

LEPIVITS Belgium  
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BELGIQUE



## Fiche technique – Spiruline 600

Code EAN : 5430002936741 (90 gélules)  
\*NUT : 3760/48

## CERTIFICAT D'ANALYSE - Organic spirulina powder

# CERTIFICATE OF ANALYSIS

*Organic product certified by Ecocert FR-BIO-01*

### Product and Batch Informations

Organic Spirulina powder

ref:SPIRUECO001

Latin name	<i>Arthrospira platensis</i>	Carrier	None
Plant part	Whole cell	Country of plant origin	Asia - China
Batch	OSP0420200629-ext	Country of manufacturing	Asia - China
MF date	29/06/2020	Expiration date	28/06/2023

ANALYSIS ITEM	SPECIFICATION	RESULT	TEST METHOD
<b>Active Ingredients/Substance to control</b>			
Assay	NLT 60% protein	66,8%	GB/T 5009.5-2010
	NLT 12% Phycocyanin	12,10%	SNT 1113-2002
	>2mg/g carotenoid*	Complies	HPLC+visible
	6-15mg/gChlorophyll*	Complies	
Substance to control *	iodide microcystins (< 1ppm)	Not tested	not tested
<b>Physical/Chemical Control</b>			
Appearance**	Dark green powder	Complies	Organoleptic
Sieve analysis	80 mesh	Conform	-
Loss on drying	NMT 7,0%	6,64%	GB 5009.3-2016
Ash	NMT 7,0%	5,90%	GB 5009.4-2016
<b>Contaminant Control*</b>			
Lead (Pb)	NMT 3ppm	0,094ppm	ICP/MS
Arsenic (As)	NMT 1ppm	0,27ppm	ICP/MS
Cadmium(Cd)	NMT 1ppm	0,011ppm	ICP/MS
Mercury (Hg)	NMT 0,1ppm	<0,005ppm	ICP/MS
Pesticides Residues	<LOQ	Complies	GC/LC
PAHs	NMT 50ppb	10ppb	GC-MS
Benzo(a)pyrene	NMT 10ppb	1,5ppb	GC-MS
Alfatoxines (B1-B2-G1-G2)	NMT 20ppb	Complies	HPLC
<b>Microbiological Control</b>			
Total aerobic microbial	NMT 500 000 cfu/g	Complies	GB 4789.2-2010
Tot. yeast and mould	NMT 50 000 cfu/g	Complies	GB/4789.15-2010
Bile tolerant gram - bacteria*	NMT 10 000 cfu/g	Complies	NF V 08-054
Salmonella	Negative	Negative	GB 4789.4-2010
E.Coli*	Negative	Negative	GB 4789.4-2010
Staphylococcus	Negative	Negative	GB 4789.10-2010
<b>Allegations</b>			
Allergens	Contains sulfites - 13ppm		
GMO	No OGM		
Irradiation	No irradiation		
<b>Packing and Storage</b>			
Packing	Suitable for food industry		
Storage	Store in dry places and keep away from strong direct light and heat.		

## DOSSIER TECHNIQUE - SPECIFICATION SHEET Organic spirulina powder

## INFORMATIONS SUR LA PLANTE

### PLANT INFORMATION

## RAW MATERIAL INFORMATION

Botanical name	<i>Arthrospira platensis</i>
Family	Pseudanabaenaceae
Common name	Spirulina
Plant part used	Whole cell
Type of culture (cultivated/wild)	Cultivated
Geographical origin of the plant	
- Continent :	Asia
- Country :	China
- Region :	
Is the plant concerned by the regulation 388/97/CE	No
Method of harvest (manual/mechanical)	Mechanical
Period of harvest (month(s) of harvest)	April to November
Stage of harvest (development stage of the plant)	Mature
Has the plant been dried after harvest	Yes
If so, what is the drying method	Artificial drying
Has the plant been treated before harvest	Yes
If so, specify	Filtration and precipitation (remove impurities)
Has the plant been treated after harvest	
If so, specify	Spray drying
Active compound	Protein, phycocyanin
Substance to be monitored* : according to French regulation)	Iodine, microcystines, iron, phycocyanin, beta-carotene

\*Limited substances are tested in control plan. Unlimited substances are tested on customer's request.

