



SAFETY DATA SHEET

SECTION 1 – IDENTIFICATION OF THE PRODUCT & THE COMPANY

- a) **Product Name** : Fluorouracil injection
- b) **Common/Trade Name** : Fluorouracil injection
Chemical Name : 5-fluoro-2,4(1H, 3H)-pyrimidinedione
- c) **Product Use** : Antineoplastic
Product Type : Regulated Prescription Drug
Container Information : Vial
- d) **Manufacturers Name & Address** : **Gland Pharma Limited**
: VSEZ -DUVVADA
: Visakhapatnam - India
- e) **Telephone Number for Info** : +91-891-2747657

SECTION 2 – HAZARDS IDENTIFICATION

Physical Hazards: Not classified

Health hazards: Acute toxicity, oral Category 4
Germ cell mutagenicity Category 1B
Reproductive toxicity Category 1A
Reproductive toxicity Effects on or via lactation

Environmental hazards: Hazardous to the aquatic environment Category 2

OSHA defined hazards: Not classified

Label Elements:



Signal word: Danger

Hazard statement: Harmful if swallowed. May cause genetic defects. May damage fertility or the unborn child. May cause harm to breast-fed children. Toxic to aquatic life.



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Prevention: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe mist or vapor. Do not eat, drink or smoke when using this product. Avoid contact during pregnancy/while nursing. Wear protective gloves/protective clothing/eye protection/face protection. Wash thoroughly after handling. Avoid release to the environment

Response If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If exposed or concerned: Get medical advice/attention.

Storage: Store at 20 – 25 °C (68 - 77°F). Protect from light.

Disposal: Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified: (HNOC) None known

Supplemental information: Fluorouracil Injection, USP, is a solution containing 5-fluorouracil, an analog of the pyrimidine uracil. It is an anti-neoplastic used in the treatment of some types of cancer. It may also be used topically for treating malignant or pre-malignant lesions of the skin. It is cytotoxic, neurotoxic, and in the workplace, should also be considered a potential occupational reproductive hazard, harmful to the fetus, potentially irritating to the skin, eyes and respiratory tract, and a photosensitizer. Based on clinical use, possible target organs may include the bone marrow, gastrointestinal system, nervous system, cardiovascular system, skin and the fetus.

Finished Pharmaceutical products in their final packages are not subject to OSHA labeling requirements. Handling pharmaceutical products in workplace is subject to OSHA requirements for labeling.

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS Number
Fluorouracil	51-21-8
Sodium hydroxide	1310-73-2
Water for Injection	7732-18-5

Additional Information: * Proprietary
Active: Each vial contains 5-Fluorouracil for injection at 50 mg/ml.



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SECTION 4 – FIRST AID MEASURES

Eye contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

SECTION 5 – FIRE FIGHTING MEASURES

Extinguishing Media Extinguish fires with CO₂, extinguishing powder, foam, or water

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire

Fire / Explosion Hazards Use standard firefighting procedures and consider the hazards of other involved materials. The product is not flammable.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Personal Precautions : Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure. For personal protection, see section 8 of the SDS.

Environmental Precautions : Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

Clean Up Methods : Prevent product from entering drains. Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water. Clean surface thoroughly to remove residual contamination.

SECTION 7 – HANDLING AND STORAGE

Precautions for safe handling: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Provide adequate ventilation. Do not breathe mist or vapor. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Do not taste or swallow. When using, do not eat, drink or smoke. Pregnant or breastfeeding women must not handle this product. Should be handled in closed systems, if possible. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices. Follow OSHA guidelines on the safe handling of cytotoxic products.

Conditions for safe storage, including any incompatibilities: Store at 20 – 25 °C (68 - 77°F). Protect from light. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).



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SECTION 8 – EXPOSURE CONTROLS/ PERSONAL PROTECTION

Occupational Exposure Limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value
Sodium hydroxide	PEL	2 mg/m ³

US ACGIH Threshold limit Values

Components	Type	Value
Sodium hydroxide	Ceiling	2 mg/m ³

US NIOSH :Pocket Guide to chemical Hazards

Components	Type	Value
Sodium hydroxide	PEL	2 mg/m ³

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

Appropriate Engineering Controls Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual Protection Measures, such as personal protective equipment

Eye/face protectionSkin protection: If significant eye exposure is anticipated, the use of chemical safety goggles is recommended

Skin protection: Wear appropriate chemical resistant gloves.

