

SAFETY DATA SHEETS

This SDS packet was issued with item:

078912046

N/A



Material Safety Data Sheet

Claris Lifesciences Inc.

MSDS No: CLI/MSDS/002.01

METRONIDAZOLE INJECTION, USP

1. PRODUCT IDENTIFICATION

Common/Trade Name:	Metronidazole Injection, USP	
How Supplied:	Strength:	NDC No:
Fill Volume 100 mL in 100 mL PVC bag	500 mg/100 mL	36000-001-24
Chemical Class:	Nitro Imidazole	
Chemical Name:	1-(β -hydroxyethyl)-2-methyl-5- nitroimidazole	
Formula:	$C_6H_9N_3O_3$	
Product Type:	Regulated Prescription Drug	
Product Use:	Pharmaceutical, Injectable	
Distributor Name:	Claris Lifesciences Inc.	
Distributor Address:	1445USHIGHWAY130 NORTH BRUNSWICK,NJ 08902	
Manufacturer's Name:	Claris Lifesciences Limited	
Address:	Chacharwadi-Vasana, Ahmedabad-382 213, India.	
Telephone Number For Information/ Medical Emergency	1-877-7CLARIS (1-877-725-2747)	
Date Prepared:	20 th April, 2008	

2. COMPOSITION INFORMATION

Component	Weight%	CAS#	OSHA PEL	ACGIH TLV
Metronidazole	<1.0	443-48-1	None	None
Sodium Chloride	<1.0	7647-14-5	None	None
Disodium Hydrogen Phosphate Anhydrous	<0.1	7558-79-4	None	None
Citric Acid Monohydrate	<0.1	5949-29-1	None	None
Water for Injection	>98.0	7732-18-5	None	None

3. HAZARDOUS IDENTIFICATION

EMERGENCY OVERVIEW: SUSPECT CANCER HAZARD.
MAY CAUSE CANCER. May cause allergic reactions.



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Routes of Entry: Absorbed through skin. Eye contact. Ingestion.

Health Hazard (Acute & Chronic): In clinical use, this material is used to treat bacterial and protozoal infections. Possible target organs include the nervous system, reproductive system, liver, lungs, and gastrointestinal system.

General Effects of Exposure:

Acute Effects of Exposure: Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Nervous System effects (may include ataxia, tremor, disturbance of speech, lethargy, headache, dizziness, blurred vision). Hypersensitivity (may include drug fever, rash, itching, anaphylaxis). Seizures. Peripheral neuropathies (may include numbness and paralysis). Neutropenia (decreased number of neutrophils).

Chronic Effects of Exposure: No data is available on the product itself.

Carcinogenicity:

NTP? Classified 2 (reasonably anticipated) by NTP

IARC Monographs? Group 2B

OSHA Regulated? None

Signs & Symptoms of Exposure: No signs or symptoms from occupational exposure are known.

Medical Conditions Generally Aggravated by Exposure: Data suggest any pre existing ailments in the following organs: nervous system, hematopoietic system, liver, gastrointestinal system. Concurrent intake of depressants like alcohol. Concurrent use of medications.

4. FIRST AID MEASURES

Eye Exposure: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Exposure: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic / supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic / supportive care as necessary.

NOTES TO HEALTH PROFESSIONALS:

See patient package insert in case pack/carton for complete information.

5. FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): Not applicable

Lower Explosion Limit: Not Established (LEL%)

Upper Explosion Limit: Not Established (UEL %)

Flammable Limits: Not applicable

Extinguishing Media: Use extinguishing media appropriate for primary cause of fire.



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Special Fire Fighting Procedures: No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

Unusual Fire/Explosion Hazards: None known

6. ACCIDENTAL RELEASE INFORMATION

Release to Land: Dispose according to local, state, and federal guidelines. Prevent contact with sewers and waterways. Wash area with soap and water. Wear personal protective equipment.

Release to Air: If aerosolized, reduce exposures by ventilating area; clean up spill immediately to prevent evaporation. Wear respiratory protection as necessary.

Release to Water: Refer to the local water authority; drain disposal is not recommended. Refer to local, state, and federal guidelines.

7. PRECAUTION FOR SAFE HANDLING AND USE

Steps to be taken in case material is released or spilled: See Section 6 above.

Wear all necessary protective equipment including nitrile or latex gloves, protective clothing, and safety glasses. A dust/mist respirator (N95) may be necessary if excessive aerosols are generated. Large spills may require the use of protective coveralls, boots, double gloves and SCBAs.

Waste Disposal Method: Dispose of according to local, state, and federal guidelines. Incineration at a licensed facility is recommended.

Storage Temperature:

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) and up to 40°C for not more than 48 hrs.

Precautions to be taken in handling and storing: Protect from light during storage. Avoid excessive heat. Protect from freezing. Do not remove unit from overwrap until ready for use. The overwrap is a moisture barrier.

Shelf Life: Do not use after expiration date.

Other Precautions: None identified.

8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection: Respiratory protection is not needed during normal product use.

Skin Protection: If solution contact with unprotected skin is likely, use of impervious gloves is a prudent practice.

Ventilation: Handle product in a well-ventilated area.



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Eye Protection: Eye protection is not required during expected product use conditions but may be warranted should a splash potential exist.

Other Protective Clothing or Equipment: Lab coat

Work/Hygienic Practices: Wash hands following use. No eating, drinking, or smoking when handling this product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid
Specific Gravity:	Approximate to water
Appearance:	Aqueous solution
Melting Point/Range:	Not applicable
Boiling Point/Range:	Approximate to water
Evaporation Rate:	Approximate to water
Vapor Pressure:	Approximate to water
Solubility in Water:	Soluble
Vapor Density:	Not Applicable
pH:	4.5 - 7.0

10. STABILITY AND REACTIVITY DATA

Stability: Stable

Incompatibility (Materials to Avoid): Oxidizing agents. See product packaging and the physicians' Desk Reference (PDR) for Drug Interaction.

Hazardous Decomposition or Byproducts: Toxic fumes of nitrogen oxides

Hazardous Polymerization: Will not occur.

Conditions to Avoid: None identified

11. TOXICOLOGICAL INFORMATION

Carcinogenicity: May be carcinogenic based on animal data.

Mutagenicity: May be mutagenic

Reproductive Toxicity: No impairment to fertility based on animal data. May be fetotoxic based on animal data. See patient package insert for additional information.



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LD50, oral, mouse =	3800 mg/kg
LD50, subcutaneous, mouse = >	3640 mg/kg
LD50, oral, rat = >	3 g/kg

12. ENVIRONMENTAL IMPACT INFORMATION

Information is currently not available on the environmental impact of Metronidazole. Handle in a manner that prevents spills or releases to the Environment.

13. DISPOSAL INFORMATION

Waste Disposal Disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal Dispose of container and unused contents in accordance with federal, state, and local regulations.

14. TRANSPORTATION INFORMATION

DOT

Not Regulated

15. REGULATORY INFORMATION

TSCA Status	Not Regulated
SARA Status	Not Regulated
CERCLA Status	Not Regulated
RCRA Status	Not Regulated
PROP 65 (Calif.)	Metronidazole is identified in the state of California to cause reproductive toxicity.

16. OTHER DATA

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