



300 Northfield Road
 Bedford, OH 44146
 Telephone: (800) 562-4797
 -or- (440) 232-3320

MATERIAL SAFETY DATA SHEET

Section I - IDENTITY

Common/Trade Name: Mitomycin for Injection, USP (5mg, 20mg, and 40mg/vial as powder)

Chemical Names: (1aR)-6-Amino-8-[[[(aminocarbonyl) oxy]methyl]-1,1a,2,8,8a,8-hexahydro-8a-methoxy-5-methylaziriono[2',3':3,4]pyrrolo[1,2-a]indole-4,7-dione

Synonyms: Amecytin; Mutamycin, NSC 26980, NCI-C04706, 7-Amino-9-alpha-methoxymitosane

Manufacturer's Name: BEN VENUE LABORATORIES, INC.

Address: 300 NORTHFIELD ROAD
 BEDFORD, OH 44146

Emergency Telephone Number: Chemtrec: 1(800)424-9300

Telephone Number for Info.: (440)232-3320 or (800)562-4797

Medical Emergency: Professional Services 1(800)521-5169

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Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Mitomycin	33%	50-07-7	NONE	NONE	0.05 mcg/m3 0.02mcg/m3
Mannitol	67%	69-65-8	NONE	NONE	NONE

Mitomycin is a sterile parenteral injectable drug presented as a powder cake. It must be reconstituted with Sterile Water for Injection prior to administration.

Section III - HEALTH HAZARD DATA

Routes of Entry: Product may be absorbed via inhalation, ingestion, or skin contact.

Health Hazard (Acute & Chronic): Mitomycin is a cytotoxic antibiotic and anticancer drug. Irritation of

exposed tissue is possible. Chronic effects due to occupational exposure are not anticipated. Patients receiving this compound via injection experience effects on the following systems: bone marrow, mucus membranes, kidneys, lungs. Allergic reactions are possible.

Carcinogenicity: NTP? NO **IARC Monographs?** Group 2B Animal sufficient evidence
OSHA Regulated? NO

Signs & Symptoms of Exposure: Mitomycin is a suspect cancer agent and may cause mutagenic, teratogenic and reproductive health effects upon excessive exposure. Also, fever, nausea, vomiting, headache, drowsiness, diarrhea, shortness of breath, bronchospasms, redness of skin, irritation, and vision disturbances may occur.

Medical Conditions Generally Aggravated by Exposure: May aggravate respiratory, kidney, and blood conditions such as coagulation disorders.

BVL Hazard Category: 4

Section IV - FIRST AID MEASURES

Eye Exposure: Flush eyes with large volumes of water for 15 or more minutes.

Skin Exposure: Wash skin with cool, soapy water.

Ingestion: If ingestion occurs, flush mouth with water and seek medical attention immediately. If person is conscious, induce vomiting; never induce vomiting on an unconscious person.

Inhalation: If difficulty breathing, administer oxygen. Seek attention of a physician immediately. Overdose should be treated symptomatically and blood chemistry monitored closely.

Section V - FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): Not Applicable **LEL:** NA **UEL:** NA

Flammable Limits: Not Applicable

Extinguishing Media: Use water or a multi-purpose ABC extinguisher.

Special Fire Fighting Procedures: As with all fires, evacuate personnel to a safe area. Fire fighters must wear self-contained breathing apparatus to avoid inhalation of smoke. Product is not expected to present a fire hazard concern.

Unusual Fire/Explosion Hazards: NONE

Section VI - ACCIDENTAL RELEASE INFORMATION

Release to Land: Wet Mitomycin with water to prevent dusting and absorb with proper absorbents. Prevent contact with sewers and waterways.

Release to Air: If dust is generated, reduce exposures by ventilating and prevent the generation of dust. Wear respiratory protection.

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

Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE

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

Wear all necessary protective equipment including nitrile or latex gloves, protective clothing, safety glasses, and air-purifying respirator with HEPA (P100) cartridges. Large spills require the use of SCBA.

Waste Disposal Method: Mitomycin is a RCRA listed hazardous waste; EPA Code: U010
Reportable Quantity (RQ)=10 lbs. Dispose of via hazardous waste disposal laws and regulations.

Precautions to be taken in handling and storing: Store at 15°- 30°C.

Other Precautions: Follow OSHA guidelines on the safe handling of cytotoxic products

(see Section XVI).

