




TECHNICAL DATA PACKAGE

CHASTE BERRY EXTRACT 0,5% (AGNUSIDE)

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PRODUCT SPECIFICATION SHEET

IDENTIFICATION				
NAME	CHASTE BERRY EXTRACT 0,5% (AGNUSIDE)			
BOTANICAL NAME	<i>Vitex agnus-castus L.</i>			
PLANT PART USED	Fruit			
SHELF LIFE	3 Years / 36 Months			
SOLVENT USED	Ethanol/ water			
EXTRACTION RATIO	7-10:1			
COUNTRY OF ORIGIN OF PRODUCT	Spain			
COUNTRY OF ORIGIN OF BIOMASS	Europe			
EXCIPIENTS	Maltodextrin and Silicon dioxide			
PHYSICAL & CHEMICAL ANALYSIS				
PARAMETER			SPECIFICATION	METHODS
1	APPEARANCE	Brown coloured powder		Visual
2	ODOUR & TASTE	Characteristic		Organoleptic
3	IDENTIFICATION	Complies		TLC- EP current monograph "2147" Id. C
4	TOTAL ASH	NMT 20,0%		USP <561>
5	LOSS ON DRYING	NMT 5,0%		USP <731>
	PARTICLE SIZE	NLT 95% (w/w) <180 µm		USP <786>
6	DENSITY	BULK DENSITY	NLT 0,30g/ml	USP <616>
		TAPPED DENSITY	NLT 0,40 g/ml	USP <616>
7	ASSAY	Agnuside	NLT 0,5% (w/w)	HPLC- USP "Powder chaste tree extract" monograph
MICROBIOLOGICAL CONTROL				
PARAMETER			SPECIFICATION	METHODS
	TOTAL AEROBIC MICROBIAL COUNT (TAMC)		NMT 10000 CFU/g	USP <61>
	TOTAL COMBINED YEASTS & MOULDS COUNT (TYMC)		NMT 100 CFU/g	USP <61>
	E. COLI		Absent/g	USP <62>
	SALMONELLA		Absent/25g	USP <62>
	BILE-TOLERANT GRAM NEGATIVE BACTERIA		NMT 100 CFU/g	USP <62>
CONTAMINANTS				
PARAMETER			SPECIFICATION	METHODS
	HEAVY METALS			
		LEAD (Pb)	NMT 3,0ppm	Raw material- ICP-MS
		CADMIUM (Cd)	NMT 2,0ppm	Raw material - ICP-MS
		MERCURY (Hg)	NMT 0,5ppm	Raw material - ICP-MS
		ARSENIC (As)	NMT 2,0ppm	Raw material - ICP-MS
	PESTICIDES		USP <561>	GC-MS/ LC-MS
	RESIDUAL SOLVENTS	ETHANOL	NMT 5000	GC (Acc. CHMP/ICH/82260/2006 guidelines)
	AFLATOXINS	B1	NMT 2,0ppb	Raw material- Eur. Ph. Ed. 2.8.18
		B1+B2+G1+G2	NMT 4,0ppb	Raw material- Eur. Ph. Ed. 2.8.18
STORAGE CONDITIONS: KEEP CONTAINER TIGHTLY SEALED AND STORE IN A DRY PLACE IN CLOSED ORIGINAL CONTAINER.				
MANUFACTURING SITE: THIS MATERIAL HAS BEEN CUSTOM MADE AND PROCESSED AT POLÍGONO INDUSTRIAL DE BUÑUEL, CALLE B, Nº5, CP 31540 BUÑUEL (NAVARRA), SPAIN, TO MEET SUANFARMA SPECIFICACIONES				
 José Manuel Crespo Quality Head - Nutra Division SUANFARMA				

ALLERGEN STATEMENT

We, Suanfarma, hereby declare the absence or presence of each allergen or intolerance according to the major Food Allergens specified in the US Federal Law of Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) and EU Directive 2003/89/CE amending EU Directive 2000/13/CE in the table below for **CHASTE BERRY EXTRACT 0,5%**:

