

LEPIVITS Belgium  
 4 Avenue Franklin – Unité 16  
 1300 Wavre  
 BELGIQUE



### Fiche technique – Collagène marin

Code EAN : 5430002936147 (30 gélules)  
 : 5430002936130 (90 gélules)  
 : 5430002936260 (180 gélules)  
 : 5430002936420 (450 gélules)  
 \*NUT : 3760/54

## FICHE TECHNIQUE/SPECIFICATION SHEET : PRODUCT : NATICOL 1000 POWDER

### Fiche technique - Specification sheet

PRODUCT DETAILS	
Latin Name:	/
Country of origin of the animal:	Europe / South Asia
Animal species :	Tilapia / Panga / Cat fish
Used part :	Fish skin
Breeding method: (Wild/Battery/Agricultural...)	Agricultural
Has it been treated by pesticides:	No
Has it been fed by antibiotics (or used during its growing period):	No
Is that species protected by any international law:	No

Appearance	Clear off white powder
Odor	Nutral
Taste	Nutral
SO2	Max 10%
Protein content	Min 93%
H2O2	Max 10%
Molecular weight	2000 Da
Sieve Analysis	Fine powder
Ash	Max 2%
Viscosity (20% - 25°C)	20 - 40mp
pH	5.6 - 7.0
Humidity (1%, 30°C)	Max 1 mS/cm
Heavy Metal	NMT 10ppm
Lead (Pb)	NMT 3ppm
Arsenic (As)	NMT 2ppm
Cadmium(Cd)	NMT 1ppm
Mercury (Hg)	NMT 0.1ppm
Pesticides Residues	Meets the EP requirements
Antibiotics Residues	None
Pentachlorophenol	Max 0.3 mg/kg
Chromium	Max 10 mg/kg

Microbiology	
Total Plate Count	NMT 1000 cfu/g
Yeast & Mould	NMT 100 cfu/g
E.Coli	Absent in 25g
Staphylococcus aureus	Absent in 1g
Salmonella	Absent in 25g
Storage & shelf life	
Packaging	Suitable for food industry
Storage	In a cool and dry place away from light. Do not freeze.
Shelf life	5 years if stored in accordance with recommendations

## Allergens

List of allergens according to Regulation 1169/2011 amending Directive 2003/89/EC, 2000/13/EC and 2006/142/CE as regards indication of the ingredients present in foodstuffs

Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridized strains) and products thereof except : see regulation 1169/2011 No

Crustaceans and products thereof Yes

Eggs and products thereof No

Fish and products thereof except : see regulation 1169/2011 Yes

Peanuts and products thereof No

Soybean and products thereof except : see regulation 1169/2011 No

Nuts and product thereof except : see regulation 1169/2011 No

Almond (*amygdalus communis*)

Hazelnut (*Coryllus avellana*)

Walnut (*Juglans regia*)

Cashew (*Anacardium occidentale*)

Pecan nut (*Carya illinoensis* (Wangenh.) K. Kock)

Brazil nut (*Bertholletia excels*)

Pistachio nut (*Pistacia vera*)

Macadamia nut and Queensland nut (*Macadamia ternifolia*)

Celery and product thereof No

Mustard and products thereof No

Sesame seeds and products thereof No

Sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10mg/L expressed as SO<sub>2</sub>  
No

Lupin and products thereof No

Molluscs and products thereof No

**Certificat non OGM - GMO Free certificate**

Par la présente nous certifions que la matière première ci-dessous est garantie sans OGM.

Product: NATICOL 1000 powder

The product above does not have to be declared or labelled as "GMO", containing or consisting of GMOs or produced from GMOs in accordance with Regulations (EC) No. 1829/2003 and 1830/2003 on genetically modified food and feed.

**Certificat de non irradiation - Irradiated free certificate**

Par la présente nous certifions que le produit ci-dessous n'a pas été irradié

Product: NATICOL 1000 powder

We hereby certify that the product above has not been irradiated.

**Absence de BSE - TSE\* / BSE - TSE Free certificate**

Par la présente nous certifions que le produit ci-dessous ne contient aucune trace de BSE - TSE.

Product: NATICOL 1000 powder

We hereby certify that the product above is BSE - TSE Free.

\*= Encéphalopathies spongiformes transmissibles (TSE), encéphalopathie spongiforme bovine (BSE)

**Certificat d'absence de nano-particule - Nano particles free certificate**

Par la présente nous certifions que le produit ci-dessous ne contient pas de nano-particules.

Product: NATICOL 1000 powder

We hereby certify that the product is above does not contain any nano-particles

AMINOGRAMME
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PRODUIT : NATICOL

Valeurs exprimées en pourcentage de chaque acide aminé par rapport aux acides aminés totaux :

Glycine -----	20,9
Proline -----	12,6
Acide glutamique -----	11,6
Hydroxyproline -----	10,5
Arginine -----	8,9
Alanine -----	8,3
Acide aspartique -----	5,1
Lysine -----	3,5
Sérine -----	3,5
Thréonine -----	2,7
Leucine -----	2,6
Phénylalanine -----	2,3
Valine -----	2,0
Isoleucine -----	1,5
Hydroxylysine -----	1,5
Histidine -----	1,3
Méthionine -----	0,8
Tyrosine -----	0,4
Cystéine + Cystine -----	0,03
Total -----	100

## Rice Starch

# Remy B KA

- Description**
- Remy B KA is a food starch manufactured from polished broken rice.
  - Remy B KA is a coarse neutral rice starch powder with stringent microbiological criteria.

## Specifications

### Physical and Chemical Parameters

Parameter	Limit	Unit	Method <sup>2</sup>	Frequency
Moisture <sup>1</sup>	max. 14	g/100 g	ISO 712	Each batch
Protein (N* 6.25) <sup>1</sup>	max. 1.0	g/100 g d.m.	ISO 1871	Each batch
Ash <sup>1</sup>	max. 1.0	g/100 g d.m.	ISO 3593	Each batch
pH (10 g to 100 mL) <sup>1</sup>	5.5 – 7.5		Potentiometric	Each batch
Oxidising substances as hydrogen peroxide	max. 0.002	g/100 g	Ph. Eur. 2.5.30	Each batch
Arsenic, inorganic	max. 0.1	mg/kg	ICP-MS	Monitoring
Lead	max. 0.1	mg/kg	ICP-MS	Monitoring
Cadmium	max. 0.1	mg/kg	ICP-MS	Monitoring

<sup>1</sup> on Certificate of Analysis

<sup>2</sup> or validated equivalent

### Microbiological Parameters

Parameter	Limit	Unit	Method <sup>2</sup>	Frequency
Total mesophilic bacteria <sup>1</sup> (aerobes)	max. 1 000	cfu/g	ISO 4833	Each batch
Yeasts and moulds <sup>1</sup>	max. 100	cfu/g	ISO 21527	Each batch
Enterobacteriaceae <sup>1</sup>	max. 10	cfu/g	ISO 21528	Each batch
Salmonella	negative	/25 g	ISO 6579	Each batch

<sup>1</sup> on Certificate of Analysis

<sup>2</sup> or acknowledged and validated equivalent

## Additional Information

### Information relevant for Nutrition Declaration

Nutritional information provided in the table shall enable food manufacturers to calculate the contribution of Remy B KA in their food products in compliance with applicable EU/US food legislation. More detailed information is available upon request.

Nutrient	Typical Value <sup>1</sup>	Unit per 100 g
Energy value/calories	1530/360	kJ/kcal
Fat <sup>2</sup>	0.7	g
saturates	0.3	g
Carbohydrates	88	g
sugars	Negligible <sup>3</sup>	g
starch	88	g
Fibre	Negligible <sup>3</sup>	g
Protein	0.5	g
Salt (sodium)	0.25 (0.10)	g
Vitamins, Minerals <sup>4</sup>	Negligible <sup>3</sup>	g

<sup>1</sup> Proposed values are typical values.

<sup>2</sup> for US: trans fats and cholesterol negligible

<sup>3</sup> Negligible means "0" for macronutrients according to applicable rounding rules in EU and US.

<sup>4</sup> Rice starch is not a typical source of vitamins/minerals.

### Other information

<b>Appearance*</b>	White powder
<b>Taste*</b>	Neutral
<b>Odour*</b>	Neutral
<b>Labelling (EU)</b>	(Rice) starch
<b>Labelling other countries</b>	Information available upon request
<b>Customs code</b>	1108 1910 00
<b>Packaging</b>	25 kg multiply paper bags
<b>Recommended storage conditions</b>	Original (unopened) packaging in a dry place protected against odours and pests
<b>Minimum durability</b>	4 years from date of production under recommended storage conditions
<b>Compliance and Certification</b>	Kosher (certificate available upon request) Halal (certificate available upon request) Suitable for vegetarians & vegans Suitable for gluten-free products: gluten ≤ 10 mg/kg Rice is not listed as allergen in Annex II of Regulation (EU) No 1169/2011 nor as a major allergen in Section 201(qq) [21 U.S.C. 321] of the Food, Drug and Cosmetic Act. Product is not derived from genetically modified organisms (GMO).  Product is produced in Belgium in compliance with applicable European Food Law (e.g. Regulation (EC) No 178/2002, Regulation (EC) No 852/2004), Belgian Law and Codex Alimentarius standards.

## 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>7</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.