SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	**FLUOROURACIL (5), USP**
PRODUCT CODE	**3185**
SUPPLIER	**MEDISCA Inc.** Tel.: 1.800.932.1039 | Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 **MEDISCA Pharmaceutique Inc.** Tel.: 1.800.665.6334 | Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 **MEDISCA Australia PTY LTD** Tel.: 1.300.786.392 | Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 3) Skin Irritation (Category 2) Eye Irritation (Category 2A) Toxic to Reproduction (Category 1B) Germ Cell Mutagenicity (Category 1B) Acute Aquatic Toxicity (Category 3) Chronic Aquatic Toxicity (Category 3) Specific Target Organ Toxicity - Repeated Exposure (Category 1) - (Bone marrow)
PICTOGRAM	
SIGNAL WORD	Danger
HAZARD STATEMENT(S)	Cytotoxic! Extremely hazardous to all tissues. Toxic if swallowed. Causes skin irritation. Causes serious eye irritation. May damage fertility or the unborn child. May cause genetic defects. Harmful to aquatic life with long lasting effects. Causes damage to organs through prolonged or repeated exposure.

ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not Available.	
PRECAUTIONARY STATEMENT(S)	**Prevention**	Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Do not breathe dust/fume/gas/mist/vapors/spray. Do not handle until all safety precautions have been read and understood. Obtain, read and follow all special instructions before use. Wear protective gloves, protective clothing, eye protection, face protection. Avoid release to the environment.
	Response	IF SWALLOWED: Immediately call a poison center. Get emergency medical help immediately. Rinse mouth. IF ON SKIN (HAIR): Wash with plenty of water. If skin irritation occurs: Get medical help. Take off contaminated clothing and wash it before reuse. 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 help. IF EXPOSED: Get emergency medical help immediately. Call a poison center or doctor.
	Storage	Store locked up.
	Disposal	Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION

Health Hazard	4	**Flammability**	0
Reactivity	0	**Personal Protection**	K

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	2,4(1H,3H)-Pyrimidinedione, 5-fluoro-
BOTANICAL NAME	Not applicable
SYNONYM	5-Fluorouracil; 5-FU
CHEMICAL FORMULA	$C_4H_3FN_2O_2$
CHEMICAL FAMILY	Pyrimidine analog
CAS NUMBER	51-21-8
ALTERNATE CAS NUMBER	Not applicable
MOLECULAR WEIGHT	130.078

COMPOSITION

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
FLUOROURACIL	51-21-8	200-085-6	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid. If at any time there is skin contact with any cytotoxic drug, thoroughly wash the affected area with soap and water for 15 minutes. The worker should not scrape or abrade the skin by using a scrub brush as this could increase exposure. It is always recommended to seek a medical evaluation by a physician.

IF SWALLOWED	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.
MEDICAL ATTENTION AND SPECIAL TREATMENT	Get emergency medical help.
SYMPTOMS CAUSED BY EXPOSURE	Refer to section 11.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL	Not applicable.
FLAMMABLE PROPERTIES	May be combustible at high temperature.
HAZARDOUS COMBUSTION PRODUCTS	Under fire conditions, hazardous fumes will be present.
SUITABLE & UNSUITABLE EXTINGUISHING MEDIA	**Small fire:** dry chemical, CO_2 or water spray. **Large fire:** dry chemical, CO_2, alcohol resistant foam or water spray. Do not get water inside containers.
PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS	Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
METHODS & MATERIAL FOR CONTAINMENT	On land, sweep or shovel into suitable containers. Minimize generation of dust. The use of chemical inactivates is not recommended as they may create a hazardous by-product. All contaminated areas should be cleaned a minimum of three times, and all contaminated products and equipment should be disposed of or cleaned in an appropriate manner.
CLEANUP PROCEDURE	A clearly labelled cytotoxic spill kit should be kept wherever cytotoxic medications are being prepared, stored, administered or received (shipping). A spill needs to be cleaned by members of the staff that have received the appropriate training and have the appropriate protective equipment; others should vacate the area as soon as it is safe to do so until the spill is cleaned. All spills should be immediately marked with a warning sign to prevent exposure to others. Glass should never be handled by hand; always use a scoop. The cleanup should be done by as few people as feasible, but there should be at least two people involved.
REFERENCE TO OTHER SECTIONS	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING	Cytotoxic! Extremely hazardous to all tissues. Avoid all contact. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40°C are acceptable.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: FLUOROURACIL CAS #: 51-21-8

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m³	ppm	mg/m³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	10:00 antineoplastic agents	FDA Pregnancy Category D
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available
PELs are 8-hour TWAs = Limit value - Eight hours
Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

Cytotoxic: There are no exposure limits set for cytotoxic drugs. Exposure must be kept to a minimum.

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Chemical splash goggles, and if necessary, full-face protection. Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Protective gloves made of vinyl or nitrile rubber. Gloves should be changed frequently, or immediately if punctured, cut, or torn. It is also recommended that workers wear two pairs at a time for additional protection. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. A moisture resistant, long sleeved gown with elastic cuffs. To prevent the spread of medication, protective clothing should not be worn outside of the preparation area. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. In cases where there is a possibility of the medication becoming airborne, a powered air purifying respirator is recommended. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used

SPECIFIC ENGINEERING CONTROLS

The following engineering controls should be put in place where cytotoxic medications are being used:
A minimum of a Class II biological safety cabinet with HEPA filter exhaust systems that does not allow air to be circulated back into the room should be used while manipulating cytotoxic drugs.
The preparation area within the cabinet should be covered with a plastic backed, absorbent material to reduce dispersion and facilitate the clean-up of any spilled medication.
Medications should be isolated and locked out in such a manner that only those properly trained have access to the storage location.
Puncture proof containers for the disposal of needles, syringes and vials must be provided.
Negative pressure rooms that prevent any spilled medication from leaving the room are also recommended.

BIOLOGICAL MONITORING	Not available
CONTROL BANDING	Not available
NOTES	Additional controls Safe work procedures for handling these materials should be developed and taught to all affected staff. Proper signage informing all employees of the presence of cytotoxic drugs and their hazards must be developed and displayed in highly visible locations. Eating, drinking, smoking, applying makeup and the storage of food should be completely prohibited in the preparation area.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE	Solid
DESCRIPTION	White to practically white, practically odorless, crystalline powder.
SOLUBILITY	Sparingly soluble in water; slightly soluble in alcohol; practically insoluble in chloroform and in ether.
ODOR	Odorless
FLAMMABILITY	May be combustible at high temperature

AUTO-IGNITION TEMPERATURE	Not available	**BOILING POINT**	(190 - 200)°C, (374-392)°F (sublimes)	**DECOMPOSITION TEMPERATURE**	(282 - 283)°C, (539.6-541.4)°F
EVAPORATION RATE	Not available	**EXPLOSIVE LIMIT**	Not available	**FLASH POINT**	Not available
log P (OCTANOL-WATER)	-0.89	**LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)**	Not available	**MELTING/FREEZING POINT**	(282 - 283)°C, (539.6-541.4)°F (decomposes)
PARTICLE CHARACTERISTICS	Not available	**OXIDIZING PROPERTY**	Not available	**pH**	4.5 - 5 (1%)
RELATIVE DENSITY (WATER = 1)	Not available	**SPECIFIC GRAVITY**	Not available	**UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)**	Not available
VAPOR DENSITY (AIR = 1)	Not available	**VAPOR PRESSURE**	< 0.0000001 kPa (25°C)	**VISCOSITY**	Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established.
CHEMICAL STABILITY	Stable under recommended storage conditions.
INCOMPATIBLE MATERIALS	Strong bases. Strong oxidizing agents.
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur.

HAZARDOUS POLYMERIZATION	Will not occur.
POSSIBLITY OF HAZARDOUS REACTION	Not established.
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures.

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): 230 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available	
SKIN CORROSION/IRRITATION	Fluorouracil is irritant; avoid contact with skin and mucous membranes. May cause dermatitis and photosensitivity. Causes skin irritation - pH: 4,5 - 5 (1%) Irritancy test. Result: Irritant. Species: Rabbit.Organ: Skin. Severity: Mild.	
SERIOUS EYE DAMAGE/EYE IRRITATION	Causes severe eye irritation - pH: 4,5 - 5 (1%) Irritancy test. Result: Irritant. Species: Rabbit. Organ: Eye. Severity: Mild.	
RESPIRATORY SENSITIZATION	Due to lack of data the classification is not possible.	
SKIN SENSITIZATION	Due to lack of data the classification is not possible.	
GERM CELL MUTAGENICITY	Exposure to cytotoxic drugs has been reported to cause increased frequency of chromosome damage in exposed workers. May cause genetic defects. This material tested positive in a battery of in vivo and in vitro genotoxicity assays, including germ cell tests.	
CARCINOGENICITY	**OSHA**	FLUOROURACIL is not listed.
	NTP	FLUOROURACIL is not listed.
	IARC	FLUOROURACIL is listed in group 3 (not classifiable as to its carcinogenicity to humans).
	California Proposition	This product contains the following chemical known to the State of California to cause birth defects or other reproductive harm: FLUOROURACIL .
ADDITIONAL CARCINOGENICITY INFORMATION	Repeated long-term occupational exposure to small amounts of cytotoxic drugs has not been identified to cause of cancer. However, many cytotoxic drugs are known to be: Genotoxic, Carcinogenetic, Mutagenic. Secondary malignancies are potential delayed effects of many antineoplastic agents, although it is not clear whether the effect is related to their mutagenic or immunosuppressive action. The effect of dose and duration of therapy is also unknown, although risk seems to increase with long-term use.	
REPRODUCTIVE TOXICITY	Cytotoxic drugs have also been associated with negative health effects for developing fetuses, including higher incidences of spontaneous abortions, congenital malformations, low birth weight, and infertility. May damage fertility or the unborn child. Antineoplastic therapy can adversely affect male and female fertility through gonadal suppression, resulting in the absence of menstruation or sperm. The effects appear to be related to dose and length of therapy and may be irreversible. 10 - 40 mg/kg Reproductivity test. Result: Maximium teratogenicity observed. Species: Mouse 125 - 250 mg/kg Reproductivity test. Result: Chromosomal changes in spermatogonia occurred. Species: Rat. 25 - 50 mg/kg Reproductivity test. Result: Fetotoxicity observed. Species: Rat 3 - 9 mg/kg Reproductivity test. Result: Embrotoxicity observed. Species: Hamster	

