

SAFETY DATA SHEET

Preparation Date: 09/02/2015

Revision Date: 09/02/2015

Revision Number: G!

1. IDENTIFICATION

Product identifier

Product code: MI150
Product Name: MICONAZOLE NITRATE, USP

Other means of identification

Synonyms: Daktacort
 Daktarin
 Daktarin talc
 1-(2,4-Dichloro-beta-((2,4-dichlorobenzyl)oxy)phenethyl)-imidazole nitrate
 1H-Imidazole, 1-(2-(2,4-dichlorophenyl)-2-((2,4-dichlorophenyl)methoxy)ethyl)-, mononitrate
 Miconazole nitrate
 (+-)-Miconazole nitrate
 Monistat
CAS #: 22832-87-7
RTECS # NI4771000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: No information available.
Uses advised against No information available

Supplier: Spectrum Chemical Mfg. Corp
 14422 South San Pedro St.
 Gardena, CA 90248
 (310) 516-8000

Order Online At: <https://www.spectrumchemical.com>

Emergency telephone number Chemtrec 1-800-424-9300
Contact Person: Martin LaBenz (West Coast)
Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity - Oral	Category 4
Skin sensitization	Category 1

Label elements

Warning**Hazard statements**

Harmful if swallowed
May cause an allergic skin reaction

**Hazards not otherwise classified (HNOC)**

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Do not eat, drink or smoke when using this product
Wear protective gloves
Avoid breathing dust/fume/gas/mist/vapors/spray
Wash face, hands and any exposed skin thoroughly after handling
Contaminated work clothing should not be allowed out of the workplace

Precautionary Statements - Response

Specific treatment (see .? on this label)
IF ON SKIN: Wash with plenty of soap and water
If skin irritation or rash occurs: Get medical advice/attention
Wash contaminated clothing before reuse
IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
Rinse mouth

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %	Trade Secret
Miconazole Nitrate 22832-87-7	22832-87-7	100	*

4. FIRST AID MEASURES**First aid measures****General Advice:**

Poison information centers in each State capital city can provide additional assistance for scheduled poisons (13 1126).

Skin Contact:

Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Get medical attention. If skin irritation persists, call a physician.

Eye Contact:

Flush eye with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.

Inhalation: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Obtain medical attention.

Ingestion: Do not give milk, alcoholic beverages or castor oil. Never give anything by mouth to an unconscious person. Obtain medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms Harmful if swallowed. May cause allergic skin reaction. May cause eye irritation. May cause skin irritation.

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically

Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Dry chemical. Carbon dioxide (CO₂). Water spray. Foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: Carbon oxides. Nitrogen oxides. halogenated compounds

Specific hazards: May be combustible at high temperatures
As with most organic solids, fire is possible at elevated temperatures
Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard

Special Protective Actions for Firefighters

Specific Methods: No information available.

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid breathing dust. Avoid dust formation. Remove all sources of ignition. All equipment used when handling the product must be grounded.

Environmental precautions Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. All equipment used when handling the product must be grounded. Remove all sources of ignition. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not breathe vapours/dust. Do not ingest. Do not smoke. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Sensitive to light. Store in light-resistant containers. Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Keep away from heat and sources of ignition. Store away from incompatible materials.

Incompatible Materials:

Oxidizing agents. Bases.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
Miconazole Nitrate 22832-87-7	None	None	None	None

Canada

Components	Alberta	British Columbia	Ontario	Quebec
Miconazole Nitrate 22832-87-7	None	None	None	None

Australia and Mexico

Components	Australia	Mexico
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Miconazole Nitrate 22832-87-7	None	None
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Appropriate engineering controls

Engineering measures to reduce exposure: Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection: Safety glasses with side-shields

Skin and body protection: Chemical resistant apron. Long sleeved clothing. Gloves.

Respiratory protection: Wear respirator with dust filter. Be sure to use an approved/certified respirator or equivalent..

Hygiene measures: Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid.	Appearance: Powder.	Color: White. Off-white.
Odor: No information available	Taste No information available	Molecular/Formula weight: 479.14
Formula: C18H14N2O-HNO3	Flammability: No information available	Flash point (°C): No data available
Flashpoint (°C/°F): No information available.	Flash Point Tested according to: Not available	Autoignition Temperature (°C/°F): No information available
Lower Explosion Limit (%): No information available	Upper Explosion Limit (%): No information available	pH: No information available
Melting point/range(°C/°F): 170.5°C/ 338.9°F	Boiling point/range(°C/°F): No information available	Bulk density: No information available
Decomposition temperature(°C/°F): No information available	Density (g/cm3): No information available	Specific gravity: No information available
Vapor pressure @ 20°C (kPa): No information available	Evaporation rate: No information available	Vapor density: No information available
VOC content (g/L): No information available	Odor threshold (ppm): No information available	Partition coefficient (n-octanol/water): No information available
Viscosity: No information available	Miscibility: No information available	Solubility: Very slightly soluble in cold water

10. STABILITY AND REACTIVITY

Reactivity

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Reactive with strong oxidizing agents
Reactive with bases

Chemical stability

Stability: Sensitive to light. Exposure to light accelerates decomposition.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Ignition sources. Incompatible materials. Avoid dust formation. Exposure to light.

