

# SAFETY DATA SHEETS

According to the UN GHS revision 9

Version: 1.0  
Creation Date: July 15, 2019  
Revision Date: July 15, 2019

## SECTION 1: Identification

### 1.1 GHS Product identifier

**Product name** Fluorouracil

### 1.2 Other means of identification

**Product number** -

**Other names** 5-Fluorouracil; fluorouracil; Fluri

### 1.3 Recommended use of the chemical and restrictions on use

**Identified uses** Industrial and scientific research use.

**Uses advised against** no data available

### 1.4 Supplier's details

**Company** Shanghai Baishun Biotechnology Co., Ltd

**Address** No. 26, Lane 918, Lianye Road, Zhelin Town, Fengxian District, Shanghai, 201400, China

**Telephone** +86-21-37581181

### 1.5 Emergency phone number

**Emergency phone number** +86-21-37581181

**Service hours** Monday to Friday, 9am-5pm (Standard time zone: UTC/GMT +8 hours).

## SECTION 2: Hazard identification

### 2.1 Classification of the substance or mixture

Acute toxicity - Category 3, Oral

Acute toxicity - Category 4, Dermal

Skin irritation, Category 2

Eye irritation, Category 2

Specific target organ toxicity – single exposure, Category 3

Germ cell mutagenicity, Category 1B

Reproductive toxicity, Category 1B

### 2.2 GHS label elements, including precautionary statements

**Pictogram(s)**



**Signal word**

Danger

<b>Hazard statement(s)</b>	H301 Toxic if swallowed H312 Harmful in contact with skin H315 Causes skin irritation H319 Causes serious eye irritation H335 May cause respiratory irritation H340 May cause genetic defects H360 May damage fertility or the unborn child
<b>Precautionary statement(s)</b>	
<b>Prevention</b>	P264 Wash ... thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/... P261 Avoid breathing dust/fume/gas/mist/vapours/spray. P271 Use only outdoors or in a well-ventilated area. P203 Obtain, read and follow all safety instructions before use.
<b>Response</b>	P301+P316 IF SWALLOWED: Get emergency medical help immediately. P321 Specific treatment (see ... on this label). P330 Rinse mouth. P302+P352 IF ON SKIN: Wash with plenty of water/... P317 Get medical help. P362+P364 Take off contaminated clothing and wash it before reuse. P332+P317 If skin irritation occurs: Get medical help. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P319 Get medical help if you feel unwell. P318 IF exposed or concerned, get medical advice.
<b>Storage</b>	P405 Store locked up. P403+P233 Store in a well-ventilated place. Keep container tightly closed.
<b>Disposal</b>	P501 Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

### 2.3 Other hazards which do not result in classification

no data available

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Chemical name	Common names and synonyms	CAS number	EC number	Concentration
Fluorouracil	Fluorouracil	51-21-8	200-085-6	100%

## SECTION 4: First-aid measures

### 4.1 Description of necessary first-aid measures

#### If inhaled

Move the victim into fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration and consult a doctor immediately. Do not use mouth to mouth resuscitation if the victim ingested or inhaled the chemical.

#### Following skin contact

Take off contaminated clothing immediately. Wash off with soap and plenty of water. Consult a doctor.

#### Following eye contact

Rinse with pure water for at least 15 minutes. Consult a doctor.

### **Following ingestion**

Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Call a doctor or Poison Control Center immediately.

## **4.2 Most important symptoms/effects, acute and delayed**

Minimum toxic dose in humans is approximately 450 mg/kg (total dose) over 30 days for the ingested drug. Intravenous minimum toxic dose in humans is a total dose of 6 mg/kg over three days. Depression of white blood cells occurred after intravenous administration of a total dose of 480 mg/kg over 32 days. Occasional neuropathy and cardiac toxicity have been reported. Do not use during pregnancy. Patients with impaired hepatic or renal function, with a history of high-dose pelvic irradiation or previous use of alkylating agents should be treated with extreme caution. Patients with nutritional deficiencies and protein depletion have a reduced tolerance to fluorouracil. (EPA, 1998)

## **4.3 Indication of immediate medical attention and special treatment needed, if necessary**

Maintain an open airway and assist ventilation if necessary. Treat coma, seizures, hypotension, and arrhythmias if they occur. Treat nausea and vomiting with metoclopramide and fluid loss caused by gastroenteritis with intravenous crystalloid fluids. Bone marrow depression should be treated with the assistance of an experienced hematologist or oncologist. Extravasation. Immediately stop the infusion and withdraw as much fluid as possible by negative pressure on the syringe. ...Very few specific treatments or antidotes are available. Decontamination. Administer activated charcoal orally if conditions are appropriate. Gastric lavage is not necessary after small to moderate ingestions if activated charcoal can be given promptly. Because of the rapid intracellular incorporation of most of these agents, dialysis and other extracorporeal removal procedures are generally not effective. Antineoplastic agents

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## **SECTION 5: Fire-fighting measures**

### **5.1 Suitable extinguishing media**

Use dry chemical, carbon dioxide, or alcohol or polymer foam extinguishers. Poisonous gases, including nitrogen oxides, hydrogen fluoride, and carbon monoxide, are produced in fire. If material or contaminated runoff enters waterways, notify downstream users of potentially contaminated waters. Notify local health and fire officials and pollution control agencies. From a secure, explosion-proof location, use water spray to cool exposed containers. If cooling streams are ineffective (venting sound increases in volume and pitch, tank discolors, or shows any signs of deforming), withdraw immediately to a secure position. If employees are expected to fight fires, they must be trained and equipped in OSHA 1910.156.

### **5.2 Specific hazards arising from the chemical**

Emits very toxic fumes of fluorides and nitrogen oxides when heated to decomposition. Avoid decomposing heat. (EPA, 1998)

### **5.3 Special protective actions for fire-fighters**

Wear self-contained breathing apparatus for firefighting if necessary.

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## **SECTION 6: Accidental release measures**

### **6.1 Personal precautions, protective equipment and emergency procedures**

Avoid dust formation. Avoid breathing mist, gas or vapours. Avoid contacting with skin and eye. Use personal protective equipment. Wear chemical impermeable gloves. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

### **6.2 Environmental precautions**

Prevent further spillage or leakage if it is safe to do so. Do not let the chemical enter drains. Discharge into the environment must be avoided.

### **6.3 Methods and materials for containment and cleaning up**

**PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:** Spill kits containing all materials needed to clean up spills of hazardous drugs should be assembled or purchased. These kits should be readily available in all areas where hazardous drugs are routinely handled. If hazardous drugs are being prepared or administered in a nonroutine area (home setting or unusual patient-care area), a spill kit should be obtained by the drug handler. The kit should include two pairs of disposable gloves (one outer pair of utility gloves and one inner latex pair); low-permeability, disposable protective garments (coveralls or gown and shoe covers); safety glasses or splash goggles; respirator; absorbent, plastic-backed sheets or spill pads; disposable toweling; at least 2 sealable thick plastic hazardous waste disposal bags (prelabeled with an appropriate warning label); a disposable scoop for collecting glass fragments; and a puncture-resistant container for glass fragments. All individuals who routinely handle hazardous drugs must be trained in proper spill management and cleanup procedures. Spills and breakages must be cleaned up immediately according to the following procedures. If the spill is not located in a confined space, the spill area should be identified and other people should be prevented from approaching and spreading the contamination. Wearing protective apparel from the spill kit, workers should remove any broken glass fragments and place them in the puncture-resistant container. Liquids should be absorbed with a spill pad; powder should be removed with damp disposable gauze pads or soft toweling. The hazardous material should be completely removed and the area rinsed with water and then cleaned with detergent. The spill cleanup should proceed progressively from areas of lesser to greater contamination. The detergent should be thoroughly rinsed and removed. All contaminated materials should be placed in the disposal bags provided and sealed and transported to a designated containment receptacle. Spills occurring in the biohazard cabinet should be cleaned up immediately; a spill kit should be used if the volume exceeds 150 ml or the contents of one drug vial or ampule. If there is broken glass, utility gloves should be worn to remove it and place it in the puncture-resistant container located in the biohazard cabinet. The biological safety cabinet, including the drain spillage trough, should be thoroughly cleaned. If the spill is not easily and thoroughly contained, the biological safety cabinet should be decontaminated after cleanup. If the spill contaminates the high efficiency particulate air filter, use of the biological safety cabinet should be suspended until the cabinet has been decontaminated and the high efficiency particulate air filter replaced. Antineoplastic agents

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## **SECTION 7: Handling and storage**

### **7.1 Precautions for safe handling**

Handling in a well ventilated place. Wear suitable protective clothing. Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Use non-sparking tools. Prevent fire caused by electrostatic discharge steam.

### **7.2 Conditions for safe storage, including any incompatibilities**

Store at 25 deg C (77 deg F); excursions permitted to 15 deg C - 30 deg C (59 deg F -86 deg F). Efudex Solutions

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## **SECTION 8: Exposure controls/personal protection**

### **8.1 Control parameters**

#### **Occupational Exposure limit values**

no data available

#### **Biological limit values**

no data available

### **8.2 Appropriate engineering controls**

Ensure adequate ventilation. Handle in accordance with good industrial hygiene and safety practice. Set up emergency exits and the risk-elimination area.

### **8.3 Individual protection measures, such as personal protective equipment (PPE)**

#### **Eye/face protection**

Wear tightly fitting safety goggles with side-shields conforming to EN 166(EU) or NIOSH (US).

### Skin protection

Wear fire/flammable resistant and impervious clothing. Handle with gloves. Gloves must be inspected prior to use. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

### Respiratory protection

If the exposure limits are exceeded, irritation or other symptoms are experienced, use a full-face respirator.

### Thermal hazards

no data available

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## SECTION 9: Physical and chemical properties and safety characteristics

<b>Physical state</b>	Fluorouracil is a white to nearly white crystalline powder; practically odorless. Used as an anti neoplastic drug, chemosterilant for insects. (EPA, 1998)
<b>Colour</b>	White to practically white crystalline powder
<b>Odour</b>	PRACTICALLY ODORLESS
<b>Melting point/freezing point</b>	283°C(dec.)(lit.)
<b>Boiling point or initial boiling point and boiling range</b>	167°C/13.5mmHg(lit.)
<b>Flammability</b>	no data available
<b>Lower and upper explosion limit/flammability limit</b>	no data available
<b>Flash point</b>	64°C(lit.)
<b>Auto-ignition temperature</b>	no data available
<b>Decomposition temperature</b>	no data available
<b>pH</b>	no data available
<b>Kinematic viscosity</b>	no data available
<b>Solubility</b>	less than 1 mg/mL at 66° F (NTP, 1992)
<b>Partition coefficient n-octanol/water</b>	no data available
<b>Vapour pressure</b>	2.68X10-6 mm Hg at 25 deg C (est)
<b>Density and/or relative density</b>	1.53 g/cm3
<b>Relative vapour density</b>	no data available
<b>Particle characteristics</b>	no data available

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

no data available

### 10.2 Chemical stability

Stable when exposed to air.

### 10.3 Possibility of hazardous reactions

FLUOROURACIL may be sensitive to prolonged exposure to light. Solutions discolor on storage. This chemical can react with oxidizing agents and strong bases. Incompatible with methotrexate sodium. (NTP, 1992)

### 10.4 Conditions to avoid

no data available

## 10.5 Incompatible materials

Oxidizers, strong bases, heat.

## 10.6 Hazardous decomposition products

When heated to decomposition it emits very toxic fumes of /hydrogen fluoride and nitrogen oxides/.

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# SECTION 11: Toxicological information

### Acute toxicity

- Oral: LD50 Dog oral 30 mg/kg
- Inhalation: no data available
- Dermal: no data available

### Skin corrosion/irritation

no data available

### Serious eye damage/irritation

no data available

### Respiratory or skin sensitization

no data available

### Germ cell mutagenicity

no data available

### Carcinogenicity

Inadequate evidence of carcinogenicity in humans. Inadequate evidence of carcinogenicity in animals. OVERALL EVALUATION: Group 3: The agent is not classifiable as to its carcinogenicity to humans.

### Reproductive toxicity

no data available

### STOT-single exposure

no data available

### STOT-repeated exposure

no data available

### Aspiration hazard

no data available

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# SECTION 12: Ecological information

## 12.1 Toxicity

- Toxicity to fish: EC50; Species: Pimephales promelas (Fathead minnow); Conditions: fresh water; static, temperature 24 deg C; Concentration: 400000 ug/L (95% confidence limit: 170000 to 910000 ug/L) for 5 days Effect: growth; abnormal /formulated product
- Toxicity to daphnia and other aquatic invertebrates: no data available
- Toxicity to algae: no data available
- Toxicity to microorganisms: no data available

## 12.2 Persistence and degradability

AEROBIC: Fluorouracil, present at 5 mg/L, was shown to biodegrade 100% within 5 days using an activated sludge inoculum and the OECD confirmatory test, detection limit = 0.2 mg/L(1). The initial rate was dependent on initial concentration: the higher concentration,

the slower the degradation. 100% biodegradation in 14 days was observed when presented as a mixture with other cytostatic compounds(1).

