

**92209-CALCIUM CHLORIDE 2-HYDRATE****1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.****1.1. Identification of the substance or preparation.**

Name: Calcium chloride 2-hydrate powder

Bulk code: 92209

Internal code: 405999

**1.2. Synonyms.**

Calcium chloride dihydrate

**2. DESCRIPTION.**

Appearance: Inorganic crystals.

Colour: Colourless.

Origen: Mineral

Geographical origin: Czech Republic

**3. COMPOSITION/INFORMATION ON COMPONENTS.**Formula:  $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$ 

CAS: 10035-04-8

EINECS: 233-140-8

Molecular weight: 147.02 g/mol

Calcium content: 27.2 g in 100 g of  $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$ 

**Method of production:** The product is manufactured via chemical processes using mineral raw materials.

**4. PHYSICO-CHEMICAL DATA.**

For more information, see the analysis report.

**Solubility:** Soluble in water and alcohol.

Hygroscopic.

**5. PROPERTIES/USES.**

Excipient for pharmaceutical use.

Food use.

**Applications:** Nutritional supplements, pharmaceutical products, bottled water, analytical chemistry and applications for special technologies, foods for babies and infant formula.



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:

**TECHNICAL DATA SHEET**

Review date:

**10.07.2023**

Version:

**9.0**

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The product is certified by HACCP and FCC.

The product is suitable for coeliacs and diabetics.

### 6. DOSAGE.

No information available.

### 7. REMARKS.

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

#### **STORAGE:**

Store at room temperature in a cool, dry place in a tightly closed container away from sunlight, heat sources and moisture.

**The documentation available related to the product's regulatory compliance is included below.**

#### **BSE/TSE:**

The product does not present a risk of BSE or TSE. Neither the source materials nor the production processes defined in section 2 of the "Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products (EMA/410/01 Rev. 03)" are used in the manufacturing process

#### **GMOs:**

The above-mentioned product is not a GMO by origin as it is manufactured via chemical synthesis from raw materials which are pure chemical substances that do not need to be labelled as GMOs or produced from GMOs, in accordance with Regulation (EC) 1829/2003 of the European Parliament and of the Council on genetically modified foodstuffs and feed.

Non-GMO origin means raw materials with non-GMO origin identity preservation are used throughout the manufacturing process. Their traceability is assured and measures are taken to prevent cross-contamination with GMO products.

#### **CMR:**

Substances classed as CMR substances in categories 1A, 1B and 2 according to Part 3 of Appendix VI of Regulation (EC) 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures are not used during the manufacturing process and it is unlikely they are present based on knowledge of the raw materials, the production process and the equipment used.

#### **SVHC:**

The above-mentioned product does not contain any substances of very high concern (SVHC) included in the Candidate List in accordance with art. 59 of Regulation (EC) No. 1907/2006 (REACH) of the

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European Parliament and of the Council, nor does it appear in Appendix XIV published on the ECHA's website (<http://echa.europa.eu>).

### NANOMATERIALS:

We hereby declare that the above-mentioned product does not present any risk of contamination by nanomaterials.

### IONISING RADIATION:

The product and its source materials and raw materials are not exposed to ionising radiation sources or UV rays during production, storage or transport. Legal reference: Directive 1999/2/EC of the European Parliament and of the Council on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation.

### ADDITIVES:

The above-mentioned product does not contain any additives.

### RESIDUAL SOLVENTS:

No residual solvents are used in the manufacturing process.

The bromide content is < 0.001%.

The above-mentioned product is free from organic residual solvents and complies with VOCs and residual solvent requirements as described in the USP, EP and CPMP/ICH/28260/06 guidelines.

