

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

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Submitted by:

Tim HarkWright, Directory of Quality Assurance
The Synergy Company
2279 South Resource Boulevard
Moab, UT 84532
tharkwright@synergy-co.com
Office 435-259-4787 ext 230
Fax: 435-259-2949

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: *Cryptosyphonia woodii*
Common Plant Name: Dumontiaceae
Plant Part used: Whole plant
Common Product Name: Dumontiaceae Powder

CONFIDENTIAL BUSINESS INFORMATION

2. Manufacture’s Contact Information

Manufacturer:

Contact:
Address:
Office:
Fax:
e-mail:

3. The intended or current use of the substance:

Dumontiaceae (*Cryptosyphonia woodii*) is used as a nutraceutical ingredient for dietary supplements and functional foods.

4. Used for handling (including processing); describe mode of action:

Dumontiaceae contains a range of important phytonutrients including the phycocolloid carrageenan, phycobilins, chlorophyll a & d, carotenes and xanthophylls.^{1,2,4}

5. The source of the substance and a detailed description of it’s manufacturing or processing procedures from the basic component to the final product:

Dumontiaceae is indigenous to the Pacific coastal areas of North America from Alaska to southern California. Dumontiaceae is ethically wild harvested from the ocean floor of the pacific, it is then air dried and packaged.

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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:

a) *Chemical interaction with other substances, especially substances used in organic production:* Dumontiaceae is naturally occurring plant with no known adverse interaction with other substances.

b) *Toxicity and environmental persistence:*

Dumontiaceae is a naturally occurring biodegradable plant. Toxicity and environmental persistence are not known to be an issue.

c) *Environmental impacts from its use or manufacture:*

Dumontiaceae is ethically harvested from the ocean floor of the pacific coast of North America. The algae is then dried and packaged.

d) *Effects on human health:*

Cytotoxic studies conducted by E.F. Deig, 1974 with dumontiaceae algal extracts demonstrated their non-toxicity.⁷ Further studies sponsored by Ellis and Calvin (Chandler, 1981) also concluded dumontiaceae extracts were not cytotoxic.³ Historical records reveal that humans have collected algae for food for over 2,500 years in China. Collection of algae in Europe for food dates back 500 years. Even today marine algae is commonly consumed as a conventional food by many people in the Far East.^{1,5}

Red and Brown algae products are consumed daily by millions of people in the United States as ingredients in chocolate milk, toothpaste, candy, cosmetics, ice creams, salad dressings, and many other foods and household products.⁶

Dumontiaceae was marketed in the U.S. prior to October 15, 1994. The Dietary Supplement Health and Education Act (DSHEA) provides that supplement ingredients that were marketed in the U.S. prior to the enactment of DSHEA on October 15, 1994 are considered safe and are "grandfathered in" as safe for use.

e) *Effects on Soil:*

As referenced above, dumontiaceae is a naturally occurring biodegradable plant. There are no toxic chemicals used to cultivate or process this plant therefore environmental impact is negligible. No negative effects on the soil are known.

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10. Safety information about the substance including a Material Safety Data Sheet (MSDS):

MSDS is attached as a 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 Dumontiaceae to the National List.

12. "Petition justification Statement":

Organic availability:

The Synergy Companies 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 dumontiaceae.

Compatibility with sustainable agriculture:

Dumontiaceae is sustainable wild harvested from the ocean in a manner which promotes continued reproduction which is consistent with principals of sustainable agriculture.

REFERENCES:

¹ Dan Lukaczer, 1993 *Marine Red Algae, Family Dumontiaceae*, Natural Product Research Consultants,

² Kingsley Stern, Shelley Jansky, James Bidlack, 2003. *Introductory Plant Biology*, McGraw Hill, Pg 333 & 345

³ Chandler, J.W., 1981, *Evaluation of the Antiviral Properties of a Preparation from Alaskan Marine Red Algae*. Corneal Disease Research Laboratory, 410 Eklind Hall, The Swedish Hospital Medical Center, 1102 Columbia, Seattle, WA 98104

⁴ Chopin, T., B. R. Kerin, R. Mazerolle, 1999. *Phycocolloid chemistry as a taxonomic indicator of phylogeny in the Gigartinales, Rhodophyceae: a review and current developments using Fourier transform infrared diffuse reflectance spectroscopy*. *Phycol. Res.* 47: 167-188.

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⁵ Tseng, C. K. 1981. *Commercial cultivation*. In *The Biology of Seaweeds*. C. S. Lobban and M. J. Wynne eds. Blackwell Scientific Publication, Oxford. pp- 680--725.

⁶ McCoy, H. D. 1987. *The Commercial Algae; Prospects for One of the Oldest Industries*. Aqu. Mag. July/August. pp. 46-54.

⁷ Deig, E.F., et al., 1974. *Inhibition of herpesvirus replication by marine algae extracts*. *Antimicrobial Agents & Chemotherapy*, Oct. 1974:524-525. *A m.Soc. Microbiol.*6, No. 4.

MATERIAL SAFETY DATA SHEET



Identity (as on label): Synergized® Raw Materials: Red Marine Algae, Dumontiaceae
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: Dumontiaceae
LATIN NAME: None
HAZARD CLASS: Not regulated
HAZARDOUS COMPONENTS: None
HEALTH HAZARD: Nuisance dust

Section III - Physical/Chemical Characteristics

BOILING POINT: Not established
SPECIFIC GRAVITY (H₂O=1): Not established
VAPOR PRESSURE (MM HG): Not established
MELTING POINT: 237 °C
SOLUBILITY IN WATER: Does not dissolve
EVAPORATION RATE: Not established
APPEARANCE: purple or gray Granulated powder
ODOR: Typical of algae

Section IV - Fire and Explosion Hazard Data

FLASH POINT: Not established
FLAMMABLE LIMITS: Not established
EXTINGUISHING MEDIA: Water, dry powder or CO₂
SPECIAL FIRE FIGHTING PROCEDURES: None
UNUSUAL FIRE AND EXPLOSION HAZARDS: None

Section V - Reactivity Data

STABILITY: Stable dry powder
CONDITIONS TO AVOID: None

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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
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 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.

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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: Red algae, (Dumontiaceae), Wild crafted,

Common Name:* Red Algae
 Latin Name:* *Dumontiaceae*
 Part ID:* TBD
 Plant part:* Algae
 Country of origin: * Required on COA
 Certification We are seeking USDA NOP 100% organic & EU council regulation EEC 2092/91 organic,
 Required:* If available, If unavailable conventional material may be substituted. Kosher Certification.
 Date of MFG:* Required on COA
 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, doubled food grade bags in multiple foil bags, shipping carton

TEST	SPECIFICATION	METHOD
ANALYTICAL		
Moisture*	≤7%	Gravimetric
Mesh size*	U.S. #60	Sieve Analysis
IDENTITY		
Color*	Red to brown	Organoleptic
Flavor*	Typical of red algae	Organoleptic
Texture*	Fine powder	Organoleptic
Aroma*	Typical of red 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
<i>E. coli</i> *	Absent	USP
<i>Salmonella</i> *	Absent	USP
<i>Staph. Aureus</i> *	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 with out the use of GMO, Irradiation, or Sewer Sludge.