## RAW MATERIAL IDENTIFICATION

## POWDER CHARACTERIZATION

Continent of manufacture	Asia - China
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### Composition

Ingredient(s)	Content (%)	Function
Organic spirulina powder	100%	Ingredient

### Analytical data

Appearance*	Dark green powder
Loss on drying	NMT 7%
Ash	NMT 7%
Carotenoid**	>2mg/g
Bulk density***	0.45-0.5g/ml (indicative information)
Tapped density***	0.60-0.65g/ml (indicative information)
Particle size	80 mesh
pH***	7.0-8.0 (informative)
Assay – Test method	NLT 60% protein / NLT 12% phycocyanin
Chlorophyll***	6-15 mg/g
Iron**	>0.1 mg/g
Beta-carotene**	>0.2 mg/g

### Storage conditions / Shelf life

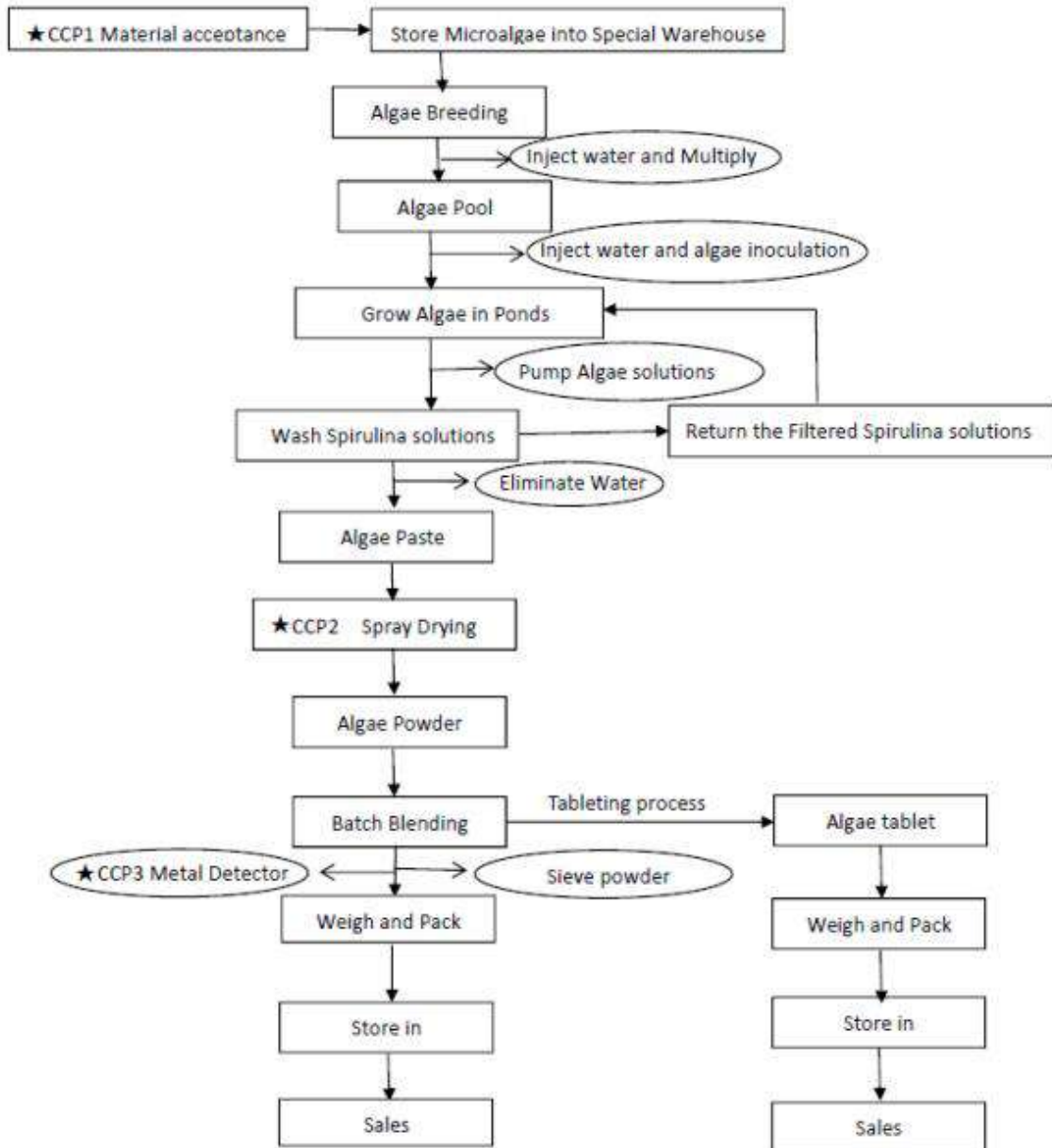
Packaging	Suitable for food industry
Storage conditions	Store at temperature below 25°C, in a well closed bag away from moisture and direct sun light
Shelf life	2-3 years if stored in accordance with recommendations
Batch size	Batch size depends of our suppliers and of customer order (kg to tons)
Stability data	Yes

