

Safety Data Sheet

acc. To OSHA HCS

Reviewed on 4/26/2022

Printing date 4/26/2022

Trade Name: Magnesium Stearate

1 Identification

1.1 Product identifier

Trade name: Magnesium Stearate

Product Code: C6020

Application of the substance / the mixture: Pharma Excipient

1.2 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

SpecializedRx Products, LLC

7237 University Ave. NE

Fridley, MN 55432

www.specializedrx.com

sales@specializedrx.com

Information department:

Tel.: 1-888-512-1209

Fax: 1-612-424-8481

1.3 Emergency telephone number:

Emergency Telephone:

US: 1-888-512-1209

International: 1-888-512-1209

2 Hazard(s) identification

Classification of the substance or mixture:

Not classified as hazardous, according to Regulation (EC) No. 1272/2008 [CLP]

GHS Signal Word: N/A

GHS Hazard Phrases:

Not applicable.

GHS Precaution Phrases:

Not applicable.

GHS Response Phrases:

Not applicable

GHS Storage and Disposal Phrases: Dust may form explosive mixture in air.

Eye Contact: MAY CAUSE EYE IRRITATION

Skin Contact: MAY CAUSE SKIN IRRITATION

Ingestion: MAY BE HARMFUL

Inhalation: MAY BE HARMFUL IF INHALED

3 Composition/information on ingredients

3.1 Chemical Characterization: Substance

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Trade Name: Magnesium Stearate

Description: Light-colored white powder
Dangerous components: Not applicable

3.2 Chemical Information:

Chemical Name: magnesium stearate

Botanical Name: Not applicable

Synonym: Octadecanoic acid, magnesium salt / Stearate, magnesium / Stearic acid, magnesium salt / Octadecanoic acid, magnesium salt (2:1) / Magnesium distearate / MAGNESIUM STEARATE / Salts of stearic acids with magnesium bases / Magnesium octadecanoate / Bis(octadecanoic acid)magnesium salt / Salt of stearic acid with magnesium base / Dioctadecanoate magnesium

Chemical Formula: C₁₈H₃₆O₂.1/2Mg

CAS Number: (CAS-No.) 557-04-0

Alternate CAS Number: (EC-No.) 209-150-3

Molecular Weight: 591.27 g/mol

3.3 Composition:

Chemical Name	CAS Number	% By Weight
Magnesium stearate	557-04-0	≈98

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this 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. If not breathing, give artificial respiration.

After skin contact: Gently wash with soap and water; remove contaminated clothing. Clothing should be laundered before reuse. If skin irritation occurs, consult medical professional.

After eye contact: Immediately rinse opened eye for 15 minutes under running water. If contact lenses are present and easily removed, do so. Continue rinsing following contact lens removal. Get medical advice/attention.

After swallowing: Do not induce vomiting without medical advice. Get immediate medical advice/attention.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/effects after eye contact: dust is a mechanical irritant.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

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5 Fire-fighting measures

Flash Pt: ≈ 190 °C Method Used: Cleveland Open Cup

Fire Fighting Instructions:

AS IN ANY FIRE, WEAR A SELF-CONTAINED BREATHING APPARATUS IN PRESSURE-DEMAND, MSHA/NIOSH (APPROVED OR EQUIVALENT), AND FULL PROTECTIVE GEAR.

Flammable Properties and Hazards:

Flammable in the presence of a source of ignition when the temperature is above the flash point. Potential for dust explosion hazard exists in instances of airborne release; high concentrations of dust or fine particulate in enclosed spaces may represent a fire/explosion risk.

Auto-ignition Pt: 410 °C

Explosive Limits: LEL: Not determined UEL: Not determined

Suitable Extinguishing Media:

Use water spray, dry chemical, carbon dioxide, or alcohol-resistant foam. Do not use a solid water stream as it may scatter and spread the fire. Use extinguishing media as appropriate for the surrounding fire.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Non-emergency personnel: Wear suitable protective clothing, and wear recommended personal protective equipment.

Emergency procedures: Immediately contact emergency personnel; evacuate the area. Avoid breathing dust.

Emergency responders:

Minimize dust generation. Wear suitable protective garments and recommended personal protective equipment.

Evacuate area and limit access; take precautionary measures against static discharge.

Material spilled on hard surfaces/walkways may constitute a serious slip/fall hazard. Spill should be handled by trained personnel equipped with respiratory and eye protection. All personnel should avoid breathing dust.

6.2 Environmental precautions:

Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up:

Contain spillage and use non-dust generating methods to clean up spill. Take up mechanically (sweeping/shoveling) and collect in suitable containers for disposal.

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.

Protective Action Criteria for Chemicals

PAC-1: None of the ingredients is listed.

PAC-2: None of the ingredients is listed.

PAC-3: None of the ingredients is listed.

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7 Handling and storage

7.1 Precautions for safe handling:

Avoid generation of airborne dust – dust may form flammable or explosive mixture in air. Avoid breathing dust and use grounded equipment when working with powder. Use an approved industrial vacuum cleaner for dust removal. Room should be properly ventilated to minimize exposure to dust.

Do not eat/drink/smoke while working with this product. Wash hands and exposed skin before eating/drinking/smoking and when leaving work. Contaminated clothing should be laundered prior to reuse.

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: Store in cool, dry conditions in well-sealed receptacles and well-ventilated place

7.3 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 item 7.

