Mitomycin for injection, USP

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Date of Issue: **01/25/2023** Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Mitomycin for injection, USP (5/20/40 mg vials)

1.2. Intended Use of the Product

In the therapy of disseminated adenocarcinoma of the stomach or pancreas in proven combinations with other approved chemotherapeutic agents and as pallative treatment when other modalities have failed.

1.3. Name, Address, and Telephone of the Responsible Party

Manufacturer

Gland Pharma Limited, Unit-II, Block C, Phase-I,
Visakhapatnam Special
Economic Zone (VSEZ),
Duvvada, Visakhapatnam -
530049. Andhra Pradesh, India
+91-891-2747657 or +91-891-2548313

Distributor

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047
General Phone Number: (847) 550-2300
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
http://www.fresenius-kabi.com/us/

1.4. Emergency Telephone Number

Emergency Number : VelocityEHS
(800)255-3924 (North America)
+1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

Acute toxicity (oral) Category 3	H301
Germ cell mutagenicity Category 2	H341
Carcinogenicity Category 2	H351
Reproductive toxicity Category 2	H361
Specific target organ toxicity (repeated exposure) Category 2	H373
Combustible Dust	

2.2. Label Elements

GHS-US/CA Labeling

Hazard Pictograms (GHS-US/CA) :

GHS06 GHS08

Signal Word (GHS-US/CA) : Danger

Hazard Statements (GHS-US/CA) : May form combustible dust concentrations in air.
H301 - Toxic if swallowed.
H341 - Suspected of causing genetic defects.
H351 - Suspected of causing cancer.
H361 - Suspected of damaging fertility or the unborn child.
H373 - May cause damage to organs (hemapoietic system, respiratory system, integumentary system) through prolonged or repeated exposure.

Precautionary Statements (GHS-US/CA) : P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P260 - Do not breathe dust.
P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P280 - Wear protective gloves, protective clothing, and eye protection.

P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P321 - Specific treatment (see section 4 on this SDS).
P330 - Rinse mouth.
P405 - Store locked up.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

Supplemental Information : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Proper grounding procedures to avoid static electricity should be followed. Prevent dust accumulation (to minimize explosion hazard). Avoid generating dust.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US/CA)

No additional information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
D-Mannitol	1,2,3,4,5,6-Hexanehexol / Mannitol, D- / Hexanehexol / MANNITOL / Mannite / Mannitol	(CAS-No.) 69-65-8	66.66	Comb. Dust
Mitomycin-C	Ametycin / Mitomycin / Azirino(2',3':3,4)pyrrolo(1,2-a)indole-4,7-dione, 6-amino-1,1a,2,8, 8a,8b-hexahydro-8-(hydroxy methyl)-8a-methoxy-5-methyl-, carbamate (ester) / Azirino [2',3':3,4]pyrrolo[1,2-a]indole-4,7-dione, 6-amino-8-[[(amino-carbonyl) oxy]methyl] -1,1a,2,8,8a,8b-hexahydro-8a-methoxy-5-methyl-, (1aS,8S, 8aR,8bS)- / Azirino[2',3':3,4] pyrrolo[1,2-a]indole-4,7-dione, 6-amino-8-[[(amino-carbonyl)oxy] methyl]-1,1a,2,8,8a,8b-hexahydro-8a-methoxy-5-methyl-, [1aS-(1a.alpha.,8.beta., 8a.alpha.,8b.alpha.)] - / Mitromycin C / Mitomycin C / Azirino [2',3':3,4]pyrrolo[1,2-a]indole-4,7-dione, 6-amino-8-[[(aminocarbonyl) oxyl] methyl] -1,1a,2,8,8a,8b-hexahydro-8a-methoxy-5-methyl-, [1aS-(1a.alpha., 8.beta.,8a.alpha., 8b.alpha.)]- / 6-Amino-1,1a,2,8,8a,8b-hexahydro-8-(hydroxy-methyl)-8a-methoxy-5-methyl-, carbamate azirino [2',3':3,4]pyrrolo[1,2-a]indole-4,7-dione, (ester) / [(1aS,8S,8aR,8bS)-6-Amino-8a-methoxy-5-methyl-4,7-dioxo-1,1a,2,4,7, 8,8a,8b-octahydroazireno [2',3':3,4]pyrrolo[1,2-a] indol-8-yl]methyl carbamate / mitomycin	(CAS-No.) 50-07-7	33.33	Acute Tox. 2 (Oral), H300 Muta. 2, H341 Carc. 2, H351 Repr. 2, H361 STOT RE 2, H373

Full text of H-statements: see section 16. Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%).

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens. Pain and swelling may occur if accidentally injected, with the potential for damage to surrounding tissues due to the pharmaologic actions of Mitomycin-C.

Inhalation: Using proper respiratory protection, move the exposed person to fresh air at once. Encourage exposed person to cough, spit out, and blow nose to remove dust. Get immediate medical assistance.

Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 5 minutes. Get medical advice/attention.

Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical advice.

Ingestion: Do NOT induce vomiting. Rinse mouth. Immediately call a POISON CENTER or doctor.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Suspected of damaging fertility or the unborn child. May cause damage to organs (hemapoietic system, respiratory system, integumentary system) through prolonged or repeated exposure. Suspected of causing genetic defects. Suspected of causing cancer. Toxic if swallowed.

Inhalation: Dust may be harmful or cause irritation.

Skin Contact: Prolonged exposure may cause skin irritation.

Eye Contact: May cause slight irritation to eyes.

Ingestion: This material is toxic in small amounts orally, and can cause adverse health effects or death.
Chronic Symptoms: Suspected of damaging fertility or the unborn child. May cause damage to organs (hemapoietic system, respiratory system, integumentary system) through prolonged or repeated exposure. Suspected of causing genetic defects. Suspected of causing cancer.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO_2), alcohol-resistant foam, or dry chemical. Use extinguishing media appropriate for surrounding fire.
Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Combustible Dust.
Explosion Hazard: Dust explosion hazard in air.
Reactivity: Product is stable and non-reactive under normal conditions of use, storage and transport.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.
Firefighting Instructions: Use water spray or fog for cooling exposed containers.
Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.
Hazardous Combustion Products: Carbon and nitrogen oxides.
Other Information: Risk of dust explosion.

5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not get in eyes, on skin, or on clothing. Do not breathe dust. Avoid generating dust. Remove ignition sources. Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking. If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).
Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Wear protective clothing and respiratory protection if dust or fumes are present.
Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams. Avoid generation of dust during clean-up of spills.
Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Contact competent authorities after a spill. Use explosion proof vacuum during cleanup, with appropriate filter. Do not mix with other materials. Vacuum clean-up is preferred. If sweeping is required use a dust suppressant. Use only non-sparking tools.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Accumulation and dispersion of dust with an ignition source can cause a combustible dust explosion. Keep dust levels to a minimum; follow applicable regulations. Accidental injection may cause pain and swelling at the injection site with the potential for damage to surrounding tissues. Sharps should be handled appropiately to minimize risk of accidents.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes, on skin, or on clothing. Do NOT breathe (dust, vapor, mist, gas). Do not breathe dust. Handle empty containers with care because they may still present a hazard. Avoid creating or spreading dust. Keep away from heat, sparks, open flames, and hot surfaces. No smoking.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations. Avoid creating or spreading dust. Use explosion-proof electrical, ventilating, lighting equipment. Proper grounding procedures to avoid static electricity should be followed.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store locked up/in a secure area.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

Storage Temperature: 25 °C / 77 °C; excursions permitted between 15 – 30 °C (59 – 86 °F). Protect from light.

7.3. Specific End Use(s)

In the therapy of disseminated adenocarcinoma of the stomach or pancreas in proven combinations with other approved chemotherapeutic agents and as pallative treatment when other modalities have failed.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

8.2. Exposure Controls

Appropriate Engineering Controls: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed. Proper grounding procedures to avoid static electricity should be followed. Use explosion-proof equipment. Use local exhaust or general dilution ventilation or other suppression methods to maintain dust levels below exposure limits. Power equipment should be equipped with proper dust collection devices. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment.

