



Material Safety Data Sheet

12601 Twinbrook Parkway
Rockville, MD 20852 USA

Telephone calls: (301) 881-0666
8:00am - 5:00pm EST Mon. - Fri.

Responsible Party: Roger Williams

ATTENTION !

USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

METRONIDAZOLE

Catalog Number: 1442009

Package Size: 100 mg

Revision Date: September 27, 2001

EMERGENCY OVERVIEW - WARNING: This material is a possible human carcinogen.

SECTION 1 - IDENTIFICATION

Common Name: Metronidazole

Formula: C₆H₉N₃O₃

Synonym: n/f

Chemical Name: 1H-Imidazole-1-ethanol, 2-methyl-5-nitro-

CAS Number: 443-48-1

RTECS Number: NI5600000

Chemical Family: An Imidazole

Therapeutic Category: Antiprotozoal (Trichomonas)

SECTION 2 - INGREDIENT INFORMATION

Principle Components

Percent

Exposure Limits

Metronidazole

Pure Material

n/f

SECTION 3 - HEALTH HAZARD INFORMATION

Usual Adult Dose: The usual oral adult dose of metronidazole depends upon the condition being treated, but should not exceed a maximum of 4 grams daily, in divided doses. Metronidazole is also used topically to the skin as a 0.75% gel.

Adverse Effects: Adverse effects may include dizziness, headache, diarrhea, loss of appetite, nausea or vomiting, stomach cramps, numbness, tingling pain or weakness in hands or feet, dry mouth, unpleasant taste, seizures, and dark urine. Drinking alcohol or using alcohol-containing preparations while exposed to this material may cause abdominal cramps, nausea, vomiting, headaches, and flushing. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

METRONIDAZOLE

Catalog Number: 1442009

Package Size: 100 mg

Revision Date: September 27, 2001

Overdose Effects: Effects of overdose are rare, but may include nausea, vomiting, tremor, weakness, and loss of coordination.

Acute: Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

Chronic: Possible hypersensitization, peripheral neuropathy, furry or swollen tongue, neutropenia, vaginitis and cancer.

Inhalation: May cause irritation. Avoid inhalation. Remove to fresh air.

Eye: May cause irritation. Avoid exposure. Flush with copious quantities of water.

Skin: May cause irritation. Avoid contact. Flush with copious quantities of water. Metronidazole is not significantly absorbed through the skin.

Ingestion: May cause irritation. Avoid ingestion. Flush out mouth with water. This material is well absorbed from the gastrointestinal tract.

Medical Conditions

Aggravated by Exposure: Hypersensitivity to material, active alcoholism or alcohol ingestion in last 24 hours, epilepsy or other active CNS disease, blood dyscrasias and severely impaired liver function.

Cross Sensitivity: Persons sensitive to other nitroimidazole derivatives may be sensitive to this material also.

Pregnancy Comments: Adequate and well-controlled pregnancy studies in humans have not been done. Oral administration of metronidazole to rats and mice has not shown that it causes adverse fetal effects, however, intraperitoneal administration in mice has caused fetotoxicity. Its therapeutic use by women in the first trimester of pregnancy is not recommended.

Pregnancy Category: B

SECTION 4 - FIRST AID MEASURES

General: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Overdose Treatment: Toxicity is unlikely following ingestion of less than 2 grams. Since there is no specific antidote, treatment for metronidazole overdose should be symptomatic and supportive.

SECTION 5 - TOXICOLOGICAL INFORMATION

Oral Rat: LD50: 3 grams/Kg

Oral Mouse: LD50: 3800 mg/kg

Irritancy Data: n/f

Target Organ(s): n/f

Listed as a Carcinogen? NTP: Yes IARC: Yes OSHA: No

Other: Metronidazole has been shown to be carcinogenic in mice and rats. It has not been shown to be carcinogenic or tumorigenic in humans.

SECTION 6 - FIREFIGHTING MEASURES

Flash Point: n/f

Upper Flammable Limit: n/f

Auto-Ignition Temperature: n/f

Lower Flammable Limit: n/f

Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Fire and Explosion Hazards: This material has a high thermodynamic potential (720 cal/Kg). Exothermic decomposition occurs between 225 - 227° C. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

SECTION 7 - PHYSICAL HAZARDS

Conditions to Avoid: Avoid exposure to light, which causes material to darken.

Incompatibilities: Strong acids, bases, oxidizers, and aluminum.

Decomposition Products: When heated to decomposition material emits toxic fumes of NOx. Emits toxic fumes under fire conditions.

Stable? Yes **Hazardous Polymerization?** No

SECTION 8 - HANDLING / SPILL / DISPOSAL MEASURES

Handling: As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.

Storage: Store in tight, light-resistant container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

Spill Response: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Wash spill site. Place spillage and all contaminated cleanup materials in a thick plastic hazardous waste disposal bag or leakproof container and label it CAUTION: HAZARDOUS CHEMICAL WASTE.

Disposal: Place material in a thick plastic hazardous waste disposal bag or leakproof container and label it CAUTION: HAZARDOUS CHEMICAL WASTE. Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION 9 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory Protection: Use a NIOSH approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. If a respirator is not required, an approved dust mask should be used.

Ventilation: Recommended.

Gloves: Rubber

Eye Protection: Safety Goggles

Protective Clothing: Protect exposed skin.

SECTION 10 - PHYSICAL AND CHEMICAL PROPERTIES

NOTE: The data reported below is general information, and is not specific to the USP Reference Standard Lot provided!

Appearance and Odor: White or cream-colored crystalline powder; odorless or slight odor.

Melting Point: 158 - 160° C

Solubility in Water: Sparingly soluble

Vapor Density: n/f

Boiling Point: n/f

Evaporation Rate: n/f

Specific Gravity: n/f

Reactivity in Water: n/f

Vapor Pressure: n/f

% Volatile by Volume: n/f