

SAFETY DATA SHEET

Preparation Date: 12/11/2018

Revision date 12/11/2018

Revision Number: G1

1. Identification

Product identifier

Product code: M1188
Product Name: MICONAZOLE, USP

Other means of identification

Synonyms: 1H-Imidazole, 1-(2-(2,4-dichlorophenyl)-2-((2,4-dichlorophenyl)methoxy)ethyl)-(9CI)
 Imidazole, 1-(2-(2,4-dichlorophenyl)-2-((2,4-dichlorophenyl)methoxy)ethyl)- (9CI)
CAS #: 22916-47-8
RTECS # Not available
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Antifungal. Medication.
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: Tom Tyner (USA - West Coast)
Contact Person: Ibad Tirmiz (USA - East Coast)

2. HAZARDS IDENTIFICATION

Classification

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

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

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 must not be allowed out of the workplace

Precautionary Statements - Response*Specific treatment (see .? on this label)*

IF ON SKIN: Wash with plenty of 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

Component	CAS No	Weight-%
Miconazole	22916-47-8	100

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

National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

Skin Contact:

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

Eye Contact:

Flush eyes 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 induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention.

Most important symptoms and effects, both acute and delayed**Symptoms**

May cause an allergic skin reaction
May cause eye irritation

May cause skin irritation
May cause burning or stinging sensation, redness of the skin, inflammation of the skin.
May cause itching and redness of the skin
Ingestion may cause nausea, vomiting, and diarrhea
Mild stomach pain
May cause headache

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 Monoxide, Carbon Dioxide. Nitrogen oxides (NO_x). Hydrogen chloride.

Specific hazards May be combustible at high temperatures.

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. Avoid contact with skin, eyes and clothing. Use personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid breathing dust. Remove all sources of ignition.

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 ingest. Do not breathe dust. 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. Store away from incompatible materials.

Incompatible Materials:

Oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters**National occupational exposure limits****United States**

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Miconazole	22916-47-8	None	None	None	None

Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Miconazole	22916-47-8	None	None	None	None

Australia and Mexico

Component	CAS No	Australia	Mexico
Miconazole	22916-47-8	None	None

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. or Goggles

Skin and body protection: Chemical resistant apron
Long sleeved clothing

Gloves

Respiratory protection: Effective dust mask. or. Wear respirator with dust filter. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. 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. Cream.
Odor: Odorless.	Taste No information available.	Formula C18H14Cl4N2O
Molecular/Formula weight (g/mole): 416.13	Flammability (solid, gas) 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	Melting point/range(°C/°F): 83-87°C/ 181-189°F	Decomposition temperature(°C/°F): No information available
Boiling point/range(°C/°F): No information available	Bulk density: No information available	Density (g/cm3): No information available
Specific gravity: No information available	pH 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 water	

10. STABILITY AND REACTIVITY

Reactivity

Reactive with strong oxidizing agents

Chemical stability

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

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

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

Incompatible Materials: Oxidizing agents

Hazardous decomposition Carbon oxides. Nitrogen oxides (NOx). Hydrogen chloride.

products:

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	
CAS No	22916-47-8

LD50/oral/rat = 550 mg/kg Oral LD50 Rat
LD50/oral/mouse = 519 mg/kg
LD50/dermal/rabbit = No information available
LD50/dermal/rat = 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 = 550 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = 519 mg/kg

LD50/dermal/rabbit
Value - Acute Tox = No information available

LD50/dermal/rat
VALUE - Acute Tox Dermal = No information available

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. May cause burning or stinging sensation, redness of the skin, inflammation of the skin. Symptoms may include redness, itching and pain.

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 mild stomach pain. May cause headache.

Aspiration hazard No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chronic Toxicity Skin: Sensitizer. May cause allergic skin reaction (allergic contact dermatitis).

Sensitization: May cause sensitization by skin contact.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Miconazole	22916-47-8	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

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 defects

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 in soil No information available
Other adverse effects 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

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Miconazole	22916-47-8	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class No information available
Subsidiary Class No information available
Packing group: No information available
Emergency Response Guide Number No information available
Marine Pollutant No data available
DOT RQ (lbs): No information available
Special Provisions No Information available
Symbol(s): No information available
Description: 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
Marine Pollutant No Information available
Description: No information available

ADR

UN Number Not regulated
Proper Shipping Name: No information available
Transport hazard class(es) No information available
Packing group No information available
Subsidiary Risk: No information available

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
Marine Pollutant No information available

RID

UN Number Not Regulated
Proper Shipping Name: No information available
Transport hazard class(es) No information available
Subsidiary Risk: No information available
Packing group No information available

ICAO (air)

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

IATA

UN Number Not Regulated
Proper Shipping Name: No information available
Transport hazard class(es) No information available
Subsidiary Risk: No information available
Packing group No information available
Precautionary Statements - Response IF exposed or concerned
Special Provisions No information available

15. REGULATORY INFORMATION

International Inventories

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia AICS	EINECS-No.
Miconazole	22916-47-8	Not Listed	Not present	Not present	Not present	Not listed	X	Present 245-324-5

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)

Component	CAS No	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Miconazole	22916-47-8	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Component	CAS No	CERCLA - Hazardous Substances and	Section 302 Extremely Hazardous	Section 302 Extremely Hazardous	Section 313 - Chemical Category	Section 313 - Reporting de minimis

		their Reportable Quantities	Substances and TPQs	Substances and RQs		
Miconazole	22916-47-8	None	None	None	None	None

U.S. TSCA

Component	CAS No	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Miconazole	22916-47-8	Not Applicable	Not Applicable

Canada

WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

The WHMIS 2015 classification of this product has not been validated or reviewed yet.

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

DSL/NDSL

Component	CAS No	Canada (DSL)	Canada (NDSL)
Miconazole	22916-47-8	Not Listed	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Miconazole	22916-47-8	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Miconazole	22916-47-8	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Miconazole	22916-47-8	No information

EU - CLP (1272/2008)

R-phrase(s)

R22 - Harmful if swallowed

R43 - May cause sensitization by skin contact

S -phrase(s)

S37 - Wear suitable gloves

S46 - If swallowed, seek medical advice immediately and show this container or label

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Miconazole	22916-47-8		No information	

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

Indication of danger:

Xn - Harmful

Xn

**16. OTHER INFORMATION**

Preparation Date: 12/11/2018
Revision date 12/11/2018
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