



Safety Data Sheet

Corporacion Sierra Madre

MAGNESIUM STEARATE

Code: 22 PSGC HS

ISO Section: 7.2.1

Revision No.: 02

Revision Date: 04/15/2015

Read the entire SDS for a complete hazard assessment.

Section 1. Product and Company Identification

1.1 Product Identifiers:

Product Name: Magnesium Stearate (all grades)

Product Grades: TEC-01, TEC, RC

Chemical Name/Synonyms: Magnesium salt of stearic acid, Magnesium Distearate, Magnesium Octadecanoate

Chemical Formula: $\text{Mg}(\text{C}_{18}\text{H}_{35}\text{O}_2)_2$

CAS RN: 557-04-0

EINECS: 209-150-3

1.2 Recommended use: Tablet and capsule lubricant, emulsifier.

Restrictions on use: Commercial formulation use only.

1.3 Manufacturer and Supplier:

Manufacturer

Corporacion Sierra Madre, SA de CV

Carretera a Garcia, km 8.5

Garcia, Nuevo Le6n, Mexico 66000

Phone: +52 (81) 8345-4024

E-mail: csm@corpsierramadre.com

Website: www.corpsierramadre.com

SDS Responsible Party

Distributor

R.E. Carroll, Inc.

1570 North Olden Avenue

Trenton, NJ 08638 USA

Fax: 609-695-0102

E-mail: johnb@recarroll.com

Website: www.recarroll.com

QA/Compliance Manager: John Boruta

1.4 Emergency telephone number:

In the US: For a transport accident or leak, fire or major spill, call CHEMTREC, (800) 424-9300.

For International CHEMTREC assistance, call 1-703-527-3887 (collect calls accepted).

Section 2. Hazards Identification

2.1 Globally Harmonized System (GHS) Hazard Classification:

OSHA Classification in accordance with 29 CFR 1910 (OSHA HCS): hazardous, combustible dust.

GHS Classification: Not classified as hazardous.

This SDS meets the requirements of GHS Revision 3.



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2.2 Label elements including precautionary:

Symbol: No pictogram needed.

Signal word: Warning!

OSHA Hazard Statement:

May form combustible dust concentrations in air. May irritate eyes, skin, and respiratory passages.

OSHA Precautionary Statements:

Prevention: Wear protective gloves/protective clothing/eye protection/face protection.

Keep away from all ignition sources. No smoking. Prevent dust accumulations to minimize explosion hazard.

Use explosion-proof (electrical/ventilation/lighting) equipment. Use non-sparking tools. Take action to prevent static discharge.

Response: If exposed or concerned: Get medical advice/attention.

If in eyes: Immediately flush eyes thoroughly with water for several minutes. Remove contact lenses after one to two minutes and continue flushing for several more minutes. If redness, itching or burning sensation develops, seek medical attention.

If on skin: Wash with plenty of soap and water. If irritation or rash occurs: Get medical advice/attention.

If Inhaled: Remove victim to fresh air. If a cough or other respiratory symptoms develop, consult medical personnel.

Storage: Store in accordance with local regional national international regulations. Ground/bond container and receiving equipment.

Disposal: Dispose of contents/container in accordance with local regional national international regulations.

2.3 Other hazards which are not included in the classification criteria:

Slipping/falling hazard. May cause mild irritation to respiratory tract and irritation to eyes and skin. This product has no known chronic effects. Repeated or prolonged exposure to this compound is not known to aggravate medical conditions. May be harmful if allowed to enter drinking water intakes. Do not contaminate domestic or irrigation water supplies, lakes, streams, ponds, or rivers.

Section 3. Composition/Information on Ingredients

Chemical Name	CAS No.	Content (%)
Stearic acid	57-11-4	1-2
Magnesium Stearate	557-04-0	98-99



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Section 4. First-Aid Measures

General advice: Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

4.1 Inhalation:

Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen and continue to monitor. Consult medical attention.

4.2 Skin contact:

Wash skin with plenty of soap and water. If symptoms persist, seek medical attention. Wash contaminated clothing before use.

