

Scientific Documentation

Fluorouracil, USP

Not appropriate for regulatory submission.

Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp
769 Jersey Avenue
New Brunswick, NJ 08901
Phone 732.214.1300



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Specification for Fluorouracil, USP (FL127)

Item Number	FL127
Item	Fluorouracil, USP
CAS Number	51-21-8
Molecular Formula	C ₄ H ₃ FN ₂ O ₂
Molecular Weight	130.08
MDL Number	
Synonyms	5-Fluorouracil ; 5-Fluoropyrimidine-2,4(1H,3H)-dione ; 5-FU

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0	102.0 %
LOSS ON DRYING		0.5 %
RESIDUE ON IGNITION		0.1 %
FLUOROURACIL RELATED COMPOUND F		0.25 %
UREA		0.2 %
ELEMENTAL IMPURITIES	AS REPORTED	
ORGANIC IMPURITIES	TO PASS TEST	
IDENTIFICATION	TO PASS TEST	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS:	TO PASS TEST	

Spectrum Chemical Mfg Corp

Corporate Headquarters:	West Coast Facility:
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

Certificate Of Analysis

Item Number	FL127	Lot Number	1MF0351
Item	Fluorouracil, USP	Manufacturer Lot	FLU-R-2212009
CAS Number	51-21-8	Manufacturer Code	7720
Molecular Formula	C ₄ H ₃ FN ₂ O ₂	Molecular Weight	130.08

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	98.0	102.0 %	100.3 %
LOSS ON DRYING		0.5 %	0.2 %
RESIDUE ON IGNITION		0.1 %	0.1 %
FLUOROURACIL RELATED COMPOUND F		0.25 %	<0.25 %
UREA		0.2 %	<0.2 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
ORGANIC IMPURITIES	TO PASS TEST		PASSES TEST
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			11-DEC-2025
DATE OF MANUFACTURE			12-DEC-2022
APPEARANCE			WHITE CRYSTALLINE POWDER
RESIDUAL SOLVENTS:	TO PASS TEST		PASSES TEST
CLASS 2 (solvent) / N,N-DIMETHYLFORMAMIDE			<880 ppm (M)
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm (M)
CLASS 2 (solvent) / TOLUENE			<890 ppm (M)
CLASS 3 (solvent) / ETHANOL			<5000 ppm (M)
MONOGRAPH EDITION			(USP-NF) 2023
NOTE: All results reported with (M) are from manufacturer certificate of analysis			.

Certificate of Analysis Results Entered By:

HBERMUDEZ
Hernan Bermudez
09-SEP-23 08:20:39

Certificate of Analysis Results Approved By:

SHANSEN
Selin Hansen
12-SEP-23 12:34:55

Spectrum Chemical Mfg Corp
14422 South San Pedro Street
Gardena 90248 CA



All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Nantong Jinghua Pharmaceutical Co., Ltd. at No. 20, 3 Haibin Road, Yanhai Economic Development Zone, Rudong, Nantong, Jiangsu 226407, China (CHN). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

SAFETY DATA SHEET

Preparation Date: 6/20/2018

Revision Date: 6/20/2018

Revision Number: G1

1. IDENTIFICATION

Product identifier

Product code: FL127
Product Name: FLUOROURACIL, USP

Other means of identification

Synonyms: 5-Fluoropyrimidine-2,4-dione
 5-Fluoro-2,4-pyrimidinedione
 5-Fluoro-2,4(1H,3H)-pyrimidinedione
 5-Fluoropyrimidine-2,4(1H,3H)-dione
 Fluorouracil
 5-Fluorouracil
 5-Fluoruracil (German)
 Fluracil
 5-FU
 2,4(1H,3H)-Pyrimidinedione, 5-fluoro
CAS #: 51-21-8
RTECS # YR0350000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Medication.
Uses advised against No information available

Supplier: Spectrum Chemical Mfg. Corp
 14422 South San Pedro St.
 Gardena, CA 90248
 (310) 516-8000

Order Online At: <https://www.spectrumchemical.com>
Emergency telephone number Chemtrec 1-800-424-9300
Contact Person: Martin LaBenz (West Coast)
Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Acute toxicity - Oral	Category 3
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2B
Germ cell mutagenicity	Category 1B
Reproductive toxicity	Category 1B

Label elements

Product code: FL127

Product name: FLUOROURACIL,
USP

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Danger

Hazard statements

Toxic if swallowed
Causes skin irritation
Causes eye irritation
May cause genetic defects
May damage fertility or the unborn child



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection
Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product

Precautionary Statements - Response

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 advice/attention.
IF ON SKIN: Wash with plenty of water
If skin irritation occurs: Get medical advice/attention
Take off contaminated clothing and wash it before reuse
IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
Rinse mouth

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Fluorouracil	51-21-8	100

4. FIRST AID MEASURES

First aid measures

General Advice:	National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.
Skin Contact:	Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention. If skin irritation persists, call a physician.
Eye Contact:	Flush eyes with water for 15 minutes. Get medical attention. If symptoms persist, call a physician.
Inhalation:	Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
Ingestion:	Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms	Causes serious eye irritation Ingestion may cause nausea, vomiting, and diarrhea May cause heartburn May cause loss of appetite Skin rash Muscle weakness May affect eyes/vision Difficult/painful and/or frequent urination Tingling and prickling sensations May cause alopecia (hair loss) Confusion Headache Dizziness
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Indication of any immediate medical attention and special treatment needed

Notes to Physician:	Treat symptomatically.
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Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media:	Dry chemical. Carbon dioxide (CO ₂). Water spray mist or foam.
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Unsuitable Extinguishing Media:	No information available.
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Specific hazards arising from the chemical

Hazardous Combustion Products:	Carbon Monoxide, Carbon Dioxide. Nitrogen Oxides. Hydrogen fluoride.
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Specific hazards:	May be combustible at high temperatures.
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Special Protective Actions for Firefighters

Specific Methods:

No information available.

Special Protective Equipment for Firefighters:

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES**Personal precautions, protective equipment and emergency procedures****Personal Precautions:**

Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Avoid contact with skin, eyes and clothing. Wear personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all sources of ignition.

Environmental precautions

Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up**Methods for containment**

Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up

Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE**Precautions for safe handling****Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

Safe Handling Advice

Avoid contact with skin, eyes and clothing. Wear personal protective equipment. Keep away from heat and sources of ignition. Do not ingest. Do not breathe dust. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities**Technical Measures/Storage Conditions:**

Keep container tightly closed. Keep in a well-ventilated place. Store at room temperature in the original container. Protect from light. Sensitive to light. Store in light-resistant containers. Store away from incompatible materials. Store in a segregated and approved area.

Incompatible Materials:

Strong bases
Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Control parameters****National occupational exposure limits****United States**

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Fluorouracil	51-21-8	None	None	None	None

Product code: FL127**Product name:** FLUOROURACIL,
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Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Fluorouracil	51-21-8	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Fluorouracil	51-21-8	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation, especially in confined areas. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection:	Goggles or Safety glasses with side-shields
Skin and body protection:	Chemical resistant apron Gloves Long sleeved clothing
Respiratory protection:	Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
Hygiene measures:	Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid	Appearance: Crystalline powder.	Color: White. Almost white.
Odor: Practically odorless.	Taste No information available.	Formula: C ₄ H ₃ FN ₂ O ₂
Molecular/Formula weight: 130.08 g/mol	Flammability: No information available	Flashpoint (°C/°F): No information available.
Flash Point Tested according to: Not available	Autoignition Temperature (°C/°F): No information available	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	Melting point/range(°C/°F): 282-283°C/536.6-541.4°F	Decomposition temperature(°C/°F): 282-283°C/536.6-541.4°F

Boiling point/range(°C/°F):

No information available

Bulk density:

No information available

Density (g/cm3):

No information available

Specific gravity:

No information available

pH:

4.5-5 (pH of a 1% solution)

Vapor pressure @ 20°C (kPa):

No information available

Evaporation rate:

No information available

Vapor density:

No information available

VOC content (g/L):

No information available

Odor threshold (ppm):

No information available

Partition coefficient**(n-octanol/water):**

No information available

Viscosity:

No information available

Miscibility:

No information available

Solubility:

Sparingly soluble in water

10. STABILITY AND REACTIVITY**Reactivity**

No information available

Chemical stability**Stability:**

Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur**Conditions to avoid:**

Heat. Incompatible materials.

Incompatible Materials:Strong bases
Strong oxidizing agents**Hazardous decomposition products:**

Carbon dioxide. Carbon monoxide. Nitrogen oxides (NOx). Hydrogen fluoride.

Other Information**Corrosivity:**

No information available

Special Remarks on Corrosivity: No information available**11. TOXICOLOGICAL INFORMATION****Information on likely routes of exposure****Principal Routes of Exposure:**

Ingestion. Inhalation.

Acute Toxicity**Component Information**

Fluorouracil	
CAS-No.	51-21-8

LD50/oral/rat = 230 mg/kg Oral LD50 Rat**LD50/oral/mouse** = 115 mg/kg**LD50/dermal/rabbit** = No information available**LD50/dermal/rat** = No information available

LC50/inhalation/rat = No information available
LC50/inhalation/mouse = No information available
Other LD50 or LC50information = No information available

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = 230 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = 115 mg/kg

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat
VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: Causes skin irritation. Moderate skin irritation.

Eye Contact: Causes eye irritation. Mild eye irritation.

Inhalation May cause irritation of respiratory tract.

Ingestion Toxic if swallowed. May cause abdominal pain, nausea, vomiting, diarrhea. May cause heartburn. May cause painful or difficult urination. May cause loss of appetite. May cause skin rash, redness or itching. May cause weakness. May affect behavior/central nervous system (dizziness, headache). May cause fatigue. May cause vision disturbances. May cause tingling, pricking feeling, or numbness in the extremities. May affect behavior/central nervous system (confusion).

Aspiration hazard No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chronic Toxicity Chronic exposure may cause hair loss. Prolonged or repeated ingestion may affect the blood (anemia).

Sensitization: No information available.

Mutagenic Effects: May cause genetic defects
DNA Damage - hamster lung
DNA damage - human leukocyte
DNA Damage - human liver
Mutagenic effects in mammalian somatic cells
Mutations in microorganisms

Experiments with bacteria and/or yeast have shown mutagenic effects

Carcinogenic effects: Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Fluorouracil	51-21-8	Group 3 - Not Classifiable as to its Carcinogenicity in Humans - Supplement 7 [1987] Monograph 26 [1981]	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity May damage fertility or the unborn child

Reproductive Effects: No information available
Developmental Effects: May cause adverse developmental effects
Teratogenic Effects: May cause birth defects (teratogenic effects)

Specific Target Organ Toxicity

STOT - single exposure No information available.
STOT - repeated exposure No information available.
Target Organs: No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: Potential for bioconcentration in aquatic organisms is low.

Mobility: It is expected to have very high mobility based on estimated Koc.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:
Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:
Empty containers should be taken for local recycling, recovery or waste disposal

Product code: FL127

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Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Fluorouracil	51-21-8	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: UN2811
Proper Shipping Name: Toxic solids, organic, n.o.s. (Fluorouacil)
Hazard Class: 6.1
Subsidiary Class: No information available
Packing group: III
Emergency Response Guide Number: 154
Marine Pollutant: No data available
DOT RQ (lbs): No information available
Special Provisions: IB8, IP3, T1, TP33
Symbol(s): [DOT]: (G) - Identifies proper shipping names for which one or more technical names of the hazardous material must be entered in parentheses, in association with the basic description.
Description: UN2811, Toxic solids, organic, n.o.s., 6.1, III

TDG (Canada)

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
Marine Pollutant: No Information available
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III

ADR

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Packing Group: III
Subsidiary Risk: No information available
Special Provisions: 274, 614
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III

