

# **Petition of Non-organically Produced Agricultural Products for Inclusion on the National List, § 205.606 for Camu Camu Extract Powder**

**Date Submitted :** 05/15/07

**Submitted by:**

Tim HarkWright, Directory of Quality Assurance  
The Synergy Company  
2279 South Resource Boulevard  
Moab, UT 84532  
[tharkwright@synergy-co.com](mailto: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:**

**Camu Camu Extract Powder**

**2. Manufacturers Contact Information:**

This information has been removed due to it’s confidential nature.

**3. The intended or current use of the substance:**

The Camu Camu Extract Powder is an agricultural ingredient used as a nutritional supplement in, dietary supplements, powdered drink mixes, functional foods & cosmetics.

**4. Used for handling (including processing):**

The Camu Camu Extract Powder is a rich source of concentrated natural vitamin C and other important nutrients used for nutritional supplementation.

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

The shrub is indigenous among the Amazonian flood plains and riparian zones of Brazil and Peru. The plant is specialized to tolerate flooding, it can withstand up to 5 months with the roots and much of the aerial parts submerged in water. Harvests are seasonal and occur only once per year. Plants flower at the end of the dry season and fruit during the rainy season.

The berries of the native Camu Camu bush (*Myrciaria dubia*) are wild harvested by hand in canoes in the Amazon rainforest during periods of high water or flooding. Immediately after harvest the Camu Camu berries are cooled until they reach the manufacturing facility for further processing. Keeping the berries cool until fully processed is imperative to preventing nutrient loss. Purified water is added to the berries to create a juice, the pulp is removed, then the juice is concentrated and spray-dried with 100% certified organic Cassava starch as a carrier and

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standardized to 20% vitamin C. The product is next tested to assure that the microbiological and physical specifications are met. By composition the finished product is composed of  $\leq 70\%$  Camu Camu powder extract and  $\geq 30\%$  of 100% Organic Cassava root starch.

To elaborate on the necessity of further processing of the Camu Camu berries after harvest, the juice of the berries must be concentrated to the required Vitamin C potency. Secondly the Camu Camu berry is susceptible to rapid nutrient loss without specialized processing<sup>1</sup>.

### **6. A summary of any available previous review by state or private certification programs or other organizations of the petitioned substance.**

Non-organic Camu Camu Extract Powder was recently approved for use by QAI (Quality Assurance International) in "Made With Organic" formulations.

A recent review of the non-organic Camu Camu Extract Powder, by QAI approved its use in products labeled "Organic" pending the following conditions:

- 1) Inclusion of non-organic Camu Camu Extract Powder to the National List as described in section § 205.606.
- 2) The use of non-organic Camu Camu Extract Powder must be in compliance with section §205.302 in regard to calculation of organic ingredient percentages in product formulations.
- 3) Ability to effectively demonstrate to the accredited certifying agent that the Camu Camu Extract Powder was not available in an organic form.

### **7. Information regarding EPA, FDA, and state regulatory authority registrations including registration numbers.**

N/A

### **8. The Chemical Abstract Service (CAS) NUMBER OR OTHER PRODUCT NUMBERS OF THE substance and labels of products that contains the petitioned substance.**

N/A

### **9. The substance's physical properties and chemical mode of action including:**

#### ***a) Chemical interaction with other substances, especially substances used in organic production:***

This is a naturally occurring wild harvested plant compatible with organic production.

#### ***b) Toxicity and environmental persistence:***

As a naturally occurring plant, it is biodegradable.

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

The Camu Camu is a sustainably wild harvested and certified to The Brazilian Institute of Environment and Renewable Natural Resources (IBAMA) standards. No chemicals or additives except water are used in the processing of the Camu Camu Powdered Extract, the environmental impact is negligible.

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### **9. The substance's physical properties and chemical mode of action including (continued):**

#### ***d) Effects on human health:***

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. The camu camu berry is included on the supplement industry trade group list of "Old Dietary Ingredients "marketed in the U.S. prior to October 15, 1994" and is listed in The American Herbal Products Association's "Herbs of Commerce".