\*For products from plant origin, minor color variation can be observed due to geographical and seasonal variation of the raw material

\*\* This values are theoretical and can vary from one batch to another. They can't lead to a non-conformity.

\*\*\*According to control plan

## FLOW CHART



★ means critical control points

Washing: After washing PH value of algae within 7.5-8.5 is qualified, if out of range needs to be rewashed.

Spray Drying: The inlet temperature is 180-230°C and the air outing temperature is 70-75°C.

Metal Detector: Limits: Fe  $\phi$   $\geq$  0.2mm; Stainless steel  $\geq$  0.35mm.

## IMPURITIES\*

Contaminants and residues		Analysis		Not tested	Content- limit	Reference and/or method
		Each batch	Control plan			
<b>Heavy metals</b>	Lead (Pb)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<3ppm	GB5009.12-2017
	Cadmium (Cd)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<1ppm	GB5009.15-2014
	Mercury (Hg)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<0.1ppm	GB5009.17-2003
	Arsenic (As)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<1ppm	GB5009.11-2003
<b>Microbiological control</b>	Total plate count	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<500 000 cfu/g	GB5009.11-2003
	Yeast & moulds	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<50 000 cfu/g	GB4789.15-2010
	Bile tolerant gram – bacteria (enterobacteria)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<10 000 cfu/g	NF V 08-054
	E. coli	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Negative	GB_4789[1].3-2010
	Salmonella	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Negative	GB4789.4-2010
	Staphylococcus aureus	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Negative	GB4789.10-2010
	Others ...	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	-	
<b>Contaminants control</b>	Residual solvent ...	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	-	
	Pesticides	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<LOQ	GC/LC
	Aflatoxin B1	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	-	
	Sum of B1, B2, G1, G2	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	-	
	Ochratoxin A	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	-	
	Dioxins and PCBs	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	-	
	Benz(o)apyrene	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<10ppb	GC-MS
	Sum of PAH (benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<50ppb	GC-MS
	Melamine and its structural analogues	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	-	-
	Iodine (algae)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	-	-
	Microcystin (algae)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Recommended : <1ppm	-
	Other contaminants :					
	Pyrrrolizidine alkaloids	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>On customer's request</i>	-
3-MCPD (3-monochloro-propanol-1,2-diol)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	-	-	

*\*Information given by our supplier on the date of updating of data sheet*

## ATTESTATIONS - STATEMENTS

### GMOs FREE STATEMENT

According to the manufacturer's declaration and to the European Regulations:

- Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed

- Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning tractability and labelling on GMOs and tractability of food and feed products produced from GMOs and amending Directive 2001/18/EC

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**GMOs FREE**

**Yes**     **No**

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If no, name and quantity (%):

## NON-IRRADIATION STATEMENT

According to the manufacturer's declaration and to the European Directive 1999/2/EC and 1999/3/EC of the European Parliament and of the Council:

**NON-IRRADIATION**

**Yes**    **No**

## BSE/TSE FREE STATEMENT

According to the manufacturer's declaration:

**BSE/TSE FREE**

**Yes**    **No**

## NANOMATERIALS FREE STATEMENT

According to the manufacturer's declaration and to the EU Regulation No 1169/2011 of the European Parliament and of the Council of 25 October 2011:

**NANOMATERIALS FREE**

**Yes**    **No**

If no, name and quantity (%):