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection: Under normal use, respirators are not required. If dust generation is likely, an air-purifying respirator with HEPA (P100) cartridges must be worn. For large spill emergencies, SCBA may be required. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard, 29 CFR 1910.134.

Ventilation: Use with adequate ventilation such as in a Class II Type B biological safety cabinet.

Protective Gloves: Nitrile or latex

Eye Protection: Safety glasses or goggles

Other Protective Clothing or Equipment: Lab coat

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

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State:	Solid	Specific Gravity:	1.418
Appearance and Odor:	Violet to gray powder with no odor	Melting Point:	360°C
Boiling Point:	Not Applicable	Evaporation Rate:	Not Applicable
Vapor Pressure:	Not Applicable	Solubility in Water:	Moderately soluble
Vapor Density:	Not Applicable	pH:	6-8 when reconstituted with water

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable

Incompatibility (Materials to Avoid): Oxidizers

Hazardous Decomposition or Byproducts: Decomposition products of this compound may include potentially hazardous byproducts of nitrogen oxides, carbon monoxide and sulfur dioxide.

Hazardous Polymerization: Will not occur.

Conditions to Avoid: Avoid contact with oxidizers.

Section XI - TOXICOLOGICAL INFORMATION

For active ingredient Mitomycin

LD₅₀ oral, rat = 30 mg/kg

LD₅₀ oral, mouse = 23 mg/kg

LD₅₀ subcutaneous, rat = 3.25 mg/kg LD₅₀ intraperitoneal, mouse = 4 mg/kg

LD₅₀ intraperitoneal, rat = 2 mg/kg

LD₅₀ subcutaneous, mouse = 7.8 mg/kg

LD₅₀ intravenous, rat = 3 mg/kg

LD₅₀ intravenous, dog = 1 mg/kg

Microsomal mutagenicity assay = 5 mcg/plate

Cytogenic analysis system test (human, fibroblast) = 100 mcg/L

Additional reproductive health and toxicity data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).

Section XII - ENVIRONMENTAL IMPACT INFORMATION

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

Section XIII - DISPOSAL INFORMATION

Mitomycin is an EPA listed hazardous waste, Code Number U010.
Dispose of according to local, state, and federal guidelines for RCRA Hazardous Wastes.

Section XIV - TRANSPORTATION INFORMATION

This material is a DOT hazardous material according to 49 CFR 172.101
Proper Shipping Name: Medicine, solid, toxic, N.O.S. (Mitomycin)
Hazard Class and Description: 6.1 (Poisonous solid)
UN I.D. Number: NA 3249
Packing Group: III
DOT Labels required: Refer to CFR 173.4
Emergency Response Guide No.: 53
Mitomycin is not a Marine Pollutant.

Section XV - REGULATORY INFORMATION

SARA 313 listed?: YES TPQ 500/10,000 pounds
CERCLA listed?: YES; Releases over 10 pounds must be reported.
RCRA listed?: YES; Code. U010
Mitomycin is listed on Section 8(b) of EPA's TSCA Chemical Inventory as Flag S
Mitomycin is listed on California's Proposition 65 List as Code C
Listed on the Florida Toxic substance list as a "Toxic Substance in the State of Florida"
Listed on Massachusetts Hazardous substance as codes 1,7*E*C*F6 F8
Listed on the Pennsylvania Hazardous Substance List as Code ES
Michigan Critical Material Report Code 2
New Jersey Right to Know Hazardous Substance: DOT 1851, Sub Number 1307, listed as an
Extremely Hazardous Substance
New York List of Hazardous Substances: Classified as an acutely hazardous substance
Reportable Quantity to Air: 10
Reportable Quantity to Land: 1

Section XVI - OTHER DATA

1. Hospital personnel preparing or administering toxic parenteral agents should wear disposable latex gloves, safety glasses, a closed-front gown with cuffs, and respiratory protection. Preparation of all toxic or potent agents should be done in a Class II laminar flow hood or biological safety cabinet with exhaust air discharged external to the room environment. All needles, syringes, vials, and other equipment or disposable clothing that have contacted this agent

should be segregated for incineration.

2. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company Management.
3. Use of this product should be through or under the direction of a physician. This MSDS does not address therapeutic use of this material.

The information provided is believed to be complete and accurate. It is the user's responsibility to use the information according to their application. Bedford Laboratories and Ben Venue Labs, Inc. assumes no additional liability or responsibility resulting from the use of or reliance on this information.