

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

106211-5-Fluorouracil



Version: 3
Revision date: 19/04/2016

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SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY/UNDERTAKING.

1.1 Product identifier.

Product Name: 5-Fluorouracil
Product Code: 106211
Chemical Name: 5-Fluorouracil
CAS No: 51-21-8
EC No: 200-085-6
Registration No: N/D

1.2 Relevant identified uses of the substance and uses advised against.

For manufacturing, processing, laboratory or repacking use only

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

Company: **DC FINE CHEMICALS Ltd.**
Address: Hill Top, 88
City: NW11 6DY London (United Kingdom)
Telephone: +44 (20) 7586 6800
Fax: +44 (20) 7504 1701
E-mail: info@dcfinechemicals.com
Web: www.dcfinechemicals.com

1.4 Emergency telephone number: (Only available during office hours)

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the substance.

In accordance with Regulation (EU) No 1272/2008:

Acute Tox. 4 : Harmful if swallowed.

Carc. 2 : Suspected of causing cancer.

2.2 Label elements.

Labelling in accordance with Regulation (EU) No 1272/2008:

Pictograms:



Signal Word:

Warning

H statements:

H302 Harmful if swallowed.
H351 Suspected of causing cancer.

P statements:

P201 Obtain special instructions before use.
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.
P330 Rinse mouth.
P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor/if you feel unwell.
P308+P313 IF exposed or concerned: Get medical advice/attention.

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Contains:
5-Fluorouracil

2.3 Other hazards.

In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

3.1 Substances.

Chemical Name:	5-Fluorouracil
CAS No:	51-21-8
CE No:	200-085-6
Registration No:	N/D

3.2 Mixtures.

Not Applicable.

SECTION 4: FIRST AID MEASURES.

4.1 Description of first aid measures.

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

Inhalation.

If wearing contact lenses, remove them. If breathing is irregular or stops, perform artificial respiration. Do not administer anything orally. If unconscious, place them in a suitable position and seek medical assistance.

Eye contact.

If wearing contact lenses, remove them. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance.

Skin contact.

Remove contaminated clothing. Wash skin vigorously with water and soap or a suitable skin cleaner. **NEVER** use solvents or thinners.

Ingestion.

If accidentally ingested, seek immediate medical attention. Keep calm. **NEVER** induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed.

Harmful Product, prolonged exposure due to inhalation may cause anaesthetic effects and the need for immediate medical assistance.

4.3 Indication of any immediate medical attention and special treatment needed.

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

SECTION 5: FIREFIGHTING MEASURES.

5.1 Extinguishing media.

Recommended extinguishing methods.

Extinguisher powder or CO₂. In case of more serious fires, also alcohol-resistant foam and water spray. Do not use a direct stream of water to extinguish.

5.2 Special hazards arising from the substance.

Special risks.

Fire can cause thick, black smoke. As a result of thermal decomposition, dangerous products can form: carbon monoxide, carbon dioxide. Exposure to combustion or decomposition products can be harmful to your health.

5.3 Advice for firefighters.

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Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account. Prevent the products used to fight the fire from going into drains, sewers, or waterways.

Fire protection equipment.

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and gloves.

SECTION 6: ACCIDENTAL RELEASE MEASURES.

6.1 Personal precautions, protective equipment and emergency procedures.

For exposure control and individual protection measures, see section 8.

6.2 Environmental precautions.

Prevent the contamination of drains, surface or subterranean waters, and the ground.

6.3 Methods and material for containment and cleaning up.

The contaminated area should be immediately cleaned with an appropriate de-contaminator. Pour the decontaminator on the remains in an opened container and let it act various days until no further reaction is produced.

6.4 Reference to other sections.

For exposure control and individual protection measures, see section 8.

For later elimination of waste, follow the recommendations under section 13.

SECTION 7: HANDLING AND STORAGE.

7.1 Precautions for safe handling.

For personal protection, see section 8. Never use pressure to empty the containers. They are not pressure-resistant containers.

In the application area, smoking, eating, and drinking must be prohibited.

Follow legislation on occupational health and safety.

Keep the product in containers made of a material identical to the original.

7.2 Conditions for safe storage, including any incompatibilities.

Store according to local legislation. Observe indications on the label. Keep far away from ignition points. Keep away from oxidising agents and from highly acidic or alkaline materials. Do not smoke. Prevent the entry of non-authorized persons. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

The product is not affected by Directive 2012/18/EU (SEVESO III).

