


Section 1: Identification

Common Name/Trade Name	MICONAZOLE USP	
Supplier Information	Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693	IN CASE OF EMERGENCY: Chemtrec 1 (800) 424-9300 (24 hours)
Product Synonym(s)	1H-Imidazole, 1-2-[(2,4-dichlorophenyl)-2-[(2,4-dichlorophenyl)]methoxy]ethyl]-, (+/-)	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Acute toxicity, Oral (Category 4), Sensitization, Skin (Category 1), Germ cell mutagenicity (Category 1B)	
Signal Word	Danger	
Hazard Statement(s)	H302 H317 H340	Harmful if swallowed May cause an allergic skin reaction May cause genetic defects
Pictogram(s)		
Precautionary Statement(s)	P201 P202 P264 P270 P272 P280 P301+P312 P302 P308+P313 P330 P333+P313 P363 P405 P501	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection. IF SWALLOWED Call a POISON CENTER or doctor/physician if you feel unwell. IF ON SKIN IF exposed or concerned Get medical advice/attention. Rinse mouth. If skin irritation or a rash occurs Get medical advice/attention. Wash contaminated clothing before reuse. Store locked up. Dispose of contents/container to an approved waste disposal plant.
Hazards Not Otherwise Classified	No data available	
Ingredient(s) with Unknown Toxicity	No data available	

Section 3: Composition/Information on Ingredients

Chemical Name	1H-Imidazole, 1-2-[(2,4-dichlorophenyl)-2-[(2,4-dichlorophenyl)]methoxy]ethyl]-, (+/-)
Common Name	Miconazole
CAS Number	22916-47-8
Impurities and/or Stabilizing Additives	No data available

Section 4: First Aid Measures

General Advice	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate attention.
If Inhaled	Move to fresh air. Call a physician if symptoms develop or persists.
In Case of Skin Contact	Wash off with soap and plenty of water. For minor skin contact, avoid spreading material on unaffected skin. If skin irritation or rash occurs. Get medical advice/attention.
In Case of Eye Contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
If Swallowed	Rinse mouth. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
Most Important Symptoms and Effects	May cause a allergic skin reaction.

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
Special Hazards Arising From the Substance/Mixture	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
Special PPE and/or Precautions for Firefighters	Wear suitable protective equipment. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Cool containers exposed to flames with water until well after the fire is out.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Wear appropriate personal protective equipment.
Methods and Materials Used for Containment	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.
Cleanup Procedures	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

Section 7: Handling and Storage

Precautions for Safe Handling	Combustible dust clouds may be created where operations produce fine material (dust). Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.
Conditions for Safe Storage	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	Material: Miconazole (CAS 22916-47-8) Type: TWA Value: 0.75 mg/l
Appropriate Engineering Controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Avoid any open handling of this material, particularly for grinding, crushing, weighing or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment. Handle in accordance with good industrial hygiene and safety practice.
PPE - Eye/Face Protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g. bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
PPE - Skin Protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to risk of latex allergy. This material is extremely potent. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.
PPE - Body Protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to risk of latex allergy. This material is extremely potent. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment. For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
PPE - Respiratory Protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place. (applicable U.S. regulation OSHA 29 CFR 1910.34)

Section 9: Physical and Chemical Properties

Appearance	Form: Powder Physical state: Solid Colour: White to pale cream colored powder
Upper/Lower Flammability or Explosive Limits	No data available
Odor	Odorless
Vapor Pressure	< 0.0000001 kPa at 25 °C
Odor Threshold	No data available
Vapor Density	No data available
pH	7.2
Relative Density	No data available
Melting Point/Freezing Point	Melting point/freezing point 172.4 - 190.4 °F (78 - 88 °C)
Solubility	Solubility in water Insoluble.
Initial Boiling Point and Boiling Range	No data available
Flash Point	No data available
Evaporation Rate	No data available
Flammability (Solid, Gas)	No data available
Partition Coefficient	5.6
Auto-Ignition Temperature	Auto-ignition temperature 950 °F (510 °C) (BAM)
Decomposition Temperature	No data available
Viscosity	No data available

Section 10: Stability and Reactivity

Reactivity	No reactivity hazards known.
Chemical Stability	Stable at normal conditions.
Possibility of Hazardous Reactions	No dangerous reaction known under conditions of normal use.
Conditions to Avoid	None known.
Incompatible Materials	Strong acids. Oxidizers.
Hazardous Decomposition Products	Cl-. NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	LD50 Oral Dog >160 mg/kg Guinea pig 275.9 mg/kg Mouse 519 kg/mg Rat 550 mg/kg
Acute Toxicity - Inhalation	Due to lack of data the classification is not possible.
Acute Toxicity - Dermal	May cause an allergic skin reaction.
Acute Toxicity - Eye	Based on available data, the classification criteria are not met.
Skin Corrosion/Irritation	Based on available data, the classification criteria are not met.
Serious Eye Damage/Irritation	Based on available data, the classification criteria are not met.
Respiratory or Skin Sensitization	Due to lack of data the classification is not possible. Rare occurrences of anaphylactic reactions following therapeutic use of this material have been reported. May cause an allergic skin reaction. Allergic skin reactions have been reported in literature.
Germ Cell Mutagenicity	Due to lack of data the classification is not possible.
Carcinogenicity IARC	This material is not considered to be a carcinogen by IARC. A related material was carcinogenic in animal studies.
Carcinogenicity ACGIH	This product is not considered to be a carcinogen by ACGIH.
Carcinogenicity NTP	This product is not considered to be a carcinogen by NTP.
Carcinogenicity OSHA	This product is not considered to be a carcinogen by OSHA.
Reproductive Toxicity	100 mg/kg/day Reproductivity study Result: No increase in the incidence of birth defects, but an increase in fetal mortality occurred. Species: Rabbit
Specific Target Organ Toxicity - Single Exposure	Based on available data, the classification criteria are not met.
Specific Target Organ Toxicity - Repeated Exposure	Based on available data, the classification criteria are not met.
Aspiration Hazard	Based on available data, the classification criteria are not met.

Section 12: Ecological Information

Toxicity	Very toxic to aquatic life with long lasting effects. A related material is very toxic in fish.
Persistence and Degradability	No data is available on the degradability of this product.
Bio-accumulative Potential	No data available
Mobility in Soil	No data available
Other Adverse Effects	No data available

Section 13: Disposal Considerations

Waste Treatment Methods Product	Dispose of contents/container in accordance with local/regional/national/international regulations.
Waste Treatment Methods Packaging	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.
Special Precautions Landfill or Incinerations	No data available
Other Information	No data available

Section 14: Transport Information

UN Number	
UN Proper Shipping Name	
Transport Hazard Class(es)	
Packaging Group	
Environmental Hazards	No data available

Section 15: Regulatory Information

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable. One or more components are not listed on TSCA. Superfund Amendments and Reauthorization Act of 1986 (SARA) Hazard categories Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No SARA 302 Extremely hazardous substance No SARA 311/312 Hazardous chemical No Other federal regulations: Safe Drinking Water Act (SDWA) Not regulated. Food and Drug Administration (FDA) Not regulated. US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

Section 16: Other Information

Additional Information	N/A
Prepared By	Lisa Russell
Revision Date	01/11/2019 09:12

Disclaimer

Letco Medical, LLC believes that the above information is correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. If the product is used as a component in another product, this information may not be applicable. NO WARRANTY OF FITNESS FOR ANY PARTICULAR PURPOSE, WARRANTY OF MERCHANTABILITY OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, IS MADE CONCERNING THE INFORMATION PROVIDED ABOVE. Letco Medical shall not be held liable for any loss or damage resulting from handling, storage, use or from contact with the above product.