



MATERIAL SAFETY DATA SHEET

SECTION 1 - PRODUCT & COMPANY IDENTIFICATION

1501 East Woodfield Road **Emergency Telephone** **(800) 551-7176**
Suite 300 East
Schaumburg, IL 60173
(847) 969-2700

Product Identifier: Mitoxantrone Injection, USP (Concentrate)
Chemical Name: Mitoxantrone Hydrochloride
Category: Antineoplastic

SECTION 2 - COMPOSITION

<u>Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Mitoxantrone Hydrochloride	70476-82-3	2 mg/mL (base)
Sodium Chloride	7647-14-5	0.8%
Sodium Acetate (anhydrous)	127-09-3	0.005%
Acetic Acid	64-19-7	0.046%

Note: NA

SECTION 3 - HAZARDS IDENTIFICATION

Route of Entry: Inhalation, eye/skin contact, or ingestion

Chemical Listing as Carcinogen

NTP: No
IARC: Yes, Group 2B. Possibly carcinogenic to humans.
OSHA: No

Note: There is limited but increasing evidence that personnel involved in the preparation and administration of parenteral antineoplastics may be at some risk due to potential mutagenicity, teratogenicity, and/or carcinogenicity of these agents. The actual risk is not known. The US Pharmacopeia advisory panels recommends the cautious handling in both preparation and disposal of antineoplastic agents. Precautions that have been suggested include: use of a biological containment cabinet during reconstitution and dilution of parenteral medications, use of disposable surgical gloves and masks, use of proper technique to prevent contamination of medication onto the work area and operator, and proper disposal of needles, syringes, vials, and ampules.

SECTION 4 - EMERGENCY & FIRST AID MEASURES

Eyes:	Hold eyes open and flush eyes continuously with water for at least 15 minutes. Seek immediate medical assistance.
Skin:	Remove contaminated clothing immediately. Flush area with water for at least 15 minutes. Wash exposed area with soap and water. Seek medical attention.
Inhalation:	Move individual(s) to fresh air immediately and seek medical attention. When appropriate and trained in CPR, provide artificial respiration.
Ingestion:	If swallowed, and the victim is conscious and alert, induce vomiting immediately, as directed by medical personnel. Seek medical attention immediately.
Contact Info:	For Adverse Event Information, please call (800) 551-7176 or (847) 969-2700.

SECTION 5 - FIRE FIGHTING MEASURES

Fire and Explosion Data

Closed Cup Flash Point:	NA
Open Cup Flash Point:	NA
Fire Point:	NA
Autoignition:	NA
Lower Explosion Limit:	NA
Upper Explosion Limit:	NA
General Hazard:	Combustion or heat of a fire may produce hazardous decomposition products and vapors.
Fire Fighting Instructions:	Water spray, dry chemical, carbon dioxide, or foam as appropriate to surroundings.
Fire Fighting Equipment:	Self-contained breathing apparatus and full protective equipment are recommended. Cool fire exposed containers with water spray.
Hazardous Combustion Products:	Emits toxic fumes and products of oxides of carbon and nitrogen, aldehydes, ketones, organic acids, possibly hydrogen cyanide & hydrogen chloride.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Clean-Up: Isolate and clear the area. Wear recommended personal protective equipment (See Section 8 - Exposure Controls/Personal Protection). Use a damp sponge, polypad, or other appropriate material to clean-up spill. Avoid generating airborne dusts of this product. Decontaminate the area of the spill thoroughly by using detergent and water. Place all spill residue in an appropriate spill container and seal.

SECTION 7 - HANDLING AND STORAGE

General Handling: Mitoxantrone Injection is a cytotoxic agent. Use precautions to limit exposure to the lowest level possible. Ensure vials are properly labeled. When handling, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product. Employees must be trained to properly handle this product.

Storage Conditions: Store between 15°-25°C (59°-77°F). Do Not Freeze.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: General room ventilation is usually satisfactory. Use local exhaust ventilation if necessary.

Personal Protective Equipment

Eye Protection: Safety glasses or chemical splash goggles recommended.