4.3 Eye contact:

Immediately flush eyes thoroughly with water for several minutes. Remove contact lenses after one to two minutes and continue flushing for several more minutes. If redness, itching or burning sensation develops, seek medical attention.

4.4 Ingestion:

DO NOT INDUCE VOMITING. Never give anything by mouth to an unconscious person. Gently wipe or rinse the inside of the mouth with water. Sips of water can be given. If symptoms persist, contact a poison control center, emergency room, or physician for treatment information.

4.5 Acute and delayed symptoms/effects:

Eye Contact: Excessive exposure may cause irritation to eyes. Irritation to the eyes will cause watering and redness.

Skin Contact: May cause mild irritation. Reddening, scaling, and itching are characteristics of skin inflammation.

Ingestion: Harmful effects not anticipated from swallowing small amounts. May be harmful in large amounts.

Inhalation: Excessive exposure may cause irritation to eyes, nose, throat, lungs, and respiratory tract.

Chronic health effects: This product has no known chronic effects.

Relevant routes of exposure: Eye, skin, inhalation.

4.6 Indication of immediate medical attention and notes for physicians:

Persons with pre-existing skin, eye, or respiratory conditions may be at an increased risk from the irritant properties of this material. Attending physician should treat exposed patients symptomatically.



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Section 5. Fire-Fighting Measures

5.1 Extinguishing media:

Suitable extinguishing media:

Non-flammable. Use extinguishing media appropriate to surrounding fire and to protect personnel. Hand held dry chemical or carbon dioxide extinguishers may be used for small fires. Dust explosion hazard may result from forceful application of fire extinguishing agents.

Unsuitable extinguishing media:

For this product, no limitations of extinguishing agents are given. Forceful application of fire extinguishing agents or water spray may spread burning material.

5.2 Special hazards arising from the chemical:

Unusual fire and explosion hazards: Concentrated dust may present an explosion hazard.

Hazardous Combustion Products: During a fire, smoke may contain the original material in addition to combustion products of varying composition, which may be toxic and/or irritating.

5.3 Special protective equipment and precautions for firefighters:

Fire Fighting Procedures:

Keep personnel away. Isolate fire and deny unnecessary entry. Do not apply direct water stream. Use fine water spray or foam. Cool surroundings with water to localize fire zone. Dust explosion hazard may result from forceful application of fire extinguishing agents. Hand held dry chemical or carbon dioxide extinguishers may be used for small fires.

Special Protective Equipment for Firefighters:

Wear positive-pressure self-contained breathing apparatus (SCBA) and protective firefighting clothing (includes firefighting helmet, coat, trousers, boots, and gloves). If protective equipment is not available or not used, fight fire from a protected location or safe distance.

Section 6. Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures:

Use personal protective equipment. Avoid breathing vapors, mist, or gas. Avoid skin and eye contact. Evacuate personnel to safe areas. Spilled material may cause a slipping hazard. Use appropriate safety equipment. See Section 8 for information on personal protection equipment.



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6.2 Environmental precautions and protective procedures:

Prevent further leakage or spillage if safe to do so. Do not let product enter drains, sewers, waterways, and/or groundwater.

6.3 Methods and material for containment and cleaning up:

Contain spilled material if possible. Sweep up using non-sparking tools. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Avoid dispersal of dust in the air. Collect in suitable and properly labeled containers. See Section 13, Disposal Considerations, for additional information.

6.4. Reference to Other Sections: See Section 8, Exposure Controls and Personal Protection.

Section 7. Handling and Storage

7.1 Precautions for safe handling:

Follow procedures specified in the National Fire Protection Association Codes and Standards for handling combustible dusts. No smoking, open flames or sources of ignition in handling and storage area. Good housekeeping and controlling of dusts are necessary for safe handling of product. When transferring material, use proper grounding to avoid electrical sparks. Product surface alterations caused by calcining or mixing with additives may alter toxicological properties.

