Petition of Non-organically Produced Agricultural Products for Inclusion of Ginger Rhizome Powdered Extract on the § 205.606 National List

Date Submitted : 07/30/07

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: *Zingiber officinale*
Common Plant Name: Ginger
Plant Part used: Rhizome
Common Product Name: Ginger rhizome powdered extract
Pinyin: Gan Jiang

CONFIDENTIAL BUSINESS INFORMATION
2. Manufacture's Contact Information
Manufacturer:
Contact:
Address:
Office:
Fax:
e-mail:

3. The intended or current use of the substance:
The rhizome of *Zingiber officinale* is used as a nutraceutical ingredient in dietary supplements, functional foods and conventional foods. The rhizomes are also used in traditional Chinese herbal medicine and Ayurvedic medicines. Note that The Synergy Company ginger rhizome powdered extract is used in our products in relatively small amounts, intended to provide nutritional support, compared with the therapeutic or medicinal amounts commonly used in traditional Chinese and Ayurvedic herbal medicine. The fresh rhizomes are juiced, eaten raw, preserved in syrup, and candied; it is used in soups, marinades, curries chutneys, pickles, meat and fish. Dried ginger is used to flavor cakes, cookies, curries, chutneys and sauces.[1]

4. Used for handling (including processing); describe mode of action:
Ginger rhizome powdered extract is used for nutritional supplementation. The rhizome is rich in volatile oils, gingerols and shogaols.[1] 1,8-cineole , ash, copper, magnesium, manganese, niacin and potassium.[2] The chemical composition of the essential oil obtained from the rhizomes of Zingiber officinale Roscoe from Cuba was examined by combined GC and GC/MS. The essensial oil containes ar-curcumene (22.1%), zingiberene (11.7%), [beta]-bisabolene (11.2%) and cadina-1,4-diene (12.5%).[3]

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:
Zingiber officinale is a member of the Zingiberaceae family. It was listed as a taxable commodity by the Romans in AD200, and first mentioned in Chinese medical literature during the later Han Dynasty (AD25-220). Ginger is a deciduous perennial with thick, branching rhizomes, stout upright stem, and pointed lanceolate leaves. Ginger is can be grown commercially in all warm regions of the world.[1]

The mature rhizomes are harvested, cleaned and dried for storage. The rhizome is sweet pungent and aromatic. The rhizome is shipped to a processor, where it is cleaned again, milled and then placed into an extraction kettle. Water and ethanol are added to the extraction kettle and heat is applied. The extracted liquid is concentrated into essential oils and is standardized to the desired concentration. The essential oils are mixed with organic astragalus root carrier and are then spray dried and ground into a powder. Finally the powder is sieved and packaged. In process and finished package testing occurs.

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:
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:***
Ginger is a naturally occurring plant with no known adverse interaction with other substances. The only components used in the processing of ginger extract powder are water, ethanol and organic astragalus root. The ethanol is evaporated from the powdered extract during the spray dry process.

b)***Toxicity and environmental persistence:***
Ginger is a naturally occurring biodegradable plant. The only components used in the processing of ginger extract powder is water, ethanol and organic astragalus rhizome. The ethanol is evaporated from the powdered extract during the spray dry process. Toxicity and environmental persistence are not an issue.

c) ***Environmental impacts from its use or manufacture:***
As referenced above, ginger is a naturally occurring biodegradable plant. There are no toxic chemicals used to cultivate or process this plant therefore environmental impact is negligible. The ginger rhizome is cultivated and processed without GMOs, irradiation and sewage sludge. The only components use in the processing of ginger rhizome extract powder is water, ethanol and organic astragalus root. The ethanol is evaporated from the powdered extract during the spray dry process.

d) ***Effects on human health:***
Zingiber officinale has a long history of use for culinary & medicinal uses dating back as early as AD25. Ginger rhizome powdered extract 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. Zingiber officinale is also listed in The American Herbal Products Association's "Herbs of Commerce", 2nd Edition.

e) ***Effects on Soil:***
As referenced above, ginger is a naturally occurring biodegradable plant. There are no toxic chemicals used to cultivate or process this plant therefore environmental impact is negligible. The only components used in the processing of ginger rhizome extract powder are water, ethanol and organic astragalus root. No negative effects on the soil are known.