## ALLERGENS AND CROSS CONTAMINATION STATEMENT

According to the manufacturer's declaration and to the EU Regulation No 1169/2011 of the European Parliament and of the Council of 25 October 2011, this product is:

ALLERGENS FREE	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<i>(if no see below)</i>		
	Present in the product (Yes/No)	Quantity (ppm) In case of presence	Presence of allergen on the production site or on the same production line (On Natural site and supplier site)		
Cereals containing gluten, namely: wheat (such as spelt and khorasan wheat), rye, barley, oats or their hybridised strains, and products thereof (1)	...	...	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Crustaceans and products thereof	...	...	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Eggs and products thereof	...	...	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Fish and products thereof (2)	...	...	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Peanuts and products thereof	...	...	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Not applicable
Soybeans and products thereof (3)	...	...	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Milk and products thereof (including lactose) (4)	...	...	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Nuts, namely: almonds ( <i>Amygdalus communis</i> L.), hazelnuts ( <i>Corylus avellana</i> ), walnuts ( <i>Juglans regia</i> ), cashews ( <i>Anacardium occidentale</i> ), pecan nuts ( <i>Carya illinoensis</i> (Wangenh.) K. Koch), Brazil nuts ( <i>Bertholletia excelsa</i> ), pistachio nuts ( <i>Pistacia vera</i> ), macadamia or Queensland nuts ( <i>Macadamia ternifolia</i> ), and products thereof (5)	...	...	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Celery and products thereof	...	...	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Mustard and products thereof	...	...	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Not applicable
Sesame seeds and products thereof	...	...	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO <sub>2</sub> (6)	<b>Yes</b>	Natural presence, depends on batch	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Lupin and products thereof	...	...	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Not applicable
Molluscs and products thereof	...	...	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable

*The risk of cross contamination on Natural site and supplier site is avoided by cleaning procedures.*

*1) Exceptions: Wheat based glucose syrups including dextrose / Wheat based maltodextrins / Glucose syrups based on barley /Cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin*

*(2) Exceptions: fish gelatin used as carrier for vitamin or carotenoid preparation / fish gelatin or Isinglass used as fining agent in beer and wine*

*(3) Exceptions: Fully refined soybean oil and fat / natural mixed tocopherols (E306), natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources / vegetable oils derived phytosterols and phytosterol esters from soybean sources / plant stanol ester produced from vegetable oil sterols from soybean sources*

*(4) Exceptions: whey used for making alcoholic distillates including ethyl alcohol of agricultural origin / lactitol*

*(5) Exceptions: nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin*

*(6) In terms of the total SO<sub>2</sub> which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers*

## EUROPEAN FOOD REGULATIONS

According to the manufacturer's declaration, this product is

EUROPEAN REGULATIONS	COMPLIANT		
Contaminants (Regulation 1881/2006/EC)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Heavy metals (Regulation 629/2008/EC)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Pesticides (Regulation 396/2005/EC and 834/2007/EC)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Extraction solvents (Directive 2009/32/EC)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Not applicable
PAH and benzoapyrene (Regulation 2015/1933/EC)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Food additive (Regulation 231/2012/CE and 1333/2008/EC)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Not applicable

## FOOD GRADE

According to the manufacturer's declaration, this product is:

STATEMENTS			
<b>Food grade</b>	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not specified
<b>Gluten free</b> (<20mg/kg - Regulation 828/2014)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Not analyzed
<b>Suitable for vegetarians</b>	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not specified
<b>Suitable for vegans</b>	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not specified
<b>Halal*</b> (until 11/06/2021) - Organism : ARA Halal certification	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not specified
<b>Kosher*</b> (until /XX/XXXX)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Not specified

\*Product certified by the supplier. Natural is not certified for halal and kosher products.

## NON-ANIMAL TESTING STATEMENT

According to the manufacturer's declaration:

<b>NON-ANIMAL TESTING</b>	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not specified
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## INFORMATIONS COMPLEMENTAIRES

### OTHER INFORMATION

## REGULATORY STATUS

The plant used for this product is approved in:

- French decree - Arrêté plante du 24 juin 2014
- Belgian decree - Arrêté royal du 29/08/97 tel que modifié Février 2017
- Italian decree - Décret du 10 août 2018
- Other : *Croatia*

<b>Europe : Risk of requalification as a medicinal product (According to EMA monograph)</b> <i>(National restriction possible)</i>	No
<b>Plant present in list B of the French Pharmacopoeia</b>	No
If plant present listed in the list B of the French Pharmacopoeia : according to the Public Health Code, food supplements containing plant or parts of plants appearing on list B of the French Pharmacopoeia can't be sold by other people than pharmacists.	