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

The Camu Camu shrub is indigenous to the Amazon Rainforest.

### **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 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 Camu Camu Powdered Extract to the national list.

### **12. "Petition justification Statement":**

The Camu Camu Extract Powder is standardized to 20% naturally occurring vitamin C, making this ingredient among the richest sources of naturally occurring vitamin C in the world. The powder is also rich in Bioflavonoids and Anthocyanins, potassium, iron, niacin, riboflavin, phosphorous, amino acids and the terpene compounds; Alpha-pinene and d-limonene<sup>2,3,4</sup>. With its unique nutritional profile in addition to its high vitamin C potency there are no known existing ingredient alternatives to the Camu Camu Extract Powder.

Due to the remote growing location and pristine nature of the Amazon rainforest makes this berry particularly unique and sought after by consumers. The demand for this berry has created a significant niche market for customers seeking a natural vitamin C.

**Organic availability:** The Camu Camu berry has never been available as organic, because the berry is harvested in remote wilderness areas of the Amazon flood plains over vast geological areas it has not yet been practical to manage under an Organic system plan.

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

The Camu Camu Berry is sustainably wild harvested and certified to The Brazilian Institute of Environment and Renewable Natural Resources (IBAMA) standards. According to ethnobotanist Mark Plotkin, Ph.D., author of *Tales of a Shaman's Apprentice*, "a forest stand of Camu Camu is worth twice the amount to be gained from cutting down the forest and replacing it with cattle." Thus, these communities now have

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the opportunity to create a sustainable economy based upon their ancient tradition of wildcrafting Camu Camu berries and saving their homeland from the destructive practice of clear-cutting for other agricultural uses.

No additives other than water is used in the processing of the Camu Camu Powdered Extract. The environmental impact is negligible and the processing is consistent with organic practices.

The Camu Camu is grown without use of sewage sludge. The Camu Camu Extract Powder was grown and processed free of genetically modified source material including genetically modified DNA or proteins derived from genetically modified DNA. The product and it's ingredients are not irradiated.

### **References:**

**<sup>1</sup> Nutritional composition and vitamin C stability in stored camu-camu (*Myrciaria dubia*) pulp.**  
Nutritional composition and vitamin C stability in stored camu-camu pulp

- **Justi KC,**
- **Visentainer JV,**
- **Evelazio de Souza N,**
- **Matsushita M.**

Department of Chemistry, State University of Maringá, Maringá, Paraná, Brazil.

Camu-camu (*Myrciaria dubia*), a native fruit of the Amazon region, is one of the richest sources of vitamin C (2.4 to 3.0 g/100 g in the pulp) found in Brazil. The purpose of this work was the physical-chemical characterization of some nutrients and the valuation of vitamin C stability in stored camu-camu pulp, produced by the Agronomic Institute of Paraná (IAPAR), Paraná State, Brazil. The vitamin C determination was made by titration with potassium iodate. The fruit produced in Paraná State, presented a lower content of vitamin C than the one native of the Amazon region, possibly due to the different development conditions of the plant, and consequently of the fruit, as well as the climatic variation, the humidity and the characteristics of the soil. Regarding the vitamin C stability in stored (-18 degrees C) camu-camu pulp, a considerable decrease in its concentration until the 28th day was observed lost 23% (from 1.57 to 1.21 g/100 g), staying approximately the same until the end of the experiment. After 335 days of storage, the content found was of approximately 1.16 g/100 g of pulp, the ascorbic acid losses amounted to 26%. This content was still higher than the one found for most fruits that are good sources of this vitamin.