IMO / IMDG

UN-No: UN2811
Proper Shipping Name: Toxic solids, organic, n.o.s. (Fluorouacil)
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
Marine Pollutant: No information available
EMS: F-A
Special Provisions: 223, 274
Description: UN2811, Toxic solid, organic, n.o.s. (FLUOROURACIL), 6.1, III

RID

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III

Special Provisions 274, 614
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III

ICAO

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III
Special Provisions A3, A5

IATA

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
ERG Code: 6L
Special Provisions No information available
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Fluorouracil	51-21-8	Present(ACTI VE)	Present KE-17055	Present	Present (9)-1180	Not present	Present	Present 200-085-6

U.S. Regulations

Fluorouracil

Massachusetts RTK: Present
New Jersey RTK Hazardous Substance List: 1966
New Jersey (EHS) List: 1966 500 lb TPQ
New Jersey - Discharge Prevention - List of Hazardous Substances: Present
Pennsylvania RTK: Environmental hazard
Pennsylvania RTK - Environmental Hazard List Present
New York Release Reporting - List of Hazardous Substances:
1 lb RQ

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Fluorouracil	51-21-8	Not Listed	developmental toxicity	Not Listed	Not Listed

CERCLA/SARA

Components	CAS-No.	CERCLA - Hazardous Substances and their Reportable	Section 302 Extremely Hazardous Substances	Section 302 Extremely Hazardous Substances and	Section 313 - Chemical Category	Section 313 - Reporting de minimis

Product code: FL127

Product name: FLUOROURACIL,
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		Quantities	and TPQs	RQs		
Fluorouracil	51-21-8	None	500 lb EPCRA RQ	None	None	1.0 % de minimis concentration

U.S. TSCA

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Fluorouracil	51-21-8	Not Applicable	Not Applicable

Canada

WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

The WHMIS 2015 classification of this product has not been validated or reviewed yet.

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

WHMIS 1988 Hazard Class

D1B Toxic materials

Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Fluorouracil	51-21-8	Not Listed	Present

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Fluorouracil	51-21-8	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Fluorouracil	51-21-8	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Fluorouracil	51-21-8	No information

EU - CLP (1272/2008)

R-phrases(s)

R22 - Harmful if swallowed.

R63 - Possible risk of harm to the unborn child.

S -phrase(s)

S46 - If swallowed, seek medical advice immediately and show this container or label.

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
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Product code: FL127

Product name: FLUOROURACIL,
USP

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Fluorouracil	51-21-8		No information	
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The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

Xn - Harmful.

Xn



16. OTHER INFORMATION

Preparation Date: 6/20/2018
Revision Date: 6/20/2018
Prepared by: Sonia Owen

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet



Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
FL127	Fluorouracil, USP

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

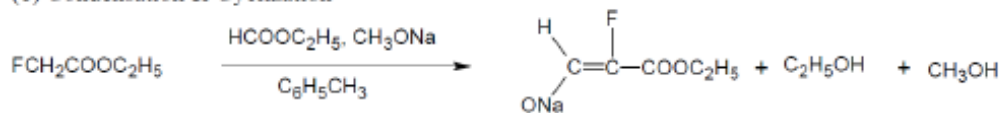
Fluorouracil, USP

Catalog FL127

Methylation, pre-step to obtain Methyl isourea



(1) Condensation & Cyclization

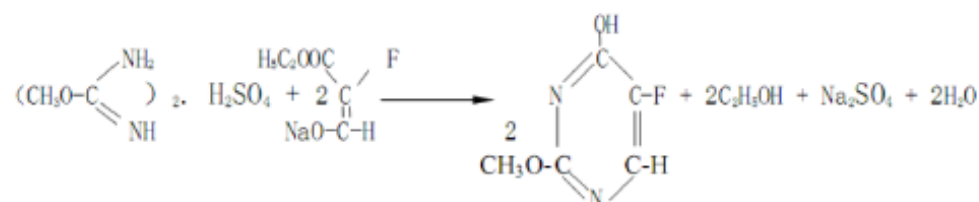
FZ[®]