Country	Source	Plant part	Substance to be monitored	Additional information
Belgium	Positive list, Royal decree 29/08/97 as amended February 2017	Unicellular algae	frqgr	
France	Positive list, Law of 24 June 2014  Doctrine DGCCRF list of algae usable in food supplements January 2019, DGCCRF health recommendations Algae in food supplements January 2019	All parts	Iodine, microcystines, Beta-carotene, iron, phycocyanin	Recommendations algae from DGCCRF: The iodine content of the finished product must be known and must not exceed the content considered safe. In case of presence of iodine, recommended warning: Not recommended for people with thyroid disorders.  For microalgae, the presence of cyanobacteria should be sought, especially the amount of microcystins should not exceed 1 µg/g. In case of presence of microcystines, recommended warning: Not recommended for children.  Iodine (recommended: ≤ 150 µg)

## NOVEL FOOD\*

Arthrospira platensis is :

Used before 15 May 1997 (according to Novel food catalogue\*\*):

As food or food ingredient, so is not subject to the Novel Food Regulation (*possible national restrictions*).

Only as or in food supplements, so is not subject but other food use has to be authorized pursuant to the Novel Food Regulation (*possible national restrictions*).

Not used before 15 May 1997 and:

Authorized and Listed in the Union List of Novel Foods in accordance with Regulation (EU) 2017/2470

Request in progress, further information is required.

Not authorized. Therefore, before it may be placed on the market in the EU as a food or food ingredient a safety assessment under the Novel Food Regulation is required.

No information available - Not in the positive list or in Catalogue of Novel Food at the date of writing.

\*Indicative information

\*\*The Novel Food Catalogue lists products of animal and plant origin and other substances subject to the Novel Food Regulation, based on information provided by the EU Member States. It is a non-exhaustive list and serves as orientation on whether a product will need an authorization under the Novel Food Regulation (national restriction are possible)"

## ALERTE RASFF\*

RASFF alert known on the product on the date of updating the data sheet:

No

Yes, see below:

*\*Indicative information*

Classification	Date of case	Reference	Notifying country	Subject	Product category	Type	Risk decision
Alert	28/10/2020	2020.4595	Estonia	sulphite (19 mg/kg - ppm) undeclared on spirulina tablets from Hungary	dietetic foods, food supplements, fortified foods	Food	Serious
Information for intention	24/12/2019	2019.4639	Poland	Polycyclic aromatic hydrocarbons (84.4 µg/kg - ppb) in spirulina powder from China	dietetic foods, food supplements, fortified foods	Food	Not serious
Information for follow-up	11/12/2015	2015.1579	Czech Republic	unauthorised irradiation of spirulina tablets from China	dietetic foods, food supplements, fortified foods	Food	Not serious

## FICHE DE SÉCURITÉ Material Safety Data Sheet

Material Safety Data Sheet contains information about employee health protection and safety. MSDS apply to dangerous substances and blends containing dangerous substances. MSDS aim at keeping the users attention on the dangers and the caution related to the product and its conservation.

The above-mentioned substance or preparation does not meet the criteria for classification as dangerous (European regulation n° 1272/2008 and its modifications) and therefore is not subject to the obligation to provide a Material Safety Data Sheet (European regulation n°1907/2006 and its modifications).

This statement is based on our current knowledge at the date indicated on this document. Attention of the users is required on potential risks caused by a usage of the product that would differ from what it was conceived for. Specifically, this item is intended for an industrial application, must not be consumed as is, and must be handled with the usual precaution.