Respiratory Equipment (Specify Type):

A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements or European standard EN 149 must be followed whenever workplace conditions warrant respirator use.

Eye Protection:

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Protective Gloves: Wear chemical-resistant gloves to prevent skin exposure.

Other Protective Clothing: Wear appropriate protective clothing to prevent skin exposure.

Engineering Controls (Ventilation etc.):

Provide adequate ventilation to minimize dust concentrations: either local exhaust or general room ventilation is usually required. Eye-wash and shower stations should be present.

Work/Hygienic/Maintenance Practices:

Handle in accordance with good industrial hygiene and safety practice. Prevent further leakage (in the event of an accident or spillage) if safe to do so. Do not let product enter drains.

Eye protection: Goggles recommended during handling.

9 Physical and chemical properties

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9.1 Information on basic physical and chemical properties

General Information

Appearance: Solid powder

Form: Solid

Color: White

Odor: slight fatty odor

pH-value: 7 - 9

Melting point/Melting range: 130 – 145 °C

Boiling point/Boiling range: Not applicable

Flash point: ≈ 190 °C (Cleveland open cup method)

Flammability (solid, gaseous): 15 g/m³ particles <74μ

Ignition temperature: Not determined

Decomposition temperature: > 200 °C

Auto igniting: 410 °C

Danger of explosion: Product does not present an explosion hazard.

Explosion limits:

Lower: Not determined.

Upper: Not determined.

Vapor pressure: Not determined.

Specific gravity: Not determined

Density: 1.095 g/cm³

Relative density: Not determined.

Vapor density: Not determined.

Evaporation rate: Not determined.

Solubility in / Miscibility with Water: Insoluble

Partition coefficient (n-octanol/water): Not determined.

Viscosity: Not determined.

Dynamic: Not determined.

Kinematic: Not determined.

9.2 Other information: No further relevant information available.

10 Stability and reactivity

10.1 Reactivity: Stable under normal use conditions.

10.2 Chemical stability: Stable under normal use conditions.

10.3 Possibility of hazardous reactions: No dangerous reactions known.

10.4 Conditions to avoid: Keep away from sparks/heat/open flame/hot surfaces – no smoking.

10.5 Incompatible materials: Oxidizing agents, alkalis.

10.6 Hazardous decomposition products: Thermal decomposition generates: magnesium oxides, carbon oxides.

11 Toxicological information

11.1 Information on toxicological effects

Acute toxicity:

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LD/LC50 values that are relevant for classification:

Oral (rat)	LD50	> 10g/kg
Dermal	LD50	Not classified
Inhalation	LD50	Not classified

Primary irritant effect:

on the skin: Not classified

on the eye: Dust is a mechanical irritant.

Sensitization: Not classified

Additional toxicological information:

No further relevant information available.

12 Ecological information

12.1 Toxicity

Aquatic toxicity: Not classified

12.2 Persistence and degradability: Readily biodegradeable.

12.3 Bioaccumulative potential: No further relevant information available.

12.4 Mobility in soil: No further relevant information available.

Additional ecological information:

General notes:

No further relevant information available.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Other adverse effects: No further relevant information available.

13 Disposal considerations

13.1 Waste treatment methods

THIS MATERIAL, AS SUPPLIED, IS NOT A HAZARDOUS WASTE ACCORDING TO FEDERAL REGULATIONS (40 CFR 261). THIS MATERIAL COULD BECOME A HAZARDOUS WASTE IF IT IS MIXED WITH OR OTHERWISE COMES IN CONTACT WITH A HAZARDOUS WASTE, IF CHEMICAL ADDITIONS ARE MADE TO THIS MATERIAL, OR IF THE MATERIAL IS PROCESSED OR OTHERWISE ALTERED. CONSULT 40 CFR 261 TO DETERMINE WHETHER THE ALTERED MATERIAL IS A HAZARDOUS WASTE. CONSULT THE APPROPRIATE STATE, REGIONAL, OR LOCAL REGULATIONS FOR ADDITIONAL REQUIREMENTS.

14 Transport information

14.1 UN-Number

DOT, ADR, ADN, IMDG, IATA

Not Regulated

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14.2 UN proper shipping name DOT, ADR, ADN, IMDG, IATA	Not Regulated
14.3 Transport hazard class(es) DOT, ADR, ADN, IMDG, IATA Class	Not Regulated
14.4 Packing group DOT, ADR, IMDG, IATA	Not applicable.
14.5 Environmental hazards:	Not applicable.
14.6 Special precautions for user	Not applicable.
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
UN "Model Regulation":	Not applicable.

15 Regulatory information

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

- Sara **Section 355 (extremely hazardous substances):** Substance is not listed.
- Sara **Section 313 (Specific toxic chemical listings):** Substance is listed.
- **TSCA (Toxic Substances Control Act):** ACTIVE
- **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

15.1.1 EU-Regulations

No REACH Annex XVII restrictions

MAGNESIUM STEARATE is not on the REACH Candidate List

MAGNESIUM STEARATE is not on the REACH Annex XIV List

15.2 Chemical safety assessment

CSA is not required; substance is not hazardous.

16 Other information

This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered to be dependable and is accurate to the best of the Company's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. The Company cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

Department issuing SDS:

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SpecializedRx Products, LLC

Quality Assurance

Contact: sales@specializedrx.com

Date of preparation / last revision: 4/26/2022

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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

VOC: Volatile Organic Compounds (USA, EU)

LD50: Median lethal dose

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit