

SAFETY DATA SHEETS

According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS) - Sixth revised edition

Version: 1.0

Creation Date: Aug 11, 2017

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1. Identification

1.1 GHS Product identifier

Product name 5-fluorouracil

1.2 Other means of identification

Product number -

Other names 5-Fluorouracil

1.3 Recommended use of the chemical and restrictions on use

Identified uses For industry use only.

Uses advised against no data available

2. Hazard identification

2.1 Classification of the substance or mixture

Acute toxicity - Oral, Category 3

Acute toxicity - Dermal, Category 4

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

Hazard statement(s)

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

Precautionary statement(s)

Prevention

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.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P271 Use only outdoors or in a well-ventilated area.

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

Response

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor/...

P321 Specific treatment (see ... on this label).

P330 Rinse mouth.

P302+P352 IF ON SKIN: Wash with plenty of water/...

P312 Call a POISON CENTER/doctor/...if you feel unwell.

P362+P364 Take off contaminated clothing and wash it before reuse.

P332+P313 If skin irritation occurs: Get medical advice/attention.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P308+P313 IF exposed or concerned: Get medical advice/ attention.

Storage

P405 Store locked up.

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

Disposal

P501 Dispose of contents/container to ...

2.3 Other hazards which do not result in classification

none

3. Composition/information on ingredients

3.1 Substances

Chemical name	Common names and synonyms	CAS number	EC number	Concentration
5-fluorouracil	5-fluorouracil	51-21-8	none	100%

4. First-aid measures

4.1 Description of necessary first-aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

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/

5. Fire-fighting measures

5.1 Extinguishing media

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.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust. For personal protection see section 8.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product 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/

7. Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Avoid exposure - obtain special instructions before use. Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

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

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

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

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

Eye/face protection

Safety glasses with side-shields conforming to EN166. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Wear impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace. Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use

in accordance with applicable laws and good laboratory practices. 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

Wear dust mask when handling large quantities.

Thermal hazards

no data available

9. Physical and chemical properties

Physical state	white to nearly white crystalline powder
Colour	White to practically white crystalline powder
Odour	PRACTICALLY ODORLESS
Melting point/ freezing point	283°C(dec.)(lit.)
Boiling point or initial boiling point and boiling range	167°C/13.5mmHg(lit.)
Flammability	no data available
Lower and upper explosion limit / flammability limit	no data available
Flash point	64°C(lit.)
Auto-ignition temperature	no data available
Decomposition temperature	no data available
pH	no data available
Kinematic viscosity	no data available
Solubility	In water:12.2 g/L 20 °C
Partition coefficient n-octanol/water (log value)	no data available
Vapour pressure	2.68X10-6 mm Hg at 25°C (est)
Density and/or relative density	1.53 g/cm ³
Relative vapour density	no data available
Particle characteristics	no data available

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.

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/.

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

12. Ecological information

12.1 Toxicity

- Toxicity to fish: EC50; Species: Pimephales promelas (Fathead minnow); Conditions: fresh water; static, temperature 24°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

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.

14. Transport information

14.1 UN Number

ADR/RID: UN2811

IMDG: UN2811

IATA: UN2811

14.2 UN Proper Shipping Name

ADR/RID: TOXIC SOLID, ORGANIC, N.O.S.

IMDG: TOXIC SOLID, ORGANIC, N.O.S.

IATA: TOXIC SOLID, ORGANIC, N.O.S.

14.3 Transport hazard class(es)

ADR/RID: 6.1

IMDG: 6.1

IATA: 6.1

14.4 Packing group, if applicable

ADR/RID: III

IMDG: III

IATA: III

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 Annex II of MARPOL 73/78 and the IBC Code

no data available

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
5-fluorouracil	5-fluorouracil	51-21-8	none
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.

16. Other information

Information on revision

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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
- 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/>
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