SUBSTANCES OR PRODUCTS CAUSING ALLERGIES OR INTOLERANCES as per Annex II of FIC regulation	Direct incorporation as a base raw material or in derivative form (including the carriers, the additives, and the processing aids)		Presence on the production line		Presence in the productions workshop		Presence on the production factory	
	Yes (precise nature)	No	Yes (precise nature)	No	Yes (precise nature)	No	Yes (precise nature)	No
Cereals containing gluten (1) and products thereof		X		X		X		X
Crustaceans and products thereof		X		X		X		X
Eggs and products thereof		X		X		X		X
Fish and products thereof		X		X		X		X
Peanuts and products thereof		X		X		X		X
Soybeans and products thereof		X	X (Soy Isoflavones extract)		X (Soy Isoflavones extract)		X (Soy Isoflavones extract)	
Milk and products thereof (including lactose)		X		X		X		X
Nuts (2) and products thereof		X		X		X		X
Celery and products thereof		X		X		X		X
Mustard and products thereof		X		X		X		X
Sesame seeds and product thereof		X		X		X		X
Suphur dioxide and sulphites at concentrations of more than 10mg/kg or 10mg/l expressed as SO ₂		X		X		X		X
Lupin and products thereof		X		X		X		X
Mollusc and products thereof		X		X		X		X

NOTES TO THE TABLE:

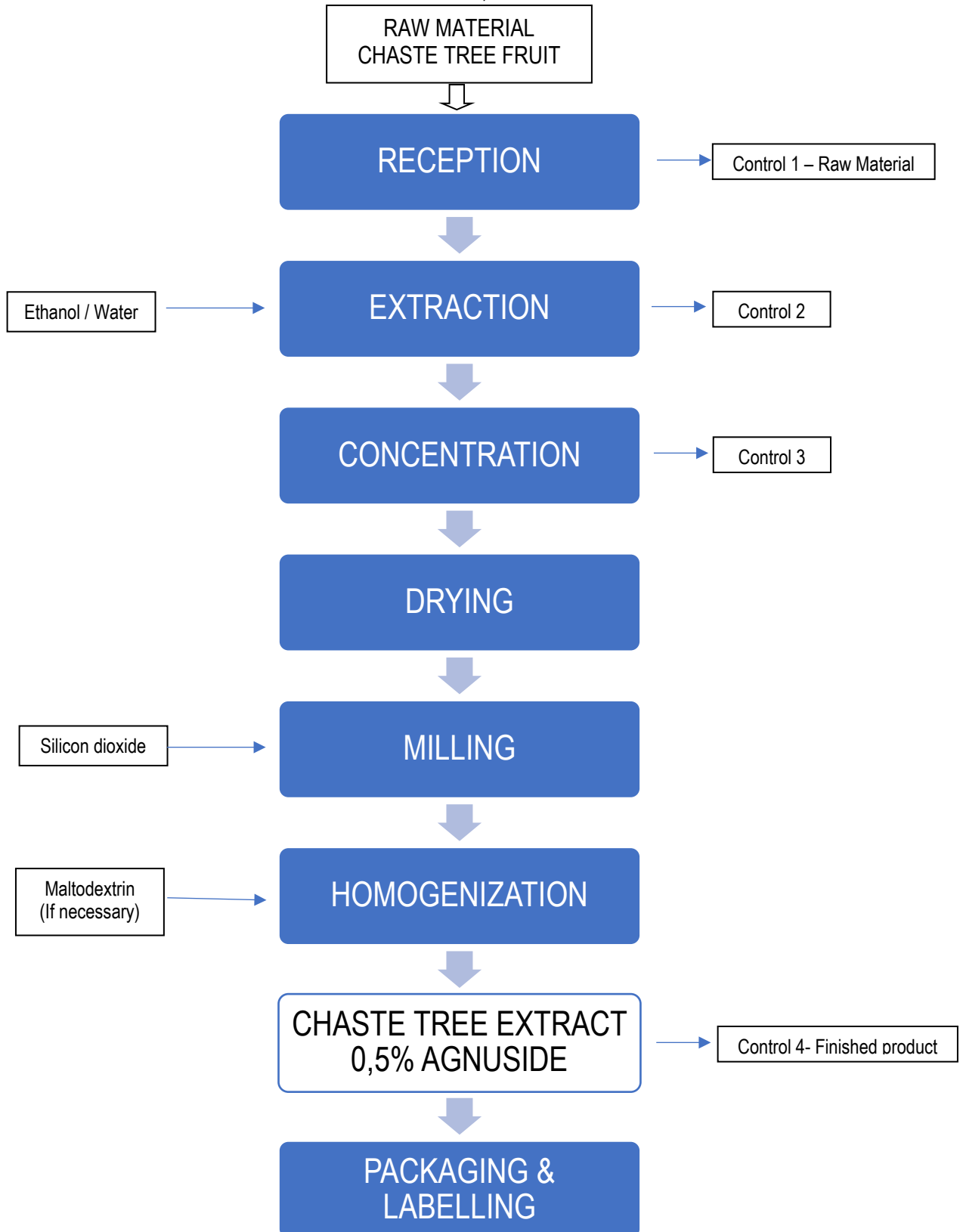
- (1) Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut or their hybridized strains, and products thereof, except:
 - a. Wheat based glucose syrups including dextrose.
 - b. Wheat based maltodextrin.
 - c. Glucose syrups based on barley.
 - d. Cereals used for making alcoholic distillates including ethyl alcohol of agriculture origin.
- (2) Namely, almonds (*Amygdalus communis* L.), hazelnuts (*Corylus avellana*), walnuts (*Junglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia or Queensland nuts (*Macadamia ternifolia*), and products thereof, except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin.



