LEPIVITS Belgium
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BELGIQUE

Fiche technique – Dolomite

Code EAN : 5430002936079
*NUT : 3760/44

CERTIFICATE OF ANALYSIS

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Product and Batch Informations			
DOLOMITE POWDER *ref: DOLO001*			
Batch	SA2109433P	**Origin (natural/synthetic)**	Natural
N° CAS	16389-88-1	**Country of origin**	Europe
MF date	01/12/2021	**Expiration date**	31/12/2024

ANALYSIS ITEM	SPECIFICATION	RESULT	TEST METHOD
Active Ingredients/Substance to control			
Assay	CaO : 32.4% MgO : 19.6% Fe2O3 : 0.15% Al2O3 : 0.43% SiO2 : 0.6%	25755mg/100g Calcium 11885mg/100g Magnesium	MOC3152
Physical/Chemical Control			
Appearance	White, pink or pastel green powder	Complies	Organoleptic
Contaminant Control*			
Heavy metals	NMT 10ppm	Complies	AAS
Lead (Pb)	NMT 3ppm	Complies	AAS
Arsenic (As)	NMT 2ppm	Complies	AAS
Cadmium(Cd)	NMT 1ppm	Complies	AAS
Mercury (Hg)	NMT 0,1ppm	Complies	AAS
PAHs	NMT 50ppb	Complies	GC
Benzo(a)pyrene	NMT 10ppb	Complies	GC
Ethylene oxide	NMT 0,01 ppm	<0,01 ppm	GC-MS-MS
Microbiological Control			
Total aerobic microbial	NMT 20 000 cfu/g	Complies	NF EN ISO 4833-1
Tot. yeast and mould	NMT 200 cfu/g	Complies	NF ISO 21527-2
Salmonella	Negative/25g	Not detected	BRD 07/11-12/05
E.Coli	Negative/g	Not detected	NF ISO 7251
Allegations			
Allergens	Allergen free		
GMO	No OGM		
Irradiation	No irradiation		
Packing and Storage			
Packing	Suitable for food industry		
Storage	Store in dry places and keep away from strong direct light and heat.		

REPORT OF ANALYSIS

Type of sample DOLOMITE POUDRE

Ordered analysis Food chemistry - Calcium Magnésium

Results of analysis

	Result	Unit	LOQ	Limit	End of analysis
Food chemistry					
Minerals and trace-elements					
Calcium*	23732	mg/100g	0,5		10/04/2020
Magnesium*	11211	mg/100g	0,5		10/04/2020

Detail of the analyzed parameters and the methods used in following page(s)

Legend

ND = Not Detected D = Detected LOQ = Limit of Quantification NA = Not Analysed NQ = Not Quantifiable NI = Not Identifiable

Used methods mentioned in following page(s) :

MOC3152(S1) version 5 : Determination of the content of calcium, magnesium, phosphorus, potassium and sodium : internal method.

(S1) : analysis carried out by Phytocontrol laboratoire d'analyses - 180 rue Philippe Maupas - Parc Georges Besse - 30035 NIMES

Comments

The analytical results are only valid within the perimeter of application of the used method.

Food chemistry

Minerals and trace-elements

	Result	LOQ	method
Unit ◊ : mg/100g			
Calcium*	23732	0,5	MOC3152
Magnesium*	11211	0,5	MOC3152

Type of sample DOLOMITE POUDRE

Ordered analysis Heavy metals - Lead Cadmium Arsenic Mercury

Results of analysis

	Result	Unit	LOQ	Limit	End of analysis
Heavy metals					
Lead*	0,74 ± 0,11	mg/kg	0,04		10/04/2020
Cadmium*	0,10 ± 0,01	mg/kg	0,01		10/04/2020
Arsenic*	0,51 ± 0,10	mg/kg	0,03		10/04/2020
Mercury*	< 0,005	mg/kg	0,005		10/04/2020

Detail of the analyzed parameters and the methods used in following page(s)

Legend

ND = Not Detected D = Detected LOQ = Limit of Quantification NA = Not Analysed NQ = Not Quantifiable NI = Not Identifiable

Used methods mentioned in following page(s) :

MOC3/85(S1) version 14 : Determination of heavy metals elements (metallic and non-metallic) in all product of animal and vegetable origin including babyfood by ICP-MS: internal method.

(S1) : analysis carried out by Phytocontrol laboratoire d'analyses - 180 rue Philippe Maupas - Parc Georges Besse - 30035 NIMES

Comments

The analytical results are only valid within the perimeter of application of the used method.

The limit values are based on the regulations and / or guidelines and / or recommendations listed below :

Heavy metals

• Food:
Regulation (EC) No 1881/2006 and subsequent amendments setting maximum levels for certain contaminants in foodstuffs.
Copper and Mercury (depending on matrix) : Regulation (EC) No 396/2005 and subsequent amendments on maximum residue levels of pesticides in or on food and feed of plant and animal origin.
• For wine: OIV - Maximum acceptable limits of various elements in wine (2015 edition).
• Animal Feed: Directive 2002/32 and subsequent amendments on undesirable substances in animal feed. The maximum levels apply to feedingstuffs with a moisture content of 12%.
• Food additives: Regulation (EU) n°231/2012 and subsequent amendments laying down specifications for food additives listed in Annexes II and III to Regulation (EC) N°1333/2008 of the European Parliament and of the council.

more information :
Arsenic : The regulation EC 1881/2006 and all of its amendments do not establish maximum limits for arsenic on food.

Heavy metals

	Result	LOQ	method
Unit ◊ : mg/kg			
Lead*	0,74	0,04	MOC3/85
Cadmium*	0,10	0,01	MOC3/85
Arsenic*	0,51	0,03	MOC3/85
Mercury*	< 0,005	0,005	MOC3/85

Analyses microbiologiques / Microbiological tests

Paramètre Parameter	Unité Unit	Résultat Result	Critère Criteria	Laboratoire Laboratory	Conclusion
Micro-organismes aérobies à 30°C Aerobic colony count at 30°C NF EN ISO 4833-1 (A)	/g	<400 MP	10 000	Wessling Paris (F)	Satisfaisant Satisfying
Levures et moisissures 25°C Yeast/mould count 25°C NF ISO 21527-2 (aw<=0,95) (A)	/g	<100	100	Wessling Paris (F)	Satisfaisant Satisfying
Entérobactéries présumées à 37°C Presumptive enterobacteria 37°C NF V08-054 (A)	/g	<10	100	Wessling Paris (F)	Satisfaisant Satisfying
Salmonella / 25 g Salmonella/25 g BRD 07/11-12/05 (A)		non détecté	absence	Wessling Paris (F)	Satisfaisant Satisfying
Escherichia coli présumés / g Presumptive Escherichia coli /g NF ISO 7251 (A)		absence	absence	Wessling Paris (F)	Satisfaisant Satisfying

MP : Le microorganisme est présent (calculs issus de la norme NF EN ISO 7218). The microorganism is present (calculations based on standard NF EN ISO 7218).

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. *) 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]).		

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, 37ºC, 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	105ºC, 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 10ºC and 25ºC and relative humidity (RH) between 35% and 65%, in tightly closed packing, protected from direct light.
Pre-filling	Recommended storage between 20ºC and 24ºC and RH between 45% and 65% at least 12 hours before opening.
Handling and filling	Temperature between 20ºC and 24ºC 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.