

MATERIAL SAFETY DATA SHEET

Clotrimazole Lozenge (troche), 10 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

Creation Date: 26 September 2005

Revision Date: 26 September 2005

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: Clotrimazole Lozenge, 10 mg Tablets
COMMON NAME: Clotrimazole Lozenge, 10 mg Tablets
CHEMICAL NAME: [1-(o-chloro-(alpha),(alpha)-diphenylbenzyl) imidazole]
SYNONYMS: NA
CHEMICAL FORMULA: C₂₂H₁₇ClN₂
CHEMICAL FAMILY: NA

SECTION 2: COMPOSITION AND INGREDIENTS

CHEMICAL NAME	CAS#	OSHA PEL	ACGIH TLV	IDLH
*Clotrimazole, USP	23593-75-1	NE	NE	NE
Dextrose, USP	50-99-7	NE	NE	NE
Povidone, USP	9003-39-8	NE	NE	NE
Microcrystalline Cellulose, NF	9004-32-4	NE	NE	NE
*Magnesium Stearate, NF	557-04-0	NE	NE	NE

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

*These ingredients are at concentrations of less than 1%.

SECTION 3: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: The troche dosage form is a large, slowly dissolving tablet (lozenge) containing 10 mg of clotrimazole dispersed in dextrose, microcrystalline cellulose, povidone, and magnesium stearate.

Symptoms of Overexposure by Route of Exposure: Possible effects on the liver.

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 4: FIRST AID MEASURES

<u>Skin Exposure:</u>	Thoroughly wash with mild soap and water. If irritation develops, seek medical attention.
<u>Eye Exposure:</u>	Immediately flush eye with copious amounts of water and seek medical attention.
<u>Inhalation:</u>	Remove to fresh air. Restore and/or support breathing as needed. Obtain medical attention.
<u>Ingestion:</u>	Vomiting may be induced if person is conscious. Give activated charcoal. Obtain medical attention.

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: OK 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 fires beyond the incipient stage, emergency responders in the immediate hazard area should wear full protective clothing and a self contained breathing apparatus. 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.

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 only in the original container and keep container tightly sealed. Store at controlled room temperature, 15°C to 30°C (59°F to 86°F). Store away from foodstuffs. Wash hands before eating. Avoid contact with eyes, skin, and clothing.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Ventilation and Engineering Controls: No special ventilation required under normal condition of use. Use adequate ventilation when working with raw materials.

Respiratory Protection: No special requirements under normal conditions.

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. Gloves should be worn during spill clean up.

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:	White/none.		

ND = No Data

SECTION 10: STABILITY AND REACTIVITY

Stability: Stable under labeled storage conditions.

Incompatible Materials: None known.

Hazardous Decomposition: Oxides of nitrogen oxides.

Conditions to Avoid: Excessive heat.

SECTION 11: TOXICOLOGICAL INFORMATION
--

Toxicity Data: No data available.

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

Irritancy of Product: During normal use of product no eye contact should occur.

Sensitization to the Product: No data available.

Reproductive Information: There are no adequate and well controlled studies in pregnant women. Clotrimazole lozenges should be used during pregnancy only if the potential benefits justifies the potential risk to the fetus.

Mutagenicity: No data available.

Embryotoxicity/Teratogenicity/Reproductive Toxicity: Pregnancy Category C: Clotrimazole has been shown to be embryotoxic in rats and mice when given in doses 100 times the adult human dose (in mg/kg), possibly secondary to maternal toxicity. The drug was not teratogenic in mice, rabbits, and rats when given in doses up to 200, 180, and 100 times the human dose. Clotrimazole given orally to mice from nine weeks before mating through weaning at a dose 120 times the human dose was associated with impairment of mating, decreased number of viable young, and decreased survival to weaning. No effects were observed at 60 times the human dose. When the drug was given to rats during a similar time period at 50 times the human dose, there was a slight decrease in the number of pups per litter and decreased pup viability.

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: No data available.

Effect of Materials on Plants/Animals/Aquatic Life: No data available.

SECTION 13: WASTE DISPOSAL

Preparing Wastes for Disposal: Dispose of material according to federal, state, and local disposal regulations or company operating procedures. Disposal by incineration is recommended.

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. This material is not regulated by the United States Department of Transportation (DOT). Ship according to state and local regulations, if applicable.

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: Not applicable

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.

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
NA:	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

SECTION 17: DISCLAIMER

The information contained in this Material Safety Data Sheet has been compiled from reliable sources and is believed to be correct as of the date issued. It is the responsibility of the user to determine the appropriateness and applicability to their situation. Paddock Laboratories, Inc. disclaims any expressed or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental, or consequential damages from use or reliance on the above information.