



Material Safety Data Sheet

Issuing Date 03-Dec-2010

Revision Date 20-May-2011

Revision Number 1

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Clotrimazole Cream 1%
Product Code(s) 0472-0350-34; 0472-0350-56; 0472-0220-63; 0472-0220-41
Recommended Use Antifungal
Synonyms 1-[(2-Chlorophenyl)diphenylmethyl]-1H-imidazole

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

For external use only
Not for ophthalmic use
Harmful if swallowed
May cause skin and eye irritation
May cause sensitization by skin contact
Contains a known or suspected carcinogen
Contains a known or suspected reproductive toxin

Appearance White to off-white

Physical State Semi-Solid Ointment.

Odor Odorless

Potential Health Effects

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. Do not ingest. Harmful if swallowed. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Chronic Effects

May cause adverse liver effects.

Nursing Mothers: Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroids production, or cause other effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when clotrimazole dipropionate cream is administered to a nursing woman.

Aggravated Medical Conditions

None known.

Environmental Hazard

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. See Section 12 for additional Ecological Information.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %
Octyldodecanol	5333-42-6	10-30
Octadecanoic acid, tetradecyl ester	17661-50-6	1-5
Sorbitan stearate	1338-41-6	1-5
Polysorbate 60	9005-67-8	1-5
Benzyl alcohol	100-51-6	0.1-1
Clotrimazole USP micronized	23593-75-1	1

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.
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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.
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<u>NFPA</u>	Health Hazard 2	Flammability 0	Instability 0	Physical and Chemical Hazards -
<u>HMIS</u>	Health Hazard 2*	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	Avoid contact with skin, eyes and clothing. Wear personal protective equipment. Remove and wash contaminated clothing before re-use. Do not breathe vapors or spray mist. Do not eat, drink or smoke when using this product.
Storage	Keep at temperatures below 25 °C / 77 °F. Excursions permitted to 15 and 30 °C (59 and 86 °F) Keep out of the reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines	This product, as supplied and used, is not expected to cause exposure via inhalation unless fine aerosols or mists are generated.
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Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Octadecanoic acid, tetradecyl ester 17661-50-6	TWA: 10 mg/m ³ except stearates of toxic metals	-	-
Sorbitan stearate 1338-41-6	TWA: 10 mg/m ³ except stearates of toxic metals	-	-

ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value. OSHA PEL: Occupational Safety and Health Administration - Permissible Exposure Limits. NIOSH IDLH: Immediately Dangerous to Life or Health.

Engineering Measures	Showers Eyewash stations Ventilation systems
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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.
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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	White to off-white.	Odor	Odorless.
Odor Threshold	No information available	Physical State	Semi-Solid Ointment
pH	4.5-6.5	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 (%)	0.99		

10. STABILITY AND REACTIVITY

Stability	Stable under recommended storage conditions.
Incompatible Products	Strong oxidizing agents.
Conditions to Avoid	None known based on information supplied.
Hazardous Decomposition Products	Carbon oxides. Nitrogen oxides (NOx).
Hazardous Polymerization	Hazardous polymerization does not occur.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Product Information Harmful if swallowed.

Component Information

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Octyldodecanol	5000 mg/kg (Rat)	-	-
Benzyl alcohol	= 1230 mg/kg (Rat)	= 2000 mg/kg (Rabbit)	= 8.8 mg/L (Rat) 4 h
Sorbitan stearate	= 31 g/kg (Rat)	-	-
Polysorbate 60	> 60 mL/kg (Rat)	-	-

Chronic Toxicity

Chronic Toxicity May cause adverse liver effects.

Nursing Mothers: Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroids production, or cause other effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when clotrimazole dipropionate cream is administered to a nursing woman.

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

Teratogenic Pregnancy: Teratogenic Effects: Pregnancy Category C: There have been no teratogenic studies performed in animals or humans with the combination of clotrimazole and betamethasone dipropionate. Corticosteroids are generally teratogenic in laboratory animals when administered at relatively low dosage levels.

Target Organ Effects Liver. Skin. Blood. Urinary tract.

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)
Octyldodecanol	EC50 72 h: = 100 mg/L (Desmodesmus subspicatus)			
Benzyl alcohol	EC50 3 h: = 35 mg/L (Anabaena variabilis)	LC50 96 h: = 10 mg/L static (Lepomis macrochirus) LC50 96 h: = 460 mg/L static (Pimephales promelas)	EC50 = 50 mg/L 5 min EC50 = 63.7 mg/L 15 min EC50 = 63.7 mg/L 5 min EC50 = 71.4 mg/L 30 min	EC50 48 h: = 23 mg/L (water flea)

Chemical Name	Log Pow
Benzyl alcohol	1.1

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 does not contain any Proposition 65 chemicals.

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
Benzyl alcohol	-	X	X	-	-

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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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