SAFETY DATA SHEETS

This SDS packet was issued with item:

078939618

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078937276 078938361

SAFETY DATA SHEET

PRODUCT: METRONIDAZOLE TABLETS, USP

1. IDENTIFICATION

Common/Trade Name (as labeled): Metronidazole Tablets, USP

Chemical Name (for active ingredient): 2-Methyl-5-nitroimidazole-1-ethanol
(1H-Imidazole-1-ethanol, 2-methyl-5-nitro)

Molecular formula (for active ingredient): $C_6H_9N_3O_3$

Molecular Weight (of active ingredient): 171.15

Product Group (for active ingredient): Nitroimidazole

Intended Use: Antibiotic agent, Antiprotozoal agent. Pharmaceutical product by prescription only.

Drug Application Holder: Innogenix, LLC.
8200 New Horizons Blvd
Amityville, NY 11701

Emergency Phone: 1-844-466-6469

2. HAZARD(S) IDENTIFICATION

WARNING: Metronidazole has been shown to be carcinogenic in mice and rats (see current product package insert). Unnecessary use of the drug should be avoided. Its use should be reserved for the conditions described in the INDICATIONS AND USAGE section of the current product package insert.

GHS Classification:

Reproductive Toxicity: Category 2 (Limited evidence of human or animal carcinogenicity)
Carcinogenicity: Category 2 (Limited evidence of human or animal carcinogenicity)

Primary Routes of Administration: Oral (Ingestion)

Health Hazards: In the workplace, exposure via inhalation in the finished pharmaceutical product is not expected. Skin contact may cause irritation. Eye contact with drug product can cause mechanical irritation. Accidental ingestion may be harmful. In therapeutic use, the most common adverse effects reported are nausea, headache, anorexia, and occasionally vomiting, diarrhea, epigastric distress, and abdominal cramping, sharp, metallic taste, overgrowth of Candida. Constipation has also been reported. Rare cases of pancreatitis have been reported. May cause adverse effects on neurological, cardiovascular system, Prolonged therapeutic use may cause super-infections. Use of alcohol while taking Metronidazole can cause an accumulation of systemic acetaldehyde, which can lead to serious effects or be fatal. Animal studies indicate significant carcinogenic potential. Limited evidence of mutagenic effects, based on animal data. These effects may be possible as a result of workplace exposure. Refer to current product package insert for additional information on adverse effects.

Flammability Hazards: This product requires substantial pre-heating before ignition occurs. When involved in a fire, this product may decompose and produce irritating vapors and toxic compounds (including carbon, iron, magnesium, sodium, silicon, titanium and nitrogen oxides).

Reactivity Hazards: This product is not reactive.

Environmental Hazards: This product contains a compound that may cause long-term harm to aquatic organisms.

Emergency Recommendations: Emergency responders must wear personal protective equipment suitable for the situation to which they are responding.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS #	Concentration % w/w
Metronidazole	443-48-1	Proprietary
Microcrystalline Cellulose	9004-34-6	Proprietary
Colliodal Silicon Dioxide	7631-86-9	Proprietary
Crospovidone	9003-39-8	Proprietary
Stearic Acid	57-11-4	Proprietary
Magnesium Stearate	557-04-0	Proprietary
Other	NA	Proprietary

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) other than listed above.

4. FIRST-AID MEASURES

Inhalation: Physical form suggests that risk of inhalation exposure is negligible. Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Skin Contact: Slightly hazardous in case of skin contact (irritant) Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Eye Contact: May Cause eye irritation. Flush with water while holding eyelids open for at least 15 minutes. Seek medical Attention Immediately.

Ingestion: If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

Overdose Treatment: In therapeutic use, pre-existing renal conditions, hepatic disease, active alcoholism, gastrointestinal disease, or Crohn's disease may be aggravated. There is no specific antidote for metronidazole overdose; therefore, management of the patient should consist of symptomatic and supportive therapy. Persons developing hypersensitivity reactions should receive medical attention.

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water

Unusual Fire & Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Special Fire Fighting Procedures: In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters. Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. Do not use water jet. In the event of fire and /or explosion don not breathe fumes.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure

Environmental precautions: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Spill Cleanup methods: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly. Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Handling: Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage: Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits.

Respiratory Protection: Wear an appropriate respirator when airborne exposure is suspected.

Hand Protection: Wear nitrile or latex gloves

Eye Protection: Wear safety glasses or goggles if eye contact is possible.

Skin and Body Protection: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Recommended Facilities: Eye wash, Washing facilities.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Physical State: Tablets (Solid Oral Dosage Form)

Appearance	**250 mg:**	White to off-white, round, convex tablet with "I" on one side and "124" on the other side.
	500 mg:	White to off-white, modified oval shape tablet with "I" on one side and "125" on the other side.
Odor	Odorless	
Taste	Not Available	
pH	Not Available	
Melting Point	Not Available	
Boiling Point	Not Available	
Vapor pressure	Not Available	
Density	Not Available	
Solubility in water	Not Available	
Specific Gravity	Not Available	
Flashpoint	Not Available	
Flammability limits	Not Available	

10. STABILITY AND REACTIVITY

Reactivity: Data not available.