PMID: 11464674 [PubMed - indexed for MEDLINE]

**<sup>2</sup> Volatile composition of some Brazilian fruits: umbu-caja (*Spondias citherea*), camu-camu (*Myrciaria dubia*), Araca-boi (*Eugenia stipitata*), and Cupuacu (*Theobroma grandiflorum*).**

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- **Franco MR,**
- **Shibamoto T.**

Faculdade de Engenharia de Alimentos, UNICAMP, Campinas-SP, CP 6121, CEP 13081-970, Brazil.  
franco@fea.unicamp.br

Twenty-one volatile compounds were identified for the first time by GC-MS in umbu-caja and in camu-camu, plus 30 volatile compounds were identified in araca-boi samples. Terpenic compounds predominated among the volatile compounds in these fruit samples, with the major compounds being identified as cis-beta-ocimene and caryophyllene in the northeastern fruit; alpha-pinene and d-limonene were the most abundant volatile compounds in the headspace of the Amazonian fruit camu-camu. Sesquiterpenes were the most abundant compounds in the araca-boi sample, with germacrene D presenting a higher relative percentage. The chemical class of esters predominated in the cupuacu sample. Ethyl butyrate and hexanoate were the major compounds in the headspace of this Amazonian fruit.

PMID: 10775382 [PubMed - indexed for MEDLINE]

### <sup>3</sup> Paper

#### **Camu-camu *Myrciaria dubia* (HBK) McVaugh: Chemical composition of fruit**

Sergio M Zapata, Jean-Pierre Dufour \*

Unité de Brasserie et des Industries Alimentaires, Catholic University of Louvain, Place Croix du Sud 2, Bte 7, B-1348 Louvain-la-Neuve, Belgium

\*Correspondence to Jean-Pierre Dufour, Unité de Brasserie et des Industries Alimentaires, Catholic University of Louvain, Place Croix du Sud 2, Bte 7, B-1348 Louvain-la-Neuve, Belgium

*Myrciaria dubia* (HBK) McVaugh • camu-camu • chemical composition • fruit maturation

#### **ABSTRACT**

**Abstract:** The chemical composition of the Peruvian camu-camu fruit *Myrciaria dubia*(HBK) McVaugh was analysed at three stages of maturity (immature, midripe and ripe). As fruit matured, levels of ascorbic and dehydroascorbic acids, reducing sugars (fructose and glucose were the major sugars), amino acids (serine, valine and leucine) and soluble solids increased. Citric acid was the major acid (from 19.8 up to 29.8 g kg<sup>-1</sup>) and was responsible for the fruit's sour taste. Unlike citric acid, malic acid increased with maturation. Among the macronutrients, potassium was the most abundant mineral (711 mg kg<sup>-1</sup>) and could be considered, like vitamin C, nutritionally significant. During maturation, the fruit pulp colour turned from yellow-green to pink, presumably due to the migration of anthocyanin pigments from the peel.

Received: 25 March 1992; Revised: 11 November 1992; Accepted: 21 December 1992

**DIGITAL OBJECT IDENTIFIER (DOI)**

10.1002/jsfa.2740610310 [About DOI](#)

### <sup>4</sup> **Determination of anthocyanins from camu-camu (*Myrciaria dubia*) by HPLC-PDA, HPLC-MS, and NMR.**

**Zanatta CF, Cuevas E, Bobbio FO, Winterhalter P, Mercadante AZ.**

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Department of Food Science, Faculty of Food Engineer, State University of Campinas, UNICAMP, Post Office Box 6121, Campinas, Sao Paulo, 13083-970, Brazil.

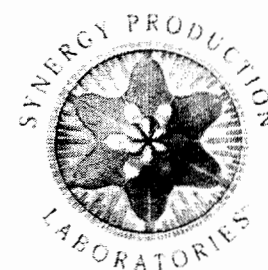
Camu-camu [*Myrciaria dubia* (HBK) McVaugh] is a small fruit native to the Amazonian rain forest. Its anthocyanin profile has now been investigated for the first time. Fruits from two different regions of the Sao Paulo state, Brazil, were analyzed. The major anthocyanins were isolated by high-speed countercurrent chromatography. HPLC-PDA, HPLC-MS/MS, and <sup>1</sup>H NMR were used to confirm the identity of the main anthocyanins of camu-camu. Cyanidin-3-glucoside was identified as the major pigment in the fruits from both regions, representing 89.5% in the fruits produced in Iguape and 88.0% in those from Mirandopolis, followed by the delphinidin-3-glucoside, ranging between 4.2 and 5.1%, respectively. Higher total anthocyanin contents were detected in the fruits from Iguape (54.0 +/- 25.9 mg/100 g) compared to those from Mirandopolis (30.3 +/- 6.8 mg/100 g), most likely because of the lower temperatures in the Iguape region.