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE	Based on available data, the classification criteria are not met.	
SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE	Causes damage to organs (bone marrow) through prolonged or repeated exposure.	
ASPIRATION HAZARDS	Based on available data, the classification criteria are not met.	
SIGNS AND SYMPTOMS OF EXPOSURE	ROUTES OF EXPOSURE: Oral, Dermal, Inhalation, Eye contact EARLY ONSET SYMPTOMS RELATED TO EXPOSURE: Not available DELAYED HEALTH EFFECT FROM EXPOSURE: Not available Symptoms related to the physical, chemical, and toxicological characteristics: Stomach pain. Cramps. Nausea. Vomiting. Heartburn. Diarrhea. Fever. Chills. Cough. Lower back or side pain. Painful or difficult urination. Black or bloody stools. Bleeding or bruising. Pinpoint red spots on skin. Skin rash. Itching. Hair loss. Loss of appetite. Weakness. Tingling and prickling sensations. Changes in vision. Tearing. Confusion. Medical conditions aggravated by exposure: Heart disease. Impaired kidney function. Impaired liver function. Infection. Bone marrow depression. Tumor cell infiltration of bone marrow. Chickenpox, existing or recent. Herpes zoster Dihydropyrimidine dehydrogenase (DPD) deficiency. Recent cytotoxic drug or radiation therapy.	
POTENTIAL HEALTH EFFECTS	**Inhalation**	May be harmful if inhaled. Causes respiratory tract irritation.
	Ingestion	Toxic if swallowed.
	Skin	May be harmful if absorbed through skin. Causes skin irritation
	Eyes	Causes eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY	EC50: 48 Hr: Crustacea: Daphnia magna: (mg/L): 25 LC50: 96 Hr: Fish: (mg/L): 1000 EC50: 72 or 96Hr: Algae (or other aqua plants): (mg/L): Not available
PERSISTENCE AND DEGRADABILITY	Biodegradation: 2
BIOACCUMULATIVE POTENTIAL	Low: LogPow: -0.89
MOBILITY IN SOIL	Sparingly soluble in water. Water Solubility: 1.11E+04 mg/L (22°C) Vapor Pressure: 2.68E-06 mm Hg (25°C) Henry's Law Constant: 1.66E-10 atm-m³/mole (25°C)
OTHER ADVERSE EFFECTS	Not available
	This product is not intended to be released into the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS	Plastic bags that are at least 2mm thick (if polypropylene) or 4mm thick (if polyethylene) should be used to collect potentially contaminated materials. Bags should be color-coded and labelled with a cytotoxic warning label. All sharps should be placed in puncture proof containers before bagging. All workplaces should have a policy for segregating waste materials resulting from cytotoxic drug preparation and administration. These plans must meet or exceed the government regulations for hazardous waste disposal. Housekeeping staff should wear protective gloves while handling waste containers. Cytotoxic waste must be handled differently than regular garbage and must be disposed according to government regulations. In cases where the waste is to be incinerated, it should be noted that completely sealed (airtight) containers that could build pressure and explode must be avoided. Temperatures of 1,000°C to 1,600°C should be used to render the cytotoxic drugs harmless.

SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME	TOXIC SOLID, ORGANIC, N.O.S.
UN NUMBER	2811
CLASS	6.1
PACKING GROUP	III
AUSTRALIA	
HAZCHEM	2X
EU	
TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE	Not Listed
ENVIRONMENTAL HAZARDS	Not available
SPECIAL SHIPPING INFORMATION	Not applicable

SECTION 15: REGULATORY INFORMATION

UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR	EPA 40 CFR Part 355 Appendix A	EPA 40 CFR Part 355 Appendix B	Right-to-know Pennsylvania	Right-to-know New Jersey	Right-to-know Massachusett	California Prop 65
FLUOROURACIL 51-21-8	N/L	X	X	X	X	X	X	X

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
FLUOROURACIL 51-21-8	N/L	Listed as Schedule 4	N/L	Listed	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
FLUOROURACIL 51-21-8	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT: Not applicable

SECTION 16: OTHER INFORMATION

REFERENCES: Available upon request

ABBREVIATIONS AND ACRONYMS: **ACGIH** - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Instituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION: 04/2024

SUPERSEDES: 03/2023

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER: This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION: For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.