Petition of Non-organically Produced Agricultural Products for Inclusion of Chlorella powder on the § 205.606 National List

Date Submitted : 12/20/07

Submitted by:
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Item A, Category for inclusion on the National List:
Non-organic agricultural substances allowed in or on processed products labeled as "organic," §205.606.

Item B,

1. The substance's chemical or material common name:
Latin Name: *Chlorella regularis*
Common Plant Name: Chlorella
Common Product Name: Chlorella Powder
Plant part used: Whole algae

CONFIDENTIAL BUISNESS INFORMATION
2. Manufactures Contact Information
Manufacture:
Contact:
Address:
Office:

3. The intended or current use of the substance:
Chlorella Powder is used as a nutritional ingredient in dietary supplements, functional and conventional foods.

4. Used for handling (including processing); describe mode of action:
Chlorella is a nutrient dense food, high in protein, chlorophyll, vitamins, caroteinoids and other bio-active ingredients. On a dry weight basis chlorella contains about 50% protein and 25% carbohydrates. Chlorella's vitamin constituents include: vitamin A (as beta-carotene), vitamin B1, vitamin B2, vitamin B6, vitamin C, vitamins E, niacin, pantothenic acid, biotin, inositol and folic acid. Chlorella's fatty acid constituents include: myristic acid, palmitoleic acid, stearic acid, oleic acid, linoleic acid and linolenic acid. Chlorella's mineral constituents include: calcium, phosphorous, magnesium, sodium and iron. Chlorella's amino acid constituents include: arginine, lysine, histidine, phenylalanine, tyrosine, leucine, isoleucine, methionine, valine, alanine, glycine, proline, glutamic acid, serine, threonine, aspartic acid, tryptophan and cysteine.

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5. The Source of the substance and a detailed description of its manufacturing or processing procedures from the basic component to the final product:
Chlorella is single-celled green algae, belonging to the phylum Chlorophyta. It is spherical in shape, 2 to 10μm in diameter, and has no flagella. Chlorella multiples rapidly and produces the pigments Chlorophyll a and b in its chloroplasts during photsynthesis.[10]

The cultivation of chlorella begins by inoculating a mineral enriched growth medium of water & nutrients with a chlorella culture in an aerated seed tank. Once the algae begins to grow it is transferred to a larger aerated culture tank until the chlorella reaches maturation. Next the algae is separated from the growth medium by centrifugation to remove the chlorella from the nutrient growth medium and is followed by a wash. The chlorella is then sterilized, spray dried, sifted and finally packaged.

6. A summary of any available previous review by state or private certification programs or other organizations of the petitioned substance:
No information available.

7. Information regarding EPA, FDA, and state regulatory authority registrations:
This information does not exist.

8. The Chemical Abstract Service (CAS) number:
No assigned CAS number

9. The substance's physical properties and chemical mode of action including:
a) ***Chemical interaction with other substances, especially substances used in organic production:***
Chlorella is naturally occurring aquatic plant.

b) ***Toxicity and environmental persistence:***
Chlorella is a naturally occurring biodegradable non-toxic plant.

c) ***Environmental impacts from its use or manufacture:***
As referenced above, Chlorella is a naturally occurring biodegradable plant. There are no toxic chemicals used to cultivate or process this plant therefore environmental impact is negligible.

d) ***Effects on human health:***
Chlorella has no adverse effect on human health. Chlorella contains most vitamins needed in human nutrition; except for vitamin C.[9] It has had a long history of research for use around the world as a potential food source. Organizations involved in research of Chlorella for food include Stanford Research Institute, Japan Chlorella Research Center, Carnegie Institution, Rockefeller Foundation, HIH, UC Berkeley, Atomic Energy Commission and Stanford University.[10]

e) ***Effects on Soil:***

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Chlorella is a naturally occurring biodegradable plant, no negative effects on the soil and water are known.

10. Safety information about the substance including a Material Safety Data Sheet (MSDS):
MSDS is attached as separate document. No other data is available.

11. Research information about the substance which includes comprehensive substance research reviews and research bibliographies which present contrasting positions to those presented by the substance's inclusions on or removal from the National List.
We are unaware of any positions held in opposition to consideration of adding hermetically-sealed tank grown, heterotrophicly fed, Chlorella to the national list.

