

SAFETY DATA SHEET

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1. Identification

Product identifier MITOSOL® (MITOMYCIN FOR SOLUTION) 0.2 MG/VIAL, KIT FOR OPHTHALMIC USE

Other means of identification

Synonyms MITOMYCIN, USP

Mitosol® is an antimetabolite indicated as an adjunct to ab externo glaucoma surgery.

Recommended use Mitosol® is a sterile drug presented as a powder cake. It must be reconstituted with Sterile Water for Injection prior to administration.

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Distributor

Company name Mobius Therapeutics, LLC

Address 1000 Executive Parkway Drive, Suite 224
St. Louis, MO 63141, USA

Telephone number 1-314-615-6930

Fax 1-314-615-6931

Contact Name Technical Representative

Website www.Mitosol.com

Emergency telephone number 1-877-393-6486

Manufacturer

Company name Intas Pharmaceuticals Limited,

Address Plot No.: 457 – 458,
Village: Matoda, Taluka: Sanand,
Sarkhej - Bavla Highway,
District: Ahmedabad
Gujarat, India. 382 210

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards

Acute toxicity, oral	Category 3
Germ cell mutagenicity	Category 2
Carcinogenicity	Category 2
Reproductive toxicity	Category 2

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement Cytotoxic. Toxic if swallowed. Suspected of causing genetic defects. Suspected of causing cancer. Suspected of damaging fertility or the unborn child.

Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection. Wash thoroughly after handling.

Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If exposed or concerned: Get medical advice/attention.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Finished Pharmaceutical products in their final packages are not subject to OSHA labeling requirements. Handling pharmaceutical products in workplace is subject to OSHA requirements for labeling.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
D-mannitol	69-65-8	Proprietary
MITOMYCIN	50-07-7	Proprietary

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Active: Each vial contains 0.2 mg.
Inactive: Each vial contains 0.4 mg Mannitol.

4. First-aid measures

Inhalation	Move to fresh air. If breathing is difficult, give oxygen. Get medical attention immediately.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact	In case of contact, flush eyes with large amounts of water for 15 minutes. Get medical attention if irritation develops and persists.
Ingestion	Call a physician or poison control center immediately. Rinse mouth. Never give anything by mouth to a victim who is unconscious or is having convulsions. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
Most important symptoms/effects, acute and delayed	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. Patients receiving this compound via injection experience effects on the following systems: bone marrow, mucus membranes, kidneys, lungs. Allergic reactions are possible.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim warm. Keep victim under observation. Symptoms may be delayed. PRE-EXISTING MEDICAL CONDITIONS WHICH MAY BE AGGRAVATED BY EXPOSURE: May aggravate respiratory, kidney, and blood conditions such as coagulation disorders.
General information	If exposed or concerned: Get medical advice/attention. If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

5. Fire-fighting measures

Suitable extinguishing media	Use water or a multi-purpose ABC extinguisher.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, hazardous combustion products are released that may include: Carbon oxides (COx). Nitrogen Oxides (NOx). Sulfur Oxides (SOx).
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Evacuate personnel to safe area. Move containers from fire area if you can do so without risk. In case of fire do not breath fumes.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Minimize dust generation and accumulation. Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Stop the flow of material, if this is without risk. 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. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Provide adequate ventilation. Do not taste or swallow. Do not breathe dust/fume/gas/mist/vapors/spray. When using, do not eat, drink or smoke. Avoid contact with eyes, skin, and clothing. Pregnant or breastfeeding women must not handle this product. Should be handled in closed systems, if possible. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices. Follow OSHA guidelines on the safe handling of cytotoxic products.
Conditions for safe storage, including any incompatibilities	Store locked up. Store in original tightly closed container. Store between 15°C - 30°C (60°F - 86°F). Store away from incompatible materials (see Section 10 of the SDS). Follow OSHA guidelines on the safe handling of cytotoxic products.

8. Exposure controls/personal protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Use with adequate ventilation such as in a Class II Type B biological safety cabinet. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Wear safety glasses with side shields (or goggles).
Skin protection	
Hand protection	Nitrile. Latex gloves.
Other	Lab coat.
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.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Keep away from food and drink. When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance	Mitosol® is a sterile dry mixture of mitomycin and mannitol, which when reconstituted with Sterile Water for Injection provides a solution for topical application to the surgical site.
Physical state	Solid.
Form	Powder.
Color	Not available.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.

Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Will not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Nitrogen oxides. Carbon monoxide. Sulfur dioxide.

11. Toxicological information

Information on likely routes of exposure

Inhalation	May cause slight respiratory tract irritation.
Skin contact	May cause skin irritation.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	Fatal if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics 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. Patients receiving this compound via injection experience effects on the following systems: bone marrow, mucus membranes, kidneys, lungs. Allergic reactions are possible.