Elemental Impurity	Symbol	Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; frequency of testing, process understanding, etc.)
			Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>			
Arsenic (inorganic)	As	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ	ICP – MS – 0.5 ppm	Each batch for limit 1 ppm by FCC limit test 1x per year by ICP MS
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ	ICP – MS – 0.1 ppm	Every 5 <sup>th</sup> batch
Mercury (inorganic)	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ	AAS – 0.05 ppm	Every 3 <sup>rd</sup> batch
Lead	Pb	1	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	0.3 ppm	ICP – MS – 0.1 ppm	Each batch
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ	ICP – MS – 0.1 ppm	1x per year
Nickel	Ni	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ	ICP – MS – 0.5 ppm	1x per year
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ	ICP – MS – 0.5 ppm	1x per year

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Elemental Impurity		Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; frequency of testing, process understanding, etc.)
			Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>			
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ	ICP – MS – 0.1 ppm	1x per year
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ	ICP – MS – 0.5 ppm	1x per year
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ	ICP – MS – 0.5 ppm	1x per year
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ	ICP – MS – 0.5 ppm	1x per year
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ	ICP – MS – 0.2 ppm	1x per year
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ	ICP – MS – 0.2 ppm	1x per year
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ	ICP – MS – 0.2 ppm	1x per year
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ	ICP – MS – 0.5 ppm	1x per year
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ	ICP – MS – 0.5 ppm	1x per year
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ	ICP – MS – 0.1 ppm	1x per year
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	3 ppm	ICP – AES – 0.5 ppm	Each batch
Chromium	Cr	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ	ICP – MS – 0.5 ppm	1x per year
Copper	Cu	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ	ICP – MS – 0.2 ppm	1x per year
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	1 ppm	ICP – MS – 0.1 ppm	1x per year
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ	ICP – MS – 0.2 ppm	1x per year
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ	ICP – MS – 0.1 ppm	1x per year
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ	ICP – MS – 0.5 ppm	1x per year

Elemental Impurity	Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; frequency of testing, process understanding, etc.)
		Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>			
Iron	Fe	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ	ICP – MS – 0.5 ppm	Each batch for limit 1 ppm by PhEur limit test 1x per year by ICP MS

Reference: ICH Q3D Guideline for Elemental Impurities, Step 4 version, September 2014

## CONTAMINANTS/IMPURITIES:

Neither the product nor its raw materials contain products of animal or biological origin and these are not used during the manufacturing process.

The product, its starting materials and raw materials do not contain any of the following substances.

- Acrylamide
- Alcohol
- Aflatoxins
- Antibiotics, stupeficients, anabolic steroids
- Aromatic amines
- Colourings and artificial flavourings

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- Asbestos
- Bisphenol A, Bisphenol F
- Biosolids or sewage sludge
- Caffeine
- Cumin
- Cyanuric acid
- 2,2-Dibromo-3-nitrilopropionamide (DBNPA)
- Dimethyl fumarate (DMF)
- Dioxins and PCBs
- Enzymes
- Ethyl alcohol and alcohol
- Ethylene oxide
- Flavouring substances
- Formaldehyde
- Furan
- Glutamates
- Gluten
- Glycol
- Hormones or hormone residues
- Latex
- Listeria
- Maleic acid
- Melamine
- Methanol
- Mineral oil hydrocarbons (MOSH/MOAH)
- Mycotoxins
- Nitrosamine
- Ortho-phenylphenol
- Partially hydrogenated oils (PHOs)
- Pesticides and herbicides
- Per- and polyfluoroalkyl substances (PFAS)
- Phthalates (DEHP: di(2-ethylhexyl) phthalate; DINP: diisononyl phthalate, or any other phthalate)
- Polycyclic aromatic hydrocarbons (PAHs)
- Polyethylene Sulfide (PPS)
- Polychlorinated Aromatics and Ethers
- Preservatives
- Prions
- Polyvinyl chloride (PVC)
- Quaternary ammonium compounds (QACs)
- Silicon
- Styrene and polystyrene
- Sugar
- Tartrazine
- Titanium oxide

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- Vanillin, methyl-vanillin and ethyl-vanillin

**HEAVY METALS:**

The above-mentioned product is free from metal catalyst or reactive metal residues and it complies with metal catalyst residues and metal reagent requirements as described in the current ICH Q3D guideline on elemental impurities.