Incompatible Materials: Oxidizing agents. Bases.

Hazardous decomposition products: Carbon oxides. Nitrogen oxides (NOx). Halogenated compounds.

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:

Inhalation. Ingestion.

Acute Toxicity

Component Information

Miconazole Nitrate - 22832-87-7

LD50/oral/rat = 920 mg/kg Oral LD50 Rat

LD50/oral/mouse = 578 mg/kg

LD50/dermal/rat = No information available

LD50/dermal/rabbit = No information available

LC50/inhalation/rat = No information available

LC50/inhalation/mouse = No information available

Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =

VALUE- Acute Tox Oral = 920mg/kg

LD50/oral/mouse =

Value - Acute Tox Oral = 578mg/kg

LD50/dermal/rabbit

VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat

VALUE -Acute Tox Dermal = No information available

Product code: MI150

Product name: MICONAZOLE
NITRATE, USP

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LC50/inhalation/rat

VALUE-Vapor = No information available

VALUE-Gas = No information available

VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse

VALUE-Vapor = No information available

VALUE - Gas = No information available

VALUE - Dust/Mist = No information available

Symptoms**Skin Contact:** May cause skin irritation. There is little absorption through the skin.**Eye Contact:** May cause eye irritation.**Inhalation** May cause respiratory tract irritation.
Ingestion Harmful if swallowed. May cause gastrointestinal tract irritation with nausea, vomiting, diarrhea. May cause ulceration or bleeding from the stomach. May affect behavior/central nervous system (ataxia).**Aspiration hazard** No information available**Delayed and immediate effects as well as chronic effects from short and long-term exposure****Chronic Toxicity** Possible allergic reaction to material if inhaled, ingested or in contact with skin. Prolonged or repeated ingestion may affect the liver, blood (changes in blood cell count).
Medical Conditions Aggravated by Exposure: Hypersensitivity to material, acute porphyria, and impaired liver function.**Sensitization:** No information available**Mutagenic Effects:** No information available**Carcinogenic effects:** Not considered carcinogenic

Components	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Prohibited Carcinogenic Substances	Australia - Notifiable Carcinogenic Substances
Miconazole Nitrate	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

Reproductive toxicity No data is available

Reproductive Effects: May cause adverse reproductive effects based on animal data after animals had been given oral doses. No human studies have been found relating oral dosage and reproductive effects.
 In humans, Miconazole has typically been used topically and intravaginally in the treatment of vulvovaginal candidiasis and other fungal infections. A variety of clinical studies have not detected and increase in congenital malformations when it has been used in this manner by pregnant women. Although the report on the most recent study did not identify an increased risk for birth defects as a group or specifically for oral clefts, spina bifida, or cardiovascular defects, the analyzed data were not sufficient to rule out possible associations with other specific defect

Developmental Effects: No information available
Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure No information available
STOT - repeated exposure No information available
Target Organs: No information available

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available

Mobility: No information available

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:
 Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:
 Empty containers should be taken for local recycling, recovery or waste disposal

Components	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Miconazole Nitrate	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available

14. TRANSPORT INFORMATION

Packing Group: None
ERG No: No information available
Marine Pollutant No data available
DOT RQ (lbs): No information available

TDG (Canada)

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Description: No information available

ADR

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Packing Group: No information available
Subsidiary Risk: No information available
Classification Code: No information available
Description: No information available
CEFIC Tremcard No: No information available

IMO / IMDG

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Description: No information available
IMDG Page: No information available
Marine Pollutant No information available
MFAG: No information available
Maximum Quantity: No information available

RID

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Classification Code: No information available
Description: No information available

ICAO

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Description: No information available

IATA

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available

14. TRANSPORT INFORMATION

Subsidiary Risk: No information available
Packing Group: No information available
Description: No information available

15. REGULATORY INFORMATION**International Inventories**

Components	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Miconazole Nitrate	Not Listed	Not present	Not present	Not present	Not present	Present	Present 245-256-6

U.S. Regulations**California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.****Chemicals Known to the State of California to Cause Cancer:**

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Miconazole Nitrate	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting <i>de minimis</i>
Miconazole Nitrate	None	None	None	None	None

U.S. TSCA

Components	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Miconazole Nitrate	Not Applicable	Not Applicable

Canada**WHMIS hazard class:**

Non-controlled

Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

Components	Canada (DSL)	Canada (NDSL)
Miconazole Nitrate	Present	Not Listed

Components	CEPA Schedule I - Toxic Substances	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting

Miconazole Nitrate	Not listed	Not listed
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EU Classification

R-phrase(s)

R22 - Harmful if swallowed.

R43 - May cause sensitization by skin contact.

S -phrase(s)

none

S36/37 - Wear suitable protective clothing and gloves.

Components	Classification	Concentration Limits:	Safety Phrases
Miconazole Nitrate		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

T - Toxic



16. OTHER INFORMATION

16. OTHER INFORMATION

Preparation Date: 09/02/2015
Revision Date: 09/02/2015
Prepared by: Sonia Owen

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet