SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Fluorouracil Injection, USP**
Manufacturer Name:	Fresenius Kabi USA, LLC
Address:	Three Corporate Drive Lake Zurich, Illinois 60047
General Phone Number:	(847) 550-2300
Customer Service Phone Number:	(888) 386-1300
Health Issues Information:	(800) 551-7176
SDS Creation Date:	January 08, 2009
SDS Revision Date:	February 19, 2024

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Respiratory sensitisation. category 1.
Reproductive toxicity. Category 2.
Skin Sensitization. category 1.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Suspected of damaging fertility or the unborn child.
May cause an allergic skin reaction.
May cause harm to breast-fed children.

Precautionary Statements:
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Do not breathe dust/fume/gas/mist/vapours/spray.
Avoid breathing dust/fume/gas/mist/vapours/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.
In case of inadequate ventilation wear respiratory protection.
IF ON SKIN: Wash with plenty of water.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
IF exposed or concerned: Get medical advice/attention.
Specific treatment (see ... on this label).
If skin irritation or rash occurs: Get medical advice/attention.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Take off contaminated clothing and wash it before reuse.
Store locked up.
Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Emergency Overview: 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.

Route of Exposure: Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health 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.
- Inhalation: Irritation have been experienced with patient administration.

Signs/Symptoms: 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.

Aggravation of Pre-Existing Conditions: Individuals with poor nutritional state, depressed bond marrow function, those with potentially serious infections, or those with a known hypersensitivity to fluorouracil.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.

Fluorouracil	51-21-8	50 mg/mL
Water for Injection	7732-18-5	Quantity Sufficient

SECTION 4 : FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e,g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature]. Do not freeze. Protect from light.
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

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.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.

Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
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 with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Clear to pale yellow
Boiling Point:	100°C (212°F)
Melting Point:	Not established.
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	Approximately 9.2
Molecular Formula:	Mixture
Molecular Weight:	130.08
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Incompatible Materials:	Strongly basic conditions (pH > 9).

SECTION 11 : TOXICOLOGICAL INFORMATION

Fluorouracil :

Acute Toxicity:	LD50 IP Rat 70 mg/kg LD50 IP Mouse 100 mg/kg LD50 Intramuscular Rat 240 mg/kg LD50 SC Rat 217 mg/kg LD50 SC Mouse 169 mg/kg LD50 IV Rat 245 mg/kg LD50 IV Mouse 81 mg/kg LD50 IV Guinea Pig 25 mg/kg

Fluorouracil :

IARC:	IARC: Group 3: Unclassifiable as to carcinogenicity to humans.
Skin:	IMMEDIATE EFFECTS: Quickly resolving skin irritation and discoloration have been reported after accidental splash contact. Allergic contact dermatitis has been reported with use of fluorouracil ointment.

Fluorouracil :

RTECS Number:	YR0350000
Skin:	Administration onto the skin - Human Standard Draize test.: 84 mg/3W
Ingestion:	Oral - Rat LD50: 230 mg/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: 115 mg/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Rat LD50: 245 mg/kg [Gastrointestinal - hypermotility, diarrhea Gastrointestinal - nausea or vomiting] Intravenous. - Mouse LD50: 81 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rabbit LDLo: 15 mg/kg [Vascular - BP elevation not characterized in autonomic section] Intravenous. - Guinea pig LD50: 25 mg/kg [Vascular - BP elevation not characterized in autonomic section] Intravenous. - Mouse TDLo: 130 mg/kg/1H [Gastrointestinal - other changes] Intravenous. - Mouse TDLo: 150 mg/kg [Tumorigenic - active as anti-cancer agent]