Avoid breathing process fumes. Use with adequate ventilation. Do not eat, drink, and/or smoke in work areas. Wash hands after use. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage (including any incompatibilities):

Store in cool place. Avoid heat and ignition sources. Keep container tightly closed in a dry and well-ventilated place. Store in accordance with good manufacturing practices.



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Section 8. Exposure Controls and Personal Protection

Consult with a Health and Safety Professional for specific selections.

8.1 Control parameter:

OCCUPATIONAL EXPOSURE LIMITS:

ACGIH TLV: (as stearates) 10 mg/m TWA

Particulates Not Otherwise Classified (Dusts)

Permissible Exposure Limit (PEL): Table Z-1 8-Hr Time Weighted Avg. (TWA) (DUSTS)

OSHA PEL: TWA 15 mg/m³ (Total Dust), TWA 5 mg/m³ (Respirable Fraction)

ACGIH: TWA 10 mg/m³ (Inhalable particles) TWA 3 mg/m³ (Respirable Particles)

NIOSH REL: TWA 10 mg/m³ (Total Dust), TWA 5 mg/m³ (Respirable Fraction)

Appropriate engineering controls:

Use adequate general or local exhaust ventilation to keep airborne concentrations below the permissible exposure limits. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen- deficient environment. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Use only appropriately classified electrical equipment and powered industrial trucks. Refer to NFPA 654, *Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids*, for safe handling.

8.2 Personal protective equipment:

Eye protection:

Use safety glasses. If there is a potential for exposure to mists which could cause eye discomfort, wear chemical goggles, or use a full-face respirator.

Body protection: Wear clean body-covering clothing to prevent skin exposure.

Hand protection:

Contact should be minimized. Protective gloves are recommended when prolonged skin contact cannot be avoided. The glove(s) listed may provide protection against permeation (gloves of other chemically resistant materials may not provide adequate protection): Polyethylene, Polyvinyl chloride (PVC), Neoprene, Nitrile, Polyvinyl alcohol, Viton. Selection of gloves will depend on the task.

Respiratory protection:

Concentration in air determines the level of respiratory protection needed. Use only NIOSH certified respiratory equipment. Respiratory protection is not usually needed unless product is heated or misted. Half-mask air purifying respirator with dust mist filters or HEPA filter cartridges is acceptable for exposures to ten (10) times the exposure limit. Full-face air purifying respirator with dust mist filters or HEPA filter cartridges is acceptable



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for exposures to fifty (50) times the exposure limit. Protection by air purifying respirators is limited. Use a positive pressure-demand full-face supplied air respirator or SCBA for exposures greater than fifty (50) times the exposure limit. If exposure is above the IDLH (Immediately Dangerous to Life and Health), or there is the possibility of an uncontrolled release, or exposure levels are unknown, then use a positive pressure-demand full-face supplied air respirator with escape bottle or SCBA. Wear a NIOSH-approved (or equivalent) full-face piece airline respirator in the positive pressure mode with emergency escape provisions.

Other:

Remove contaminated clothing and wash before reuse. For non fire emergencies, respiratory protection may be necessary and wear appropriate protective clothing to avoid contact with material. Have eyewash station in work area. Do not consume or store food in the work area. Wash hands before smoking or eating.

Section 9. Physical and Chemical Properties

Appearance: Solid, powder to granular (depending on the grade).

Odor: Slightly fatty odor

Color: White to off white

Solubility: Insoluble in water, ethanol, ether; slightly soluble in benzene

Specific Gravity: 1.03

pH: Not available

% Volatiles by volume: < 4 %

Boiling Point: Not available

Melting Point: 98-118°C (208-244°F)

Vapor Density (Air=1): No information found

Vapor Pressure (mm Hg): No information found

Evaporation Rate (BuAc=1): No information found

Flash Point: 347°F/175°C

Flammable Limits in Air: Not available

Auto Ignition Temperature: 743°F/395°C

Remarks: The above information is not intended for use in preparing product specification. Contact CSM before writing specifications.

Section 10. Stability and Reactivity

10.1 Chemical stability: Stable under normal temperature conditions and recommended use.

10.2 Possibility of hazardous reactions: No hazardous reactions if stored and handled as prescribed/indicated.

10.3 Conditions to avoid: Strong heating, sparks, open flames, moisture.



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10.4 Incompatible materials:

Strong oxidizing agents, strong acids. Strong bases, oxidizers, hydrogen fluoride, fluorine, xenon hexafluoride, oxygen difluoride, and chlorine trifluoride.

10.5 Hazardous decomposition products:

Decomposition products including Magnesium oxide, Carbon dioxide and Carbon monoxide, depend upon temperature, air supply and the presence of other materials. Processing may release fumes and other decomposition products. Fumes can be irritating.

10.6 Hazardous Polymerization: Will not polymerize.

Section 11. Toxicological Information

11.1 Information on the likely routes of exposure: Inhalation, ingestion, skin and eye contact.

11.2 Information on toxicological effects:

Acute toxicity:

Oral	LD 50: > 2,000 mg/kg (rat)
Inhalation	No data available
Dermal	LD 50: > 5,000 mg/kg (rabbit)

GHS Classifications:

Skin corrosion/irritation: May cause mild skin irritation. GHS Classification: Not Classified.

Serious eye damage/irritation: Eye contact can result in mild irritation. GHS Classification: Not Classified.

Inhalation: This material may cause mild respiratory tract irritation. GHS Classification: Not Classified.

Respiratory or skin sensitization: Not known to be a sensitizer. GHS Classification: Not Classified.

Germ Cell Mutagenicity: No known significant effects or critical hazards. GHS Classification: Not Classified.

Reproductive Toxicity: No known significant effects or critical hazards. GHS Classification: Not Classified.

Teratogenicity: No known significant effects or critical hazards. GHS Classification: Not Classified.

Specific target organ toxicity (STOT):

STOT-single exposure: The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.



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11.3 Carcinogenicity: This product does not contain any material at > 0.1% that is listed by IARC, NTP, EPA, ACGIH, or OSHA as a carcinogen.

11.4 Other Studies Relevant to Material:

A short-term inhalation study resulted in seven out of ten rats exposed to a single one-hour exposure to 200 mg/L died. In a similar exposure to 2 mg/L, two out of 10 deaths occurred in the second week.

Chronic ingestion studies showed an increased incidence of stone formation in the lower urinary tract, and four deaths were seen in rats fed a diet containing 20 % Magnesium Stearate for 90 days. Reduced liver weight was seen in rats fed a diet containing 10 or 20 % Magnesium Stearate. No adverse effects were seen in rats fed a 5 % diet (2500 mg/kg body weight/day).

Section 12. Ecological Information

12.1 Mobility: No information available.

12.2 Aquatic and terrestrial ecotoxicity: No information available.

12.3 Persistence and degradability: No information available.

12.4 Bioaccumulative potential: No information available.

12.5 Other adverse effects:

May be harmful if allowed to enter drinking water intakes. Do not contaminate domestic or irrigation water supplies, lakes, streams, ponds, or rivers.

Section 13. Disposal Considerations

13.1 Disposal methods:

Uncontaminated discarded product is not a hazardous waste under RCRA. Do not dump into any sewers, on the ground or into any body of water. All disposal practices must comply with all federal, state, and local laws and regulations. Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this.

13.2 Container disposal:

Empty container retains product residue. Observe all hazard precautions. Do not distribute, make available, furnish or reuse empty container except for storage and shipment of original product. Remove all product residue. Puncture or otherwise destroy empty container and dispose of in a facility permitted for nonhazardous waste.



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Section 14. Transport Information

14.1 UN number: Not regulated

14.2 UN proper shipping name: Not regulated

14.3 Transport hazard class: Not regulated

14.4 Packing group (if applicable): Not regulated

14.5 Marine Pollutant (Yes/No): No

14.6 Special precaution: No information available

Call CSM shipping department [+52 (81)8345-1024] if any additional information is required.

