

# Fluorouracil Injection, USP

## Safety Data Sheet

### SECTION 1: Identification

#### 1.1. Identification

Product name : Fluorouracil Injection, USP  
Other means of identification : 500 mg/10 mL single-dose vials individually boxed; NDC 55150-496-01  
500 mg/10 mL, single-dose vials, 10 individually boxed vials in an outer carton; NDC 55150-496-10  
1 g/20 mL single-dose vials individually boxed; NDC 55150-497-01  
1 g/20 mL, single-dose vials, 10 individually boxed vials in an outer carton; NDC 55150-497-10  
2.5 g/50 mL, Pharmacy Bulk Package, one box with one vial; NDC 55150-498-01  
5 g/100 mL, Pharmacy Bulk Package, one box with one vial; NDC 55150-499-01

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

#### 1.3. Details of the supplier of the safety data sheet

Eugia US LLC  
279 Princeton Hightstown Road  
East Windsor, NJ 08520

#### 1.4. Emergency telephone number

Emergency number : 1-888-238-7880

### SECTION 2: Hazard(s) identification

#### 2.1. Classification of the substance or mixture

##### GHS US classification

Acute Tox. 4 (Oral) H302  
Skin Irrit. 2 H315  
Eye Irrit. 2 H319  
Muta. 1B H340  
Repr. 1B H360

Full text of hazard classes and H-statements : see section 16

#### 2.2. Label elements

##### GHS US labeling

Hazard pictograms (GHS US) :



GHS07

GHS08

Signal word (GHS US) :

Danger

Hazard statements (GHS US) :

H302 - Harmful if swallowed  
H315 - Causes skin irritation  
H319 - Causes serious eye irritation  
H340 - May cause genetic defects  
H360 - May damage fertility or the unborn child

Precautionary statements (GHS US) :

P201 - Obtain special instructions before use.  
P202 - Do not handle until all safety precautions have been read and understood.  
P264 - Wash hands, forearms and face thoroughly after handling.  
P270 - Do not eat, drink or smoke when using this product.  
P280 - Wear protective gloves/protective clothing/eye protection/face protection.  
P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell.  
P302+P352 - If on skin: Wash with plenty of water.  
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P308+P313 - If exposed or concerned: Get medical advice/attention.  
P321 - Specific treatment (see supplemental first aid instruction on this label).  
P330 - Rinse mouth.  
P332+P313 - If skin irritation occurs: Get medical advice/attention.  
P337+P313 - If eye irritation persists: Get medical advice/attention.  
P362+P364 - Take off contaminated clothing and wash it before reuse.  
P405 - Store locked up.

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P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

### 2.3. Other hazards

No additional information available

### 2.4. Unknown acute toxicity (GHS US)

Not applicable

## SECTION 3: Composition/Information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	GHS US classification
5-Fluorouracil	(CAS-No.) 51-21-8	5	Acute Tox. 3 (Oral), H301 Acute Tox. 4 (Dermal), H312 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Muta. 1B, H340 Repr. 1B, H360 STOT SE 3, H335
Sodium hydroxide	(CAS-No.) 1310-73-2	≤ 1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318

Full text of hazard classes and H-statements : see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures after inhalation	: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
First-aid measures after skin contact	: In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Get medical attention.
First-aid measures after eye contact	: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.
First-aid measures after ingestion	: Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation	: May be irritating to respiratory system.
Symptoms/effects after skin contact	: Causes skin irritation.
Symptoms/effects after eye contact	: Causes serious eye irritation.
Symptoms/effects after ingestion	: Harmful if swallowed.

### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	: None.

### 5.2. Special hazards arising from the substance or mixture

Fire hazard	: None known.
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### 5.3. Advice for firefighters

Protection during firefighting	: Firefighters should wear full protective gear.
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## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures	: No special measures required.
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#### 6.1.1. For non-emergency personnel

No additional information available

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### 6.1.2. For emergency responders

No additional information available

### 6.2. Environmental precautions

Prevent entry to sewers and public waters.

### 6.3. Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.

### 6.4. Reference to other sections

No additional information available

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Do not ingest. Avoid skin contact. Avoid eye contact. Wash thoroughly after handling.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at 20° to 25°C (68° to 77°F)

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 5-Fluorouracil (51-21-8)

Not applicable

#### Sodium hydroxide (1310-73-2)

ACGIH	ACGIH OEL Ceiling	2 mg/m <sup>3</sup>
OSHA	OSHA PEL TWA	2 mg/m <sup>3</sup>
IDLH	IDLH	10 mg/m <sup>3</sup>
NIOSH	NIOSH REL (Ceiling)	2 mg/m <sup>3</sup>

### 8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.  
Hand protection : Use latex or rubber gloves.  
Eye protection : None required under normal product handling conditions.  
Skin and body protection : Wear suitable working clothes.  
Respiratory protection : If airborne concentrations are above the applicable exposure limits, use NIOSH approved respiratory protection.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state : Liquid  
Color : Colorless or yellow  
Odor : Odorless  
Odor threshold : No data available  
pH : 8.6 – 9.4  
Melting point : No data available  
Freezing point : No data available  
Boiling point : No data available  
Flash point : No data available  
Relative evaporation rate (butyl acetate=1) : No data available  
Flammability : No data available  
Vapor pressure : No data available  
Relative vapor density at 20°C : No data available  
Relative density : No data available  
Solubility : No data available  
Partition coefficient n-octanol/water (Log Pow) : No data available

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Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

The product is stable at normal handling and storage conditions.