Intravenous. - Human TDLo: 7.5 mg/kg [Gastrointestinal - hypermotility, diarrhea Skin and Appendages - dermatitis, allergic (after systemic exposure)]
Intravenous. - Human TDLo: 7.5 mg/kg [Gastrointestinal - hypermotility, diarrhea Gastrointestinal - nausea or vomiting]
Intravenous. - Mouse TDLo: 150 mg/kg [Blood - normocytic anemia Blood - leukopenia Blood - thrombocytopenia]
Intravenous. - Rabbit LDLo: 50 mg/kg [Cardiac - cardiomyopathy including infarction Cardiac - changes in coronary arteries]
Intravenous. - Rabbit LDLo: 15 mg/kg [Cardiac - changes in coronary arteries Cardiac - other changes]
Intravenous. - Human TDLo: 6 mg/kg/3D [Cardiac - EKG changes not diagnostic of specified effects Cardiac - other changes Lungs, Thorax, or Respiration - other changes]
Intravenous. - Rat TDLo: 700 mg/kg/7D (continuous) [Liver - tumors Tumorigenic - protects against induction of experimental tumors Tumorigenic - active as anti-cancer agent]
Intravenous. - Mouse TDLo: 300 mg/kg/29D (intermittent) [Nutritional and Gross Metabolic - weight loss or decreased weight gain Tumorigenic - active as anti-cancer agent]
Intravenous. - Human TDLo: 630 mg/kg/12W (intermittent) [Skin and Appendages - hair Tumorigenic - active as anti-cancer agent]
Intravenous. - Human TDLo: 52.5 mg/kg/7D (intermittent) [Blood - normocytic anemia Blood - leukopenia Blood - thrombocytopenia]
Intravenous. - Human TDLo: 168.8 mg/kg/27W (intermittent) [Gastrointestinal - nausea or vomiting Blood - leukopenia Skin and Appendages - hair]
Intravenous. - Mouse TDLo: 195 mg/kg/14D (intermittent) [Tumorigenic - active as anti-cancer agent]
Intravenous. - Mouse TDLo: 255 mg/kg/14D (intermittent) [Nutritional and Gross Metabolic - weight loss or decreased weight gain Tumorigenic - active as anti-cancer agent]
Intravenous. - Human TDLo: 630 mg/kg/12W (intermittent) [Gastrointestinal - hypermotility, diarrhea Blood - granulocytopenia Tumorigenic - active as anti-cancer agent]
Intravenous. - Human TDLo: 281 mg/kg/48W (intermittent) [Blood - leukopenia Liver - other changes Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - multiple enzyme effects]
Intravenous. - Mouse TDLo: 200 mg/kg/8D (intermittent) [Tumorigenic - protects against induction of experimental tumors]
Intravenous. - Rat TDLo: 100 mg/kg/2D (intermittent) [Blood - changes in bone marrow (not otherwise specified)]
Intravenous. - Rat TDLo: 40 mg/kg/4D (intermittent) [Blood - changes in bone marrow (not otherwise specified)]
Intravenous. - Rabbit TDLo: 60 mg/kg/21D (intermittent) [Cardiac - changes in coronary arteries Cardiac - changes in heart weight Related to Chronic Data - death]
Intravenous. - Human TDLo: 95.625 mg/kg/51D (intermittent) [Kidney/Ureter/Bladder - other changes in urine composition Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - cytochrome oxidases (including oxidative phosphorylation)]
Intravenous. - Mouse Unscheduled DNA synthesis: 40 mg/kg
Intravenous. - Mouse Sperm Morphology: 50 mg/kg
Intravenous. - Rat DNA damage: 50 mg/kg
Intravenous. - Rat TDLo: 330 mg/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intravenous. - Mouse TDLo: 67 mg/kg [Reproductive - Paternal Effects - spermatogenesis (incl. genetic material, sperm morphology, motility, and count)]
Subcutaneous - Rat LD50: 217 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Mouse LD50: 169 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Mouse TDLo: 160 mg/kg [Blood - leukopenia Blood - agranulocytosis]
Subcutaneous - Rat TDLo: 21 mg/kg/7D (intermittent) [Blood - changes in bone marrow (not otherwise specified) Blood - changes in leukocyte (WBC) count Blood - changes in platelet count]
Subcutaneous - Mouse TDLo: 300 mg/kg/60D (intermittent) [Endocrine - changes in spleen weight Related to Chronic Data - death Related to Chronic Data - changes in testicular weight]
Subcutaneous - Rat TDLo: 20 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]
Subcutaneous - Rat TDLo: 30 mg/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Rat LD50: 70 mg/kg [Gastrointestinal - hypermotility, diarrhea Gastrointestinal - nausea or vomiting]
Intraperitoneal. - Mouse LD50: 100 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse TDLo: 10 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse TDLo: 10 mg/kg [Tumorigenic - protects against induction of experimental tumors Tumorigenic - active as anti-cancer agent]
Intraperitoneal. - Mouse TDLo: 150 mg/kg [Tumorigenic - active as anti-cancer agent]
Intraperitoneal. - Mouse TDLo: 200 mg/kg [Gastrointestinal - other changes Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - peptidases]
Intraperitoneal. - Rat TDLo: 10 mg/kg [Gastrointestinal - other changes]
Intraperitoneal. - Mouse TDLo: 200 mg/kg [Liver - other changes Tumorigenic - protects against induction of experimental tumors]
Intraperitoneal. - Mouse TDLo: 100 mg/kg [Blood - changes in bone marrow (not otherwise specified)]
Intraperitoneal. - Rat TDLo: 910 mg/kg/26W (intermittent) [Gastrointestinal - other changes Blood - changes in erythrocyte (RBC) count]
Intraperitoneal. - Rat TDLo: 360 mg/kg/60D (intermittent) [Related to Chronic Data - death]
Intraperitoneal. - Rat TDLo: 780 mg/kg/30D (intermittent) [Endocrine - changes in thymus weight Blood - normocytic anemia Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - transaminases]
Intraperitoneal. - Rat TDLo: 2340 mg/kg/13W (intermittent) [Liver - changes in liver weight Kidney/Ureter/Bladder - changes in bladder weight Blood - normocytic anemia]
Intraperitoneal. - Mouse TDLo: 120 mg/kg/5D (intermittent) [Liver - tumors Tumorigenic - protects against induction of experimental tumors Tumorigenic - active as anti-cancer agent]
Intraperitoneal. - Mouse TDLo: 100 mg/kg/5D (intermittent) [Blood - changes in other cell count (unspecified) Blood - changes in leukocyte (WBC) count Tumorigenic - active as anti-cancer agent]
Intraperitoneal. - Mouse TDLo: 100 mg/kg/5D (intermittent) [Blood - leukopenia Tumorigenic - active as anti-cancer agent]
Intraperitoneal. - Mouse TDLo: 200 mg/kg/5D (intermittent) [Tumorigenic - protects against induction of experimental tumors]
Intraperitoneal. - Rat Micronucleus test: 250 mg/kg
Intraperitoneal. - Rat Cytogenetic analysis: 50 mg/kg
Intraperitoneal. - Mouse Micronucleus test: 12500 ug/kg
Intraperitoneal. - Mouse Micronucleus test: 26018 ug/kg
Intraperitoneal. - Mouse Mutation test systems not otherwise specified: 500 umol/kg
Intraperitoneal. - Mouse Unscheduled DNA synthesis: 50 mg/kg
Intraperitoneal. - Mouse DNA inhibition: 50 mg/kg
Intraperitoneal. - Mouse Cytogenetic analysis: 20 mg/kg
Intraperitoneal. - Mouse Sperm Morphology: 50 mg/kg
Intraperitoneal. - Mouse Micronucleus test: 15 mg/kg/3D (intermittent)
Intraperitoneal. - Rat TDLo: 13500 ug/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants) Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Effects on Embryo or Fetus - fetal death]
Intraperitoneal. - Rat TDLo: 15 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants) Reproductive - Effects on Embryo or Fetus - fetal death Reproductive - Specific Developmental Abnormalities - other developmental abnormalities]
Intraperitoneal. - Rat TDLo: 30 mg/kg [Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Specific Developmental Abnormalities - musculoskeletal system Reproductive - Specific Developmental Abnormalities - gastrointestinal system]
Intraperitoneal. - Rat TDLo: 30 mg/kg [Reproductive - Specific Developmental Abnormalities -