Publication Types:

Research Support. Non-U.S. Gov't

PMID: 16302773 [PubMed - indexed for MEDLINE]

# PRODUCT SPECIFICATION



A Division of The Synergy Company™

## Synergized® Raw Materials:

**Camu Camu Extract Powder – Wildcrafted, Kosher  
standardized to a minimum of 20% naturally occurring Vitamin C**

Common Name: Camu Camu  
Latin Name: *Myrciaria dubia*  
Plant part: Berry  
Part ID: RM10289  
Country of origin: Brazil

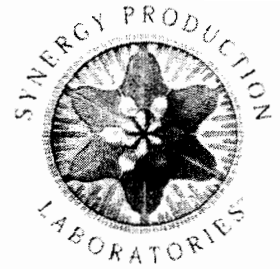
Kosher certifier: Kosher Overseers Associates of America

Shelf life: 36 months from date of manufacture, unopened in original packaging  
Storage: Store away from moisture, light and heat; ≤70°F  
Packaging: 25 kg net weight, double food grade poly bags, fiber drum

TEST	SPECIFICATION	METHOD
<b>ANALYTICAL</b>		
Moisture	≤6%	Gravimetric
Mesh size	40% max through a US 230 mesh	Sieve Analysis
Density	≥0.35 g/cm <sup>3</sup>	Volumetric
Potency	≥20% natural Vitamin C	AOAC 984.26
Carrier	≥30% Organic (non-GMO) manioc root	Formula
Drying Method	≤60°C	Spray dried
<b>IDENTITY</b>		
Color	Varies seasonally from light pink to dark beige	Organoleptic
Flavor	Sweet and sour fruit	Organoleptic
Texture	Fine powder	Organoleptic
Aroma	Typical of Camu Camu	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

Certified to meet IBAMA Wildcrafting standards and processed in accordance with NOP guidelines which do not allow for the use of GMO or Irradiation.

# MATERIAL SAFETY DATA SHEET



**Identity (as on label):** Synergized® Camu-Camu Extract Powder:  
Wildcrafted Camu-Camu Berry,  
Standardized to a minimum 20% naturally occurring Vitamin C

**Use:** Dietary Supplement

## 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:	April 10, 2007
PREPARED BY:	Tim HarkWright

## Section II - Hazardous Ingredients/Identity Information

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IDENTITY/Common Name:	Camu Camu Extract Powder
LATIN NAME:	<i>Myrciaria dubia</i>
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
APPEARANCE:	Tan to Brown Powder
ODOR:	Typical of apple

## 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

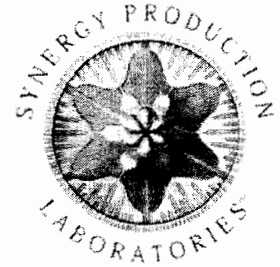
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STABILITY:	Stable dry powder
CONDITIONS TO AVOID:	None
INCOMPATIBILITY:	None
HAZARDOUS POLYMERIZATION:	Will not occur
HAZARDOUS DECOMPOSITION OR BY-PRODUCTS:	None known

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# MATERIAL SAFETY DATA SHEET



**Identity (as on label):** Synergized® Camu-Camu Extract Powder:  
Wildcrafted Camu-Camu Berry,  
Standardized to a minimum 20% naturally occurring Vitamin C

**Use:** Dietary Supplement

## ***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