Ethyl formate, Sodium methoxide, Toluene

Sodium ethyl fluoro
malonaldehyde

Ethanol

Methanol



Methylisourea

Sodium ethyl fluoro
Malonaldehyde

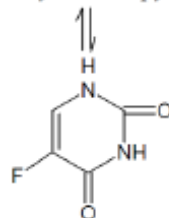
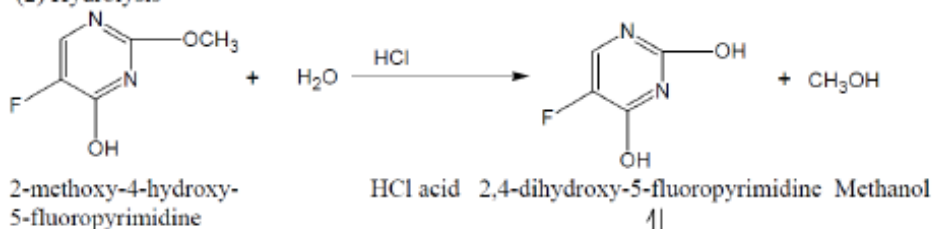
Sodium ethyl fluoro 2-methoxy-4hydroxy-
Malonaldehyde 5-fluoro pyrimidine

Ethanol

Sodium 8

Sulfate Water

(2) Hydrolysis



* FZ is the abbreviation name of Ethyl fluoroacetate.

5-fluoropyrimidine-2,4(1H,3H)-dione (Fluorouracil)

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

FL127, Fluorouracil, USP

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above-mentioned catalog item is typically assigned a shelf life of 36 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- | | |
|---------------------|-----------------|
| • Aflatoxins | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |



RE: Elemental Impurities - Fluorouracil, USP(Cat# FL127))

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

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RE: Residual Solvents – Fluorouracil, USP (Cat# FL127)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
<i>N,N</i> -Dimethylformamide	2	< 880 ppm
Methanol	2	< 3000 ppm
Toluene 890	2	< 890 ppm
Ethanol	3	< 5000 ppm

No Class 1 or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.

DANGER

- Toxic if swallowed • Causes skin and eye irritation • May damage fertility or the unborn child • May cause genetic defects.
- Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • Do not eat, drink or smoke when using this product • Wear protective gloves, protective clothing, eye protection, face protection • Wash face, hands and any exposed skin thoroughly after handling.

FIRST AID: 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. IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. If skin irritation or rash occurs: Get medical attention. IF SWALLOWED: Immediately call a POISON CENTER or physician. Rinse mouth.

KEEP FROM CHILDREN

WARNING:
Cancer and Reproductive Harm
www.P65Warnings.ca.gov

FL127

Fluorouracil
[5-Fluoropyrimidine-2,4(1*H*,3*H*)-dione;
5-Fluorouracil; 5-FU]
USP
CAS 51-21-8

CAUTION: For manufacturing, processing, repacking, or for prescription compounding. Rx only.
Read and understand the label and Safety Data Sheet (SDS) prior to use.

DOT: UN2811, Toxic solids, organic, n.o.s.
(fluorouracil), 6.1, PG III

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

SIZ SY

USP 600
HALLMARK BRAND

$C_4H_3FN_2O_2$ F.W. 130.08

Manufacturer/Supplier Code ?
Manufacturer Lot Number ?

Assay (Dried Basis) 98.0-102.0%

MAXIMUM LIMITS	
Loss on Drying	0.5%
Residue on Ignition	0.1%
Fluorouracil Related Compound F	0.25%
Urea	0.2%
Elemental Impurities	As reported
Organic Impurities:	
Fluorouracil Related Compound A	0.15%
Fluorouracil Related Compound B	0.15%
Uracil	0.15%
5-Methoxyuracil	0.15%
Fluorouracil Related Compound E	0.15%
Any Individual Unspecified Impurity	0.10%
Total Impurities	0.5%
Residual Solvents	To pass test

LIGHT SENSITIVE: Keep tightly closed in light-resistant containers.

Repackaged by Spectrum as:
B 12/J2GHS-A ? Lot No. XQ####

Spectrum Chemical Mfg Corp

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West Coast Facility:

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