Information on toxicological effects

Acute toxicity Fatal if swallowed.

Components	Species	Test Results
MITOMYCIN (CAS 50-07-7)		
Acute		
<i>Oral</i>		
LD50	Bird	7.5 mg/kg
	Mouse	23 mg/kg
	Rat	30 mg/kg
<i>Other</i>		
LD50	Cat	1 - 2.5 mg/kg, intravenous
	Dog	1 - 2.5 mg/kg, intravenous
	Monkey	1 - 2.5 mg/kg, intravenous
	Mouse	7.3 mg/kg, subcutaneous
		5 mg/kg, intravenous
		4 mg/kg, intraperitoneal
	Rabbit	3.4 mg/kg, intravenous
	Rat	3.25 mg/kg, subcutaneous
		3 mg/kg, intravenous
		2 mg/kg, intraperitoneal

Skin corrosion/irritation

May cause skin irritation.

Serious eye damage/eye irritation

Direct contact with eyes may cause temporary irritation.

Respiratory or skin sensitization

Respiratory sensitization

Not available.

Skin sensitization

This product is not expected to cause skin sensitization.

Germ cell mutagenicity

Suspected of causing genetic defects.

Mutagenicity

MITOMYCIN, USP

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

Microsomal mutagenicity assay = 5 mcg/plate

Carcinogenicity

Suspected of causing cancer.

IARC Monographs. Overall Evaluation of Carcinogenicity

MITOMYCIN (CAS 50-07-7)

2B Possibly carcinogenic to humans.

NTP Report on Carcinogens

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity

Suspected of damaging fertility or the unborn child.

Specific target organ toxicity - single exposure

Not classified.

Specific target organ toxicity - repeated exposure

Not classified.

Aspiration hazard

Not available.

Chronic effects

Patients receiving this compound via injection experience effects on the following systems: bone marrow, mucus membranes, kidneys, lungs. Allergic reactions are possible.

Further information

May aggravate respiratory, kidney, and blood conditions such as coagulation disorders.

12. Ecological information

Ecotoxicity

This material has not been tested for environmental effects.

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

D-mannitol (CAS 69-65-8)

-3.1

Mobility in soil	No data available.
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	Mitomycin is an EPA listed hazardous waste, Code Number U010. The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

UN number	UN3249
UN proper shipping name	Medicine, solid, toxic, n.o.s. (MITOMYCIN RQ = 1250 LBS)
Transport hazard class(es)	
Class	6.1(PGIII)
Subsidiary risk	-
Label(s)	6.1
Packing group	III
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.
Special provisions	T1, TP33
Packaging exceptions	153
Packaging non bulk	213
Packaging bulk	240

IATA

UN number	UN3249
UN proper shipping name	Medicine, solid, toxic, n.o.s. (MITOMYCIN)
Transport hazard class(es)	
Class	6.1(PGIII)
Subsidiary risk	-
Packing group	III
Environmental hazards	No.
ERG Code	6L
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

IMDG

UN number	UN3249
UN proper shipping name	MEDICINE, SOLID, TOXIC, N.O.S. (MITOMYCIN)
Transport hazard class(es)	
Class	6.1(PGIII)
Subsidiary risk	-
Packing group	III
Environmental hazards	
Marine pollutant	No.
EmS	F-A, S-A
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

15. Regulatory information

US federal regulations	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
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TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

MITOMYCIN (CAS 50-07-7)

0.1 % One-Time Export Notification only.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

MITOMYCIN (CAS 50-07-7)

LISTED

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
 Immediate Hazard - Yes
 Delayed Hazard - Yes
 Fire Hazard - No
 Pressure Hazard - No
 Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Chemical name	CAS number	Reportable quantity (pounds)	Threshold planning quantity (pounds)	Threshold planning quantity, lower value (pounds)	Threshold planning quantity, upper value (pounds)
MITOMYCIN	50-07-7	10		500	10000

SARA 311/312 Hazardous chemical Yes

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations**US. Massachusetts RTK - Substance List**

MITOMYCIN (CAS 50-07-7)

US. New Jersey Worker and Community Right-to-Know Act

MITOMYCIN (CAS 50-07-7)

US. Pennsylvania Worker and Community Right-to-Know Law

MITOMYCIN (CAS 50-07-7)

US. Rhode Island RTK

MITOMYCIN (CAS 50-07-7)

US. California Proposition 65

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

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

MITOMYCIN (CAS 50-07-7)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes

Country(s) or region	Inventory name	On inventory (yes/no)*
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	30-October-2017
Revision date	30 -October-2017
Version #	E
NFPA ratings	



Disclaimer

Mobius Therapeutics, LLC. cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.