



SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: DUAL ACTION ACID REDUCER COMPLETE

Synonyms: 546

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: Acid reducer

Restrictions on use: Use only as directed.

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
Calcium Carbonate	471-34-1	40-60%
Magnesium Hydroxide	1309-42-8	5-10%
Famotidine	76824-35-6	<5%
Microcrystalline Cellulose	9004-34-6	Proprietary
Lactose Anhydrous	63-42-3	Proprietary
Lactose Monohydrate	64044-51-5	Proprietary
Magnesium Stearate	557-04-0	Proprietary
Talc	14807-96-6	Proprietary
Aspartame	22839-47-0	Proprietary
Dextrates	68131-37-3	Proprietary
Ferric Oxide	1309-37-1	Proprietary
Glyceryl Monostearate	31566-31-1	Proprietary
Natural Peppermint Flavor	8006-90-4	Proprietary
Polyacrylate Dispersion	9003-01-4	Proprietary

Polysorbate 80	9005-65-6	Proprietary
Povidone	9003-39-8	Proprietary
Pregelatinized Starch	9005-25-8	Proprietary
Sodium Starch Glycolate	9063-38-1	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 or symptoms develop, get medical attention.

Skin contact: In the case of contact with crushed or broken tablets, remove contaminated clothing. Wash skin with soap and water. If irritation develops, get medical attention. Launder clothing before reuse.

Eye contact: Flush eyes with water 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 mild eye irritation. Inhalation of dust from damaged tablets may cause upper respiratory tract irritation. Swallowing may cause gastrointestinal effects, headache, dizziness, constipation and diarrhea.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is not required.

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. Fine dust from crushed tablets will present a dust explosion hazard.

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. Avoid generating airborne dust during cleanup. If dust is present, eliminate all sources of ignition.

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. If dust is present, do not use vacuum unless explosion-proof.

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. Wash thoroughly with soap and water after handling.

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION**Exposure guidelines:**

Chemical name	Exposure Limit
Calcium Carbonate	1000 ug/m ³ TWA (Perrigo OEB1) 15 mg/m ³ (total dust) TWA OSHA PEL 5 mg/m ³ (respirable dust) TWA OSHA PEL
Magnesium Hydroxide	None Established
Famotidine	100 ug/m ³ TWA (Perrigo OEB2)
Microcrystalline Cellulose	10 mg/m ³ TWA ACGIH TLV 15 mg/m ³ (total dust) TWA OSHA PEL 5 mg/m ³ (respirable dust) TWA OSHA PEL
Lactose Anhydrous	None Established
Lactose Monohydrate	None Established
Magnesium Stearate	10 mg/m ³ TWA total dust ACGIH TLV
Talc	20 mppcf TWA OSHA PEL 2 mg/m ³ (respirable) TWA ACGIH TLV
Aspartame	None Established
Dextrates	None Established
Ferric Oxide	5 mg/m ³ TWA (respirable) ACGIH TLV 10 mg/m ³ (as fume) TWA OSHA PEL
Glyceryl Monostearate	None Established
Natural Peppermint Flavor	None Established
Polyacrylate Dispersion	None Established
Polysorbate 80	None Established
Povidone	None Established
Pregelatinized Starch	10 mg/m ³ TWA ACGIH TLV 15 mg/m ³ (total dust) TWA OSHA PEL 5 mg/m ³ (respirable dust) TWA OSHA PEL
Sodium Starch Glycolate	None Established

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

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 required.

Eye protection: Chemical safety goggles recommended for handling damaged tablets.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Tablets, peach colored with white speckles.

Odor: Mint odor

Odor threshold: Not available	pH: Not applicable
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): Partially soluble in water
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 oxides.

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 may cause gastrointestinal effects, headache, dizziness, constipation and diarrhea.

Skin contact: No adverse effects expected.

Eye contact: Contact with damaged tablets may cause slight irritation with redness and tearing.

Chronic Effects: None known.

Sensitization: Components are not known to be sensitizers.

Germ Cell Mutagenicity: None of the components have been shown to cause germ cell mutagenicity.

Famotidine was negative in the microbial mutagen test (Ames test) using *Salmonella typhimurium* and *Escherichia coli* with or without rat liver enzyme activation at concentrations up to 10,000 mcg/plate. In *in vivo* studies in mice, with a micronucleus test and a chromosomal aberration test, no evidence of a mutagenic effect was observed.

Reproductive Toxicity: None of the components are reproductive toxins. In studies with rats given oral doses of up to 2000 mg/kg/day or intravenous doses of up to 200 mg/kg/day, fertility and reproductive performance were not affected. Reproductive studies have been performed in rats and rabbits at oral doses of up to 2000 and 500 mg/kg/day, respectively, and in both species at I.V. doses of up to 200 mg/kg/day, and have revealed no significant evidence of impaired fertility or harm to the fetus due to famotidine. While no direct fetotoxic effects have been observed, sporadic abortions occurring only in mothers displaying marked decreased food intake were seen in some rabbits at oral doses of 200 mg/kg/day.

Carcinogenicity: Titanium dioxide is classified by IARC as a suspected carcinogen (Group 2B). The titanium dioxide is bound in the capsule matrix and no inhalation exposure will occur during the handling of these tablets. None of the other components are listed as carcinogens or suspected carcinogens by IARC, NTP, ACGIH or OSHA. In a 106 week study in rats and a 92-week study in mice given oral doses of up to 2000 mg/kg/day, there was no evidence of carcinogenic potential for famotidine.

Acute Toxicity Values:

Calcium Carbonate: Oral rat LD50 6450 mg/kg

Magnesium Hydroxide: Oral rat LD50 8500 mg/kg

Famotidine: Oral rat LD50 4049 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 CERCLA 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

16. OTHER INFORMATION

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

SDS Revision History: New SDS

Date of preparation: May 28, 2016

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).