

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078928843

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

078056379 078079039 078088780



# 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

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

### 5. FIRE-FIGHTING MEASURES

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

\*Indicates a chronic health hazard.

### 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions</b>	Use personal protective equipment. Avoid contact with the skin and the eyes.
<b>Environmental Precautions</b>	Refer to protective measures listed in Sections 7 and 8.
<b>Methods for Containment</b>	Prevent further leakage or spillage if safe to do so.
<b>Methods for Cleaning Up</b>	Cover liquid spill with sand, earth or other noncombustible absorbent material. Pick up and transfer to properly labeled containers.

## 7. HANDLING AND STORAGE

<b>Handling</b>	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Wear personal protective equipment.
<b>Storage</b>	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

<b>Exposure Guidelines</b>	This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.
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Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
White mineral oil 8042-47-5	TWA: 5 mg/m <sup>3</sup> inhalable fraction excluding metal working fluids, highly & severely refined	TWA: 5 mg/m <sup>3</sup> (vacated) TWA: 5 mg/m <sup>3</sup>	IDLH: 2500 mg/m <sup>3</sup> TWA: 5 mg/m <sup>3</sup> STEL: 10 mg/m <sup>3</sup>

<b>Engineering Measures</b>	Showers Eyewash stations Ventilation systems
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### Personal Protective Equipment

<b>Eye/Face Protection</b>	Safety glasses with side-shields.
<b>Skin and Body Protection</b>	Protective gloves.
<b>Respiratory Protection</b>	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

<b>Hygiene Measures</b>	Handle in accordance with good industrial hygiene and safety practice.
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## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance</b>	White.	<b>Odor</b>	No information available
<b>Odor Threshold</b>	No information available	<b>Physical State</b>	Semi-Solid Cream
<b>pH</b>	2.0-4.0	<b>Autoignition Temperature</b>	No information available.
<b>Flash Point</b>	Not applicable.	<b>Boiling Point/Boiling Range</b>	No information available
<b>Decomposition Temperature</b>	No information available.	<b>Explosion Limits</b>	No information available.
<b>Melting Point/Range</b>	No information available	<b>Evaporation Rate</b>	No information available
<b>Flammability Limits in Air</b>	No information available.	<b>Vapor Density</b>	Not applicable
<b>Solubility</b>	No information available.		
<b>Vapor Pressure</b>	Not applicable		
<b>VOC Content (%)</b>	0.2		

## 10. STABILITY AND REACTIVITY

<b>Stability</b>	Stable under recommended storage conditions.
<b>Incompatible Products</b>	Oxidizing agents. Reducing agents.
<b>Conditions to Avoid</b>	Protect from light.
<b>Hazardous Decomposition Products</b>	Carbon oxides. Nitrogen oxides (NOx).
<b>Hazardous Polymerization</b>	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

<b>Waste Disposal Methods</b>	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.
<b>Contaminated Packaging</b>	Dispose of in accordance with local regulations. Do not re-use empty containers.
<b>California Hazardous Waste Codes</b>	311
<b>California Waste Code Legend</b>	Pharmaceutical waste

### 14. TRANSPORT INFORMATION

<b><u>DOT</u></b>	Not regulated
<b><u>TDG</u></b>	Not regulated
<b><u>MEX</u></b>	Not regulated
<b><u>IATA</u></b>	Not regulated
<b><u>IMDG/IMO</u></b>	Not regulated

### 15. REGULATORY INFORMATION

#### **International Inventories**

<b>TSCA</b>	Exempt
<b>DSL</b>	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**

<b>Acute Health Hazard</b>	Exempt
<b>Chronic Health Hazard</b>	Exempt
<b>Fire Hazard</b>	Exempt
<b>Sudden Release of Pressure Hazard</b>	Exempt
<b>Reactive Hazard</b>	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 <sup>3</sup> Mexico: STEL 10 mg/m <sup>3</sup>

**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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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