

92654-MAGNESIUM CHLORIDE 6-HYDRATE**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION****1.1. Identification of the substance or preparation**

Name: Magnesium chloride 6-hydrate

Bulk code: 92654

Internal code: 405999

1.2. Synonyms

Magnesium chloride hexahydrate

2. DESCRIPTION

Appearance: Crystalline powder.

Colour: Colourless.

Origin: Synthetic from pure chemical substances. No material of animal, human or biological origin is used as a starting raw material, nor during the production process or distribution.

Geographical origin: Czech Republic.

3. COMPOSITION/INFORMATION ON COMPONENTSFormula: $\text{MgCl}_2 \cdot 6\text{H}_2\text{O}$

CAS: 7791-18-6

EINECS: 232-094-6

Molecular weight: 203,303 g/mol

Magnesium content: 11.8 g in 100 g of $\text{MgCl}_2 \cdot 6\text{H}_2\text{O}$ **4. PHYSICO-CHEMICAL DATA**

For more information see the analysis report.

Solubility: The product is soluble in water and alcohol.

The product is hygroscopic.

5. PROPERTIES/USES

Excipient for pharmaceutical use.


Oral use.

Not suitable for the manufacture of food supplements or foods.

The product can be used by celiacs and diabetics.

6. DOSAGE

No information available.

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	TECHNICAL DATA SHEET	
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7. REMARKS

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

STORAGE:

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

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

BSE/TSE:

Free of BSE/TSE. The above-mentioned product does not present a risk of BSE or TSE. Neither the source materials nor the production processes as 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:

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

NANOMATERIALS:

The product does not present a risk of contamination due to nanomaterials.

92654-MAGNESIUM CHLORIDE 6-HYDRATE**RADIATION:**

Neither the product nor its source materials or raw materials are 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.

PESTICIDES:

The product, its starting materials and raw materials do not contain pesticides or herbicides.

ADDITIVES:

The product does not contain any additives.

RESIDUAL SOLVENTS:

No organic solvents are used in production. The material complies with USP, the Eur. Ph. and EMA/CHMP/ICH/82260/2006 requirements for residual solvents.

ELEMENTAL IMPURITIES:

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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.)
Arsenic (inorganic)	As	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (0.20 mg/kg)	ICP MS – 0.07 mg/kg	Each batch for limit 1 ppm by PhEur limit test 1x per year by ICP MS 3 batches
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (0.10 mg/kg)	ICP MS – 0.03 mg/kg	Every 5 th batch for limit 1 ppm on AAS 1x per year by ICP MS 3 batches
Mercury (inorganic)	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (0.10 mg/kg)	ICP MS – 0.03 mg/kg	Every 3 rd batch
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (0.10 mg/kg)	ICP MS – 0.03 mg/kg	Each batch for limit 2 ppm by USP limit test 1x per year by ICP MS 3 batches
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (0.10 mg/kg)	ICP MS – 0.03 mg/kg	1x per year 3 batches
Nickel	Ni	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (0.50 mg/kg)	ICP MS – 0.17 mg/kg	1x per year 3 batches
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (0.50 mg/kg)	ICP MS – 0.17 mg/kg	1x per year 3 batches
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (0.10 mg/kg)	ICP MS – 0.03 mg/kg	1x per year 3 batches
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (0.50 mg/kg)	ICP MS – 0.17 mg/kg	1x per year 3 batches
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (0.50 mg/kg)	ICP MS – 0.17 mg/kg	1x per year 3 batches
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (0.50 mg/kg)	ICP MS – 0.17 mg/kg	1x per year 3 batches
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (0.20 mg/kg)	ICP MS – 0.07 mg/kg	1x per year 3 batches
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (0.20 mg/kg)	ICP MS – 0.07 mg/kg	1x per year 3 batches
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (0.20 mg/kg)	ICP MS – 0.07 mg/kg	1x per year 3 batches
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (0.50 mg/kg)	ICP MS – 0.17 mg/kg	1x per year 3 batches
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (0.50 mg/kg)	ICP MS – 0.17 mg/kg	1x per year 3 batches
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (0.10 mg/kg)	ICP MS – 0.03 mg/kg	1x per year 3 batches
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (1.00 mg/kg)	ICP MS – 0.33 mg/kg	Each batch by ICP AES 1x per year by ICP MS 3 batches
Chromium	Cr	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (0.50 mg/kg)	ICP MS – 0.17 mg/kg	1x per year 3 batches
Copper	Cu	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	1.0 ppm	ICP MS – 0.33 mg/kg	1x per year 3 batches
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (1.00 mg/kg)	ICP MS – 0.33 mg/kg	1x per year 3 batches
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (0.20 mg/kg)	ICP MS – 0.07 mg/kg	1x per year 3 batches
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (0.10 mg/kg)	ICP MS – 0.03 mg/kg	1x per year 3 batches
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<LOQ (0.50 mg/kg)	ICP MS – 0.16 mg/kg	1x per year 3 batches

