Safety Data Sheet

acc. to OSHA HCS

1 Identification

- · Product identifier
- Trade name: <u>Magnesii orotas dihydricus</u> Magnesiumorotate Dihydrate
- · Article number: 700445, 100681
- · CAS Number:
- 34717-03-8
- · EC number:
- 252-167-6
- · Application of the substance / the mixture Pharma Active ingredients

Details of the supplier of the safety data sheet Manufacturer/Supplier: Fagron Inc 2400 Pilot Knob Road St. Paul, MN 55120 www.fagron.us QA@fagron.us

Information department: Tel.: 800-423-6967
Fax: 800-339-1596
Emergency telephone number: Emergency Telephone: US: 1-800-535-5053 International: 1-352-323-3500

2 Hazard(s) identification

• Classification of the substance or mixture The substance is not classified, according to the Globally Harmonized System (GHS).

· Label elements

- · GHS label elements Void
- · Hazard pictograms Void
- Signal word Void
- · Hazard statements Void
- · Classification system:
- · NFPA ratings (scale 0 4)



· HMIS-ratings (scale 0 - 4)



· Other hazards

- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · **vPvB:** Not applicable.



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3 Composition/information on ingredients

- · Chemical characterization: Substances
- · CAS No. Description
- CAS: 34717-03-8 Magnesii orotas dihydricus
- Magnesiumorotate Dihydrate
- Identification number(s)
- EC number: 252-167-6

4 First-aid measures

- · 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.
- Information for doctor:
- Most important symptoms and effects, both acute and delayed
- No further relevant information available.
- Indication of any immediate medical attention and special treatment needed
- No further relevant information available.

5 Fire-fighting measures

- · Extinguishing media
- Suitable extinguishing agents:
- Water spray
- Carbon dioxide
- Fire-extinguishing powder
- Use fire fighting measures that suit the environment.
- · Special hazards arising from the substance or mixture
- Formation of toxic gases is possible during heating or in case of fire.
- Advice for firefighters
- · Protective equipment: Wear fully protective suit.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

- Avoid formation of dust.
- · Environmental precautions: No special measures required.
- Methods and material for containment and cleaning up: Pick up mechanically.
- 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.
- Protective Action Criteria for Chemicals
- · PAC-1: Substance is not listed.
- · PAC-2: Substance is not listed.
- · PAC-3: Substance is not listed.



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7 Handling and storage

- · Handling:
- · Precautions for safe handling No special measures required.
- · Information about protection against explosions and fires: No special measures required.
- · 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.

• Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

· Additional information about design of technical systems: No further data; see section 7.

- · Control parameters
- · Components with limit values that require monitoring at the workplace: Not required.
- Additional information: The lists that were valid during the creation were used as basis.
- · Exposure controls
- Personal protective equipment:
- General protective and hygienic measures:
- The usual precautionary measures for handling chemicals should be followed.
- · Breathing equipment: Suitable respiratory protective device recommended.
- · Protection of hands:

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 protection: Not required.
- Body protection: Protective work clothing

9 Physical and chemical properties

 Information on basic physical and General Information 	chemical properties	
· Appearance: Form:	Crystalline powder	
Color:	White	
· Odor: · Odor threshold:	Odorless Not determined.	
· pH-value:	Not applicable.	
 Change in condition Melting point/Melting range: 	Undetermined.	Fagron
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Boiling point/Boiling range:	Undetermined.	
· Flash point:	>360°C (>680°F)	
· Flammability (solid, gaseous):	Product is not flammable.	
· Decomposition temperature:	Not determined.	
· Ignition temperature:	Not determined.	
· Danger of explosion:	Product does not present an explosion hazard.	
· Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
· Vapor pressure:	Not applicable.	
· Density:	Not determined.	
Relative density	Not determined.	
 Vapor density 	Not applicable.	
 Evaporation rate 	Not applicable.	
· Solubility in / Miscibility with		
Water:	Insoluble.	
· Partition coefficient (n-octanol/wa	ater): Not determined.	
· Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
· Other information	No further relevant information available.	

10 Stability and reactivity

- · Reactivity No further relevant information available.
- Chemical stability
- Thermal decomposition / conditions to be avoided:
- No decomposition if used according to specifications.
- · Possibility of hazardous reactions Reacts with strong oxidizing agents.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.

Hazardous decomposition products:

- Carbon monoxide and carbon dioxide
- Nitrogen oxides (NOx)

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:

· LD/LC50 values that are relevant for classification:

- Oral LD50 >7400 mg/kg (rat)
- Primary irritant effect:
- on the skin: No irritant effect.
- · Sensitization: No sensitizing effects known.



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personalizing medicine

· Additional toxicological information:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. The substance is not subject to classification.

- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer) Substance is not listed.
- · NTP (National Toxicology Program) Substance is not listed.
- · OSHA-Ca (Occupational Safety & Health Administration) Substance is not listed.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- Mobility in soil No further relevant information available.
- Additional ecological information:
- · General notes: Not hazardous for water.
- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

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

14 Transport information

· UN-Number · DOT, IMDG, IATA	not regulated	
 UN proper shipping name DOT, IMDG, IATA 	not regulated	
· Transport hazard class(es)		
· DOT, ADN, IMDG, IATA · Class	not regulated	
 Packing group DOT, IMDG, IATA 	not regulated	
· Environmental hazards:	Not applicable.	
· Special precautions for user	Not applicable.	
• Transport in bulk according to Annex MARPOL73/78 and the IBC Code	Il of Not applicable.	
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• UN "Model Regulation":

not regulated

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture

No further relevant information available.

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· Section 355 (extremely hazardous substances): Substance is not listed.

Section 313 (Specific toxic chemical listings): Substance is not listed.

· TSCA (Toxic Substances Control Act): INACTIVE

· Hazardous Air Pollutants Substance is not listed.

· Proposition 65

· Chemicals known to cause cancer: Substance is not listed.

· Chemicals known to cause reproductive toxicity for females: Substance is not listed.

Chemicals known to cause reproductive toxicity for males: Substance is not listed.

· Chemicals known to cause developmental toxicity: Substance is not listed.

Carcinogenic categories

· EPA (Environmental Protection Agency) Substance is not listed.

- · TLV (Threshold Limit Value) Substance is not listed.
- · NIOSH-Ca (National Institute for Occupational Safety and Health) Substance is not listed.
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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 US

Quality Assurance

Contact: QA@fagron.us

- Date of preparation / last revision 09/29/2023
- Abbreviations and acronyms:
- IMDG: International Maritime Code for Dangerous Goods
- DOT: US Department of Transportation
- IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

- CAS: Chemical Abstracts Service (division of the American Chemical Society) NFPA: National Fire Protection Association (USA)
- HMIS: Hazardous Materials Identification System (USA)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative
- NIOSH: National Institute for Occupational Safety OSHA: Occupational Safety & Health
- TLV: Threshold Limit Value
- PEL: Permissible Exposure Limit
- **REL: Recommended Exposure Limit**
- * Data compared to the previous version altered.



USA