



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 Cream 2% USP
Product Code(s) 0472-0735-14; 0472-0735-26; 0472-0735-56; 0472-0735-42; 0472-0730-63; 0472-0730-41
Recommended Use Antifungal
Synonyms 1H-imidazole,1-[2-(2,4-dichlorophenyl)-2-[(2,4 -dichlorophenyl)-methoxy] ethyl], 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

WARNING!

Emergency Overview

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

Appearance White

Physical State Semi-Solid, Cream.

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. Butylated hydroxyanisole has been classified by the International Agency for Research on Cancer (IARC) as possibly carcinogenic to humans (Group 2B).

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 %
White mineral oil	8042-47-5	1-5
Miconazole Nitrate USP Micronized	22832-87-7	2
Butylated Hydroxyanisole NF	25013-16-5	0.1 - 1.0

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.			
<u>Explosion Data</u>				
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.			
<u>NFPA</u>	Health Hazard 1	Flammability 0	Instability 0	Physical and Chemical Hazards -
<u>HMIS</u>	Health Hazard 1*	Flammability 0	Physical Hazard 0	Personal Protection B

*Indicates a chronic health hazard.

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	Cover liquid spill with sand, earth or other noncombustible absorbent material. 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 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.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
White mineral oil 8042-47-5	TWA: 5 mg/m ³ inhalable fraction excluding metal working fluids, highly & severely refined	TWA: 5 mg/m ³ (vacated) TWA: 5 mg/m ³	IDLH: 2500 mg/m ³ TWA: 5 mg/m ³ STEL: 10 mg/m ³

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.	Odor	No information available
Odor Threshold	No information available	Physical State	Semi-Solid Cream
pH	2.0-4.0	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	No information available	Evaporation Rate	No information available
Flammability Limits in Air	No information available.	Vapor Density	Not applicable
Solubility	No information available.		
Vapor Pressure	Not applicable		
VOC Content (%)	0.2		

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
Butylated Hydroxyanisole NF	= 2 g/kg (Rat)	-	-
White mineral oil	> 5000 mg/kg (Rat)	-	-
Miconazole Nitrate USP Micronized	920 mg/kg (Rat)	-	-

Chronic Toxicity

Chronic Toxicity May produce an allergic reaction. Butylated hydroxyanisole has been classified by the International Agency for Research on Cancer (IARC) as possibly carcinogenic to humans (Group 2B).

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 The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical Name	ACGIH	IARC	NTP	OSHA
White mineral oil	A2			
Miconazole Nitrate USP Micronized		Group 2A		X
Butylated Hydroxyanisole NF	-	Group 2B	-	-

ACGIH: (American Conference of Governmental Industrial Hygienists)

IARC: (International Agency for Research on Cancer)

Group 2B - Possibly Carcinogenic to Humans

NTP: (National Toxicity Program)

OSHA: (Occupational Safety & Health Administration)

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. Ecotoxicity effects of component substances.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
White mineral oil		LC50 96 h: > 10000 mg/L (Lepomis macrochirus)		

Chemical Name	Log Pow
White mineral oil	6.006

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

<u>DOT</u>	Not regulated
<u>TDG</u>	Not regulated
<u>MEX</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMDG/IMO</u>	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 contains the following Proposition 65 chemicals:

Chemical Name	CAS-No	California Prop. 65
Butylated Hydroxyanisole NF	25013-16-5	Carcinogen

U.S. State Right-to-Know Regulations

"X" designates that the ingredients are listed on the state right to know list.

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
White mineral oil	X	X	X		X
Butylated Hydroxyanisole NF		X			
Benzoic acid	X	X	X		

International Regulations

Chemical Name	Carcinogen Status	Exposure Limits
White mineral oil		Mexico: TWA 5 mg/m ³ Mexico: STEL 10 mg/m ³

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

Issuing Date 03-Dec-2010
Revision Date 20-May-2011
Revision Note (M)SDS sections updated: 2.

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