1. Identification

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

Other means of identification

Synonyms
MITOMYCIN, USP

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

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,
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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>D-mannitol</td>
<td>69-65-8</td>
<td>Proprietary</td>
</tr>
<tr>
<td>MITOMYCIN</td>
<td>50-07-7</td>
<td>Proprietary</td>
</tr>
</tbody>
</table>

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.

General information

PRE-EXISTING MEDICAL CONDITIONS WHICH MAY BE AGGRAVATED BY EXPOSURE: May aggravate respiratory, kidney, and blood conditions such as coagulation disorders.

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).

  - 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
Flash point
Evaporation rate
Flammability (solid, gas)
Upper/lower flammability or explosive limits
Flammability limit - lower (%)
Flammability limit - upper (%)
Explosive limit - lower (%)
Explosive limit - upper (%)
Vapor pressure
Vapor density
Relative density
Solubility(ies)
Solubility (water)
Partition coefficient (n-octanol/water)
Auto-ignition temperature
Decomposition temperature
Viscosity
Other information
Explosive properties
Oxidizing properties

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

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, 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.
Information on toxicological effects
Acute toxicity
Fatal if swallowed.
### MITOMYCIN (CAS 50-07-7)

#### Acute

<table>
<thead>
<tr>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Oral</em></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td></td>
</tr>
<tr>
<td>Bird</td>
<td>7.5 mg/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>23 mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>30 mg/kg</td>
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</tbody>
</table>

**Other**

<table>
<thead>
<tr>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50</td>
<td></td>
</tr>
<tr>
<td>Cat</td>
<td>1 - 2.5 mg/kg, intravenous</td>
</tr>
<tr>
<td>Dog</td>
<td>1 - 2.5 mg/kg, intravenous</td>
</tr>
<tr>
<td>Monkey</td>
<td>1 - 2.5 mg/kg, intravenous</td>
</tr>
<tr>
<td>Mouse</td>
<td>7.3 mg/kg, subcutaneous 5 mg/kg, intravenous 4 mg/kg, intraperitoneal</td>
</tr>
<tr>
<td>Rabbit</td>
<td>3.4 mg/kg, intravenous</td>
</tr>
<tr>
<td>Rat</td>
<td>3.25 mg/kg, subcutaneous 3 mg/kg, intravenous 2 mg/kg, intraperitoneal</td>
</tr>
</tbody>
</table>

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

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

Further information

- Further 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)

<table>
<thead>
<tr>
<th>Substance</th>
<th>Kow</th>
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<tbody>
<tr>
<td>D-mannitol (CAS 69-65-8)</td>
<td>-3.1</td>
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</tbody>
</table>

12. Ecological information
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
No.
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.
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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS number</th>
<th>Reportable quantity (pounds)</th>
<th>Threshold planning quantity (pounds)</th>
<th>Threshold planning quantity, lower value (pounds)</th>
<th>Threshold planning quantity, upper value (pounds)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MITOMYCIN</td>
<td>50-07-7</td>
<td>10</td>
<td>500</td>
<td>10000</td>
<td></td>
</tr>
<tr>
<td>SARA 311/312 Hazardous chemical</td>
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<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

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