The end use function is also different where organic *Chlorella* products are used for delivering nutrients as a dietary supplement and where Whole Algal Flour is used as a food additive to provide a partial replacement for dietary fat.

Appropriate quantity

As noted above, there are no commercially available *Chlorella protothecoides* products and no known producers of organic *Chlorella protothecoides*. Production of *Chlorella protothecoides* is done in fermentation vessels and not in open ponds since the algae are heterotrophic.

We would like to request that the NOSB review the applicability of listing Whole Algal Flour under 205.606 based on the information presented above with respect to fermentation of the algal strain and the non-photosynthetic nature of the source organism. In the past, the Materials Review Board indicated that algae may be considered agricultural because they are photosynthesizing plants. However, it should be noted that algae is also a single-celled organism (microorganism) which could place it in 205.605(a) – Nonagricultural (nonorganic) substance (non-synthetic). The particular strain of algae used to make Whole Algal Flour is not cultivated in a soil-based system and is also not photosynthetic; it is a heterotrophic alga that does not use sunlight for growth but instead is cultured in fermenters.

Summary

Table 3, below, summarizes the differences between organic *Chlorella* products and Whole Algal Flour.

²⁶ <<http://www.sunchlorella.com/corporate-activity/manufacturing-process.html>>; site accessed June 17, 2013

²⁷ <http://rfiingredients.com/sourcestainable_Spirulina_Chlorella.asp>; site accessed June 17, 2013

²⁸ <<http://www.algomed.de/index.php?lang=eng&op=algenfarm>>; site accessed June 17, 2013

	Commercially available Chlorella products	Whole Algal Flour
Strain	<i>Chlorella pyrenoidosa</i> <i>Chlorella vulgaris</i>	<i>Chlorella protothecoides</i>
Function	Dietary supplement to deliver nutrients	Food additive to provide partial replacement for dietary fat, improve nutrition, or add texture
Manufacturing	Photosynthetic process in open ponds or photobioreactors	Heterotrophic process in fermenters
GMP	21 CFR 111 – Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements	21 CFR 110 – Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food
GRAS	Not applicable for dietary supplements/dietary supplement ingredients. However, one company noted they have a self-affirmed GRAS for Chlorella ²⁹	GRAS (GRN 469)

Table 3: Summary of the differences between commercially available organic Chlorella and Whole Algal Flour

Describe industry information on substance non-availability of organic sources including but not limited to the following guidance regarding commercial availability evaluation criteria:

As indicated above, there are no known organic production of *Chlorella protothecoides* products and no suitable organic Chlorella substitute for the source organism.

(1) Regions of production, including factors such as climate and number of regions,

Many Chlorella products (organic-certified and non-organic) are produced mainly in South East Asia, the United States, or Germany^{30,31,32}. Many Chlorella producers have open ponds in China or Taiwan. Again, none of these Chlorella products use the same species of algae that is used to make Whole Algal Flour. *Chlorella protothecoides* is a heterotrophic alga and is cultivated in a fermenter, which is not climate or region dependent.

²⁹ <http://rfiingredients.com/sourcestainable_Spirulina_Chlorella.asp>; site accessed June 17, 2013

³⁰ <http://rfiingredients.com/sourcestainable_Spirulina_Chlorella.asp>; site accessed June 17, 2013

³¹ <http://www.starwest-botanicals.com/organic-chlorella_powder-cracked-cell-walls-4-oz.html>; site accessed June 17, 2013

³² <http://www.algomed.de/index.php?op=algenfarm_anlage>; >; site accessed June 17, 2013



(2) Number of suppliers and amount produced,

There are numerous companies that sell Chlorella products but none of them use *Chlorella protothecoides* and none of the algal species used for current Chlorella products are a suitable substitute for making products similar in composition to Whole Algal Flour.

(3) Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies,

Commercial production of many Chlorella products is done in open ponds in South East Asia. This can lead weather-induced shortages, especially during monsoon season, supply chain disruptions, and cost instability. Whole Algal Flour is produced in closed fermenters and can be produced in any region without having seasonal weather related concerns.

(4) Trade related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict suppliers,

We are unaware of any current trade related issues with Chlorella products; however, there is political tension in South East Asia that may affect trade and supplies. Whole Algal Flour is currently being made in the United States.

(5) Other issues which may present a challenge to a consistent supply

There are no known issues with presenting a consistent supply of Whole Algal Flour. There are no known organic certified *Chlorella protothecoides* algae and no current production of *Chlorella protothecoides* food products.

13. A Confidential Business Information Statement which describes the specific required information contained in the petition that is considered to be Confidential Business Information (CBI) or confidential commercial information and the basis for that determination.

There is no CBI in this petition.



APPENDIX I

Sample Product Label



Solazyme
225 Gateway Boulevard, South San Francisco, CA 94080

Whole Algal Flour

Ingredients:
Whole algal flour, Mixed tocopherols

Manufacturing date: XX / XXXX

Net : XX kg

Batch / Lot: XXXXX

For best results, store under cool dry conditions,
away from direct sunlight

Made in U.S.A.



APPENDIX II

Material Safety Data Sheet



MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Product Name: Whole Algal Flour

Product Use: Food Uses

Manufacturer: Solazyme, Inc.
225 Gateway Boulevard
South San Francisco, CA 94080
USA

EMERGENCY TELEPHONE NUMBER: + 1 (650) 780-4777

2. HAZARDS IDENTIFICATION

GHS Classification:

Health	Environmental	Physical
Not classified – Not a health hazard	Not determined	Not classified – Not a hazardous material

Potential Health Effects: It is recommended that users handle the material in a conservative fashion, minimizing exposure by all routes of entry.

Inhalation: Not determined

Eye Contact: Not determined

Skin Contact: Low hazard for usual handling. Protection is recommended to maintain the microbial purity of the product.

Ingestion: Low hazard for usual handling.

HMIS: Health: 0 Flammability: 0 Physical Hazard (Reactivity): 0

NFPA: Health: 0 Flammability: 0 Instability: 0

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.
Whole Algal Flour	Not applicable



4. FIRST AID MEASURES

EYES: Flush immediately with plenty of water for at least 15 minutes. Seek medical attention if irritation occurs.

SKIN: Wash the area thoroughly with soap and plenty of water. Seek medical attention if irritation occurs.

INGESTION: Product not hazardous when ingested. Seek medical attention if symptoms occur.

INHALATION: Remove to fresh air and seek medical attention.

5. FIREFIGHTING MEASURES

SUITABLE EXTINGUISHING MEDIA: Water spray.

UNSUITABLE EXTINGUISHING MEDIA: Dry chemicals or foams.

FIRE AND EXPLOSION HAZARDS: Fire or excessive heat may produce hazardous decomposition products. If generated, organic dusts can form explosive mixtures in the atmosphere. See Section 10.

SPECIAL PROTECTIVE EQUIPMENT: No special instructions apply. All responders should wear appropriate personal protective equipment (PPE). Use self-contained breathing apparatus to avoid exposure to smoke and vapor.

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: See Section 8.

ENVIRONMENTAL PRECAUTIONS: Not expected to cause any environmental hazards based on intended use.

METHODS FOR CONTAINMENT/CLEAN UP: Use appropriate equipment to collect solids in a disposable waste container. Finish cleaning with plenty of water and dispose in accordance with federal, state, and local regulations.

7. HANDLING AND STORAGE

SPECIAL PRECAUTIONS: None.

STORAGE: Store in a cool, dry place; may be refrigerated. After opening, make sure to carefully reseal.



8. EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: Process in a well ventilated area. Local exhaust ventilation should be used when handling dry material.