12. "Petition justification Statement":

We are currently unable to obtain the Chlorella powder that meets our specifications organically. We source exclusively, hermetically-sealed tank grown, heterotrophicly fed, soft shell chlorella powder for six reasons:

1) Because hermetically-sealed tank grown chlorella allows for elimination of contamination from ubiquitous free living organisms including, BMAA (b-N-methylamino-L-Alanine) or microcystins. BMAA is a neurotoxic amino acid "*produced by ubiquitous cyanobacteria that has a potential to contaminate cynanobacterial symbionts and free-living cynobacteria. The ubiquity of cynobacteria in terrestrial as well as freshwater, brackish, and marine environments, suggest a potential for widespread human exposure*". [1]
2) Extensive research has been published on chlorella's tendency to absorb and concentrate heavy metals from the environment. Growing chlorella in hermetically-sealed tanks in an environmentally controlled environment increases the likelihood to maintain the lowest levels of heavy metals possible.[2,3,4,5,6,7]
3) Hermetically-sealed tank grown chlorella allows for production of a finished product with the lowest possible microbiological counts.
4) Much of the Chlorella currently grown is not from a soft shelled strain of chlorella; sourcing a soft cell chlorella is an important purchase specification. Historically one of the greatest obstacles to using chlorella as a food source is that its hard cellulose cell wall prevented chlorella's high nutrient content from being bio-available to humans.[8] In the mid seventies a new technique was developed that broke down the chlorella's cell walls to yield a digestibility rate of greater than 80%. However, this technique adds to production costs and most importantly leaves many of the vital nutrients susceptible to degradation by oxidation. In recent years soft cell stains of chlorella have been developed that allow for human absorption of the nutrients without physically breaking the cell walls down.
5) Hermetically-sealed tank grown heterotrophiclly fed chlorella maintains more consistent nutrient levels batch to batch and yields higher average nutrient levels then outdoor grown, autotropically fed chlorella.
6) Hermetically-sealed tank grown heterotrophiclly fed chlorella produces a milder, more palatable tasting ingredient; this is particularly important in finished products such as ours where the ingredients are added directly to beverages and consumed.

The Synergy's Company procurement department is continuously searching for organic

forms of the non-organic ingredients used in the company's formulations. Regular searches include monthly reviews of trade journals, ingredient source contacts, internet searches and websites of both the Organic Trade Association and Quality Assurance International. We continue with R&D efforts to find substitute organic ingredients to replace non-organic ingredients in our formulations where possible. None of these recurring efforts has yielded a positive result for a functionally equivalent organic ingredient that is commercially available for chlorella powder.

Compatibility with sustainable agriculture:

Chlorella is grown in an aquatic environment with added nutrients and is consistent with principals of sustainable agriculture.

REFERENCES:

[1] "Diverse taxa of cyanobacteria produce b-N-methylamino-L-Alanine, a neurotoxic amino acid" by Cox et al., which appears in the April 2005 issue of the Proceedings of the National Academy of Sciences (PNAS 102: 5074-5078)

[2] "Distribution and chemical state of heavy metal ions absorbed by *Chlorella* cells". *Agriculture and Biological Chemistry and* Vol. 45, 903-908 (1981).

[3] "Accumulation of uranium by *Chlorella* cells grown under autotrophic and heterotrophic and mixotrophic culture conditions". *Agriculture and Biological Chemistry and* Vol. 45, 781-783 (1981).

[4] "Studies on the accumulation of heavy metal elements in biological systems. XVIII. Accumulation of molybdenum by green microalgae". *European Journal of Applied Microbiology and Biotechnology and* Vol. 12, 84-89 (1981).

[6] "Accumulation of cadmium by green microalgae". *European Journal of Applied Microbiology and Biotechnology and* Vol. 8, 207-215 (1979).

[7] "Uptake of manganese Ion by Chlorella regularis", *Agriculture and Biological Chemistry and* Vol. 43, 1461-1466 (1979).

[8] "Algae Burgers for a Hungry World"? The Rise and fall of Chlorella Cuisine", Belasco, W. (July 1997),vol. 38, pp. 608-634

[9] "Introductory Plant Biology", Kingsley Stern, Shelley Jansky, James Bidlack, McGraw Hill, ©2003, Pg 333 & 345

[10] "Chlorella", Nov 2007, Wikipedia on-line Encyclopedia - http://en.wikipedia.org/wiki/Chlorella

MATERIAL SAFETY DATA SHEET

Identity (as on label): Synergized® Raw Materials: Pure Chlorella™
Hermetically-sealed tank grown, soft cell wall, Kosher
Use: Dietary Supplement

Section I

MANUFACTURER:	The Synergy Company of Utah, L.L.C.
ADDRESS:	2279 South Resource Blvd.
	Moab, UT 84532
PHONE:	435-259-4787
DATE MSDS PREPARED:	June 30, 2007
PREPARED BY:	Tim HarkWright

Section II - Hazardous Ingredients/Identity Information

IDENTITY/COMMON NAME:	Chlorella
LATIN NAME:	Chlorella regularis
HAZARD CLASS:	Not regulated
HAZARDOUS COMPONENTS:	None
HEALTH HAZARD:	Nuisance dust, occur diarrhea if ingested large quantity

Section III - Physical/Chemical Characteristics

BOILING POINT:	Not established
SPECIFIC GRAVITY (H_2O=1):	Not established
VAPOR PRESSURE (MM HG):	Not established
MELTING POINT:	Not established
SOLUBILITY IN WATER:	Soluble
EVAPORATION RATE:	Not established
APPEARANCE:	Dark green, Fine Powder
ODOR:	Typical of green micro algae

Section IV - Fire and Explosion Hazard Data

FLASH POINT:	Not established
FLAMMABLE LIMITS:	Not established
EXTINGUISHING MEDIA:	Water, dry powder or CO_2
SPECIAL FIRE FIGHTING PROCEDURES:	None
UNUSUAL FIRE AND EXPLOSION HAZARDS:	None

Section V - Reactivity Data

STABILITY:	Stable dry powder

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CONDITIONS TO AVOID:	None
INCOMPATIBILITY:	None
HAZARDOUS POLYMERIZATION:	Will not occur
HAZARDOUS DECOMPOSITION OR BY-PRODUCTS:	None known

Section VI - Health Hazard Data

ROUTES OF ENTRY:	Inhalation, skin, ingestion
HEALTH HAZARDS:	Nuisance dust; occur diarrhea if ingested large quantity
CARCINOGENICITY:	None known
NTP:	Not applicable
IARC MONOGRAPHS:	None
SIGNS AND SYMPTOMS OF EXPOSURE:	None known
OSHA REG.:	None
MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE:	Nuisance dust; respiratory irritation possible if inhaled
EMERGENCY AND FIRST-AID PROCEDURES:	
EYES:	Irrigate thoroughly with water
SKIN:	Wash off thoroughly with soap and water
INGESTION:	No hazard anticipated
INHALATION:	Nuisance dust; remove from exposure. If irritation persists, obtain medical attention

Section VII - Precautions for Safe Handling and Use

STEPS TO TAKE IN CASE MATERIAL IS RELEASED OR SPILLED:	None
WASTE DISPOSAL METHOD:	Non-hazardous (dumpster or compost)
PRECAUTIONS TO BE TAKEN IN	

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Use: Dietary Supplement

HANDLING AND STORING:	Store in well-closed containers to prevent exposure to Moisture. Store below 70 degrees F and prevent exposure to sunlight to preserve optimal nutritional values.

Section VIII - Control Measures

RESPIRATORY PROTECTION:	Dust mask or respirator
VENTILATION:	Use local ventilation
PROTECTIVE GLOVES:	Recommended
EYE:	Goggles or safety glasses recommended
OTHER:	None

PURCHASE SPECIFICATION

A Division of The Synergy Company™

Synergized® Raw Materials:
Pure Chlorella™
Hermetically-sealed tank grown, heterotrophicly fed, soft cell wall, Kosher

Common Name:* Chlorella
Latin Name:* *Chlorella regularis*
Plant part:* Algae
Part ID:* RM10001
Country of origin:* Japan

Kosher certifier:* Kosher Overseers Associates of America

Shelf life:* 36 months from date of manufacture, unopened in original packaging
Storage:* Store away from moisture, light and heat; ≤70°F
Packaging:* 10 kg net weight, food grade bag, tin drum

TEST	SPECIFICATION	METHOD
ANALYTICAL		
Moisture*	≤7%	Gravimetric
Mesh size*	U.S. #80	Sieve Analysis
IDENTITY		
Color*	Dark green	Organoleptic
Flavor*	Typical of green micro algae	Organoleptic
Texture*	Fine powder	Organoleptic
Aroma*	Typical of green micro algae	Organoleptic
MICROBIOLOGICAL	Based on USP and EP Guidelines	
Standard plate count (SPC)*	≤10,000 CFU/g	FDA/BAM
Coliform*	≤100 CFU/g	AOAC 991.14
*E. coli**	Absent	USP
*Salmonella**	Absent	USP
*Staph. aureus**	Absent	USP
Yeast and Mold*	≤1,000 CFU/g	AOAC 997.02
HEAVY METAL	Based on NSF, EP, WHO and EPA Guidelines	
Arsenic (inorganic) (As)	≤5.0 µg/g	ICP-MS
Cadmium (Cd)	≤1.0 µg/g	ICP-MS
Lead (Pb)	≤5.0 µg/g	ICP-MS
Mercury (Hg)	≤0.2 µg/g	ICP-MS
*Required on COA		

Grown and processed without the use of GMO, Irradiation or sewer sludge.

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