SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Ferrous Gluconate Tablets, USP 324mg
Synonyms: 7H5

Manufacturer Name: Perrigo Company
Address: 515 Eastern Avenue
Allegan, MI 49010 USA

Telephone number: 269-673-8451

Emergency phone number: 888-464-2986 (U.S. calls)
+1 760-476-3962 Code 333304 (International calls)

Email Address: SDSRequest@perrigo.com

Recommended use: Dietary Supplement
Restrictions on use: Use only as directed.

Date of Preparation: February 17, 2015

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Not hazardous

Label Elements

Not hazardous in accordance with the GHS and OSHA Hazcom 2012.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Ferrous Gluconate	6047-12-7	50-60%
Cellulose	9004-34-6	Proprietary
Corn Starch	977050-51-3	Proprietary
Sodium Starch Glycolate	9063-38-1	Proprietary
Collodial Silicon Dioxide	7631-86-9	Proprietary
Talc	14807-96-6	Proprietary
Stearic Acid	57-11-4	Proprietary
Sucrose	57-50-1	Proprietary
Titanium Dioxide (bound in tablet)	13463-67-7	Proprietary
Polyethylene Glycol	25322-68-3	Proprietary
Magnesium Stearate	557-04-0	Proprietary
Calcium Carbonate	471-34-1	Proprietary

Copovidone	25086-89-9	Proprietary
Shellac	9000-59-3	Proprietary
Cocoa Butter	8002-31-1	Proprietary
FD&C Blue #1 Aluminum Lake	68921-42-6	Proprietary
Maltodextrin	9050-36-6	Proprietary
Hypromellose	9004-65-3	Proprietary
Riboflavin	83-88-5	<0.1%
Carnauba Wax	8015-86-9	Proprietary
White Wax	8012-89-3	Proprietary

The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST-AID MEASURES

Inhalation: Remove victim to fresh air. If irritation occurs, get medical attention.
Skin contact: In the case of contact with crushed or broken tablets, remove contaminated clothing. Wash skin thoroughly with soap and water for several minutes. If irritation develops, get medical attention. Launder clothing before reuse.
Eye contact: Flush eyes thoroughly with water for several minutes while lifting the upper and lower lids. Get medical attention if irritation persists**.**
Ingestion: In the case of unintended ingestion, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if any adverse effects occur.

Most important symptoms/effects, acute and delayed: Dust may cause eye irritation. Inhalation of dust from broken tablets may cause upper respiratory tract irritation. Swallowing large amounts above the recommended dosage may be harmful or fatal. May cause vomiting, severe abdominal pain and diarrhea.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is required for large overdoses.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use water spray, carbon dioxide, dry chemical or foam to extinguish a fire.

Specific hazards arising from the chemical: Tablets are not a fire hazard but may burn under fire conditions.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8. If tablets are damaged, respiratory protection may be required. Avoid generating airborne dust during cleanup.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Collect using methods that avoid the generation of dust and damage to tablets (scoop up carefully) and place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of dust. If tablets are damaged, avoid contact with eyes, skin and clothing and avoid breathing dust.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Ferrous Gluconate	None Established
Cellulose	10 mg/m3 TWA ACGIH TLV 5 mg/m3 (respirable) 15 mg/m3 (total dust) TWA OSHA PEL
Corn Starch	10 mg/m3 TWA ACGIH TLV 5 mg/m3 (respirable) 15 mg/m3 (total dust) TWA OSHA PEL
Sodium Starch Glycolate	None Established
Colloidal Silicon Dioxide	80 mg/m3/%SiO2 TWA OSHA PEL
Talc	20 mppcf TWA OSHA PEL 2 mg/m3 TWA (respirable) ACGIH TLV
Stearic Acid	None Established
Sucrose	10 mg/m3 TWA ACGIH TLV 5 mg/m3 (respirable) 15 mg/m3 (total dust) TWA OSHA PEL
Titanium Dioxide (bound in tablet)	10 mg/m3 TWA ACGIH TLV 15 mg/m3 (total dust) TWA OSHA PEL
Polyethylene Glycol	None Established
Magnesium Stearate	10 mg/m3 TWA total dust ACGIH TLV
Calcium Carbonate	5 mg/m3 (respirable) 15 mg/m3 (total dust) TWA OSHA PEL
Copovidone	None Established
Shellac	None Established
Cocoa Butter	None Established
FD&C Blue #1 Aluminum Lake	None Established
Maltodextrin	None Established
Hypromellose	None Established
Riboflavin	4000 ug/m3 Perrigo OEL
Carnauba Wax	None Established
White Wax	None Established

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits.

Individual protection measures:
Respiratory protection: None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.
Skin protection: None normally required.
Eye protection: Safety glasses or goggles recommended for handling damaged tablets.
Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Green Tablet
Odor: None

Odor threshold: Not applicable	**pH:** 4.0-5.5
Melting point/freezing point: Not applicable	**Boiling Point:** Not applicable
Flash point: Not applicable	**Evaporation rate:** Not applicable
Flammability (solid, gas): Not flammable	**VOC:** Not applicable
Flammable limits: LEL: Not applicable	**UEL:** Not applicable
Vapor pressure: Not applicable	**Vapor density:** Not applicable
Relative density: Not available	**Solubility(ies):** Not available
Partition coefficient: n-octanol/water: Not available	**Auto-ignition temperature:** Not available
Decomposition temperature: Not available	**Viscosity:** Not applicable

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.
Chemical stability: Stable.
Possibility of hazardous reactions: None known.
Conditions to avoid: None known.
Incompatible materials: Avoid oxidizing agents.
Hazardous decomposition products: Thermal decomposition may yield carbon and iron.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:
Inhalation: Inhalation of dust from damaged tablets may cause irritation of the mucous membranes and upper respiratory tract.
Ingestion: Swallowing large amounts above the recommended dosage may be harmful or fatal. May cause vomiting, severe abdominal pain and diarrhea.
Skin contact: Contact with damaged tablets may cause mild irritation.
Eye contact: Contact with damaged tablets may cause mild irritation with redness and tearing.
Chronic Effects: Prolonged absorption of iron may cause iron poisoning.
Sensitization: Components are not known to be sensitizers.
Germ Cell Mutagenicity: None of the components have been shown to cause germ cell mutagenicity.
Reproductive Toxicity: None of the components have been shown to cause reproductive toxicity.
Carcinogenicity: Titanium dioxide is classified by IARC as a suspected carcinogen (Group 2B). Titanium dioxide causes cancer only by inhalation of respirable particles. The titanium dioxide is bound in the caplet matrix and no inhalation exposure will occur during the handling of these capsules. None of the other components are listed as carcinogens or suspected carcinogens by IARC, NTP, ACGIH or OSHA.

Acute Toxicity Values:
Ferrous gluconate: LD50 oral rat 2237-4600 mg/kg.

12. ECOLOGICAL INFORMATION

Ecotoxicity values: No data is available
Persistence and degradability: No data is available
Bioaccumulative potential: No data is available
Mobility in soil: No data is available.
Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Not Hazardous

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA**.**
CANADA:
Canadian CEPA: This product is a drug and not subject to CEPA regulations.
Canadian WHMIS Classification: Drugs are exempt from WHMIS
This product has been classified under the CPR and this SDS discloses information elements required by the CPR.

16. OTHER INFORMATION

NFPA Rating: Health = 1 Flammability = 1 Instability = 0
HMIS Rating: Health = 1 Flammability = 1 Physical Hazard = 0

SDS Revision History: Correction Section 15 - CERCLA
Date of last revision: October 2, 2017 – updated color of tablet Section 9

Disclaimer: This SDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).