SAFETY DATA SHEETS

This SDS packet was issued with item:

078494271

N/A

Perrigo®

Quality Affordable Healthcare Products™

SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Flavoxate Hydrochloride Tablets, 100mg
Synonyms: 7H7

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: Human Drug - Symptomatic relief of dysuria, urgency, nocturia, suprapubic pain, frequency and incontinence
Restrictions on use: Prescription use only.

Date of Preparation: January 25, 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
Flavoxate Hydrochloride	3717-88-2	15-25%
Microcrystalline Cellulose	9004-34-6	Proprietary
Lactose Monohydrate	63-42-3	Proprietary
Sodium Starch Glycolate	9063-38-1	Proprietary
Collodial Silicon Dioxide	7631-86-9	Proprietary
Hypromellose	9004-65-3	Proprietary
Polyacrylate	Proprietary	Proprietary
Polyethylene Glycol	25322-68-3	Proprietary
Magnesium Stearate	557-04-0	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 cause drowsiness and blurred vision.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is recommended 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. 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. If tablets are damaged, respiratory protection may be required. 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. Clean area thoroughly. 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:

Flavoxate Hydrochloride	500 ug/m3 TWA Perrigo OEL
Microcrystalline Cellulose	10 mg/m3 TWA ACGIH TLV 5 mg/m3 (respirable) 15 mg/m3 (total dust) TWA OSHA PEL
Lactose Monohydrate	None Established
Sodium Starch Glycolate	None Established
Collodial Silicon Dioxide	80 mg/m3/%SiO2 TWA OSHA PEL
Hypromellose	None Established
Polyacrylate	None Established
Polyethylene Glycol	None Established
Magnesium Stearate	10 mg/m3 TWA total dust ACGIH TLV

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: Impervious gloves recommended for handling damaged tablets.
Eye protection: Safety glasses or goggles recommended for handling damaged tablets.
Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

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

Odor threshold: Not applicable	**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):** 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 and chlorine compounds.

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 cause drowsiness and blurred vision.
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: 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.
Reproductive Toxicity: None of the components have been shown to cause reproductive toxicity. Reproduction studies have been performed in rats and rabbits at doses up to 34 times the human dose and revealed no evidence of impaired fertility or harm to the fetus due to flavoxate HCl.
Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, ACGIH or OSHA.

Acute Toxicity Values:
Flavoxate Hydrochloride: LD50 oral rat 4273 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: CERCLA: This product has a reportable quantity of 2500 lbs based on the RQ of cupric sulfate of 10 lbs. 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: New SDS
Date of preparation: January 25, 2015
Date of last revision: New SDS

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).