### 12.3 Bioaccumulative potential

An estimated BCF of 3 was calculated in fish for fluorouracil(SRC), using a log Kow of -0.89(1) and a regression-derived equation(2). According to a classification scheme(3), this BCF suggests the potential for bioconcentration in aquatic organisms is low(SRC).

### 12.4 Mobility in soil

The Koc of fluorouracil is estimated as 8(SRC), using a log Kow of -0.89(1) and a regression-derived equation(2). According to a classification scheme(3), this estimated Koc value suggests that fluorouracil is expected to have very high mobility in soil.

### 12.5 Other adverse effects

no data available

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## SECTION 13: Disposal considerations

### 13.1 Disposal methods

#### Product

The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.

#### Contaminated packaging

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

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## SECTION 14: Transport information

### 14.1 UN Number

ADR/RID: no data available      IMDG: no data available      IATA: no data available

### 14.2 UN Proper Shipping Name

ADR/RID: no data available      IMDG: no data available      IATA: no data available

### 14.3 Transport hazard class(es)

ADR/RID: 6.1 (For reference only, please check.)      IMDG: 6.1 (For reference only, please check.)      IATA: 6.1 (For reference only, please check.)

### 14.4 Packing group, if applicable

ADR/RID: III (For reference only, please check.)      IMDG: III (For reference only, please check.)      IATA: III (For reference only, please check.)

### 14.5 Environmental hazards

ADR/RID: No      IMDG: No      IATA: No

### 14.6 Special precautions for user

no data available

### 14.7 Transport in bulk according to IMO instruments

no data available

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## SECTION 15: Regulatory information

## 15.1 Safety, health and environmental regulations specific for the product in question

Chemical name	Common names and synonyms	CAS number	EC number
Fluorouracil	Fluorouracil	51-21-8	200-085-6
European Inventory of Existing Commercial Chemical Substances (EINECS)			Listed.
EC Inventory			Listed.
United States Toxic Substances Control Act (TSCA) Inventory			Listed.
China Catalog of Hazardous chemicals 2015			Not Listed.
New Zealand Inventory of Chemicals (NZIoC)			Listed.
Philippines Inventory of Chemicals and Chemical Substances (PICCS)			Listed.
Vietnam National Chemical Inventory			Listed.
Chinese Chemical Inventory of Existing Chemical Substances (China IECSC)			Not Listed.
Korea Existing Chemicals List (KECL)			Listed.

## SECTION 16: Other information

### Information on revision

Creation Date July 15, 2019

Revision Date July 15, 2019

### Abbreviations and acronyms

- CAS: Chemical Abstracts Service
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- RID: Regulation concerning the International Carriage of Dangerous Goods by Rail
- IMDG: International Maritime Dangerous Goods
- IATA: International Air Transportation Association
- TWA: Time Weighted Average
- STEL: Short term exposure limit
- LC50: Lethal Concentration 50%
- LD50: Lethal Dose 50%
- EC50: Effective Concentration 50%

### References

- IPCS - The International Chemical Safety Cards (ICSC), website: <http://www.ilo.org/dyn/icsc/showcard.home>
- HSDB - Hazardous Substances Data Bank, website: <https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm>
- IARC - International Agency for Research on Cancer, website: <http://www.iarc.fr/>
- eChemPortal - The Global Portal to Information on Chemical Substances by OECD, website: [http://www.echemportal.org/echemportal/index?pageID=0&request\\_locale=en](http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en)
- CAMEO Chemicals, website: <http://cameochemicals.noaa.gov/search/simple>
- ChemIDplus, website: <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>
- ERG - Emergency Response Guidebook by U.S. Department of Transportation, website: <http://www.phmsa.dot.gov/hazmat/library/erg>
- Germany GESTIS-database on hazard substance, website: <http://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp>
- ECHA - European Chemicals Agency, website: <https://echa.europa.eu/>

**Any questions regarding this SDS, Please send your inquiry to [sds@xixisys.com](mailto:sds@xixisys.com)**

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