



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: Fluorouracil Injection, USP
Chemical Name: Fluorouracil
Category: Antineoplastic

SECTION 2 - COMPOSITION

<u>Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Fluorouracil	51-21-8	50 mg/mL
Water for Injection	7732-18-5	QS

SECTION 3 - HAZARDS IDENTIFICATION

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

**Chemical Listing as
Carcinogen**

NTP: No

IARC: Group 3 - Not classifiable as to carcinogenicity to humans

OSHA: No

Note: On the basis of the available data, no evaluation can be made of the carcinogenic risk of fluorouracil to humans.

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:	Immediately flush eyes with water for at least 15 minutes. Seek medical attention.
Skin:	Remove contaminated clothing immediately. Flush area with water for at least 15 minutes. Wash exposed area with soap and water. Seek medical attention if pain, redness, or swelling persists.
Inhalation:	Move exposed subject to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention.
Ingestion:	If swallowed, seek emergency medical attention. If victim is drowsy, unconscious, or vomiting, place individual on the left side with the head down and do not give anything by mouth. If individual is not vomiting and professional advice is not available, do not induce vomiting.
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:	NE
Open Cup Flash Point:	NE
Fire Point:	NE
Autoignition:	NE
Lower Explosion Limit:	NE
Upper Explosion Limit:	NE
General Hazard:	When heated to decomposition, toxic fumes may be emitted.
Fire Fighting Instructions:	Water spray, dry chemical, carbon dioxide, or foam as appropriate to surroundings.
Fire Fighting Equipment:	Wear self-containing breathing apparatus and protective clothing.
Hazardous Combustion Products:	When heated to decomposition, material may emit carbon oxides, urea, fluoride, and ammonia.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Clean-Up:	Wear recommended personal protective equipment (See Section 8 - Exposure Controls/Personal Protection). Use absorbent towels or brooms to clean-up spill. Wipe surface area clean with soap and water.
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SECTION 7 - HANDLING AND STORAGE

- General Handling:** When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.
- Storage Conditions:** Store at controlled room temperature 15°-30°C (59°-86°F). Do not freeze. Protect from light.

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 goggles recommended.
- Hand Protection:** Disposable latex, nitrile, or rubber gloves recommended.
- Respiratory Protection:** With satisfactory ventilation, respiratory protection is usually not required. A NIOSH certified air-purifying respirator with a type 95 filter may be used under conditions where airborne concentrations are expected to be excessive.
- Skin Protection:** No special body protection required for routine medical administration. Wear disposable garments or lab coat if direct skin contact is anticipated.

Exposure Limits:

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Fluorouracil	OSHA	PEL	NE
	ACGIH	TLV	2.5 mg/m ³
	---	STEL	2 mg/m ³
Water for Injection	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

- Physical Form/
Appearance:** Colorless to yellow aqueous solution
- Boiling Point/Boiling
Range:** 100°C (212°F)
- Melting Point/Melting
Range:** NA
- Freezing Point:** 0°C (32°F)
- Vapor Pressure :** NA
- Relative Vapor Density:** 1

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES...continued

Percent Volatiles: NA
pH: Approximately 9.2
Molecular Weight: 130.08
Solvent Solubility: Soluble in water
Note: NA

SECTION 10 - STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: Strongly basic conditions (pH > 9)
Hazardous Polymerization: Does 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: anorexia, nausea, dry mouth, stomatitis, diarrhea, leukopenia, thrombocytopenia, anemia, hair loss, nail changes, dermatitis, increased pigmentation, and skin atrophy. Occupational exposure has not been fully investigated.

Medical Conditions Aggravated by Accidental Exposure: Individuals with poor nutritional state, depressed bone marrow function, those with potentially serious infections, or those with a known hypersensitivity to fluorouracil.

Acute Toxicity:

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dosage</u>
Fluorouracil	LD ₅₀	Oral	Rat	230 mg/kg
	LD ₅₀	Oral	Mouse	115 mg/kg
	LD ₅₀	Oral	Dog	30 mg/kg
	LD ₅₀	Oral	Rabbit	18900 µg/kg
	LD ₅₀	IP	Rat	70 mg/kg
	LD ₅₀	IP	Mouse	100 mg/kg
	LD ₅₀	Intramuscular	Rat	240 mg/kg
	LD ₅₀	SC	Rat	217 mg/kg
	LD ₅₀	SC	Mouse	169 mg/kg
	LD ₅₀	IV	Rat	245 mg/kg
	LD ₅₀	IV	Mouse	81 mg/kg
	LD ₅₀	IV	Guinea Pig	25 mg/kg

SECTION 11 - TOXICOLOGY INFORMATION...continued

Other:**IMMEDIATE EFFECTS:**

Eye - Visual disturbances and extreme lacrimation have been reported with therapeutic administration. Stinging and burning with blurred vision have been reported with splash contact. Permanent eye injury was not reported.

Skin - Quickly resolving skin irritation and discoloration have been reported after accidental splash contact. Allergic contact dermatitis has been reported with use of fluorouracil ointment.

Respiratory - Irritation have been experienced with patient administration.

DELAYED EFFECTS:

Eye - Ocular lesions, visual disturbances, and reversible optic neuropathy have been reported in patients receiving fluorouracil therapy.

Inhalation - Long-term inhalation exposure may lead to systemic effects.

Skin - Hair loss, hyperpigmentation, and light sensitivity have been reported with therapeutic doses.

Based on animal data, fluorouracil is considered a potential reproductive toxicant.

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 : Treatment, storage, transportation, and disposal must be in accordance with applicable federal, state, and local regulations.

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

SECTION 14 - OTHER...continued

Key to**Abbreviations:**...continued

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

Disclaimer:

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