

MATERIAL SAFETY DATA SHEET

Flavoxate HCl 100 mg Tablets

Paddock Laboratories, Inc.
3940 Quebec Avenue North
Minneapolis, MN 55427

Emergency Assistance:
CHEMTREC® (24-hour) 1-800-424-9300

Tel: (763) 546-4676

Paddock Technical Assistance: 1-800-328-5113

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SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: Flavoxate HCl 100 mg Tablets
COMMON NAME: Flavoxate HCl 100 mg Tablets
CHEMICAL NAME: 2-piperidinoethyl 3-methyl-4-oxo-2-phenyl-4H-1-benzopyran-8-carboxylate hydrochloride
SYNONYMS: NA
CHEMICAL FORMULA: C₂₄H₂₅NO₄ • HCl
DRUG FAMILY: Muscarinic antagonists

SECTION 2: COMPOSITION AND INGREDIENTS

CHEMICAL NAME	CAS#	OSHA PEL	ACGIH TLV	IDLH
Flavoxate HCl	3717-88-2	NE	NE	NE
Microcrystalline Cellulose	9004-34-6	15 mg/m ³	10 mg/m ³	NE
Lactose monohydrate	63-42-3	NE	NE	NE
Sodium Starch Glycolate	9004-34-6	NE	NE	NE
*Colloidal Silicon Dioxide	7631-86-9	10 mg/m ³	10 mg/m ³	NE
Hypromellose USP	009004-65-3	NE	NE	NE
Polyacrylate Dispersion 30%	Not Determined	NE	NE	NE
*Magnesium Stearate	557-40-0	NE	NE	NE
*Opadry Clear (YS-1-7006)	Not Determined	NE	NE	NE
*Purified Water USP	Not Determined	NE	NE	NE

NE = Not Established, Specific amounts are considered proprietary information.

* These ingredients are present in concentrations of <1%.

TO THE BEST OF OUR KNOWLEDGE THE INFORMATION CONTAINED HEREIN IS ACCURATE AS OF THE DATE HEREOF. ANY DETERMINATION AS TO THE SUITABILITY OF THE PRODUCT FOR ANY PARTICULAR PURPOSE, ITS SAFE USE OR DISPOSAL SHALL BE THE RESPONSIBILITY OF THE USER. THE INFORMATION CONTAINED HEREIN IS IN NO WAY INTENDED TO SUPPLEMENT, MODIFY OR SUPERSEDE THE INFORMATION PROVIDED IN THE PRODUCT PACKAGE INSERT WITH RESPECT TO THE USE OF THE PRODUCT FOR MEDICAL PURPOSES.

SECTION 3: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: Flavoxate HCl 100 mg tablets are white, round tablets, debossed "PAD" and "0115" on one side and no deboss on the other side. The ingredients listed are non-hazardous.

Symptoms of Overexposure by Route of Exposure: None for occupational exposure.

Inhalation: Inhalation is not likely to occur, however avoid breathing or creating dust. If symptoms occur, move to fresh air and seek medical attention.

Contact with Skin or Eyes: Contact with eyes is not likely to occur. Minor irritation or redness may occur following direct contact.

Skin: There is no hazards associated with contact with skin, however if irritation occurs, wash thoroughly with soap and water and seek medical attention.

Ingestion: Effects of accidental ingestion may include headache, drowsiness, dizziness, confusion, nervousness, blurred vision, palpitations, skin rash, or diarrhea.

SECTION 4: FIRST AID MEASURES

Skin Exposure: Thoroughly wash with mild soap and water if irritation develops.

Eye Exposure: Immediately flush eye with copious amounts of water and seek medical attention if symptoms occur.

Inhalation: Inhalation exposure is not expected to occur. If symptoms occur, move to fresh air and seek medical attention.

Ingestion: In the case of occupational overexposure, get medical attention if symptoms develop.

NOTE TO PHYSICIANS: Medical treatment in cases of overexposure should be treated as an overdose of flavoxate. Refer to current prescribing information or to local poison control information centers

SECTION 5: FIRE / EXPLOSION HAZARDS & FIRE-FIGHTING MEASURES

Flash Point: NE

Autoignition Temperature: NE

Flammable Limits (in air by volume, %): Lower: NE Upper: NE

Fire Extinguishing Equipment: Use extinguishing agent suitable for type of surrounding fire.

Water Spray: OK Carbon Dioxide: no Halon: OK

Foam: OK Dry Chemical: OK Other: Any "ABC" Class

Unusual Fire and Explosion Hazards: No unusual fire or explosion hazards are expected.

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

Special Fire Fighting Procedures: For single units, no special requirements are needed. For fires beyond the incipient stage, emergency responders in the immediate hazard area should wear bunker gear. When the potential chemical hazard is unknown, in enclosed or confined spaces, or when explicitly required by the DOT *Emergency Response Guidebook*, a self-contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see Section 8). Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Move undamaged containers from immediate hazard area if it can be done with minimal risk. Cool equipment exposed to fire with water, if it can be done with minimal risk.

Hazardous Decomposition Products: Toxic, corrosive, or flammable thermal decomposition products are expected when the material is exposed to fire.

SECTION 6: SPILL AND LEAK PROCEDURES

Spill and Leak Response: Clean up material and place in an appropriate disposal container. Avoid runoff into storm sewers and ditches which lead to waterways. Consult local authorities regarding notification requirements.

