SAFETY DATA SHEET
FLUOROURACIL INJECTION USP

SECTION 1: IDENTIFICATION

Product Identifier:	Fluorouracil Injection 50 mg/mL
Product Code:	F100
Chemical Name:	5-fluoropyrimidine-2,4(1H,3H)-dione
Chemical Family:	Pyrimidine uracil analog
Therapeutic Class:	Antineoplastic
Product Use:	Fluorouracil Injection is indicated in the palliative treatment of colorectal carcinoma and carcinoma of the breast, and in the treatment of carcinoma of the stomach, pancreas, prostate, ovary, bladder and head and neck, either as a single agent or in combination with radiation therapy and/or other chemotherapeutic agents.
Manufacturer's Name:	Biolyse Pharma Corp.
Address:	59 Welland Vale Rd, St. Catharines, ON, Canada L2S 3Y2
Business No.:	(1) 905 687 8008
Emergency No.:	(1) 905 687 8008
Supplier's Name and Address:	Biolyse Pharma Corp., 59 Welland Vale Rd, St. Catharines, ON, Canada L2S 3Y2
Business No.:	(1) 905 687 8008
Emergency No.:	(1) 905 687 8008

SECTION 2: HAZARD IDENTIFICATION

- Classification:
  IARC: Carcinogen: Group 3 (Not Classifiable)
  US OSHA: Target Organ Toxin, Reproductive Toxin, Possible Irritant
- GHS Pictograms:

- Signal Word: DANGER
- Hazard Statements: May damage fertility or the unborn child. May cause Genetic Detects. May cause harm to breast-fed children. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling. Get medical attention if you feel unwell.
- Precautionary Statements: Do not breathe dust/fume/gas/mist/vapors/spray. Avoid contact during pregnancy and while nursing. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	Common Name / Synonym	% Composition or other measure	CAS No.	Impurities / Stabilizing Additives
2, 4(1H, 3H)-Pryimidinedione, 5- fluorouracil	Fluorouracil	50 mg/mL	51-21-8	N/A
Sodium Hydroxide	Sodium Hydroxide	Adjust pH to 8.6 – 9.4	1310-73-2	N/A
Water	Water for Injection	q.s.	7732-18-5	N/A

Common Name / Synonym	Quantity for 500 mg/10 mL	Quantity for 5 g/100 mL
Fluorouracil	50 mg/mL	50 mg/mL
Sodium Hydroxide	Adjust pH to 8.6 – 9.4	Adjust pH to 8.6 – 9.4
Water for Injection	q.s to 10 mL	q.s to 100 mL

q.s = quantity sufficient

SECTION 4: FIRST AID MEASURES

- Eye Exposure: Immediately flush eyes with water for at least 15 minutes. Seek medical attention.
- Skin Exposure: 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.
- 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.
- Injection: Seek Medical Attention.
- Inhalation: Move exposed subject to fresh air immediately. Give artificial respiration and Cardiopulmonary resuscitation (CPR) if required. Seek medical attention.

SECTION 5: FIRE FIGHTING MEASURES

- Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.
- Hazardous Combustion Products: Carbon monoxide, carbon dioxide, nitrogen oxides and fluorine-containing compounds.
- Special Protective Equipment / Precautions: No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self-contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Spill: Contain the source of the spill if it is safe to do so. Soak up with inert absorbent material and dispose of as hazardous waste.
Release to Air: Not Available
Release to Water: Not Available

SECTION 7: HANDLING AND STORAGE

- General Handling: 5-fluorouracil is a cytotoxic agent. Appropriate procedures should be implemented during the handling and disposal of cytotoxic anti-neoplastic agents to minimize potential exposures. Several guidelines on handling cytotoxic anti-neoplastic agents have been published. There is no general agreement that all of the procedures recommended in the guidelines are necessary or appropriate. Consult your hygienist or safety professional for your site requirements. Avoid ingestion, inhalation, skin contact, and eye contact. Precautions may include the use of a containment cabinet during the weighing, reconstitution and/or solubilization of this anti-neoplastic agent. The use of disposable gloves and respiratory protection is recommended. Proper disposal of contaminated vials, syringes, or other materials is required when working with this material.
- Storage Conditions: Store between 15°C - 25°C. Protect from light. Do not freeze.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

- Engineering Controls: General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
- Respiratory Protection: No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a

controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator may be permissible under certain circumstances.