Respiratory Protection: Respiratory protection not required, under normal use. Use a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, exposure levels are not known, or any other circumstances where air-purifying respirators may not provide adequate protection. If respirators are used, a program should be instituted to assure compliance with OSHA 29 CFR 1910.134

Thermal hazards: Wear appropriate thermal protective clothing, when necessary

General hygiene: When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants



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SECTION 09 – PHYSICAL AND CHEMICAL PROPERTIES

a)	Physical State	:	Colorless to faint yellow solution
b)	Odor	:	Not available
c)	Solubility	:	Partially Soluble in water.
d)	Odor Threshold	:	No data available
e)	Melting/Freezing Point	:	No data available
f)	Boiling Point	:	No data available
g)	Partition Coefficient Irinotecan Hydrochloride	:	No data available
h)	Decomposition Temperature	:	No data available
i)	Evaporation Rate	:	No data available
j)	Vapor Pressure	:	No data available
k)	Vapor Density	:	No data available
l)	Relative Density	:	No data available
m)	Viscosity	:	No data available
n)	Autoignition Temperature	:	No data available
o)	Flammability (Solids)	:	No data available
p)	Flash Point (Liquid) (°C)	:	No data available
q)	Explosive Limits	:	No data available

SECTION 10 – STABILITY AND REACTIVITY

a)	Chemical Stability	Stable under normal conditions
b)	Possibility of Hazardous Reactions	Hazardous Polymerization does not occur
c)	Incompatible Materials	Strong oxidizing agents. strong acids
d)	Hazardous Decomposition Products	Carbon oxides. Nitrogen oxides. Hydrogen fluoride



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SECTION 11 – TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation	May cause slight respiratory tract irritation. Not a likely route of exposure under normal product handling conditions. May be harmful if inhaled. May cause inhalation hypersensitivity (occupational asthma) in sensitive individuals.
Skin contact	May cause skin irritation. May be harmful in contact with skin. May cause allergic skin disorders in sensitive individuals.
Eye contact	Direct contact with eyes may cause temporary irritation
5-FLUOROURACIL (CAS 51-21-8)	Irritancy test Result: Irritant Species: Rabbit Organ: Eye Severity: Mild
Ingestion	Not a likely route of exposure under normal product handling conditions. Harmful if swallowed
5-FLUOROURACIL (CAS 51-21-8)	May cause gastrointestinal toxicity

Symptoms related to the physical, chemical and toxicological characteristics

In clinical use, adverse effects may include bone marrow and gastrointestinal toxicity. Adverse effects on bone marrow include leucopenia, thrombocytopenia, and anemia. Adverse gastrointestinal effects may include nausea, vomiting, stomatitis, gastrointestinal ulceration and bleeding, diarrhea, or hemorrhage. Rashes and alopecia are also common. Ocular irritation, central neurotoxicity (cerebellar ataxia), and myocardial ischemia have also occurred. Topical application of solutions or creams with 1-5% fluorouracil caused skin irritation and allergic skin reactions. These solutions or creams can also cause eye irritation. Dermatitis and, rarely, erythema multiforme have been reported.

Information on toxicological effects

Components	Species	Test Results
Acute		
Oral		
LD50	Dog	30 mg/kg
	Mouse	115 mg/kg
	Rat	230 mg/kg
Skin corrosion/irritation	May cause skin irritation	
	Irritancy test	
	Result: Irritant	
	Species: Rabbit	
	Organ: Skin	
	Severity: Mild	
Serious eye damage	Direct contact with eyes may cause temporary irritation	
	Irritancy test	
	Result: Irritant	
	Species: Rabbit	
	Organ: Eye	
	Severity: Mild	



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Respiratory or skin sensitisation

Respiratory sensitization Not available.

