



# Material Safety Data Sheet

## Section 1. Product Identification

Common Name/Trade Name	<b>Mitosol® Kit for Ophthalmic Use (mitomycin for solution)</b>
How supplied	single-dose vial, 0.2 mg / vial as powder
Manufacturer / Supplier	Mobius Therapeutics, LLC 4041 Forest Park Avenue St. Louis, MO 63108
Company Contact	Alan T. Beckman (314) 615-6930
Emergency phone	1-877-EYE-MITO (1-887-393-6486)
Synonyms	mitomycin-C
NDC#	49771-002-01 (single unit) 49771-002-03 (case of 3 units)

## Section 2. Composition and Information on Ingredients

Name	CAS #	% by Weight	Exposure Limits	
			OSHA PEL	ACGIH TLV
Mannitol	69-65-8	67 %		
Mitomycin	50-07-07	33 %	ND	ND

## Section 3. Hazards Identification

### Potential Health Effects

<b>Acute Effects:</b>	<b>May be fatal if inhaled, ingested or absorbed through skin. Severe over-exposure can result in death.</b>
Eye:	May cause eye irritation. Very dangerous in case of eye contact (irritant). Inflammation of the eye is characterized by redness, watering and itching.
Skin:	May cause skin irritation. Slightly dangerous to dangerous in case of skin contact (irritant, permeator).
Ingestion:	Harmful if swallowed. May cause liver damage. May cause digestive tract irritation. May cause bone marrow

ND: Not Determined

NA: Not Applicable

depression.

Inhalation: May cause respiratory tract irritation. May cause pulmonary fibrosis, permanent damage and effects similar to those described for ingestion.

**Chronic Effects: Potential cancer hazard. May alter genetic material. May cause cancer and cause reproductive disorders based on animal studies. Chronic exposure may cause liver damage. Repeated exposure to any highly toxic material may produce general deterioration of health by an accumulation in one or many human organs. Target organs: bone marrow, liver.**

**Primary Routes of Entry: Injection into the skin; ingestion; inhalation; skin contact.**

#### Section 4. First Aid Measures

Eyes: Remove any contact lenses. Immediately flush eyes with water for 15 minutes keeping eyelids open. Cold water may be used. Do not use an eye ointment. Seek medical help

Skin: Gently wash thoroughly the contaminated skin with water and non-abrasive soap. Cold water may be used. Cover the irritated skin with an emollient. If irritation persists, seek medical attention. If the chemical gets on your clothing, remove the contaminated clothing carefully, using personal protective equipment, and wash areas of body. Wash clothing before reusing. **For serious skin contact:** Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Seek immediate medical attention.

Inhalation: Remove to fresh air, seek immediate medical attention. **For serious inhalation:** Remove to fresh air. Loosen clothing. If having difficulty breathing, administer oxygen. Giving mouth-to-mouth resuscitation may be dangerous. Seek immediate medical attention.

Ingestion: Have conscious person drink several glasses of water or milk. **INDUCE VOMITING** by sticking finger in throat or give Ipecac if ingestion has been less than 30 minutes. If greater than 30 minutes or unknown, activated charcoal may be administered if victim is alert and conscious (15-30g children; 50-100g adults). Seek immediate medical attention.

Accidental Injection: Seek prompt medical attention.

### Section 5. Fire and Explosion Data

Flash point and method:	ND
Extinguishing medium:	Small Fire: CO <sub>2</sub> , Dry Chem, Water Spray or Foam. Large Fire: Water Spray, Fog or Foam. Do not use Water Jet.
Special Fire Fighting Procedures:	Use NIOSH/MSHA approved self-contained breathing Procedures apparatus and protective clothing.
Hazardous Decomposition or Combustion Products:	Oxides of carbon (CO, CO <sub>2</sub> ) and nitrogen (NO, NO <sub>2</sub> )
Flammability of the Product:	Combustible
Unusual Fire Hazards:	NA
Unusual Explosion Hazards:	NA

### Section 6. Accidental Release Measures

Small Spill:	Prevent exposure. Wear latex or nitrile gloves and safety glasses when cleaning up spilled product. Contain the spill. Clean up spilled material with a damp, absorbent paper, pillow or pad and place in an appropriate waste disposal container. Use care in the cleanup of broken glass. Decontaminate area using a bleach solution or a product like Surface Safe→ (available from SuperGen).
Large Spill:	Trained personnel should wear respiratory protection, appropriate gloves, eye protection, boots and chemically resistant body protection. Stop leak if without risk. Use water spray to reduce vapors. Prevent entry into sewers, basements or confined areas. Eliminate all sources of ignition.