PERSONAL PROTECTION EQUIPMENT: Avoid breathing dust. Handle in accordance with good industrial hygiene and safety practices.

EYE PROTECTION: Wear safety goggles with side shields and other suitable PPE.

SKIN PROTECTION: Use glove and other suitable PPE. Wear a lab coat and other suitable PPE.

RESPIRATORY PROTECTION: None

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE: Golden yellow powder/flake

ODOR: Mild, neutral odor

pH: Not applicable

MELTING POINT/FREEZING POINT: Not applicable

BOILING POINT/RANGE: Not applicable

FLASH POINT: Not determined

EVAPORATION RATE: Not applicable

FLAMMABILITY (solid, gas): Non-flammable

EXPLOSIVE LIMITS:

Maximum Explosion Pressure: ~4.4 bar

Kst Value: ~ 80 bar.m/s

Explosion Class: st 1

VAPOR PRESSURE: Not applicable

VAPOR DENSITY: Not applicable

RELATIVE DENSITY: Not determined

SOLUBILITY: Dispersible



PARTITION COEFFICIENT: Not applicable

AUTOIGNITION TEMPERATURE: ~ 323 °C

DECOMPOSITION TEMPERATURE: Not determined

VISCOSITY: Not applicable

10. STABILITY AND REACTIVITY

CHEMICAL STABILITY: Material is stable under normal conditions.

HAZARDOUS DECOMPOSITION REACTIONS: Carbon dioxide, carbon monoxide.

CONDITIONS/MATERIALS TO AVOID: Prevent dust cloud. If generated, organic dust may form an explosive mixture in the atmosphere.

11. TOXICOLOGICAL INFORMATION

ORAL TOXICITY:

28-day study in rats: No reported adverse effects.

90-day study in rats: NOAEL > 4000 mg/kg; no adverse effects.

DERMAL TOXICITY: Non-sensitizing

INHALATION TOXICITY: Not determined

CARCINOGENICITY INFORMATION: IARC not listed. The ingredients of this product are not classified as carcinogenic by the ACGIH, CIRC, OSHA, or NTP.

12. ECOLOGICAL INFORMATION

ECOTOXICITY: The material is a natural microalgae.

BIOACCUMULATION: Not determined

BIODEGRADATION: Not determined

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL: Follow local, state, and federal disposal regulations.



14. TRANSPORT INFORMATION

UN NUMBER: Not applicable

UN PROPER SHIPPING NAME: Not applicable

US DOT STATUS: Not regulated

IMDG: Not classified

IATA/ICAO: Not classified

IMO: Not classified

15. REGULATORY INFORMATION

TSCA: This product is not subject to the Toxic Substances Control Act.

FDA: GRAS (Generally Recognized As Safe) for use in foodstuffs.

CERCLA: Not determined

SARA Title III (Superfund Amendments and Reauthorization Act)

Section 302 (Extremely Hazardous Substances): None

Section 311/312 (Hazard Categories): Not hazardous

Section 313 (Toxic Chemicals): None

CALIFORNIA PROP 65: This product contains no chemicals known to the state of California to cause cancer.

16. OTHER INFORMATION

Prepared By: Solazyme Regulatory Affairs

Disclaimer: The data and recommendations presented in this data sheet concerning the use of our product and the materials contained therein are believed to be accurate and are based on information which is considered reliable as of the date hereof. However, the customer should determine the suitability of such materials for his purpose before adopting them on a commercial scale. Since the use of our products by others is beyond our control, no guarantee, express or implied, is made and no responsibility assumed for the use of this material or the results to be obtained therefrom. Information on this form is furnished for the purpose of compliance with Government, Health and Safety Regulations and shall not be used for any other purposes. Moreover, the recommendations contained in this data sheet are not to be construed as a license to operate under, or a recommendation to infringe any existing patents, nor should they be confused with state, municipal or insurance requirements, or with national safety codes.



APPENDIX III

References



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