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

IMPURITIES/CONTAMINANTS:

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

- Acrylamide
- Alcohol
- Aflatoxins
- Antibiotics, stupefacients, anabolic steroids
- Aromatic amines
- Colourings and artificial flavourings
- Asbestos
- Bisphenol A, Bisphenol F
- Biosolids or sewage sludge
- Caffeine
- Compounds mentioned in the WADA's Prohibited List.
- 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)
- Per- and polyfluoroalkyl substances (PFAS)
- Phthalates (DEHP: di(2-ethylhexyl) phthalate; DINP: diisononyl phthalate, or any other phthalate).
- Polycyclic aromatic hydrocarbons (PAHs)
- Polyethylene sulphide (PPS)
- Aromatic polychlorinated compounds and ethers
- Preservatives

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- Prions
- Polyvinyl chloride (PVC)
- Quaternary ammonium compounds (QACs)
- Silicon
- Styrene and polystyrene
- Sugar
- Tartrazine
- Titanium oxide
- Vanillin, methyl-vanillin and ethyl-vanillin

HEAVY METALS:

The product is free of metal catalysis residues and metal agents and it complies with the limits specified in the ICH Q3D guides on elemental impurities.

CALIFORNIA PROPOSITION 65:

No contaminated material has been used during the manufacturing process, according to the materials present in this Proposition's list.

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 used intentionally during the manufacturing process.

GRAS:

The product is generally recognised as safe.

HALAL:

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

This means the product is:

1. Free of 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 Halal certified.

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KOSHER:

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

The product is Kosher certified.

VEGANS/VEGETARIANS:

Neither the product nor the source materials contain substances of animal or biological origin. No starting raw material used in the manufacturing process is of animal or biological origin.

Suitable for vegan/vegetarian diets.

WADA:

The product is free of the prohibited substances listed in the List of Prohibited Substances of the World Anti-Doping Agency (WADA).

NUTRITIONAL COMPOSITION:

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 g:

Calories	0	Kcal	Vit. E. – Alpha	0	mg
Protein	0	g	Eq		
Total	0	g	Calcium	4	mg
Carbohydrates			Copper	0	mg
Dietary Fiber	0	g	Iron	0	mg
Fat Total	0	g	Magnesium	11940	mg
Saturated Fat	0	g	Phosphorus	0	mg
Mono Fat	0	g	Potassium	4	mg
Poly Fat	0	g	Sodium	0.5	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)	53.2	g
Vitamin B6	0	mg	Vitamin C	0	mg
Vitamin B12	0	mcg	Insoluble Fiber	0	g
Ash	46.8	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	1	mg
Chloride	34975	mg			

ANIMAL TESTS:



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The product has not been tested on animals.

RSPO:

Neither the product nor the starting materials contain palm oil.

REACH:

01-2119485597-19-0001

TARIFF ITEM NUMBER:

2827.31.00.00