### Section 7. Handling and Storage

Storage:	Store as stated in product labeling.  Store dry powder at room temperature, protected from light.  Protect reconstituted solution from light. Store reconstituted solution at room temperature, discard after 1 hour.
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### Section 8. Exposure Controls/Personal Protection

Engineering Controls:	General ventilation.
Personal Protection:	Material should be handled in such a way as to avoid skin and eye contact. Exercise caution when purging air from the administration system. Hand and eye protection is recommended. If contact should occur, wash contaminated skin promptly. Launder contaminated clothing and clean protective equipment before reuse. Hospital personnel preparing antineoplastic agents for use on patients, such as this product, should wear disposable latex gloves, safety glasses, closed-front gowns with knit cuffs and masks.

### Section 9. Physical and Chemical Properties

Physical State and Appearance	Bulk Solution: Liquid; clear, colorless to pale yellow, Aqueous Filled Vials: Powder; violet to blue-grey cake or powder
pH (@ 25°C)	Reconstituted Solution: Between 5.0 – 8.0
Odor Threshold	None reported
Specific Gravity (water=1)	ND
Solubility (water)	Moderate
Solubility (pH 9 borate buffer)	ND
Melting point	>360°C
Boiling point	NA
Vapor Pressure	NA
Vapor Density	NA

### Section 10. Stability and Reactivity Data

Stability and Polymerization	Under normal storage conditions, this product is stable and hazardous polymerization should not occur.
Materials to avoid	Strong oxidizing agents, strong acids, strong bases

### Section 11. Toxicological Information

**The following information pertains to the ingredient(s) individually and not to the product as marketed. Included will be any data which emphasize the potential effects that may occur with the occupational handling (by inhalation or by dermal or ocular contact) of this product.**

MITOMYCIN:

LD50 (Oral):	Acute: 30 mg/kg (Rat), 23 mg/kg (Mouse)
Carcinogenicity:	OSHA: possible select carcinogen IARC: Group 2B carcinogen
Epidemiology:	IARC Group 2B: Proven animal carcinogenic substance of potential relevance to humans. No data available on human carcinogenicity, however there is sufficient evidence of carcinogenicity in animals. Experimental reproductive effects have been reported.
Teratogenicity:	No information found.
Reproductive Effects:	Reproductive effects have occurred in experimental animals.
Neurotoxicity:	No information found.
Mutagenicity:	Mutagenic effects have occurred in experimental animals.

*(See current package insert for further information)*

### Section 12. Ecological Information

ND

### Section 13. Disposal Considerations

Waste Disposal:	Use EPA guidelines for determining classification as listed in 40 CFR. Dispose of in accordance with local, state and federal regulations or the authority having jurisdiction. Incineration in a permitted incinerator is the preferred disposal method. RCRA Waste number: U010.
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### Section 14. Transport Information

**DOT:** (As packaged)  
49CFR173.15

Proper Shipping Name: Consumer Commodity

Hazard Class: ORM-D  
ID/UN Number: None  
Label: None  
Packing Group: NA  
Shipping limitations: 250 grams Inner Vial  
30 kg Maximum Net Quantity

**IATA:** (As packaged)  
DGR 2.7

Proper Shipping Name: Dangerous Goods in Excepted Quantity  
Hazard Class: 6.1  
ID/UN Number: UN2811  
Label: Dangerous Goods in Excepted Quantity  
Packing Group: III  
Shipping limitations: 30 grams Inner Vial  
1 kg Maximum Net Quantity

*(For greater quantities refer to the IATA Dangerous Goods Regulations (DGR))*

<b>Section 15. Regulatory Information</b>
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US Federal Regulations: Chronic Toxic  
TSCA inventory: On List  
SARA Title III:  
EHS TPQ – 500/10,000 (pounds)  
EHS RQ - 4.54 kg (10 pounds)  
CERCLA RQ - 4.54 kg (10 pounds)  
OSHA: None of the chemicals in this product are considered highly hazardous by OSHA.  
US State Regulations: Mitomycin can be found on the following right to know lists:  
California, New Jersey, Florida, Pennsylvania, Minnesota,  
Massachusetts

California Proposition 65 Warnings: WARNING: This product contains a chemical known to the State of California to cause cancer.

Chemical ingredient(s) requiring this warning:  
Mitomycin C

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

Chemical ingredient(s) requiring this warning:  
None

Other Classifications: National Fire Protection Association (U.S.A)  
HEALTH: 3 FLAMMABLE: 1 REACTIVITY: 0

HMIS (U.S.A.)  
HEALTH HAZARD: 3 FIRE HAZARD: 1 REACTIVITY: 0  
PERSONAL PROTECTION: e

#### Section 16. Other Information

The information contained within this Material Safety Data Sheet (MSDS) is based on currently available scientific studies and is accurate and reliable to the best of our knowledge. SuperGen, Inc. makes no warranties, expressed or implied, and assumes no responsibility or liability for any damage or injuries of any kind which may result from use or reliance upon this information.

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APPROVED BY: Ed Timm