

SCHEDA TECNICA
TECHNICAL DATA SHEET

Date 22/11/2019

Product	Papaya fruit fermented granulated powder
Botanic Name	Carica papaya L.
CAS Number	--
Product Code	ECRCP5PD01
Production Site	Italy / India
Excipients	Maltodextrin
Tapped Density	about 0.3 g/ml
Other information	- Particle size 250 - 500 microns - Control is made on raw material with following limits: <5ppb aflatoxine B1 <10ppb 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 The product complies to Reg.(EC) No. 1933/2015

TEST	LIMITS	METHODS
Characters	Off white - light yellow granulated 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		
Loss on drying	<= 8.0%	105° C - 3 hours
Heavy Metals	<= 10 ppm (Pb <3 ppm, Cd <1 ppm, Hg <0.1 ppm)	Atomic absorption
Antimicrobial Preservatives	Absent	
Manufacturing Process	Fermentation - Granulation	
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

I metodi di analisi non indicati sono metodi interni del produttore ottenibili su specifica richiesta.
Le informazioni sopra riportate non Vi sollevano dall'obbligo di identificare il prodotto prima dell'impiego.
Dermolife non si assume alcuna responsabilità per danni a persone o cose derivanti dall'impiego dei prodotti da noi commercializzati.
The analytical methods not listed are internal methods of the manufacturer obtainable upon specific request.
The above information will not relieve you to identify the product before use.
Dermolife does not assume any responsibility for damage to persons or property arising by the use of the products we sell.

ALLERGENS FORM

Product(s) name:	Papaya fruit fermented granulated powder ECRCP5PD01	
Composition (complete formulation of our products including additives and adjuvants):	– Carica papaya fruit – Maltodextrin	
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	

I metodi di analisi non indicati sono metodi interni del produttore ottenibili su specifica richiesta.
Le informazioni sopra riportate non Vi sollevano dall'obbligo di identificare il prodotto prima dell'impiego.
Dermolife non si assume alcuna responsabilità per danni a persone o cose derivanti dall'impiego dei prodotti da noi commercializzati.
The analytical methods not listed are internal methods of the manufacturer obtainable upon specific request.
The above information will not relieve you to identify the product before use.
Dermolife does not assume any responsibility for damage to persons or property arising by the use of the products we sell.

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 2019	_____	_____

PRODUCT OF VEGETAL ORIGIN: BSE/TSE FREE

I metodi di analisi non indicati sono metodi interni del produttore ottenibili su specifica richiesta.
Le informazioni sopra riportate non Vi sollevano dall'obbligo di identificare il prodotto prima dell'impiego.
Dermolife non si assume alcuna responsabilità per danni a persone o cose derivanti dall'impiego dei prodotti da noi commercializzati.
The analytical methods not listed are internal methods of the manufacturer obtainable upon specific request.
The above information will not relieve you to identify the product before use.
Dermolife does not assume any responsibility for damage to persons or property arising by the use of the products we sell.

AGRONOMIC INFORMATION FORMAT	
Plant (Raw Material)	
Scientific (Latin) Name (Genus, species, Author's name):	Carica papaya L.
Regulatory reference	Drug included in the D.M. 10 August 2018
Botanical Family:	Caricaceae
Variety or Chemotype:	not available
Common name:	PAPAYA
English Name:	PAPAYA
Part used:	Fruit
Geographical Origin:	India
Growth conditions:	
- Cultivated	X
- Wild	
Harvesting conditions:	
- Manual	X
- Mechanical	
Period of harvest	from February to April
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

Rev. 00 November 2019

I metodi di analisi non indicati sono metodi interni del produttore ottenibili su specifica richiesta.
Le informazioni sopra riportate non Vi sollevano dall'obbligo di identificare il prodotto prima dell'impiego.
Dermolife non si assume alcuna responsabilità per danni a persone o cose derivanti dall'impiego dei prodotti da noi commercializzati.
The analytical methods not listed are internal methods of the manufacturer obtainable upon specific request.
The above information will not relieve you to identify the product before use.
Dermolife does not assume any responsibility for damage to persons or property arising by the use of the products we sell.