Personal Protective Equipment: Gloves. Protective clothing. Protective goggles or glasses. Insufficient ventilation: wear respiratory protection.

Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles or safety glasses with side shields.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	:	Solid
Appearance	:	**Mitomycin for injection, USP** is a sterile dry mixture of mitomycin and mannitol, which when reconstituted with Sterile Water for Injection provides a solution for intravenous administration.
Odor	:	Odorless or with mild odor
Odor Threshold	:	No data available
pH	:	6.0 – 8.0 (0.5% solution)
Evaporation Rate	:	No data available

Melting Point	:	No data available
Freezing Point	:	No data available
Boiling Point	:	No data available
Flash Point	:	No data available
Auto-ignition Temperature	:	No data available
Decomposition Temperature	:	No data available
Flammability (solid, gas)	:	No data available
Lower Flammable Limit	:	No data available
Upper Flammable Limit	:	No data available
Vapor Pressure	:	No data available
Relative Vapor Density at 20°C	:	No data available
Relative Density	:	No data available
Specific Gravity	:	No data available
Solubility	:	Soluble.
Partition Coefficient: N-Octanol/Water	:	No data available
Viscosity	:	No data available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

Product is stable and non-reactive under normal conditions of use, storage and transport.

10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

10.4. Conditions to Avoid:

Direct sunlight, extremely high or low temperatures, and incompatible materials. Sparks, heat, open flame and other sources of ignition. Dust accumulation (to minimize explosion hazard).

10.5. Incompatible Materials:

Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products:

Thermal decomposition may produce: Carbon and nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Acute Toxicity (Oral): Toxic if swallowed.

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

LD50 and LC50 Data:

Mitomycin for injection, USP	
ATE US/CA (oral)	65-90 mg/kg body weight

Skin Corrosion/Irritation: Not classified

pH: 6.0 – 8.0 (0.5% solution)

Eye Damage/Irritation: Not classified

pH: 6.0 – 8.0 (0.5% solution)

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Suspected of causing genetic defects.

Carcinogenicity: Suspected of causing cancer.

Specific Target Organ Toxicity (Repeated Exposure): May cause damage to organs (hemapoietic system, respiratory system, integumentary system) through prolonged or repeated exposure.

Reproductive Toxicity: Suspected of damaging fertility or the unborn child.

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Dust may be harmful or cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: This material is toxic in small amounts orally, and can cause adverse health effects or death.

Chronic Symptoms: Suspected of damaging fertility or the unborn child. May cause damage to organs (hemapoietic system, respiratory system, integumentary system) through prolonged or repeated exposure. Suspected of causing genetic defects. Suspected of causing cancer.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Mitomycin-C (50-07-7)	
LD50 Oral Rat	30 mg/kg
LD50 Oral Mouse	23 mg/kg
LD50 Oral Bird	7.5 mg/kg
LD50 Intravenous Mouse	5 mg/kg
LD50 Intravenous Mouse	3.4 mg/kg
LD50 Intravenous Mouse	3 mg/kg
LD50 Intravenous Cat	1 – 2.5 mg/kg
LD50 Intravenous Dog	1 – 2.5 mg/kg
LD50 Intravenous Monkey	1 – 2.5 mg/kg
LD50 Intraperitoneal Mouse	4 mg/kg
LD50 Intraperitoneal Rat	2 mg/kg
LD50 Subcutaneous Mouse	7.3 mg/kg
LD50 Subcutaneous Rat	3.25 mg/kg

D-Mannitol (69-65-8)	
LD50 Oral Rat	13500 mg/kg

Mitomycin-C (50-07-7)	
IARC Group	2B
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

12.2. Persistence and Degradability

Mitomycin for injection, USP	
Persistence and Degradability	Expected to be biodegradable.

12.3. Bioaccumulative Potential

Mitomycin for injection, USP	
Bioaccumulative Potential	Not expected to bioaccumulate.

