according to 1907/2006/EC, Article 31

Printing date 29.09.2023 Revision: 27.09.2023

Version number 1.7 (replaces version 1.6)

# SECTION 1: Identification of the substance/mixture and of the company/undertaking

- · 1.1 Product identifier
- Trade name: Magnesii orotas dihydricus
  Magnesiumorotate Dihydrate
- · Article number: 700445, 100681
- CAS Number: 34717-03-8 EC number:
- EC number: 252-167-6
- 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Pharma Active ingredients
- · 1.3 Details of the supplier of the safety data sheet

Fagron UK Ltd 4B Coquet St Newcastle upon Tyne England NE1 2QB Tel. 0845 6522525

· Further information obtainable from:

Emergency response telephone number:

+44 (0) 845 652 2525

1.4 Emergency telephone number:

Emergency response telephone number:

+44 (0) 845 652 2525

#### **SECTION 2: Hazards identification**

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

The substance is not classified, according to the GB CLP regulation.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008 Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · **vPvB**: Not applicable.

## **SECTION 3: Composition/information on ingredients**

- · 3.1 Substances
- · CAS No. Description

CAS: 34717-03-8 Magnesii orotas dihydricus

Magnesiumorotate Dihydrate

- Identification number(s)
- · EC number: 252-167-6



#### Page 2/6

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 29.09.2023 Revision: 27.09.2023

Version number 1.7 (replaces version 1.6)

Trade name: Magnesii orotas dihydricus Magnesiumorotate Dihydrate

(Contd. of page 1)

#### **SECTION 4: First aid measures**

- · 4.1 Description of first aid measures
- · General information: No special measures required.
- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact: If skin irritation continues, consult a doctor.
- · After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing:

Rinse out mouth and then drink plenty of water.

Seek medical treatment.

· 4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

· 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

#### **SECTION 5: Firefighting measures**

- · 5.1 Extinguishing media
- Suitable extinguishing agents:

Water spray

Carbon dioxide

Fire-extinguishing powder

Use fire extinguishing methods suitable to surrounding conditions.

5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

- 5.3 Advice for firefighters
- · Protective equipment: Wear fully protective suit.

### **SECTION 6: Accidental release measures**

- 6.1 Personal precautions, protective equipment and emergency procedures Avoid formation of dust.
- · 6.2 Environmental precautions: No special measures required.
- 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- · 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

### **SECTION 7: Handling and storage**

- · 7.1 Precautions for safe handling No special measures required.
- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- Storage:
- · Requirements to be met by storerooms and receptacles: No special requirements.
- Information about storage in one common storage facility: Not required.
- Further information about storage conditions: Protect from humidity and water.
- · 7.3 Specific end use(s) No further relevant information available.



according to 1907/2006/EC, Article 31

Printing date 29.09.2023 Revision: 27.09.2023

Version number 1.7 (replaces version 1.6)

Trade name: Magnesii orotas dihydricus Magnesiumorotate Dihydrate

(Contd. of page 2)

### **SECTION 8: Exposure controls/personal protection**

- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace: Not required.
- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

- · Respiratory protection: Suitable respiratory protective device recommended.
- · Hand protection

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- Eye/face protection Not required.
- · Body protection: Protective work clothing

## **SECTION 9: Physical and chemical properties**

- · 9.1 Information on basic physical and chemical properties
- · General Information

Physical state
Colour:
Odour:
Odourless
Odour threshold:
Melting point/freezing point:

Solid
White
Odourless
Not determined.
Undetermined.

· Boiling point or initial boiling point and

boiling range Undetermined.

· **Flammability** Product is not flammable.

· Lower and upper explosion limit

Lower: Not determined.
Upper: Not determined.
Flash point: >360°C

• Decomposition temperature: Not determined. Not applicable.

Viscosity:

Kinematic viscosityDynamic:Not applicable.Not applicable.

· Solubility

· water: Insoluble.

Partition coefficient n-octanol/water (log

value) Not determined.



according to 1907/2006/EC, Article 31

Printing date 29.09.2023 Revision: 27.09.2023

Version number 1.7 (replaces version 1.6)

Trade name: Magnesii orotas dihydricus Magnesiumorotate Dihydrate

	(Contd. of pa	
Vapour pressure:	Not applicable.	
Density and/or relative density		
Density:	Not determined.	
Relative density	Not determined.	
Vapour density	Not applicable.	
9.2 Other information		
Appearance:		
Form:	Crystalline powder	
Important information on protection of		
health and environment, and on safety.		
Ignition temperature:	Not determined.	
Explosive properties:	Product does not present an explosion hazard.	
Molecular weight	370.5 g/mol	
Change in condition		
Evaporation rate	Not applicable.	
Information with regard to physical haza	rd	
classes		
Explosives	Void	
Flammable gases	Void	
Aerosols	Void	
Oxidising gases	Void	
Gases under pressure	Void	
Flammable liquids	Void	
Flammable solids	Void	
Self-reactive substances and mixtures	Void	
Pyrophoric liquids	Void	
Pyrophoric solids	Void	
Self-heating substances and mixtures	Void	
Substances and mixtures, which emit		
flammable gases in contact with water	Void	
Oxidising liquids	Void	
Oxidising solids	Void	
Organic peroxides	Void	
Corrosive to metals	Void	
Desensitised explosives	Void	

# **SECTION 10: Stability and reactivity**

- $\cdot$  10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- 10.3 Possibility of hazardous reactions Reacts with strong oxidising agents.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products:

Carbon monoxide and carbon dioxide

Nitrogen oxides (NOx)



according to 1907/2006/EC, Article 31

Printing date 29.09.2023 Revision: 27.09.2023

Version number 1.7 (replaces version 1.6)

Trade name: Magnesii orotas dihydricus Magnesiumorotate Dihydrate

(Contd. of page 4)

### **SECTION 11: Toxicological information**

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Based on available data, the classification criteria are not met.
- · LD/LC50 values relevant for classification:

Oral LD50 >7400 mg/kg (rat)

- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.
- · 11.2 Information on other hazards
- · Endocrine disrupting properties Substance is not listed.

### **SECTION 12: Ecological information**

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- vPvB: Not applicable.
- 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- 12.7 Other adverse effects
- · Additional ecological information:
- · General notes: Not hazardous for water.

## **SECTION 13: Disposal considerations**

- 13.1 Waste treatment methods
- · Recommendation Must be specially treated adhering to official regulations.
- Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

## **SECTION 14: Transport information**

- · 14.1 UN number or ID number
- · ADR, IMDG, IATA not regulated
- · 14.2 UN proper shipping name
- · ADR, IMDG, IATA not regulated



according to 1907/2006/EC, Article 31

Printing date 29.09.2023 Revision: 27.09.2023

Version number 1.7 (replaces version 1.6)

Trade name: Magnesii orotas dihydricus Magnesiumorotate Dihydrate

		(Contd. of page
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA · Class	not regulated	
· 14.4 Packing group · ADR, IMDG, IATA	not regulated	
· 14.5 Environmental hazards:	Not applicable.	
· 14.6 Special precautions for user	Not applicable.	
· 14.7 Maritime transport in bulk according IMO instruments	ng to Not applicable.	
UN "Model Regulation":	not regulated	

### **SECTION 15: Regulatory information**

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I Substance is not listed.
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

#### **SECTION 16: Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

#### · Department issuing SDS:

Fagron UK

Quality Assurance

- · Contact: quality@fagron.co.uk
- Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

\* Data compared to the previous version altered.

**EFGGTON**personalizing medicine

GE