Chemical Stability: Stable at labeled storage condition [20° to 25°C (68° to 77°F), see USP Controlled Room Temperature]

Conditions to Avoid: Data not available.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

Hazardous Decomposition Products: Data not available.

11. TOXICOLOGICAL INFORMATION

General information: The information included in this section describes the potential hazard of the Active Pharmaceutical Ingredient (Metronidazole USP)

Long Term: Animal studies indicate that this material may cause adverse effects on the developing fetus

Known clinical effect: Clinical use of this drug has caused nausea, dizziness and effect on blood forming organs.

Acute Toxicity: Metronidazole

Species	Route	End Point	Dose
Rat	Oral	LD50	3 g/kg
Mouse	Oral	LD50	3800 mg/kg

Carcinogenesis: Tumors affecting the liver, lungs, mammary, and lymphatic tissues have been detected in several studies of metronidazole in rats and mice, but not hamsters. Pulmonary tumors have been observed in

all six reported studies in the mouse, including one study in which the animals were dosed on an intermittent schedule (administration during every fourth week only). Malignant liver tumors were increased in male mice treated at approximately 1500 mg/m^2 (similar to the maximum recommended daily dose, based on body surface area comparisons). Malignant lymphomas and pulmonary neoplasms were also increased with lifetime feeding of the drug to mice. Mammary and hepatic tumors were increased among female rats administered oral metronidazole compared to concurrent controls. Two lifetime tumorigenicity studies in hamsters have been performed and reported to be negative.

Genetic Toxicity: Metronidazole has shown mutagenic activity in in-vitro assay systems including the Ames test. Studies in mammals in-vivo have failed to demonstrate a potential for genetic damage.

Reproductive Toxicity & Developmental Toxicity: There are no adequate and well controlled studies of metronidazole in pregnant women. There are published data from case-control studies, cohort studies, and 2 meta-analyses that include more than 5000 pregnant women who used metronidazole during pregnancy. Many studies included first trimester exposures. One study showed an increased risk of cleft lip, with or without cleft palate, in infants exposed to metronidazole in-utero; however, these findings were not confirmed. In addition, more than ten randomized placebo-controlled clinical trials enrolled more than 5000 pregnant women to assess the use of antibiotic treatment (including metronidazole) for bacterial vaginosis on the incidence of preterm delivery. Most studies did not show an increased risk for congenital anomalies or other adverse fetal outcomes following metronidazole exposure during pregnancy. Three studies conducted to assess the risk of infant cancer following metronidazole exposure during pregnancy did not show an increased risk; however, the ability of these studies to detect such a signal was limited.
Metronidazole crosses the placental barrier and its effects on the human fetal organogenesis are not known. Reproduction studies have been performed in rats, rabbits, and mice at doses similar to the maximum recommended human dose based on body surface area comparisons. There was no evidence of harm to the fetus due to metronidazole.

12. ECOLOGICAL INFORMATION

General information: The environmental characteristics of this formulation have not been fully evaluated. The active ingredient in this formulation may be harmful to aquatic organisms. Releases to the environment should be avoided.

Persistence and Degradability: No data available.

Bio-accumulative potential: No data available.

Mobility in Soil: No data available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of waste in accordance with all applicable Federal, state and Local laws and regulations. Member state specific and community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release.it is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and waste water.

14. TRANSPORT INFORMATION

DOT: Not Regulated

IMDG: Not regulated ICAO/IATA: Not Regulated

15. REGULATORY INFORMATION

DEA: Metronidazole is not a controlled substance

FDA: Metronidazole Tablets, USP is an approved prescription medication

CERCLA/SARA 313 Emission Reporting: Not Listed

Standard for the uniform scheduling for Drug and poisons: Schedule 4

EU EINECS/ELINCS list: 207-136-1

OSHA: In accordance with OSHA Hazard Communication Standards, 29 CFR 1910.1200(b)(6)(vii), *"Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), when it is in solid, final form for direct administration to the patient (e.g., tablets or pills); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs); and drugs intended for personal consumption by employees while in the workplace (e.g., first aid supplies)"*, are exempted from the requirements of the Hazard Communication Standard. Pharmaceutical drug products are labeled in compliance with the requirements of the Food and Drug Administration (FDA) and must be used in the prescribed manner. Each package of the finished pharmaceutical product is supplied with a package outsert/insert (approved labeling) which provides necessary drug safety information.

SEE CURRENT PRODUCT PACKAGE INSERT FOR DETAILED INFORMATION

16. OTHER INFORMATION

This document is prepared by Innogenix, LLC. in good faith to provide relevant available information about handling of this drug product distributed into interstate commerce material in the workplace. The information provided is based on references from Drug Bank, Physician Desk Reference (PDR) and approved labeling for Metronidazole Tablets, USP.

THIS SAFETY DATA SHEET IS WITHOUT WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE).

In the event of an adverse incident associated with this product, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute or product literature which may accompany the finished product.

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End of Safety Data Sheet