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 that 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 ginger powdered extract to the national list.

12. "Petition justification Statement":

Organic availability:
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 ginger extract powdered extract.

Compatibility with sustainable agriculture:

The ginger rhizome extract powder is cultivated and processed without GMOs, irradiation and sewage sludge. The only components used in the processing of ginger extract powder are water, ethanol and organic astragalus root. The cultivation and harvest of the ginger plant and processing of the ginger extract powder are consistent with principles of sustainable agriculture.

REFERENCES:

[1] Deni Bown, (2001).**The Herb Society of America New Encyclopedia of Herbs and Their Uses.** Pg 410 – 411.

[2] **Dr. Duke's Phytochemical and Ethnobotanical Database,** A Phytochemical and Ethnobotanical Database compiled by Dr. Jim Duke of the Agricultural Research Service/USDA. www.ars-grin.gov/duke/

[3] **Chemical Composition of the Essential Oil of Zingiber officinale,** Roscoe L. from Cuba, Journal of Essential Oil Research: JEOR, May/Jun 2004 by Pino, Jorge A, Marbot, Rolando, Rosado, Aristides, Batista, Aidelys

MATERIAL SAFETY DATA SHEET

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Identity (as on label): Synergized® Raw Materials Chinese Herbs Powder Extracts: Jujube fruit, Ligusticum root, Atractylodes root, Peony (white) root, Polygonum (Fo-Ti) Root, Poria Root, Ginger rhizome, Tangerine Peel, Polygala Root, Rehmannia (Cooked Root),Codonopsis,

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 29, 2007
PREPARED BY:	Tim HarkWright

Section II - Hazardous Ingredients/Identity Information

IDENTITY/COMMON NAME:	Jujube fruit, Ligusticum root, Atractylodes root, Peony (white) root, Polygonum (Fo-Ti) Root, Poria Root, Ginger rhizome, Tangerine Peel, Polygala Root, Rehmannia (Cooked Root), Codonopsis,
HAZARD CLASS:	Not regulated
HAZARDOUS COMPONENTS:	None
HEALTH HAZARD:	Nuisance dust

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

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

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SYNERGY PRODUCTION LABORATORIES™

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Section VI - Health Hazard Data

ROUTES OF ENTRY:	Inhalation, skin, ingestion
HEALTH HAZARDS:	Nuisance dust; no hazard associated with ingestion
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.

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

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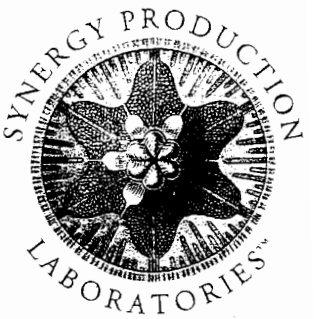
MATERIAL SAFETY DATA SHEET



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PURCHASE SPECIFICATION

Synergized® Raw Materials: Ginger Rhizome, Kosher

Common Name:*	Ginger Rhizome
Latin Name:*	Zingiber officinale
Part ID:*	TBD
Plant part:*	Rhizome
Country of origin:*	Required on COA
Certification required:*	We are seeking USDA NOP 100% organic & EU council regulation EEC 2092/91 organic, If available, If unavailable conventional material may be substituted. Kosher Certification.
Date of MFG:*	Required on COA
Shelf life:*	48 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*	≤6%	Gravimetric
Drying Method*	Spray-dried	
IDENTITY		
Color*	Beige to Brown	Organoleptic
Flavor*	Typical of Ginger Rhizome	Organoleptic
Texture*	Fine powder	Organoleptic
Aroma*	Typical of Ginger Rhizome	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 with out the uses of GMO, Irradiation, or Sewer Sludge.

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