- Eye Protection: Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.
- Skin Protection: When handling this product, disposable gloves should be worn at all times. Further, the use of double gloves is recommended. Disposable gloves made from nitrile, neoprene, polyurethane or natural latex generally have low permeability to chemotherapeutic agents. Persons known to be allergic to latex rubber should select a non-latex glove. Gloves should be changed regularly, and removed immediately after known contamination. Care should be taken to minimize inadvertent contamination when removing and/or disposing of gloves.
- Other Protective Equipment: Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid	Melting Point: Not available	Molecular Weight: 130.08 g/mol
Appearance: Colorless or almost colorless solution	Boiling Point: 100°C	pH: Approximately 9.2
Odor: Not available	Solubility: Soluble in water	Flash Point: Not available
Odor Threshold: Not available	Vapor Density: Not available	Evaporation Rate: Not available
Coefficient of Oil/Water Distribution: Not available	Vapor Pressure: Not available	Auto Ignition Temperature: Not available

SECTION 10: STABILITY AND REACTIVITY

Reactivity: Not determined
Chemical Stability: Stable under recommended storage conditions and use
Possibility of Hazardous Reactions: Not determined
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and hydrogen fluoride

SECTION 11: TOXICOLOGICAL INFORMATION

- Likely Routes of Exposure: Inhalation, eye/skin contact, or ingestion.
- Symptoms related to the physical, chemical and toxicological characteristics: Adverse reactions from therapeutic doses include: anorexia, nausea, dry mouth, stomatitis, diarrhea, leukopenia, thrombocytopenia, diarrhea, anemia, hair loss, nail changes, dermatitis, increased pigmentation, and skin atrophy. Occupational exposure has not been fully investigated.
- Delayed and immediate effects and also chronic effects from short and long term exposure:
  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.

Acute Toxicity:

Component	Type	Route	Species	Dosage
Fluorouracil	LD_{50}	Oral	Rat	230 mg/kg
Fluorouracil	LD_{50}	Para-periosteal	Rat	245 mg/kg
Fluorouracil	LD_{50}	Oral	Mouse	115 mg/kg
Fluorouracil	LD_{50}	Intravenous	Mouse	81 mg/kg
Sodium Hydroxide	LD_{50}	IP	Mouse	40 mg/kg

Hazardous Chemical Listings: NTP: No IARC: Group 3 – Not classifiable as to carcinogenicity to humans

SECTION 12: ECOLOGICAL INFORMATION

All work practices must be aimed at eliminating environmental contamination.
Ecotoxicity: No ecotoxicity data found for this product
Environmental Stability: No environmental information found for this product

SECTION 13: DISPOSAL CONSIDERATIONS

Dispose of waste in accordance with all applicable Local, State, Federal and Provincial regulations.

SECTION 14: TRANSPORT INFORMATION

DOT: Regulated; ICAO/IATA: Regulated

SECTION 15: REGULATORY INFORMATION

This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

Canada DSL: Listed
U.S. SARA 302: Listed
U.S. SARA 313: Listed
U.S. TSCA Inventory status: Listed
U.S. CERCLA: Not on this list

SECTION 16: ADDITIONAL 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.

SDS Issue Date: September 06, 2019

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

CAS Number: Chemical Abstract Service Registry Number	NIOSH: National Institute for Occupational Safety and Health
CERCLA: Comprehensive Environmental Response Compensation and Liability Act (of 1980)	NTP: National Toxicology Program
DOT: Department of Transportation	OSHA: Occupational Safety and Health Administration
DSL: Domestic Substances List	SARA: Superfund Amendments and Reauthorization Act
IARC: International Agency for Research on Cancer	TSCA: Toxic Substances Control Act
ICAO/IATA: International Civil Aviation Organization/International Air Transport Association	