**CALIFORNIA PROPOSITION 65:**

To manufacture this product, no materials that could be contaminated with compounds mentioned in Proposition 65's List are used.

**ALLERGENS:**

- **Food allergens:** the product complies with Regulation (EU) No. 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers in relation to certain food ingredients. The product does not contain any of the allergens listed in Annex II.
- **Cosmetic allergens:** The substances mentioned in Appendix II (List of substances prohibited in cosmetic products) and in Appendix III (List of substances which cosmetic products should not contain except subject to the restrictions laid down) to Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products are not added intentionally during the manufacturing process.

**HALAL:**

The above-mentioned product is not Haram (minimum requirement) and is Halal in accordance with the guidelines of the Codex Alimentarius Commission. This means the product is:

1. Free from products of animal origin, alcohol and genetically modified products (as defined by the Halal terms in CAC/GL 24-1997) and there is no cross-contamination with Haram products.
2. Halal as defined in the general guidelines of the Codex CAC/GL 24-1997 (Link: <http://www.fao.org/3/Y2770e/y2770e08.htm>) with the exception of the labelling.

The product is certified.

**KOSHER:**

The above-mentioned product is manufactured via chemical processes using mineral raw materials. The product does not contain any ingredients of animal origin, blood or blood derivatives or any alcohol. Alcohol has not been used in the manufacturing process. The equipment used to manufacture and package the product is not used to manufacture and package products of animal origin or products containing animal products or ingredients of animal origin.

The product is certified.

**VEGAN/VEGETARIAN:**

The product is suitable for vegan/vegetarian use.

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**NUTRITIONAL VALUE:**

The product is a completely inorganic substance and constitutionally does not include carbohydrates, fats or proteins. Therefore, the above-mentioned product has no nutritional value.

Listed in Amounts Per 100 Grams

Calories	0	Kcal	Vit. E. – Alpha	0	mg
Protein	0	g	Eq		
Total	0	g	Calcium	27211	mg
Carbohydrates			Copper	0	mg
Dietary Fiber	0	g	Iron	0	mg
Fat Total	0	g	Magnesium	0	mg
Saturated Fat	0	g	Phosphorus	0	mg
Mono Fat	0	g	Potassium	0	mg
Poly Fat	0	g	Sodium	0.3	mg
Cholesterol	0	mg	Zinc	0	mg
Total Vit. A	0	mcg	Total Sugars	0	g
Thiamine –B1	0	mg	Vitamin D	0	mcg
Riboflavin-B2	0	mg	Starch	0	g
Niacin – B3	0	mg	Water (moisture)	24.5	g
Vitamin B6	0	mg	Vitamin C	0	mg
Vitamin B12	0	mcg	Insoluble Fiber	0	g
Ash	75.5	g	Soluble Fiber	0	g
Alcohol	0	g	Crude Fiber	0	g
Sugar Alcohol	0	mcg	Biotin	0	mg
Folic Acid	0	mcg	Iodine	0	mg
Pantothenic Acid	0	mg	Trans Fat	0	g
Chromium	0	mcg	Added Sugars	0	g
Molybdenum	0	mcg	Vitamin K	0	mcg
Selenium	0	mcg	Manganese	0	mg
Chloride	48299	mg			

**WADA:**

Neither the product nor the starting materials contain the compounds mentioned in the WADA's List of Prohibited Substances. The product is free of prohibited substances.

**GRAS:**

The product is generally recognised as safe.

**TESTED ON ANIMALS:**

The product has not been tested on animals.

**RSPO:**

Neither the product nor the starting materials contain palm oil.

**REACH No.:**

01-2119494219-28-0006

**TARIFF ITEM NUMBER:**

2827.20.00.00