### 10.3. Possibility of hazardous reactions

Will not occur.

### 10.4. Conditions to avoid

None.

### 10.5. Incompatible materials

None known.

### 10.6. Hazardous decomposition products

None known.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Not classified

Fluorouracil Injection, USP	
ATE US (oral)	2000 mg/kg body weight
5-Fluorouracil (51-21-8)	
ATE US (oral)	100 mg/kg body weight
ATE US (dermal)	1100 mg/kg body weight
Sodium hydroxide (1310-73-2)	
LD50 oral rat	140 – 340 mg/kg
LD50 dermal rabbit	1350 mg/kg
ATE US (dermal)	1350 mg/kg

Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: May cause genetic defects.
Carcinogenicity	: Not classified
Reproductive toxicity	: May damage fertility or the unborn child.
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

## SECTION 12: Ecological information

### 12.1. Toxicity

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### Sodium hydroxide (1310-73-2)

LC50 - Fish [1]

45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

### 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

No additional information available

### 12.4. Mobility in soil

No additional information available

### 12.5. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

## SECTION 14: Transport information

### Department of Transportation (DOT)

In accordance with DOT

Transport document description (DOT) : UN3082 Environmentally hazardous substances, liquid, n.o.s. (5-Fluorouracil), 9, III

UN-No.(DOT) : UN3082

Proper Shipping Name (DOT) : Environmentally hazardous substances, liquid, n.o.s.  
5-Fluorouracil

Class (DOT) : 9 - Class 9 - Miscellaneous hazardous material 49 CFR 173.140

Packing group (DOT) : III - Minor Danger

Hazard labels (DOT) : 9 - Class 9 (Miscellaneous dangerous materials)



DOT Packaging Non Bulk (49 CFR 173.xxx) : 203

DOT Packaging Bulk (49 CFR 173.xxx) : 241

DOT Symbols : G - Identifies PSN requiring a technical name

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DOT Special Provisions (49 CFR 172.102)	: 8 - A hazardous substance that is not a hazardous waste may be shipped under the shipping description "Other regulated substances, liquid or solid, n.o.s.", as appropriate. In addition, for solid materials, special provision B54 applies. 146 - This description may be used for a material that poses a hazard to the environment but does not meet the definition for a hazardous waste or a hazardous substance, as defined in 171.8 of this subchapter, or any hazard class as defined in Part 173 of this subchapter, if it is designated as environmentally hazardous by the Competent Authority of the country of origin, transit or destination. 173 - An appropriate generic entry may be used for this material. 335 - Mixtures of solids that are not subject to this subchapter and environmentally hazardous liquids or solids may be classified as "Environmentally hazardous substances, solid, n.o.s," UN3077 and may be transported under this entry, provided there is no free liquid visible at the time the material is loaded or at the time the packaging or transport unit is closed. Each transport unit must be leak-proof when used as bulk packaging. IB3 - Authorized IBCs: Metal (31A, 31B and 31N); Rigid plastics (31H1 and 31H2); Composite (31HZ1 and 31HA2, 31HB2, 31HN2, 31HD2 and 31HH2). Additional Requirement: Only liquids with a vapor pressure less than or equal to 110 kPa at 50 C (1.1 bar at 122 F), or 130 kPa at 55 C (1.3 bar at 131 F) are authorized, except for UN2672 (also see Special Provision IP8 in Table 2 for UN2672). T4 - 2.65 178.274(d)(2) Normal..... 178.275(d)(3) TP1 - The maximum degree of filling must not exceed the degree of filling determined by the following: Degree of filling = $97 / 1 + a (tr - tf)$ Where: tr is the maximum mean bulk temperature during transport, and tf is the temperature in degrees celsius of the liquid during filling. TP29 - A portable tank having a minimum test pressure of 1.5 bar (150.0 kPa) may be used provided the calculated test pressure is 1.5 bar or less based on the MAWP of the hazardous materials, as defined in 178.275 of this subchapter, where the test pressure is 1.5 times the MAWP.
DOT Packaging Exceptions (49 CFR 173.xxx)	: 155
DOT Quantity Limitations Passenger aircraft/rail (49 CFR 173.27)	: No Limit
DOT Quantity Limitations Cargo aircraft only (49 CFR 175.75)	: No Limit
DOT Vessel Stowage Location	: A - The material may be stowed "on deck" or "under deck" on a cargo vessel and on a passenger vessel.
Emergency Response Guide (ERG) Number	: 171
Other information	: No supplementary information available.

### Air transport

UN-No. (IATA)	: 3082
Proper Shipping Name (IATA)	: Environmentally hazardous substance, liquid, n.o.s.
Class (IATA)	: 9 - Miscellaneous Dangerous Substances and Articles
Packing group (IATA)	: III - Low danger

## SECTION 15: Regulatory information

### 15.1. US Federal regulations

<b>Sodium hydroxide (1310-73-2)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	1000 lb

### 15.2. US State regulations

<b>Sodium hydroxide (1310-73-2)</b>
U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

## SECTION 16: Other information

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Full text of H-phrases:

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Met. Corr. 1	Corrosive to metals Category 1
Muta. 1B	Germ cell mutagenicity Category 1B
Repr. 1B	Reproductive toxicity Category 1B
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation
H290	May be corrosive to metals
H301	Toxic if swallowed
H302	Harmful if swallowed
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H340	May cause genetic defects
H360	May damage fertility or the unborn child

*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.*