José Manuel Crespo
Quality Head – Nutra Division
SUANFARMA

MANUFACTURING PROCESS FLOW CHART

Product Name: CHASTE BERRY EXTRACT 0,5%



SAFETY DATA SHEET
(According to Regulation 453/2010)

SECTION 1: PRODUCT & COMPANY IDENTIFICATION

1.1 Product Identifier:

Product Name: CHASTE BERRY EXTRACT 0,5%
Botanical Name: *Vitex agnus-castus L.*

1.2 Supplier details:

Supplier Name: Suanfarma, Inc.
17-09 Zink Place, Unit 7, Fair Lawn,
NJ 07410, USA
Phone: +1-201-343-1188
Fax: +1-201-343-1102
E-mail: adminus@suanfarma.com

1.3 Emergency number:

CHEMTREC (24hr Access) 800-424-9300
International CHEMTREC, call: +1-703-527-3887

1.4 Use of the substance or the mixture: Pharmaceutical, food supplements, and cosmetic industry.

SECTION 2: HAZARD(S) IDENTIFICATION

2.1 Classification

None, if it is used as the intended purpose.

2.2 Labelling

None, if it is used as the intended purpose.

2.3 Other hazards

None, if it is used as the intended purpose.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Component

Substance	Vitex agnus-castus fruit extract	Maltodextrin	Silicon dioxide
CAS	91722-47-3	9050-36-6	112945-53-5 7631-86-9
EINECS Number	294-446-5	232-940-4	231-545-4

SAFETY DATA SHEET
(According to Regulation 453/2010)

SECTION 4: PRECAUTIONS FOR SAFE HANDLING AND USE

4.1 First aid measures:

General advice	In case of adverse health effects seek medical advice.
If inhaled	After prolonged or massive inhalation of the powder, remove from the exposure to fresh air. Get medical attention for any breathing difficulty.
In case of skin contact	Rinse with running water.
In case of eye contact	Rinse immediately with plenty of running water (for 10 minutes). Get medical attention, it is necessary.
If swallowed	After massive ingestion, rinse the mouth. Drink 1-2 glasses of water, and get medical attention, it is necessary.

4.2 Most important symptoms and effects (acute and delayed):

No data available.

4.3 Indication of any immediate medical attention and special treatment needed:

No data available.

SECTION 5: FIRE AND EXPLOSION HAZARD DATA

Suitable extinguishing media:	Water spray jet. Extinguishing powder.
Special hazards:	Carbon monoxide may be formed during combustion.
Special protective equipment for fire fighters:	Wear self- contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURE

Personal precautions:	Avoid dust formation.
Environmental precautions:	Do not allow to enter into surface water or drains. Do not allow to enter into soil/ subsoil.
For emergency personnel:	See section 8.
Methods and material for containment and cleaning up:	Remove mechanically

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:	Minimize dust formation and accumulation. Use adequate ventilation. Avoid open flames and sources of ignition.
Storage Conditions:	Store in a tightly sealed container. Store in a cool, dry well-ventilated place in closed original container at recommended temperature <30°C and away from heat and direct sun light.
Specific end-use:	Pharmaceutical, food supplements and cosmetic industry.

SAFETY DATA SHEET
(According to Regulation 453/2010)

SECTION 8: EXPOSURE CONTROLS & PERSONAL PROTECTION

Exposure controls:	
Additional information for system design:	Ensure good ventilation/suction at the workplace
Eye protection	Wear safety glasses.
Hand protection	Wear protective gloves.
Respiratory protection	Use precaution to avoid inhalation. In absence of suitable containment facilities, a dust mask should be worn when handling small quantities of material. For larger quantities, a dust respirator is recommended.
General protection:	Immediately remove soiled or soaked clothing. Wash hands before work breaks and after finishing work. Do not eat, drink, or smoke while working.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

