

# **Petition of Non-organically Produced Agricultural Products for Inclusion of Polygala 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: *Polygala tenuifolia*  
Common Plant Name: Polygala, Siberian milkwort  
Plant Part used: Root  
Common Product Name: Polygala root powdered extract  
Pinyin: Yuan Zhi

**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 dried root of *Polygala tenuifolia* (polygala) is used as a nutraceutical ingredient in dietary supplements and traditional Chinese herbal medicine. Note that The Synergy Company uses polygala root powdered extract in its products in relatively small amounts intended to provide nutritional support, compared with the therapeutic medicinal amounts commonly used in traditional Chinese herbal medicine.

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

Polygala root powdered extract is used as a nutritional supplement.

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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:**

*Polygala tenuifolia* is a member of the Polygalaceae family. Polygala root powdered extract has been used in traditional Chinese herbal medicine during the earlier Han dynasty (206BC – AD23).<sup>1</sup> The plant prefers well-drained soils, in full sun or part shade, with ample moisture. Polygala is a perennial with thin stems and linear leaves. It has pale violet to blue flowers that are produced in lateral branches. It is native to Siberia, Mongolia and China.<sup>1</sup>

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

Polygala is a naturally occurring plant with no known adverse interaction with other substances. The only components used in the processing of polygala root 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:***

Polygala is a naturally occurring biodegradable plant. The only components used in the processing of polygala extract powder is water, ethanol and organic astragalus root. The ethanol is evaporated from the powdered extract during the spray dry process. 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, polygala is a naturally occurring biodegradable plant. There are no toxic chemicals used to cultivate or process this plant therefore environmental impact is negligible. The polygala root is cultivated and processed without GMOs, irradiation and sewage sludge. The only

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components use in the processing of polygala 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:***

Polygala root has been used in traditional Chinese herbal medicine during the earlier Han dynasty (206BC – AD23).<sup>1</sup> Polygala 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. *Polygala tenuifolia* is also listed in The American Herbal Products Association’s “Herbs of Commerce”, 2<sup>nd</sup> Edition.

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

As referenced above, polygala 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 polygala root extract powder are 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) and a substance report from the National Institute of Environmental Health Studies:**

MSDS is attached as separate document. No other data 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 Polygala 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 polygala root powdered extract.

#### **Compatibility with sustainable agriculture:**

The polygala root extract powder is cultivated and processed without GMOs, irradiation and sewage sludge. The only components used in the processing of polygala 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 polygala plant and

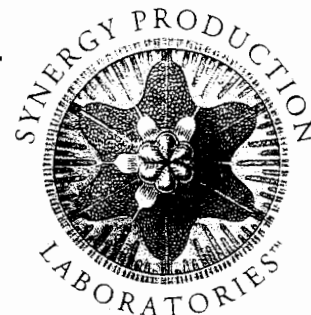
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processing of the polygala root extract powder are consistent with principles of sustainable agriculture.

### **REFERENCES:**

<sup>1</sup>Deni Bown, (2001). **The Herb Society of America New Encyclopedia of Herbs and Their Uses.** Pg 326

# MATERIAL SAFETY DATA SHEET



**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

*A Division of The Synergy Company™*

## Section I

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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

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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

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BOILING POINT:	Not established
SPECIFIC GRAVITY (H <sub>2</sub> O=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

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FLASH POINT:	Not established
FLAMMABLE LIMITS:	Not established
EXTINGUISHING MEDIA:	Water, dry powder or CO <sub>2</sub>
SPECIAL FIRE FIGHTING PROCEDURES:	None
UNUSUAL FIRE AND EXPLOSION HAZARDS:	None

## Section V - Reactivity Data

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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**

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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**

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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.

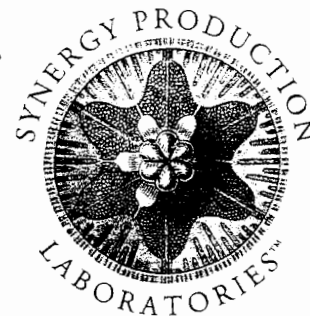
## **Section VIII - Control Measures**

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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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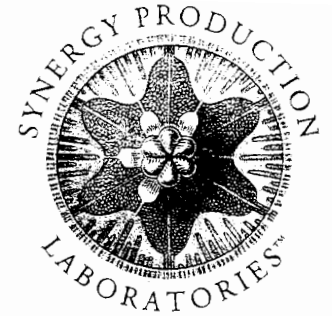
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**Use:** Dietary Supplement

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# PURCHASE SPECIFICATION



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## Synergized® Raw Materials: Polygala Root Powder Extract

Common Name:\* Polygala Root  
 Latin Name:\* Polygala tenuifolia  
 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
<b>ANALYTICAL</b>		
Moisture*	≤6%	Gravimetric
Drying Method*	Spray-dried	
<b>IDENTITY</b>		
Color*	Beige to Brown	Organoleptic
Flavor*	Typical of Polygala Root	Organoleptic
Texture*	Fine powder	Organoleptic
Aroma*	Typical of Polygala Root	Organoleptic
<b>MICROBIOLOGICAL</b> 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
<b>HEAVY METAL</b> 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.