12.4. Mobility in Soil

Mitomycin for injection, USP	
Ecology - Soil	Leaches if exposed to water.

12.5. Other Adverse Effects

Other Adverse Effects: None known.

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Treatment Methods: Incineration is the preferred method for disposal of waste product.

Sewage Disposal Recommendations: Do not dispose of waste into sewer. Do not empty into drains.

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Additional Information: Biologically contaminated materials should be incinerated.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Proper Shipping Name : MEDICINE, SOLID, TOXIC, N.O.S.(MITOMYCIN RQ = 1250 LBS./ 566 KG)
Hazard Class : 6.1
Identification Number : UN3249
Label Codes : 6.1

Packing Group : III
ERG Number : 151

14.2. In Accordance with IMDG

Proper Shipping Name : MEDICINE, SOLID, TOXIC, N.O.S.(MITOMYCIN)
Hazard Class : 6.1
Identification Number : UN3249
Label Codes : 6.1

Packing Group : III
EmS-No. (Fire) : F-A
EmS-No. (Spillage) : S-A

14.3. In Accordance with IATA

Proper Shipping Name : MEDICINE, SOLID, TOXIC, N.O.S. (MITOMYCIN)
Hazard Class : 6.1
Identification Number : UN3249
Label Codes : 6.1

Packing Group : III
ERG Code (IATA) : 6L

14.4. In Accordance with TDG

Proper Shipping Name : MEDICINE, SOLID, TOXIC, N.O.S.(MITOMYCIN)
Hazard Class : 6.1
Identification Number : UN3249
Label Codes : 6.1

Packing Group : III

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Mitomycin for injection, USP	
SARA Section 311/312 Hazard Classes	Health hazard - Reproductive toxicity Health hazard - Specific target organ toxicity (single or repeated exposure) Health hazard - Germ cell mutagenicity Health hazard - Carcinogenicity Health hazard - Acute toxicity (any route of exposure) Physical hazard - Combustible dust

Mitomycin-C (50-07-7)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active Listed on the United States SARA Section 302	
EPA TSCA Regulatory Flag	S - S - indicates a substance that is identified in a final Significant New Use Rule.
CERCLA RQ	10 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 – 10000 lb

D-Mannitol (69-65-8)
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

15.2. US State Regulations

California Proposition 65

WARNING: This product can expose you to Mitomycin-C, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

Chemical Name (CAS No.)	Carcinogenicity	Developmental Toxicity	Female Reproductive Toxicity	Male Reproductive Toxicity
Mitomycin-C (50-07-7)	X			

Mitomycin-C (50-07-7)
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List
U.S. - Massachusetts - Right To Know List
U.S. - Pennsylvania - RTK (Right to Know) - Special Hazardous Substances
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

15.3. Canadian Regulations

Mitomycin-C (50-07-7)
Listed on the Canadian NDSL (Non-Domestic Substances List)

D-Mannitol (69-65-8)
Listed on the Canadian DSL (Domestic Substances List)

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : **01/25/2023**

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

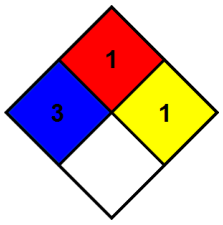
GHS Full Text Phrases:

H300	Fatal if swallowed
H301	Toxic if swallowed
H341	Suspected of causing genetic defects
H351	Suspected of causing cancer
H361	Suspected of damaging fertility or the unborn child
H373	May cause damage to organs through prolonged or repeated exposure

NFPA Health Hazard : 3 - Materials that, under emergency conditions, can cause serious or permanent injury.

NFPA Fire Hazard : 1 - Materials that must be preheated before ignition can occur.

NFPA Reactivity Hazard : 1 - Materials that in themselves are normally stable but can become unstable at elevated temperatures and pressures.



HMIS III Rating

Health : 3 Serious Hazard - Major injury likely unless prompt action is taken and medical treatment is given

Flammability : 1 Slight Hazard

Physical : 1 Slight Hazard

Personal protection : E

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

NA GHS SDS 2015 (Can, US)