



Dermolife di Margonari Maria Franca
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Mail : info@dermolife.it
Web : www.dermolife.it
P.I. 02202500225
C.F. MRGMFR66A69L378D

SPECIFICA TECNICA

TECHNICAL SPECIFICATION

DESCRIPTION

This product is a polysaccharide produced by fermentation of carbohydrates with *Xanthomonas campestris* and used as texturant. It is a thickener particularly suitable for various pharmaceutical (excipient EU & US) applications, as binding or suspending agent.

This product consists of:

- Xanthan gum

Country of Origin

France

SPECIFICATIONS

Chemical/physical specifications

Parameter		Unit	Min	Typical	Max	Text
Viscosity	1% sol.(+ 1% KCl)	mPa.s	1200		1600	*
Granulometry	< 75 µm (US 200#)	%	92			
Nitrogen content	-	%			1.5	

* Viscosity: measured on a Brookfield LVF viscometer, spindle N°3, 60 rpm

Microbiological specifications

Parameter		Unit	Min	Typical	Max	Text
E. coli	/10g					absent

European Pharmacopoeia

Parameter		Unit	Min	Typical	Max	Text
Appearance	Ph.Eur.					Pass*
Solubility	Ph.Eur.					Pass
pH	Ph.Eur.		6		8	
Identification A	Ph.Eur.					Pass
Identification B	Ph.Eur.					Pass
Apparent viscosity 24°C	Ph.Eur.	mPa.s	600			
Loss on drying	Ph.Eur.	%			15	
2-propanol	Ph.Eur.	ppm			750	
Assay: Pyruvoyl groups	Ph.Eur. on d.b.	%	1.5			
Other polysaccharides	Ph.Eur.					Pass**
Total ash	Ph.Eur.	%	6.5		16	
Tot. aerobic microbial count	Ph.Eur.	CFU/g			1000	
Tot. combined yeasts/moulds count	Ph.Eur.	CFU/g			100	

*Appearance: A white or yellowish white, free flowing powder

**Purity: Other polysaccharides: no other bands are visible

Specifications are either tested on each batch (CoA), either guaranteed based on statistical data (CoC)

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

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United States Pharmacopoeia / National Formulary

Parameter		Unit	Min	Typical	Max	Text
Identification	USP/NF					Pass
Assay: Yield as CO ₂	USP/NF on d.b.	%	4.2		5	
Loss on drying	USP/NF	%			15	
Ash	USP/NF on d.b.	%	6.5		16	
Isopropyl alcohol	USP/NF	%			0.075	
Pyruvic acid	USP/NF	%	1.5			
Viscosity 24°C	USP/NF	cps	600			
Arsenic	USP/NF	ppm			3	
Lead	USP/NF	ppm			5	
E. coli	USP/NF					absent
Salmonella	USP/NF					absent

Specifications are guaranteed based on statistical data (CoC)

Allergens (Legal directives)

Allergen information

	Presence	Comment
Cereals containing gluten and products thereof	No	*
Wheat and products thereof	No	
Crustaceans and products thereof	No	
Eggs and products thereof	No	
Fish and products thereof	No	
Peanuts and products thereof	No	
Soybeans and products thereof	No	
Milk and products thereof (including lactose)	No	
Nuts and products thereof	No	**
Celery and products thereof	No	
Mustard and products thereof	No	
Sesame seeds and products thereof	No	
Sulphur dioxide and sulphites	No	
Lupins and products thereof	No	
Molluscs and products thereof	No	

The above list of allergens is in accordance with Annex II of Regulation (EU) n° 1169/2011 on food information to consumers

The above list of allergens is in accordance with Food Allergen Labeling and Consumer Protection Act (FALCPA)

The above list of allergens is in accordance with Health Canada, the Canadian Food Inspection Agency (CFIA)

* Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains)

** Nuts i.e.: almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia nuts or Queensland nuts

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This product is not required to be labeled in accordance with the GMO labeling provisions of (EC) regulations N° 1829/2003 and 1830/2003.
This product has been produced with a non genetically modified carbohydrate and a non genetically modified nitrogen source

Legal requirements

This product is in compliance with:

This product is not intended to be used in pharmaceutical products as active ingredient since it is not manufactured according to pharma cGMPs.

The current version of the European Pharmacopoeia monograph.

The current version of the United States / National Formulary Pharmacopoeia monograph.

STANDARD PACKAGING

25 kg (net) PE bags hermetically sealed

Single plastic: white outside/blue inside

RECOMMENDED STORAGE CONDITIONS

Store in original packaging until use

Store under cool and dry conditions

SHELF LIFE FOR PACKED PRODUCT

Shelf life after production date (months): 36

SHELF LIFE COMMENTS

The specified shelf life can only be guaranteed for this product if the above mentioned recommended storage conditions are respected.

FUNCTIONALITY

DISPERSION

To disperse the product without lumps:

- premix the powder with the other dry ingredients,
 - or, disperse it in a non-solvent medium (oil, alcohol),
- and pour the preparation into the liquid while stirring. Continue stirring to obtain a complete dispersion.

DISSOLUTION

The dissolution of the product depends on the medium and the process:

it is improved by heat-treatment (time, temperature), shear-stress (propeller, exchanger, homogenizer).
A complete dissolution can be obtained in cold conditions.

APPLICATION

Pharmaceutical excipient EU/US

MEDIA / USES

The product can be used in aqueous, dairy, or fruit media, with various total solids contents.
The maximum dosage is about 1.5% according to the medium and the required final texture.

This product may contain residual cellulase and amylase activities.

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TECHNICAL SPECIFICATION

Country of origin definition:

Country of Origin or product origin is defined as the country where the material was manufactured/produced/cultivated.

When the material undergoes substantial transformation in a second country, the country in which the transformation is performed shall be considered the country of origin.

Disclaimer:

The information contained herein is believed to be true and accurate. However, all statements, recommendations or suggestions are made without any guarantee, representation or warranty, express or implied, on our part. WE THEREFORE DISCLAIM TO THE FULLEST EXTENT PERMITTED BY LAW, ANY AND ALL WARRANTIES, EXPRESS OR IMPLIED REGARDING THE INFORMATION OR PRODUCTS REFERRED TO HEREIN, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF SATISFACTORY QUALITY OR FITNESS FOR A PARTICULAR PURPOSE. We accordingly also exclude all liability in connection with the purchaser's/user's use of the products or the information referred to herein. All such risks are assumed by the purchaser/user. Further, the information contained herein is subject to change without notice. For the avoidance of doubt, however, nothing in this document excludes or limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.

Dietary information

Suitable for	Certified		Comment
Halal	Yes	Yes	
Kosher	Yes	Yes	Parve

GMO statement

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SPECIFICA TECNICA TECHNICAL SPECIFICATION

Satiaxane™ UCX 911

Nutritional Information

Average values per 100g	Unit	EU	US	Japan	Comment
Energy (kcal)	kcal	180	328	28	
Energy (kJ)	kJ	720	1394	120	
Total fat	g	0	0	0	
of which saturated	g	0	0	0	
of which Trans Fat	g	0	0	0	
Cholesterol	mg	0	0	0	
Total carbohydrates	g	0	75	0	
of which sugars	g	0	0	0	
Added sugars	g		0		
Dietary Fiber	g	75	0	75	
Protein	g	7	7	7	
Sodium	mg	3550	3550	3550	
Calcium	mg	50	50	50	
Potassium	mg	320	320	320	
Magnesium	mg	70	70	70	
Iron	mg	0	0	0	
Vitamin A	mcg (RAE)	0	0	0	
Vitamin C	mg	0	0	0	
Vitamin D	mcg	0	0	0	
Water	g	9	9	9	
Ash	g	9	9	9	

The list comprises relevant nutritional components only.

Values are calculated based on the average of product specifications. In those cases where only a minimum or a maximum value is specified, these values were taken respectively.

The EU column lists the nutritional values in accordance with Regulation (EU) n° 1169/2011 on food information to consumers.

The US column lists the nutritional values in accordance with Code of Federal Regulations (CFR 21).

The Japan column lists the nutritional values in accordance with the Japanese Legislation.

The energy values may differ per region because of different calculations.

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