Petition of Non-organically Produced Agricultural Products for Inclusion of Rehmannia Root 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: *Rehmannia glutinosa*
Common Plant Name: Rehmannia, Chinese foxglove
Plant Part used: Root
Common Product Name: Rehmannia root powdered extract
Pinyin: Shu Di Huang

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

3. The intended or current use of the substance:
The powdered extract of *Rehmannia glutinosa root* is used as a nutraceutical ingredient in dietary supplements, and in traditional Chinese herbal medicine. Note that The Synergy Company uses rehmannia root powdered extract in its products in relatively small amounts, intended to provide nutritional support, compared with the therapeutic or medicinal amounts commonly used in traditional Chinese herbal medicine.

4. Used for handling (including processing); describe mode of action:
Rehmannia root powdered extract is used in traditional Chinese herbal medicine for its therapeutic & tonic use.[1] The root contains the following constituents: alanine, arginine, Aspartic-acid, aucubin, beta-sitosterol, calcium, catalpol, copper, d-fructose, d-galactose, d-

glucose, gaba, Glucosamine, glutamic- acid, glycine, histidine, iron, isoleucine, ieucine, Lysine, Magnesium, Manganese, manninotriose, mannitol, melittoside, methionine, Phenylalanine, phosphoric-acid, potassium, proline, raffinose, rehmaglutins, rehmanniosides, serine, stachyose, sucrose, threonine, tyrosine, valine, verbascose, zinc.[2]

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

Rehmannia glutionosa is a member of the Scrophulariaceae Genus. The use of rehmannia root in traditional Chinese herbal medicine was first recorded during the Han Dynasty (206BC-AD23). It is one of the most popular tonic herbs in Chinese medicine and among the 50 most important Chinese Herbs.[1]

Rehmannia prefers well-drained soils, in full sun or part shade, it is prone to fugal infections in damp conditions. Rehmannia is a perennial with slender, tuberous, orange roots and a basal rosette of ovate, scalloped leaves. It has red-brown to dull yellow, purple-streaked, pendant, tubular flowers. It is native to E Asia and has been cultivated in the west.[1]

The roots are harvested in the autumn, cleaned, dried and stored. The root has a pungent and bitter flavor. During processing the root 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 as a carrier and is 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 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:***

Rehmannia is a naturally occurring plant with no known adverse interaction with other substances. The only components used in the processing of rehmannia 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:***
Rehmannia is a naturally occurring biodegradable plant. The only components used in the processing of rehmannia extract powder are water, ethanol and organic astragalus root. 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, rehmannia is a naturally occurring biodegradable plant. There are no toxic chemicals used to cultivate or process this plant therefore environmental impact is negligible. The rehmannia root is cultivated and processed without GMOs, irradiation and sewage sludge. The only components use in the processing of rehmannia root 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:***
The use of rehmannia root in traditional Chinese herbal medicine was first recorded during the Han Dynasty (206BC- AD23). It is one of the most popular tonic herbs in Chinese medicine and among the 50 most important Chinese Herbs.[1] Rehmannia root extract powder 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. Rehmannia root is also listed in the American Herbal Products Association's "Herbs of Commerce", 2nd Edition. Note that The Synergy Company uses the rehmannia root powdered extract in relatively small amounts, intended to provide nutritional support, compared with the therapeutic or medicinal amounts commonly used in traditional Chinese herbal medicine.

e) ***Effects on Soil:***
As referenced above, rehmannia 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 rehmannia root extract powder is water, ethanol and organic astragalus root. The ethanol is evaporated from the powdered extract during the spray dry process. 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 rehmannia root powdered extract to the National List.

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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 rehmannia root powdered extract.

Compatibility with sustainable agriculture:
The rehmannia root extract powder is cultivated and processed without GMOs, irradiation and sewage sludge. The only components used in the processing of rehmannia extract powder are water, ethanol and organic astragalus root. The ethanol is evaporated from the powdered extract during the spray dry process. The cultivation and, harvest of the rehmannia plant and processing of the rehmannia 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.** pp. 341-342.

[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/

MATERIAL SAFETY DATA SHEET

A Division of The Synergy Company™

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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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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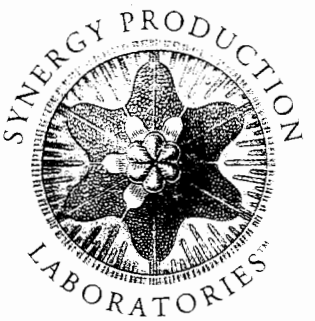
PURCHASE SPECIFICATION



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Synergized® Raw Materials:
Rehmannia Root Powder Extract

Common Name:*	Rehmannia Root
Latin Name:*	Rehmannia glutinosa
Part ID:*	TBD
Plant part:*	Root
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 Rehmannia Root	Organoleptic
Texture*	Fine powder	Organoleptic
Aroma*	Typical of Rehmannia Root	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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