Physical state:	Solid
Appearance:	Powder
Odor:	Characteristic
Color:	Brown
pH:	N.A.
Boiling point:	N.A.
Melting point:	N.A.
Flash point:	N.A.
Evaporation rate:	N.A.
Flammable limits:	N.A.
Self-flaming:	N.A.
Explosion limits:	N.A.
Combustion properties:	N.A.
Vapor pressure:	N.A.
Refractive Index:	N.A.
Density:	Not specified.
Solubility:	N.A.
Sharing coefficient:	N.A.
Viscosity	N.A.
Loss on drying	NMT 5%

SECTION 10: STABILITY AND REACTIVITY DATA

Chemical stability:	No data available.
Reactivity:	This product presents no significant reactivity hazard.
Conditions to avoid:	Avoid temperatures over 30°C, open flames and sources of ignition. Keep away from heat and direct sun light.
Materials to avoid:	No data available.
Hazardous decomposition products:	Carbon monoxide may be formed during combustion.
Possibility of hazardous reactions:	This product presents no significant reactivity hazard.

SAFETY DATA SHEET
(According to Regulation 453/2010)**SECTION 15: REGULATORY INFORMATION**

Safety, health, and environmental regulations/legislation specific for the substance
EU Regulations:

- Contains no substances with annex XVII restrictions.
- Contains no substances on the REACH Candidate list.
- Contains no REACH Annex XIV substances.

Chemical safety assessment

A chemical safety assessment has not been carried out for the mixture.

SECTION 16: OTHER INFORMATION

The information contained herein is based on the current state of knowledge and describes the product from the standpoint of appropriate precautions for use, handling, transport, and storage. There is no guarantee of product properties.

This information above is believed to be accurate and represents the best information currently available to us.

The user is responsible for verifying the data on the present MSDS and determining whether the product is suitable for your particular purpose and assume all risk of use, handling, and disposal of waste.

This information relates only to the product and does not relate to the combinations that can be made from this or processes that can be included.

ADDITIONAL INFORMATION

We, SUANFARMA, hereby declare that CHASTE BERRY EXTRACT 0,5% is manufactured in accordance with the following guidelines:

- Botanical source: *Vitex agnus-castus L.*
- The above material is manufactured in Spain.
- The biomass used is from Europe.
- No animal derived products have been used in the manufacture of the above material. The product does not enter in contact with animal derived material. For these reasons this material is free from components which can cause Bovine Spongiform Encephalopathy (BSE) or Transmissible Spongiform encephalopathy (TSE).
- The above material has not been genetically modified or exposed to genetically modified organisms during the production process and is therefore GMO free (according to EU Regulation 1829/2003 & 1830/2003).
- The above material complies with the pesticide limits set forth by USP <561>.
- Only the following organic solvents are used in the manufacturing process: Ethanol/Water
- The above material complies with California Proposition 65 Compliance and is safe for human consumption.
- The above material complies with Aflatoxin limits fixed by USP.
- The above material and its constituents are naturally free of products containing gluten.
- The above material and its constituents is free of Melamine and PCB's.
- The above material is suitable for vegetarian and vegan consumption.
- This material has not been tested on animals.
- The above material does not contain any ingredient specified in EU Directive 2003/89/CE amending EU Directive 2000/13/CE: wheat, rye, barley, oat, spelt, kamut, crustacean, egg, fish, peanut, soybean, milk, nuts (almonds, hazelnuts, walnuts, cashew, pecan nuts, Brazil nuts, pistachio nuts, macadamia), celery, mustard, sesame seeds, lupin, molluscs and products made thereof.
- The above material has not been irradiated per 7 CFR 205.105(f) requirements with understanding that "irradiation" shall be defined as outlined in 21 CFR 179.26.
- The above material has been affirmed as GRAS by FDA, when used within the limitations set forth in 21 CFR 172.510.
- The above material and its raw material have not been treated with ethylene oxide (ETO) or any other chemical sterilization agent.
- At no point in the process is the above material is manufactured, handled, or comes in contact with sewage sludge, as defined in 7 CFR 205.105(g).
- The above material neither contains nor comes in contact with banned substances listed by NSF, NFL, and WADA.
- The above material is Kosher certified.
- The above material meets the dictates of the Sharia, although it is NOT Halal certified.

The CHASTE BERRY EXTRACT 0,5% is composed by the following:

- 50%-80% Native Extract
- 20%-50% Maltodextrin (Characteristics: Corn, Food grade, geographical origin Europe)
- 0%-2% Silicon Dioxide (Characteristics: Food grade, Geographical origin Europe)

Typical nutritional data for the above material are as follows:

PARAMETER	RESULT	UNITS
Energy	45	kCal/100g
Protein	< 15	g/100g
Fat	< 6	g/100g
Carbohydrates	< 85	g/100g



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