



NFPA	HMIS	PPE	Transport Symbol						
	<table border="1"> <tr> <td>Health Hazard</td> <td>2*</td> </tr> <tr> <td>Fire Hazard</td> <td>0</td> </tr> <tr> <td>Reactivity</td> <td>0</td> </tr> </table>	Health Hazard	2*	Fire Hazard	0	Reactivity	0		
Health Hazard	2*								
Fire Hazard	0								
Reactivity	0								

Issuing Date 26-Jan-2007

Revision Date 23-Feb-2007

Revision Number 1

* Indicates a chronic health hazard.

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Fluorouracil Injection, USP, 50 mg/mL

Product Code(s)
10139-063-10 – 10 mL Vial
10139-063-11 – Shelf Pack (10 mL Vials x 10)
10139-063-20 – 20 mL Vial
10139-063-12 – Shelf Pack (20 mL Vials x 10)
10139-063-50 – 50 mL Pharmacy Bulk Vial
10139-063-01 – 100 mL Pharmacy Bulk Vial

Recommended Use Antineoplastic

Supplier Address
 GeneraMedix Inc.
 150 Allen Road
 Liberty Corner, New Jersey 07938, USA
 TEL: 908-504-1300

Chemical Emergency Phone Number Chemtrec 1-800-424-9300

2. HAZARDS IDENTIFICATION

Emergency Overview
 May produce an allergic reaction.
 Contains a known or suspected reproductive toxin.
 Harmful if swallowed.

Appearance Colorless to yellow **Physical State** Liquid **Odor** No data available

Potential Health Effects

Principle Routes of Exposure	Inhalation, skin contact, eye contact.
Acute Toxicity	
Eyes	Irritating to eyes.
Skin	Substance may cause slight skin irritation. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons.
Inhalation	Not an expected route of exposure.
Ingestion	Not an expected route of exposure. Harmful if swallowed. Do not taste or swallow.
Chronic Effects	Experiments have shown reproductive toxicity effects on laboratory animals. See Section 11 for additional Toxicological Information.
Aggravated Medical Conditions	Cardiovascular, central nervous system, respiratory disorders.
Environmental Hazard	See Section 12 for additional Ecological information.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %
Water for Injection	7732-18-5	95
Fluorouracil	51-21-8	5

Sodium Hydroxide added to adjust pH to approximately 9.2 (10 & 20 mL vials) & 8.6 – 9.4 (50 & 100 mL vials)

4. FIRST AID MEASURES

Eye Contact	Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Get medical attention immediately if irritation persists.
Skin Contact	Wash off immediately with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
Inhalation	Move victim to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. If symptoms persist, call a physician.
Ingestion	Immediate medical attention is required. Do not induce vomiting. Never give anything by mouth to an unconscious person.
Notes to Physician	Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Flammable Properties	Not flammable.
Flash Point	N/A
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Explosion Data	
Sensitivity to mechanical impact	No data available.
Sensitivity to static discharge	No data available.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA	Health Hazard 2	Flammability 0	Stability 0	Physical and Chemical Hazards N/A
HMIS	Health Hazard 2*	Flammability 0	Stability 0	Personal Precautions N/A

* Indicates a chronic health hazard.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Avoid contact with skin, eyes and clothing. Ensure adequate ventilation. Use personal protective equipment.
Methods for Containment	Prevent further leakage or spillage if safe to do so. Dike far ahead of liquid spill for later disposal. Soak up condensate with inert absorbent material and collect in ventilated waste container for disposal.
Methods for Cleaning Up	Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Keep in suitable and closed containers for disposal.