Hand Protection: A double layer of disposable latex, nitrile, or rubber gloves is recommended. Wash hands before putting on gloves and after removing gloves.

Respiratory Protection: Under normal use, respirators are not required if the material is being used in a closed system such as a biologic safety cabinet. Use NIOSH approved self-contained breathing apparatus if TLV is exceeded or using in confined spaces.

Skin Protection: Disposable garments if direct skin contact is anticipated. Head cover, coverall, long sleeves, protect exposed skin.

Exposure Limits:

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Mitoxantrone Hydrochloride	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE
Sodium Chloride	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE
Sodium Acetate (anhydrous)	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE
Acetic Acid	OSHA	PEL	NE
	ACGIH	TLV	NE

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION...continued

Exposure**Limits:...**continuedCompoundIssuerTypeOEL

STEL

NE

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

**Physical Form/
Appearance:** Sterile, nonpyrogenic dark blue aqueous solution.**Boiling Point/Boiling
Range:** 100°C (212°F)**Melting Point/Melting
Range:** NE**Freezing Point:** NE**Vapor Pressure :** NE**Relative Vapor Density:** NE**Percent Volatiles:** NE**pH:** 3.0 - 4.5**Molecular Weight:** 517.41**Solvent Solubility:** Freely soluble in water.**Note:** NA

SECTION 10 - STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions.**Conditions to Avoid:** Avoid high heat.**Hazardous
Polymerization:** Will not occur

SECTION 11 - TOXICOLOGY INFORMATION

**Signs & Symptoms of
Exposure &
Overexposure:** This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Adverse reactions from therapeutic doses include: nausea, fatigue, alopecia, anorexia, hyperglycemia, constipation, dyspnea, nail bed changes, edema, systemic infection, mucositis, urinary tract infection, vomiting, pain, and fever. Occupational exposure has not been fully investigated.

SECTION 11 - TOXICOLOGY INFORMATION...continued

Medical Conditions Individuals with hypersensitivity to mitoxantrone.
Aggravated by
Accidental Exposure:

Acute Toxicity:

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dosage</u>
Mitoxantrone Hydrochloride	LD ₅₀	Oral	Rat	682-721 mg/kg
Sodium Acetate (anhydrous)	LD ₅₀	Oral	Rat	3530 mg/kg
	LC ₅₀	Inhalation	Rat	30 gm/m ³
	LD ₅₀	Dermal	Rabbit	10mg/kg

Other:

ACUTE EXPOSURE:

Hypersensitivity manifested by hypotension, urticaria, dyspnea, and rashes. Extravasation at the infusion site may result in erythema, swelling, pain, burning, and/or blue discoloration of the skin.

CHRONIC EXPOSURE:

Myelosuppression.

PREGNANCY CATEGORY D:

Mitoxantrone injection can cause fetal harm and should not be given during pregnancy. Women of childbearing age should be advised to avoid becoming pregnant during therapy with mitoxantrone.

INFORMATION FOR PATIENTS: Mitoxantrone may impart a blue-green color to the urine for 24 hours after administration, and patients should be advised to expect this during therapy. Bluish discoloration of the sclera may also occur. Patients should be advised of the signs and symptoms of myelosuppression.

SECTION 12 - TRANSPORTATION INFORMATION

UN/NA Number: NA
U.S. DOT Hazard Class: NA
Proper Shipping Name: NA
Shipping Label: NA

SECTION 13 - DISPOSAL INFORMATION

Disposal Procedure : Dispose of in accordance with federal, state, and local regulations. Incineration is recommended at an approved facility.

SECTION 14 - OTHER

Key to Abbreviations: ACGIH - American Conference of Governmental Industrial Hygienists
HEPA - High Efficiency Particulate Air
IARC - International Agency for Research on Cancer
NA - Not Applicable
NE - Not Established
NG - Not Given
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OEL - Occupational Exposure Limit
OSHA - Occupational Safety and Health Administration
PEL - Permissible Exposure Limit
PPM - Parts Per Million
QS - Quantity Sufficient
RCRA - Resource Conservation and Recovery Act
STEL - Short Term Exposure Limit
TLV - Threshold Limit Value
USP - United States Pharmacopeia

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