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
Date Revised: September 14, 2009

Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

Component	%	CAS#	OSHA PEL	ACGIH TLV	Other Limits Recommended
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, broncospasms, 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. Use a 1% bleach solution to effectively degrade and remove from non-porous surfaces.

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
Appearance and Odor: Violet to gray powder with no odor
Boiling Point: Not Applicable
Vapor Pressure: Not Applicable
Vapor Density: Not Applicable
Specific Gravity: 1.418
Melting Point: 360°C
Evaporation Rate: Not Applicable
Solubility in Water: Moderately soluble
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: RTECS # CN0700000

- LD_{50} oral, rat = 30 mg/kg
- LD_{50} subcutaneous, rat = 3250 ug/kg
- LD_{50} intraperitoneal, rat = 1 mg/kg
- LD_{50} intravenous, rat = 3 mg/kg
- LD_{50} oral, mouse = 23 mg/kg
- LD_{50} intraperitoneal, mouse = 4 mg/kg
- LD_{50} subcutaneous, mouse = 7300 ug/kg
- LD_{50} intravenous, dog = 720 ug/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

Mitomycin is a DOT hazardous material according to 49 CFR 172.101
Proper Shipping Name: Medicine, solid, toxic, n.o.s., (Mitomycin)
Hazard Class: 6.1 (Poisonous solid)
UN I.D. Number: NA 3249
Packing Group: III
DOT Labels required: Refer to CFR 173.4 (Small Quantity Exemptions)
Emergency Response Guide No.: 151
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 EPAs 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.

4. BVL Hazard Category Definitions (internal hazard ranking used by Ben Venue Laboratories):
1 = Low Toxicity
2= Moderate Toxicity
3 = Potent or Toxic
4 = Highly Potent or Toxic
5 = Extremely Potent or Toxic

5. OEL=Occupational Exposure Limit. An internal limit set by Ben Venue Laboratories for the recommended limit of employee exposure to airborne dusts or aerosols that should not be exceeded over an eight-hour time-weighted average.

6. Mitomycin is considered a Hazardous Drug as described in the NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings. Employees who prepare or administer hazardous drugs or who work in areas where these drugs are used should follow specific handling guidelines in order to prevent exposure to these agents in the air or on work surfaces, clothing, or equipment.

7. **The Following Guidance Information is excerpted from the NIOSH Alert:**

Elements of a Hazardous Drug Handling Program include:

- Establishment and implementation of written policies and protocols to ensure the safe handling of oncolytic and/or potent drugs, including receipt of product.
- Training and education of employees on the recognition, evaluation and control of Hazardous Drugs
- Effective Planning and design of the workplace
- Use of best practice control measures and specialized equipment such as ventilated cabinets or isolators designed for worker protection
- Wearing recommended personal protective equipment
- An integrated health surveillance program that: includes the assessment and counseling of prospective employees before they commence any work involving oncolytic and/or potent drugs and related waste

8. **Published guidance on the handling and transport of cytotoxic drugs:**

NIOSH Alert – Preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings
http://www.cdc.gov/niosh/docs/2004-165/

National Study Commission on Cytotoxic Exposure: Recommendation for handling Cytotoxic Agents:
http://www.nih.gov/od/ors/ds/pubs/cyto/index.htm

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