Section 15. Regulatory Information

U.S. Regulations

15.1 US TSCA inventory:

All chemical substances in this product comply with all rules or orders under TSCA. All intentionally added ingredients either are listed on the TSCA Inventory list or exempt from listing.

15.2 SARA Section 311/312 Hazard Categories:

Acute Hazard: No

Chronic Hazard: No

Fire Hazard: Yes

Reactive Hazard: No

Sudden Pressure Release: No

15.3 CERCLA Hazardous Substance SARA Section 304 Release Reporting:

Component(s)

None assigned

Reportable Quantity

Reporting

Threshold

Concentration

Min Max

CAS Number

None



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15.4 SARA Section 302 Extremely Hazardous Substances:

Component(s)/ CAS Number	Reporting Threshold	Concentration Min Max
None		

15.5 SARA Section 313 Toxic Chemicals:

Component(s)/ CAS Number	Reporting Threshold	Concentration Min Max
None		

US State Regulations

15.6 California Proposition 65:

This product is not known to contain chemical(s) known to the State of California to cause cancer or reproductive harm.

15.7 Pennsylvania Worker and Community Right To Know Act:

Magnesium distearate: 557-04-0

15.8 New Jersey Worker and Community Right To Know Act:

Magnesium distearate: 557-04-0

15.9 Massachusetts Right To Know Act:

Magnesium distearate: 557-04-0

15.10 Rhode Island Right To Know Act:

Magnesium distearate 557-04-0

15.11 International Regulations:

Canadian Regulations:

WHMIS Statement: This product has been classified in accordance with the hazard criteria of the *Controlled Products Regulations* and the SDS contains all the information required by the *Controlled Products Regulations*. This product is classified as controlled in accordance with the Canadian Controlled Products Regulations

International Inventory status:

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes

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Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

* A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s).

Section 16. Other Information

16.1 NFPA and HMIS Hazard Ratings:

We assigned NFPA and HMIS ratings to this product based on the hazards of its ingredient(s). Because the customer is most aware of the application of the product, the customer must ensure that the proper personal protective equipment (PPE) is provided consistent with information contained in the product SDS. This information is intended solely for the use of individuals trained in the particular hazard rating system.

Key: 0 = least, 1 = slight, 2 = moderate, 3 = high, 4 = extreme

NFPA (National Fire Protection Association) - Classification

Health	1 slight
Flammability	1 minimal
Instability or Reactivity	0 minimal
Special Hazards	none

HMIS® [Hazardous Materials Identification System (Paint & Coating)] - Classification

Health	1 slight
Flammability	1 minimal
Reactivity	0 minimal

NFPA, HMIS® rating involves data interpretations that may vary from company to company. They are intended only for rapid, general identification of the magnitude of the specific hazard. To deal adequately with the safe handling of this material, all the information contained in this SDS must be considered. This information is supplied solely for the use of individuals trained in the particular hazard rating system.



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16.2 Revision information:

Date of the previous revision: 12/03/2015 (Version 1)

Date of this revision: 04/15/2015 (Version 2.0)

Revision summary: Revised GHS/OSHA compliant SDS

Prepared by RC² Consulting, Inc. for R. E. Carroll, Inc.

Approved by: John Boruta

16.3 Training advice: Provide adequate information, instruction and training for operators.

16.4 Key or legend to abbreviations and acronyms used in the safety data sheet:

ACGIH	American Conference of Governmental Industrial Hygienists
BEI	Biological Exposure Index
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit
ppm	parts per million
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value
TWA	Time Weighted Average
REL	Recommended exposure limits from NIOSH
NIOSH	National Institute for Occupational Safety and Health
Action Level	An exposure value set by OSHA that is lower than the PEL that will trigger the need for activities such as exposure monitoring and medical surveillance.

This Safety Data Sheet conforms to US GHS (Revision 3) Hazcom 2012

16.5 Declare to reader: The opinions expressed herein are those of qualified experts within R.E. Carroll, Inc. The information provided in this Safety Data Sheet is correct to the best of our knowledge, information, and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal, and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

END OF SDS
