

LEPIVITS Belgium
4 Avenue Franklin – Unité 16
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BELGIQUE



Fiche technique – Magnésium malate

Code EAN : 5430002936826 (60 gélules)
*NUT : 3670/31

FICHE TECHNIQUE Specification sheet : MAGNESIUM MALATE

PRODUIT Product Details

CAS N°	6150-86-3
Scientific name	Magnesium malate trihydrate
Country of origin	China
Molecular formula	C4H4MgO5.3H2O
Origin	Synthetic
Natural from:	/

DONNEES ANALYTIQUES Analytical data

Analysis	Specification
Appearance	White powder
Content of magnesium	11.3-11.8% Magnesium
Loss on Drying (Water content)	NMT 27%
Sieve Analysis	100% through 10 mesh 98% through 60 mesh
Residue on ignition	18-21%

Métaux lourds /Preté

Lead	NMT 10ppm
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Microbiologie

Total Plate Count	NMT 10 000 cfu/g
Yeast & Mould	NMT 100 cfu/g
E.Coli	Absent in 1g
Salmonella	Absent in 25g

Conservation et durée optimale d'utilisation

Packaging	Suitable for food industry
Storage	In a cool and dry place away from light. Do not freeze
Shelf life	2 years if stored in accordance with recommendations

Certificat Allergènes

Allergen certificate

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

-Celery and product thereof No

-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 No

-Eggs and products thereof No

-Fish and products thereof except : see regulation 1169/2011 No

-Lupin and products thereof No

-Milk and products thereof (including lactose) except : see regulation 1169/2011 No

-Molluscs and products thereof No

-Mustard and products thereof No

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

- Almond (*amygdalus communis*)
- Brazil nut (*Bertholletia excels*)
- Cashew (*Anacardium occidentale*)
- Hazelnut (*Coryllus avellana*)
- Macadamia nut and Queensland nut (*Macadamia ternifolia*)
- Pecan nut (*Carya illinoiesis* (Wangenh.) K. Kock)
- Pistachio nut (*Pistacia vera*)
- Walnut (*Juglans regia*)

-Peanuts and products thereof No

-Sesame seeds and products thereof No

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

-Sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10mg/L expressed as SO₂
No

Certificat Non OGM GMO free certificate

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

Magnesium malate

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

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

Certificat de Non Irradiations Irridiated free certificate

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

Magnesium malate

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

- According to directives 1992/2/EC and 1999/3/EC

Absence de BSE – TSE * BSE - TSE certificate

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

Magnesium malate

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

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

Certificat d'absence de nano-particules Nano particles free certificate

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

Magnesium malate

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

-According to EU regulation (EU) N° 1169/2011 of the European Parliament and of the council of 25 October 2011.

Fiche de sécurité

MSDS

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 uses attention on the dangers and the caution related to the product and its conservation.

Currently, this product does not belong to the list of dangerous substance of directive 1272/2008.

This product cannot be considered as dangerous regarding its carrying.

Consequently, this product does not need a material safety data sheet. The usual safety measures must be observed in the event of handling of chemicals.

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 ²	Frequency
Moisture ¹	max. 14	g/100 g	ISO 712	Each batch
Protein (N* 6.25) ¹	max. 1.0	g/100 g d.m.	ISO 1871	Each batch
Ash ¹	max. 1.0	g/100 g d.m.	ISO 3593	Each batch
pH (10 g to 100 mL) ¹	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

¹ on Certificate of Analysis

² or validated equivalent

Microbiological Parameters

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

¹ on Certificate of Analysis

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

¹ Proposed values are typical values.

² for US: trans fats and cholesterol negligible

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

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

Other information

Appearance*	White powder
Taste*	Neutral
Odour*	Neutral
Labelling (EU)	(Rice) starch
Labelling other countries	Information available upon request
Customs code	1108 1910 00
Packaging	25 kg multiply paper bags
Recommended storage conditions	Original (unopened) packaging in a dry place protected against odours and pests
Minimum durability	4 years from date of production under recommended storage conditions
Compliance and Certification	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

Description	Empty, two-piece, cylindrical hard natural capsules, typical in taste and odour.		
Manufacturer	Shanxi Guangsheng Medicinal Capsule Co., Ltd.		
Manufacturer certifications	BRC, NSF-GMP, ISO9001, ISO14001, OHSAS18001, Halal, and Kosher		
Legal status	EU legislation for food supplements	Country of origin	China
Composition	Pullulan (FCC & E-1204) and purified water (Ph. Eur.)		
Colour range	Clear transparent and opaque, with colours according to agreement		
Imprint	Text and colour according to agreement	Ink type	Edible
Excipients	Gellan gum, xanthan gum, carrageenan, and potassium chloride. <small>⁷ 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
Weight, mg	186 ±9	140 ±8	108 ±7	78 ±6
Volume, cc	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

Storage	Store between 10°C and 25°C and relative humidity (RH) between 35% and 65%, in tightly closed packing, protected from direct light.
Pre-filling	Recommended storage between 20°C and 24°C and RH between 45% and 65% at least 12 hours before opening.
Handling and filling	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.
Shelf life	5 years from date of manufacturing, when stored and handled as described.