## Natural Pullulan Capsules

### General parameters

<b>Description</b>	Empty, two-piece, cylindrical hard natural capsules, typical in taste and odour.		
<b>Manufacturer</b>	Shanxi Guangsheng Medicinal Capsule Co., Ltd.		
<b>Manufacturer certifications</b>	BRC, NSF-GMP, ISO9001, ISO14001, OHSAS18001, Halal, and Kosher		
<b>Legal status</b>	EU legislation for food supplements	<b>Country of origin</b>	China
<b>Composition</b>	Pullulan (FCC & E-1204) and purified water (Ph. Eur.)		
<b>Colour range</b>	Clear transparent and opaque, with colours according to agreement		
<b>Imprint</b>	Text and colour according to agreement	<b>Ink type</b>	Edible
<b>Excipients</b>	Gellan gum, xanthan gum, carrageenan, and potassium chloride. <small><sup>†</sup> The excipients are suitably controlled by the rules laid down by Commission Regulation 1333/2008/EC on food additives; however they are not required to be included in the list of ingredients as they serve no technological function in the finished capsules (Commission Regulation 1169/2011/EU, Article 20 (b)(i)).</small>		

### Galenic properties (AQL-defect rate: Critical: 0.01 %, Major: 0.10 %, Minor: 0.40 %, on fully automatic testing machines)

Size	000	00	0	1
<b>Weight, mg</b>	186 ±9	140 ±8	108 ±7	78 ±6
<b>Volume, cc</b>	1.35	0.93	0.68	0.50

### Dose (mg/capsule) as function of bulk density

- 0.6 g/cc	810	558	408	300
- 0.8 g/cc	1080	744	544	400
- 1.0 g/cc	1350	930	680	500
- 1.2 g/cc	1620	1116	816	600

### Length, mm

- Cap	13.1 ±0.4	11.8 ±0.4	10.9 ±0.4	9.8 ±0.4
- Body	22.0 ±0.4	20.2 ±0.4	18.6 ±0.4	16.5 ±0.4
- Overall closed (filled)	25.7 ±0.5	23.4 ±0.5	21.7 ±0.5	19.3 ±0.5

### External diameter, mm

- Cap	9.85 ±0.05	8.55 ±0.05	7.66 ±0.05	6.95 ±0.05
- Body	9.49 ±0.05	8.20 ±0.05	7.35 ±0.05	6.65 ±0.04

### Single wall thickness, mm

- Cap	0.115 ±0.02	0.105 ±0.02	0.100 ±0.02	0.100 ±0.02
- Body	0.110 ±0.02	0.105 ±0.02	0.100 ±0.02	0.095 ±0.02

For elongated or other sizes: please request our full dimensions table.

**Analytical parameters****Galenic properties**

Disintegration time ≤ 30 min. (EP, 37°C, guided disc)

**Chemical**

Arsenic (As)	NMT 1.0 mg/kg	
Lead (Pb)	NMT 1.0 mg/kg	
Cadmium (Cd)	NMT 1.0 mg/kg	
Mercury (Hg)	NMT 0.1 mg/kg	
Sulphated ash, clear trans.	NMT 2.0% w/w	
Sulphated ash, opaque	NMT 5.0% w/w	
Loss on drying	10.0 to 15.0 % w/w	105°C, 4 hours or constant weight

**Microbiology**

Total viable count	≤ 1000 cfu/g	
Yeasts and moulds	≤ 100 cfu/g	
Enterobacteria	≤ 100 cfu/g	
E. coli	Negative in 1 g	Ph. Eur. 2.4.12./13 or equivalent
Salmonella	Negative in 10 g	
Staphylococcus aureus	Negative in 1 g	
Pseudomonas aeruginosa	Negative in 1 g	

**Packaging**

Size	000	00	0	1
Capsules/box	50 000	70 000	100 000	125 000
Packaging material	Double polyethylene food grade bag in sturdy cardboard-box			
Box dimensions	585 x 385 x 730 mm (length x width x height)			

**Storage and handling**

<b>Storage</b>	Store between 10°C and 25°C and relative humidity (RH) between 35% and 65%, in tightly closed packing, protected from direct light.
<b>Pre-filling</b>	Recommended storage between 20°C and 24°C and RH between 45% and 65% at least 12 hours before opening.
<b>Handling and filling</b>	Temperature between 20°C and 24°C and RH between 45% and 65% during usage. Use only stainless steel scoops and spatulas. Do not leave capsules in a filling machine hopper for prolonged period, when not in use. Keep mouth of the bag closed when not in use.
<b>Shelf life</b>	5 years from date of manufacturing, when stored and handled as described.