7. HANDLING AND STORAGE

Handling	Avoid contact with skin, eyes and clothing. Do not eat, drink or smoke when using this product. Ensure adequate ventilation.
Storage	Keep containers tightly closed in a dry, cool and well-ventilated place.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines	N/A
Engineering Measures	Showers, eyewash stations, and ventilation systems.
Personal Protective Equipment	
Eye/face Protection	Safety glasses with side-shields.
Skin and body protection	Wear latex or nitrile gloves.
Respiratory Protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
Hygiene Measures	Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Colorless to yellow	Odor	No data available.
Physical State	Liquid	pH	9.2 (10 & 20 mL Vials) 8.6 – 9.4 (50 & 100 mL Vials)
Flash Point	N/A	Autoignition Temperature	N/A
Boiling Point/Range	100°C / 212°F	Melting Point/Range	No data available.
Flammability Limits in Air	No data available.		
Solubility	Soluble in water.	VOC Content	N/A

10. STABILITY AND REACTIVITY

Stability	Stable under recommended storage conditions.
Conditions to Avoid	None known based on information supplied.
Incompatible Products	Strong oxidizing agents. Acids. Bases.
Hazardous Decomposition Products	Carbon dioxide (CO ₂).
Hazardous Polymerization	Hazardous polymerization does not occur.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Product Information

Chemical Name	LD50 Oral	LD50 IP	LD50 Intramuscular	LD50 SC	LD50 IV	LD 50 Dermal
Fluorouracil	230 mg/kg (Rat) 115 mg/kg (Mouse) 30 mg/kg (Dog) 18900 µg/kg (Rabbit)	70 mg/kg (Rat) 100/mg/kg (Mouse)	240 mg/kg (Rat)	217 mg/kg (Rat) 169 mg/kg (Mouse)	245 mg/kg (Rat) 81 mg/kg (Mouse) 25 mg/kg (Guinea Pig)	N/A

Subchronic Toxicity (28 days) N/A

Chronic Toxicity

Chronic Toxicity Experiments have shown reproductive toxicity effects on laboratory animals.

Carcinogenicity There are no known carcinogenic chemicals in this product.

Mutagenicity

Reproductive Toxicity Product is or contains a chemical which is a known or suspected reproductive hazard. This material is classified as a Pregnancy Category D: Positive evidence of risk.

Target Organ Effects Cardiovascular system, central nervous system (CNS) and immune system.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

12. ECOLOGICAL INFORMATION

Ecotoxicity Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method This material, as supplied, is not a hazardous waste according to state and federal regulations (40 CFR 261).

Contaminated Packaging Dispose of in accordance with local regulations.

14. TRANSPORT INFORMATION

DOT Not regulated

TDG Not regulated

MEX Not regulated

ICAO Not regulated

IATA Not regulated

IMDG/IMO Not regulated

RID Not regulated

ADR Not regulated

ADN Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA	Does not Comply
DSL	Does not Comply
EINECS/ELINCS	Complies
ENCS	Does not Comply
CHINA	Does not Comply
KECL	Complies
PICCS	Complies
AICS	Complies

U.S. Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

Chemical Name	CAS-No	Weight %	SARA 313 - Threshold Values
Fluorouracil	51-21-8	5	1.0

SARA 311/312 Hazard Categories

Acute Health Hazard	Yes
Chronic Health Hazard	Yes
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Clean Water Act

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302).

Chemical Name	Hazardous Substances RQs	Extremely Hazardous Substances RQs
Fluorouracil	N/A	500 lbs

U.S. State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals:

Chemical Name	CAS-No	California Prop. 65
Fluorouracil	51-21-8	Developmental

U.S. State Right-to-Know Regulations

Chemical Name	Massachusetts	New Jersey	Pennsylvania	Illinois	Rhode Island
Fluorouracil	X	X	X	N/A	N/A

International Regulations

Canada

This product is regulated by the Food and Drug Administration of Health Canada and is therefore exempt from the requirements of CEPA.

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all the information required by the CPR.

WHMIS Hazard Class

Non-controlled

16. OTHER INFORMATION

Revision Date

Revision Note

Disclaimer

The information provided on this MSDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of MSDS