Skin sensitization May cause skin sensitization in hypersensitive individuals

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA

IARC Monographs. Overall Evaluation of Carcinogenicity

5-FLUOROURACIL (CAS 51-21-8)	3 Not classifiable as to carcinogenicity to humans.
NTP Report on Carciogens	Not listed
OSHA Specifically regulated Substances	Not listed
Reproductive Toxicity	May cause harm to breast feed babies. May damage fertility of un born
Specific organ toxicity	Not classified
Aspiration hazard	Not available
Chronic hazard	Repeat-dose studies in animals have shown a potential to cause adverse effects on blood and blood forming organs.

Further information: There are scientific studies that suggest that personnel (e.g. nurses, pharmacists, etc.) who prepare and administer parenteral antineoplastics (e.g. in hospitals) may be at some risk due to potential mutagenicity, teratogenicity, and/or carcinogenicity of these materials if workplace exposures are not properly controlled. The actual risk in the workplace is not known. Adverse effects associated with therapeutic use include gastrointestinal disturbances such as nausea, dyspepsia, and vomiting and gastrointestinal irritation. Effects on blood and blood forming organs have also occurred.

SECTION 12 – ECOLOGICAL INFORMATION

Eco toxicity Toxic to aquatic life.

Components	Species	Test results
5-FLUOROURACIL		
Other	Vibrio fisheri	0.12 mg/l, 24 hours
Algae	Pseudokirchneriella subcapitata	0.11 mg/l, 96 hours
Crustacea	Daphnia magna	36 mg/l, 48 hours
Fish	Pimephales promelas	400 mg/l, 120 hours
Bacteria	Pseudomonas putida	0.027 mg/l, 16 hours
Sodium Hydroxide		
Crustacea	Water flea (Ceriodaphnia dubia)	34.59 - 47.13 mg/l, 48 hours
Fish	Bluegill (Lepomis macrochirus)	99 mg/l, 48 hours
	Mosquitofish (Gambusia affinis affinis)	125 mg/l, 96 hours



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Persistence and degradability

Bioaccumulative potential

Partition coefficient n-octanol/water (log K_{ow})

5-FLUOROURACIL < 3, (EC)
< 4, (GHS)

Bioconcentration factor

5-FLUOROURACIL 3, (estimated)

Mobility in soil No data available

SECTION 13 – DISPOSAL CONSIDERATIONS

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.
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.
Waste from residues	Dispose of in accordance with local regulations. 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. Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14 – TRANSPORTATION INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, IATA, or IMDG regulations.

SECTION 15 – REGULATORY INFORMATION

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

All components are on the U.S. EPA TSCA Inventory List.

This product is exempt from SARA 311/312 reporting requirements when used as a food, food additive, color additive, drug or cosmetic under 40 CFR 370.13(a).

TSCA Section 12(b) Export Notification Not regulated



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OSHA Specifically Regulated Substances Not listed
CERCLA Hazardous Substance List
Sodium hydroxide Listed
Superfund Amendments and Reauthorization Act of 1986

Hazard categories Immediate Hazard – Yes

Delayed Hazard - Yes

Fire Hazard - No

Pressure Hazard - No

Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Chemical name number	CAS	Reportable quantity (pounds)	Threshold planning quantity(pounds)	Threshold planning quantity,lower value (pounds)	Threshold planning quantity,upper value (pounds)
5-FLUOROURACIL	51-21-8	500		500	10000

SARA 311/312 Hazardous chemical Yes

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.
5-FLUOROURACIL	51-21-8	Proprietary

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section(r) Accidental Release Prevention

Not regulated.

Safe Drinking Water Act Not regulated.

US state regulations

US. Massachusetts RTK – Substance list

5-FLUOROURACIL (CAS 51-21-8)

Sodium hydroxide (CAS 1310-73-2)

US. New Jersey Worker and Community Right-to-Know Act

5-FLUOROURACIL (CAS 51-21-8)

Sodium hydroxide (CAS 1310-73-2)

US. Pennsylvania Worker and Community Right-to-Know Law

5-FLUOROURACIL (CAS 51-21-8)

Sodium hydroxide (CAS 1310-73-2)

US. Rhode Island RTK

5-FLUOROURACIL (CAS 51-21-8)

Sodium hydroxide (CAS 1310-73-2)

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductiveharm.

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US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT)

5-FLUOROURACIL (CAS 51-21-8)

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)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates this product complies 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).

SECTION 16 – OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.