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BELGIQUE



Fiche technique – Cuivre

Code EAN : 5430002936505 (90 gélules)
*NUT : 3760/43

CERTIFICAT OF ANALYSIS Copper Gluconate

CERTIFICAT OF ANALYSIS

Product Name	Copper Gluconate	Batch Number	040015201006
Package	1.0Kg per bag	Manufacture Date	Oct 06, 2020
Analysis Standard	GB 1903.8-2015	Best Used Before	Oct 05, 2024

Items	Specifications	Results
Appearance	Light blue fine powder	Conforms
$C_{12}H_{22}CuO_{14}, \omega/\%$	98.0-102.0	100.15
Reducing substances(As D-C ₆ H ₁₂ O ₆), $\omega/\%$	≤ 1.0	< 1.0
Chloride(As Cl), $\omega/\%$	≤ 0.07	< 0.07
Sulfate(As SO ₄), $\omega/\%$	≤ 0.05	< 0.05
As(mg/kg)	≤ 3.0	< 3.0
Pb(mg/kg)	≤ 2.0	< 2.0

Conclusion: Qualified

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.