homeostasis]
Intraperitoneal. - Rat TDLo: 20 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants) Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - other developmental abnormalities]
Intraperitoneal. - Mouse TDLo: 50 mg/kg [Reproductive - Effects on Embryo or Fetus - cytological changes (including somatic cell genetic material)]
Intraperitoneal. - Mouse TDLo: 20 mg/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue)]
Intraperitoneal. - Mouse TDLo: 20 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants) Reproductive - Specific Developmental Abnormalities - other developmental abnormalities]
Intraperitoneal. - Mouse TDLo: 30 mg/kg [Reproductive - Fertility - abortion]
Intraperitoneal. - Mouse TDLo: 10 mg/kg [Reproductive - Specific Developmental Abnormalities - eye/ear Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Mouse TDLo: 30 mg/kg [Reproductive - Effects on Newborn - live birth index (measured after birth) Reproductive - Effects on Newborn - viability index (e.g., number alive at day 4 per number born alive) Reproductive - Effects on Newborn - growth statistics (e.g.%, reduced weight gain)]
Intraperitoneal. - Mouse TDLo: 1500 mg/kg/50W (intermittent) [Tumorigenic - carcinogenic by RTECS criteria Lungs, Thorax, or Respiration - tumors Blood - tumors]

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Fluorouracil :

TSCA Inventory Status:	Listed
EINECS Number:	200-085-6
SARA:	EPCRA - 40 CFR Part 372 - (SARA Title III) Section 313 Listed Chemical.
Section 302 EHS:	EPCRA (SARA Title III) Section 302 (40 CFR Part 355) Extremely Hazardous Substances (EHS) Threshold Planning Quantity (TPQ) in pounds.: 500/10,000 Lbs.
Section 304 RQ:	EPCRA (SARA Title III) Section 304 Extremely Hazardous Substances (EHS) Reportable Quantities (RQ) in pounds.: 500 Lbs.
California PROP 65:	Listed: developmental.
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	3*
HMIS Fire Hazard:	0
HMIS Reactivity:	0
HMIS Personal Protection:	X

SDS Creation Date:	January 08, 2009
SDS Revision Date:	February 19, 2024
SDS Revision Notes:	Overall SDS review - no changes to formulation. Added HMIS ratings for Health, Flammability, Reactivity, and Personal Protective Equipment (PPE).

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