SECTION 7: HANDLING AND STORAGE

Work and Hygiene Practices: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Storage and Handling Practices: Store at controlled room temperature 15°C to 30°C (59°F to 86°F). Wash hands before eating, avoid breathing dust. Avoid contact with eyes, skin, and clothing.

Protective Practices During Maintenance of Contaminated Equipment: ND

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Ventilation and Engineering Controls: No special ventilation required under normal condition of use.

Respiratory Protection: No special requirements under normal conditions, avoid breathing excessive dust.

Eye Protection: Although the risk from eye exposure is minimal, prudence recommends the use of safety glasses.

Hand Protection: No special requirements under normal condition of use.

Body Protection: No special requirements under normal conditions of use.

Product Preparation Instructions for Medical Personnel: Follow standard procedure for handling pharmaceutical materials and recommendations presented on the Package Insert.

SECTION 9: PHYSICAL / CHEMICAL PROPERTIES

Boiling Point:	ND	Vapor Pressure:	ND
Melting/Freezing Point:	ND	pH:	ND
Water Solubility:	Soluble	Water Reactive:	No
Specific Gravity (Water =1):	ND	Evaporation Rate (Butyl acetate = 1):	ND
Appearance/Odor:	Flavoxate HCl 100 mg tablets are white, round tablets, debossed "PAD" and "0115" on one side and no deboss on the other side.		

ND = No Data

SECTION 10: STABILITY AND REACTIVITY

Stability: Stable under labeled storage conditions.

Incompatible Materials: None Known

Hazardous Polymerization: Will not occur.

Conditions to Avoid: Protect from excessive moisture. Store between 15°C and 30°C (59°F to 86°F).

SECTION 11: TOXICOLOGICAL INFORMATION

Toxicity Data: The following information is for Flavoxate HCl.

Oral LD₅₀ Rat = 4273 mg/kg

Oral LD₅₀ Mice = 1837 mg/kg

Suspected Cancer Agent: This product has **NOT** been identified as a carcinogen by NTP, IARC or OSHA.

Irritancy of Product: Minor irritation may occur based on effects of individual components.

Sensitization to the Product: Not Known.

Reproductive Toxicity Information: This material is classified as a Pregnancy Category B (Risk to Fetus Cannot be Ruled-Out). Reproductive studies have been performed in rats and rabbits up to 34 times the human dose and revealed no evidence of impaired fertility or harm to the fetus due to Flavoxate HCl. There are, however, no well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Mutagenicity: ND

ACGIH Biological Exposure Indices: Currently there are no Biological Exposure Indices (BEIs) associated with the components of this product.

SECTION 12: ECOLOGICAL INFORMATION

All work practices must be aimed at eliminating environmental contamination.

Environmental Stability: This product will be relatively stable under ambient environmental conditions.

Effect of Materials on Plants or Animals: Ecological tests results for Moexipril HCl revealed that the compound is non-toxic to invertebrate and microbial organisms.

Effect of Chemicals on Aquatic Life: No specific information is available on the effects of Moexipril on aquatic life.

SECTION 13: WASTE DISPOSAL

Preparing Wastes for Disposal: This material, if discarded as produced, is not a RCRA "listed" or "characteristic" hazardous waste. Use resulting in chemical or physical change or contamination may subject it to regulation as a hazardous waste. Along with properly characterizing all waste materials consult state and local regulations regarding the proper disposal of this material.

U.S. EPA Waste Number: None

SECTION 14: TRANSPORTATION INFORMATION

This Material is not Hazardous as Defined by 49 CFR 172.101 by the U. S. Department of Transportation

Proper Shipping Name: Not applicable

Hazard Class Number and Description: Not applicable

UN Identification Number: Not applicable

Packing Group: Not applicable

DOT Label(s) Required: Not applicable

North American Emergency Response Guidebook Number (1996): Not applicable.

MARINE POLLUTANT: No component of this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B)

Transport Canada Transportation of Dangerous Goods Regulations: Not applicable

SECTION 15: REGULATORY INFORMATION

U.S. REGULATIONS:

U.S. SARA Reporting Requirements: 311/312 Hazard Categories: Immediate Health, 313 Reportable Ingredients: None

U.S. SARA Threshold Planning Quantity: Not applicable

U.S. CERCLA Reportable Quantities (RQ): Not applicable

U.S. TSCA Inventory Status: Flavoxate HCl is a “drug” as defined by the Federal Food, Drug and Cosmetic Act and is therefore not a chemical substance under TSCA.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): This product does NOT contain a chemical known to the State of California to cause developmental and reproductive effects.

ANSI Labeling (Based on 129.1. Provided to Summarize Occupational Exposure Hazards):

SECTION 16: OTHER INFORMATION

DEFINITIONS OF ABBREVIATIONS USED:

ACGIH:	American Conference of Governmental Industry Hygienists
CAS:	Chemical Abstract Service
IARC:	International Agency for Research on Cancer
IDLH:	Immediately Dangerous to Life or Health Level
LC ₅₀ :	Medial Lethal Concentration
LD ₅₀ :	Medial Lethal Dose
MSHA:	Mine Safety and Health Administration
N/A:	Not Available
NIOSH:	National Institute for Occupational Safety and Health
NTP:	National Toxicology Program
OSHA:	Occupational Safety and Health Administration
PEL:	Permissible Exposure Limit
STEL:	Short Term Exposure Limit
TLV:	Threshold Limit Value
TWA:	Time Weighted Average