

# SELECT BOTANICAL

## CHASTE TREE FRUIT Technical-Scientific report

### GENERAL INFORMATION

Select Botanical, SL manufactures highest quality extracts following strictest Quality Management System in compliance with the "Good Manufacturing Practices" requirements, carrying on the last manufacturing steps in classified areas (Clean Rooms).

Select Botanical, SL assures the traceability with rigorous analysis from raw material to finished product.

### REGISTRY NUMBERS

**CAS:** 91722-47-3  
**EINECS:** 264-446-5  
**INCI/ UE:** VITEX AGNUS CASTUS EXTRACT

### INFORMATION ABOUT PLANT ORIGIN

#### SPECIFICATIONS/ TECHNICAL CHARACTERISTICS

##### Raw material

Definition: Fruit of *Vitex agnus-castus* L.  
Description:  
- Macroscopic: Complies Ph.Eur.current Ed  
- Microscopic: Complies Ph.Eur.current Ed  
Loss on drying: ≤ 10 % w/w  
Pesticides: Acc. to Ph. Eur. current ed.  
Assay (HPLC): Casticin  
Assay (HPLC): Agnuside

##### Composition of Extract Preparation

Native Dry Extract  
Maltodextrin  
Colloidal Silicon Dioxide

##### Extract Specifications

Loss on drying: ≤ 6 % w/w  
Total ash: ≤ 15 % w/w  
Heavy metals: Analysis of Pb,As,Hg and Cd.  
Microbiological assay: Acc.to Ph. Eur.current Ed. "5.1.8.Point B".  
Residual solvents: According to guidelines CPMP/ICH/283/95  
Assay (HPLC): Casticin  
Assay (HPLC): Agnuside

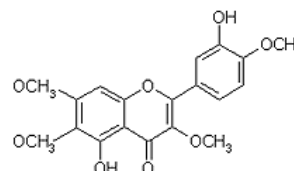
#### Botanical Description

Deciduous shrub to 6 m; leaves palmately compound; leaflets linear lanceolate, entire, white tomentose beneath, glabrous above, to 10 cm long; flowers blue to pink in spikelike panicles.

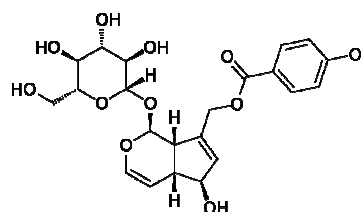
Native to Southern Europe.

Part used is the dried fruit (a small reddish black drupe). <sup>(3)</sup>

#### Analytical marker / Active principle



Casticin



Agnuside

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### PHARMACOLOGICAL STUDIES

Dopaminergic activity: Several available publications describe the effects of extracts of fruits of *Vitex agnus-castus* on prolactin secretion and dopaminergic effects in vitro and in vivo.<sup>(10)</sup> The effects of Chaste Tree have been described as similar to those of the corpus luteum. The mechanism of action may also be related to modulation of stress induced prolactin secretion via dopamine, without directly affecting luteinising hormone or follicle stimulating hormone.<sup>(5,7,8)</sup>

### PHYTOTHERAPY

#### Activities

##### Oral use:

sb Dopaminergic activity.<sup>(5, 6, 7)</sup>

##### Indications:

##### Oral use:

sb Indicated in the treatment of menstrual cycle disorders such as polymenorrhoea, oligomenorrhoea or amenorrhoea.<sup>(8)</sup>

sb Herbal medicinal product for the treatment of premenstrual syndrome.<sup>(7)</sup>

sb Traditional herbal medicinal product for the relief of minor symptoms in the days before menstruation (premenstrual syndrome).<sup>(7)</sup>

##### Undesirable effects:

There are no reported toxic effects or intolerance phenomenon to normal use doses. Cases of allergic reactions have been reported.<sup>(4, 7, 8)</sup>

##### Precautions and overdose:

Chaste Tree Extract should not be used during pregnancy and lactation without medical advice.<sup>(7,8)</sup> Patients who are using dopamine agonists, dopamine antagonists, oestrogens and antioestrogens should consult their doctor before using *Vitex agnus-castus*.<sup>(7)</sup>

##### Dosage and administration:

Chaste-Tree Dry Extract may be found formulated in liquid and solid preparations by oral use.

##### Oral use:

###### 1. Well established use:

Dry extract (DER 6-12:1), extraction solvent: ethanol 60% m/m: Once daily 20 mg extract equivalent to 180 mg of the herbal substance<sup>(7)</sup>

###### 2. Traditional use:

sb Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 58-60% V/V: once daily 40 drop<sup>(7)</sup>

sb Dry extract (DER 7-13:1), extraction solvent: ethanol 60% m/m : once daily 4 mg dry extract corresponding to 28-52 mg herbal substance<sup>(7)</sup>

sb Dry extract (DER 10.0-18.5:1), extraction solvent: ethanol 50-52% m/m : once daily 2-3 mg dry extract corresponding to 30-48 mg herbal substance<sup>(7)</sup>

### BIBLIOGRAPHY AND OTHER REFERENCE SOURCES

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Revision: 01  
January 2014