



Material Safety Data Sheet

Issuing Date 03-Dec-2010

Revision Date 20-May-2011

Revision Number 1

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Miconazole Nitrate Vaginal Suppositories 100 mg
Miconazole Nitrate Vaginal Suppositories 200 mg

Product Code(s) 0472-1736-07; 0472-1738-03

Recommended Use Topical antifungal

Synonyms 1H-imidazole, 1-[2-(2,4-dichlorophenyl)-2-[(2,4-dichlorophenyl)-methoxy] ethyll], mononitrate

Supplier Address

Actavis Mid Atlantic LLC
1877 Kawai Road
Lincolnton, NC 28092
TEL: 704-735-5700

Chemical Emergency Phone Number Chemtrec 1-800-424-9300

Poison Control Center (USA): 1-800-222-1222

2. HAZARDS IDENTIFICATION

CAUTION!

Emergency Overview

May be harmful if swallowed
May cause skin and eye irritation
May produce an allergic reaction
Contains a known or suspected reproductive toxin

Appearance White, Bullet-shaped

Physical State Solid.

Odor No information available

Potential Health Effects

Principle Routes of Exposure

Eye contact. Skin contact.

Acute Toxicity

Eyes

May cause irritation.

Skin

May cause irritation. May cause sensitization by skin contact.

Inhalation

Not an expected route of exposure.

Ingestion

Not an expected route of exposure. May be harmful if swallowed. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Do not ingest.

Chronic Effects

May produce an allergic reaction.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Aggravated Medical Conditions

Skin disorders. Allergies.

Environmental Hazard

See Section 12 for additional Ecological Information.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %
Miconazole Nitrate USP Micronized	22832-87-7	4.26 - 8.70

Note: This section lists OSHA and WHMIS hazardous chemicals at or above threshold as well as active pharmaceutical ingredients. For a full list of ingredients, please see product packaging.

4. FIRST AID MEASURES

Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If symptoms persist, call a physician.
Skin Contact	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.
Inhalation	Move to fresh air in case of accidental inhalation of vapors or decomposition products. If symptoms persist, call a physician.
Ingestion	Do NOT induce vomiting. Rinse mouth. Drink plenty of water. Consult a physician.
Notes to Physician	Treat symptomatically. May cause sensitization by skin contact.
Protection of First-aiders	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. FIRE-FIGHTING MEASURES

Flammable Properties	Not flammable.			
Flash Point	Not applicable.			
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.			
Explosion Data				
Sensitivity to Mechanical Impact	None			
Sensitivity to Static Discharge	None			
Specific Hazards Arising from the Chemical	May cause sensitization by skin contact.			
Protective Equipment and Precautions for Firefighters	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.			
NFPA	Health Hazard 1	Flammability 0	Instability 0	Physical and Chemical Hazards -
HMIS	Health Hazard 1	Flammability 0	Physical Hazard 0	Personal Protection B

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Use personal protective equipment. Avoid contact with the skin and the eyes.
Environmental Precautions	Refer to protective measures listed in Sections 7 and 8.
Methods for Containment	Prevent further leakage or spillage if safe to do so.
Methods for Cleaning Up	Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Handling	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Wear personal protective equipment.
Storage	Store at room temperature. Keep at temperatures between 15 and 30 °C (59 and 86 °F). Avoid heat over 59 °C/ 86 °F. Keep out of the reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines	This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.
Engineering Measures	Showers Eyewash stations Ventilation systems
Personal Protective Equipment	
Eye/Face Protection	Safety glasses with side-shields.
Skin and Body Protection	Protective gloves.
Respiratory Protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
Hygiene Measures	Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	White, Bullet-shaped.	Odor	No information available
Odor Threshold	No information available	Physical State	Solid
pH	No information available.	Autoignition Temperature	No information available.
Flash Point	Not applicable.	Boiling Point/Boiling Range	No information available
Decomposition Temperature	No information available.	Explosion Limits	No information available.
Melting Point/Range	34-38 °C / 93.2-100.4 °F	Evaporation Rate	No information available
Flammability Limits in Air	No information available.	Vapor Density	Not applicable
Solubility	No information available.		
Vapor Pressure	Not applicable		

10. STABILITY AND REACTIVITY

Stability	Stable under recommended storage conditions.
Incompatible Products	Oxidizing agents. Reducing agents.
Conditions to Avoid	Protect from light.
Hazardous Decomposition Products	Carbon oxides. Nitrogen oxides (NOx).
Hazardous Polymerization	Hazardous polymerization does not occur.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Product Information May be harmful if swallowed. May cause eye and skin irritation.

Component Information

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Miconazole Nitrate USP Micronized	920 mg/kg (Rat)	-	-

Chronic Toxicity

Chronic Toxicity May produce an allergic reaction.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Carcinogenicity Contains no ingredients above reportable quantities listed as a carcinogen.

Chemical Name	ACGIH	IARC	NTP	OSHA
Miconazole Nitrate USP Micronized		Group 2A		X

Sensitization May cause sensitization by skin contact.

Reproductive Toxicity Pregnancy: Since imidazoles are absorbed in small amounts from the human vagina, they should not be used in the first trimester of pregnancy unless the physician considers it essential to the welfare of the patient.

Target Organ Effects Skin.

12. ECOLOGICAL INFORMATION

Ecotoxicity

The environmental impact of this product has not been fully investigated.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

Contaminated Packaging Dispose of in accordance with local regulations. Do not re-use empty containers.

California Hazardous Waste Codes 311

California Waste Code Legend Pharmaceutical waste

14. TRANSPORT INFORMATION

DOT Not regulated

TDG Not regulated

MEX Not regulated

IATA Not regulated

IMDG/IMO Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA Exempt
DSL Exempt

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

U.S. Federal Regulations

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute Health Hazard	Exempt
Chronic Health Hazard	Exempt
Fire Hazard	Exempt
Sudden Release of Pressure Hazard	Exempt
Reactive Hazard	Exempt

This is an FDA regulated product and as such is exempted from SARA Tier II reporting.

Clean Water Act

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

U.S. State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances above threshold limits that are regulated by state right-to-know.

International Regulations

Canada

This product is regulated by the Food and Drug Administration of Health Canada and is not subject to the WHMIS Requirements of the Hazardous Products Act and the Controlled Products Regulations.

16. OTHER INFORMATION

Prepared By	Product Stewardship 23 British American Blvd. Latham, NY 12110 1-800-572-6501
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General Disclaimer

The information provided on this MSDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet