

TECHNICAL DATA SHEET

Product	Saw palmetto fruit dry extract $\geq 15.0\%$ fatty acids
Botanic Name	Serenoa repens (W. Bartram) Small (syn. Serenoa serrulata Michx G.Nicholson)
CAS Number	84604-15-9
Product Code	ESRNR5DR15
Production Site	Italy / America
Extraction Solvent	Water / Ethanol (80/20 V/V)
Excipients	Maltodextrin
Auxiliary Substances	$\leq 0.5\%$ colloidal anhydrous silica
Tapped Density	about 0.5 g/ml
Particle size	$\geq 90\%$ - goes through sieve nr.500 (sieve method Eur.Ph.)
Other information	<ul style="list-style-type: none"> - Control is made on raw material with following limits: $<5\text{ppb}$ aflatoxine B1 $<10\text{ppb}$ total aflatoxin (sum of B1,B2, G1 and G2) - Residual pesticides comply to Reg.(EC) No.396/2005 and subs. amendments and updates - product gluten free and not irradiated - Product does not contain and it is not manufactured from OGM components (EEC Reg. 1829/2003 and 1830/2003) - Storage in cool, dark and dry place <p>The product complies to Reg.(EC) No. 1933/2015</p>

Date 23/04/2019

TEST	LIMITS	METHODS
Characters	Off-white, yellowish fine powder	Inspection
Identification	Positive (TLC may be performed on the extract or on the half-processed product or on the drug)	TLC and/or botanical identification
Content	$\geq 15.0\%$ total fatty acids	gas-chromatographic
Drug extract ratio (DER)	2:1 (indicative)	
Loss on drying	$\leq 5\%$	105° C - 3 hours
Residual Solvents	$\leq 0.5\%$ ethanol	Gas Chromatography
Heavy Metals	≤ 10 ppm (Pb <3 ppm; Cd <1 ppm; Hg <0.1 ppm)	Atomic absorption
Antimicrobial Preservatives	Absent	
Microbial contamination		
Aerobic microorganism *	≤ 10000 c.f.u./g	as per Eur.Ph
Moulds-Yeasts *	≤ 100 c.f.u./g	as per Eur.Ph
Enterobacteriaceae	≤ 100 c.f.u./g	as per Eur.Ph
E.Coli (1 g)	Absent	
Salmonella (25g)	Absent	

* all indicated limits have to be interpreted as 5X according to Eur.Ph

ALLERGENS FORM		
Product(s) name:	Saw palmetto fruit dry extract $\geq 15.0\%$ fatty acids ESRNR5DR15	
Composition (complete formulation of our products including additives and adjuvants):	<ul style="list-style-type: none"> – <i>Serenoa repens</i> fruit – Maltodextrin – Colloidal anhydrous silica 	
MAIN ALLERGENS	PRESENCE (YES / NO)	QUANTITY (ppm) in case of presence
Sulphur dioxide and sulfites (specify quantity if higher than 10 ppm or 10 mg / kg)	< 10 ppm	
Peanut seed and derived products (including oil)	NO	
Cashew - nut (including oil)	NO	
Walnut (including oil)	NO	
Hazelnut (including oil)	NO	
Brazil nut (including oil)	NO	
Pecan nut (including oil)	NO	
Macadamia nut (including oil)	NO	
Pistachio - nut (including oil)	NO	
Pine kernel (including oil)	NO	
Almond (including oil)	NO	
Eggs and derived products	NO	
Fishes – crustaceans and derived products (including gelatin...)	NO	
Molluscs and derived products	NO	
Soya and derived products (including lecithin..)	NO	
Gluten (specify quantity) of following origin	NO	
▪ Wheat	NO	
▪ Rye	NO	
▪ Barley	NO	
▪ rustic wheat (lat. spelta)	NO	
▪ oat	NO	
▪ Kamut®	NO	
▪ hybrid species and derived products from gluten	NO	
Milk	NO	
Dairy products including lactose (specify quantity)	NO	
Sesame seed and derived products (including oil)	NO	
Lupin (lat. lupinus) and derived products	NO	
Celery and derived products	NO	
Mustard and derived products	NO	

THERE IS NO RISK OF CROSS-CONTAMINATION IN OUR PLANTS

In case the formula is subjected to modifications or any of the conditions we have guaranteed are changed, we oblige ourselves to inform you immediately.

DATE	POSITION	SIGNATURE OF THE PERSON RESPONSIBLE
November 2018	_____	_____

PRODUCT OF VEGETAL ORIGIN: BSE/TSE FREE

AGRONOMIC INFORMATION FORMAT	
Plant (Raw Material)	
Scientific (Latin) Name (Genus, species, Author's name):	<i>Serenoa repens</i> (W. Bartram) Small.
Regulatory reference	Drug included in the D.M. 10 August 2018
Botanical Family:	<i>Arecaceae</i>
Variety or Chemotype:	not available
Common name:	Serenoa
English Name:	SAW PALMETTO
Part used:	Fruit
Geographical Origin:	America
Growth conditions:	
- Cultivated	X
- Wild	
Harvesting conditions:	
- Manual	X
- Mechanical	
Period of harvest	September-October.
Primary processing	
- Washing	yes
- Pressing	yes
- Drying	yes
- Milling	yes

* All information included in the present document are strictly in accordance to the original documentation provided by the supplier of the product

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