



SAFETY DATA SHEET

1. Identification

Product identifier	Mitomycin	
Other means of identification		
Catalog number	1444707	
CAS number	50-07-7	
Synonyms	Ametycin	
Chemical name	7-amino-9alpha-methoxymitosane	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 2
	Skin corrosion/irritation	Category 1
	Serious eye damage/eye irritation	Category 1
	Germ cell mutagenicity	Category 1
	Carcinogenicity	Category 2
	Reproductive toxicity	Category 2
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	

Label elements



Signal word	Danger
Hazard statement	Fatal if swallowed. Causes severe skin burns and eye damage. May cause 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. Wash thoroughly after handling. Do not breathe dust/fume/gas/mist/vapors/spray. Wear protective gloves/protective clothing/eye protection/face protection.

Response	If exposed: Immediately call a poison center/doctor. If swallowed: Do NOT induce vomiting. Rinse mouth. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Wash contaminated clothing before reuse. If inhaled: Remove person to fresh air and keep comfortable for breathing. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
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	Potent pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Mitomycin	Ametycin	50-07-7	100

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin contact	Take off immediately all contaminated clothing. Rinse skin with water/shower. Chemical burns must be treated by a physician. Call a physician or poison control center immediately. Wash contaminated clothing before reuse.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician or poison control center immediately.
Ingestion	Call a physician or poison control center immediately. Rinse mouth thoroughly. Do not induce vomiting without advice from poison control center. Do not use mouth-to-mouth method if substance is ingested. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
Most important symptoms/effects, acute and delayed	Corrosive effects. Bone marrow suppression. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Administer activated charcoal with sorbitol to decrease absorption. Administer a saline cathartic or sorbitol to promote excretion. Monitor vital signs.
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
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. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
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Methods and materials for containment and cleaning up

Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. 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**

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities

Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection**Occupational exposure limits**

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values**Industrial Use
Material****Type****Value**

Mitomycin (CAS 50-07-7)

TWA

0.05
micrograms/m3

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment**Eye/face protection**

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection**Hand protection**

Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties**Appearance**

Appearance descriptions are general information and not specific to any USP lot.

Physical state

Solid.

Form

Powder.

Color

Blue. Violet.

Odor

Odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

> 680 °F (> 360 °C)

Initial boiling point and boiling range	993.2 °F (534 °C)
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
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	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble.
Solubility (other)	Methanol: Soluble. Cyclohexane: Soluble. Ether: Slightly soluble. Carbon tetrachloride: Slightly soluble. Acetone: Soluble.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Pyrroloindole.
Molecular formula	C15H18N4O5
Molecular weight	334.33
pH in aqueous solution	6 - 7.5 (5 mg/ml aqueous suspension)
Specific gravity	1.42

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	Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Oxidizing agents. Strong acids. Strong bases.
Hazardous decomposition products	NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Causes severe skin burns.
Eye contact	Causes serious eye damage.
Ingestion	Fatal if swallowed. Based on information from therapeutic use, this material may cause: Bone marrow suppression.
Symptoms related to the physical, chemical, and toxicological characteristics	Gastrointestinal disturbances. Hair loss. Bleeding or bruising. Drowsiness. Chills. Fever. Headache. Lower back or side pain. Painful or difficult urination. Burning pain and severe corrosive skin damage.

Information on toxicological effects

Acute toxicity	Fatal if swallowed.	
Product	Species	Test Results
Mitomycin (CAS 50-07-7)		
Oral		
LD50	Mouse	23 mg/kg
	Rat	30 mg/kg
		14 mg/kg
Skin corrosion/irritation	Causes severe skin burns and eye damage.	
Serious eye damage/eye irritation	Causes serious eye damage.	
Local effects		
Skin irritation test		
Result: Corrosive effects.		
Species: Rabbit		
Respiratory or skin sensitization		
Respiratory sensitization	Knowledge about health hazard is incomplete.	
Skin sensitization	Knowledge about health hazard is incomplete.	
Germ cell mutagenicity	May cause genetic defects.	
Mutagenicity		
Dominant lethal test		
Result: Positive.		
Species: Rodent		
Carcinogenicity	Suspected of causing cancer.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Mitomycin (CAS 50-07-7)	2B Possibly carcinogenic to humans.	
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)		
Not regulated.		
US. National Toxicology Program (NTP) Report on Carcinogens		
Not listed.		
Reproductive toxicity	Suspected of damaging fertility or the unborn child.	
Reproductivity		
1 - 2 mg/kg Reproductivity test		
Result: Cytological changes occurred.		
Species: Hamster		
5 - 10 mg/kg Reproductivity test		
Result: Malformations observed.		
Species: Mouse		
7.5 - 2 mg/kg Reproductivity test		
Result: Abnormalities of the urogenital system.		
Species: Rat		
Specific target organ toxicity - single exposure	Knowledge about health hazard is incomplete.	
Specific target organ toxicity - repeated exposure	Knowledge about health hazard is incomplete.	
Aspiration hazard	Based on available data, the classification criteria are not met.	
Further information	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.	

12. Ecological information

Ecotoxicity		
Product	Species	Test Results
Mitomycin (CAS 50-07-7)		
Aquatic		
Fish	LC50 Fish	860 mg/l, 96 hours
Persistence and degradability	No data is available on the degradability of this substance.	
Bioaccumulative potential	No data available.	

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	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

US RCRA Hazardous Waste U List: Reference

Mitomycin (CAS 50-07-7)

U010

Waste from residues / unused products	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.

14. Transport information

DOT

UN number	UN2811
UN proper shipping name	Toxic solid, organic, n.o.s. (Mitomycin)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	II

IATA

UN number	UN2811
UN proper shipping name	Toxic solid, organic, n.o.s. (Mitomycin)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	II
Other information	

Passenger and cargo aircraft Allowed with restrictions.

Cargo aircraft only Allowed with restrictions.

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

DOT; IATA



General information It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

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.

CERCLA Hazardous Substance List (40 CFR 302.4)

Mitomycin (CAS 50-07-7) Listed.

SARA 304 Emergency release notification

Mitomycin (CAS 50-07-7) 10 LBS

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**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

Classified hazard categories

Acute toxicity (any route of exposure)
 Skin corrosion or irritation
 Serious eye damage or eye irritation
 Germ cell mutagenicity
 Carcinogenicity
 Reproductive toxicity

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**California Proposition 65**

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

California Proposition 65 - CRT: Listed date/Carcinogenic substance

Mitomycin (CAS 50-07-7)

Listed: April 1, 1988

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
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates that all components of this product comply 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	09-29-2009
Revision date	02-13-2020
Version #	05
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