7.3 Specific end use(s).

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

8.1 Control parameters.

The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

8.2 Exposure controls.

Measures of a technical nature:

Provide adequate ventilation, which can be achieved by using good local exhaust-ventilation and a good general exhaust system.

Concentration:	100 %
Uses:	For manufacturing, processing, laboratory or repacking use only
Breathing protection:	
PPE:	Filter mask for protection against gases and particles.
Characteristics:	«CE» marking, category III. The mask must have a wide field of vision and an anatomically designed form in order to be sealed and watertight.
CEN standards:	EN 136, EN 140, EN 405
Maintenance:	Should not be stored in places exposed to high temperatures and damp environments before use. Special attention should be paid to the state of the inhalation and exhalation valves in the face adaptor.



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Observations:	Read carefully the manufacturer's instructions regarding the equipment's use and maintenance. Attach the necessary filters to the equipment according to the specific nature of the risk (Particles and aerosols: P1-P2-P3, Gases and vapours: A-B-E-K-AX), changing them as advised by the manufacturer.		
Filter Type needed:	A2		
Hand protection:			
PPE:	Protective gloves against chemicals.		
Characteristics:	«CE» marking, category III.		
CEN standards:	EN 374-1, En 374-2, EN 374-3, EN 420		
Maintenance:	Keep in a dry place, away from any sources of heat, and avoid exposure to sunlight as much as possible. Do not make any changes to the gloves that may alter their resistance, or apply paints, solvents or adhesives.		
Observations:	Gloves should be of the appropriate size and fit the user's hand well, not being too loose or too tight. Always use with clean, dry hands.		
Material:	PVC (polyvinyl chloride)	Breakthrough time (min.):	> 480
		Material thickness (mm):	0,35
Eye protection:			
PPE:	Protective goggles with built-in frame.		
Characteristics:	«CE» marking, category II. Eye protector with built-in frame for protection against dust, smoke, fog and vapour.		
CEN standards:	EN 165, EN 166, EN 167, EN 168		
Maintenance:	Visibility through lenses should be ideal. Therefore, these parts should be cleaned daily. Protectors should be disinfected periodically following the manufacturer's instructions.		
Observations:	Some signs of wear and tear include: yellow colouring of the lenses, superficial scratching of the lenses, scraping etc.		
Skin protection:			
PPE:	Anti-static protective clothing.		
Characteristics:	«CE» marking, category II. Protective clothing should not be too tight or loose in order not to obstruct the user's movements.		
CEN standards:	EN 340, EN 1149-1, EN 1149-2, EN 1149-3, EN 1149-5		
Maintenance:	In order to guarantee uniform protection, follow the washing and maintenance instructions provided by the manufacturer.		
Observations:	The protective clothing should offer a level of comfort in line with the level of protection provided in terms of the hazard against which it protects, bearing in mind environmental conditions, the user's level of activity and the expected time of use.		
PPE:	Anti-static safety footwear.		
Characteristics:	«CE» marking, category II.		
CEN standards:	EN ISO 13287, EN ISO 20344, EN ISO 20346		
Maintenance:	The footwear should be checked regularly		
Observations:	The level of comfort during use and acceptability are factors that are assessed very differently depending on the user. Therefore, it is advisable to try on different footwear models and, if possible, different widths.		

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Appearance: Solid
Colour: N.A./N.A.
Odour: N.A./N.A.
Odour threshold: N.A./N.A.
pH: 4,3-5,3 (1%, 20°C)
Melting point: 283 °C
Boiling Point: N.A./N.A.
Flash point: N.A./N.A.
Evaporation rate: N.A./N.A.
Inflammability (solid, gas): N.A./N.A.
Lower Explosive Limit: N.A./N.A.
Upper Explosive Limit: N.A./N.A.
Vapour pressure: N.A./N.A.
Vapour density: N.A./N.A.
Relative density: N.A./N.A.
Solubility: 12 g/l (20°C)

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Liposolubility: N.A./N.A.
Hydrosolubility: N.A./N.A.
Partition coefficient (n-octanol/water): -0,89 (log Pow)
Auto-ignition temperature: N.A./N.A.
Decomposition temperature: N.A./N.A.
Viscosity: N.A./N.A.
Explosive properties: N.A./N.A.
Oxidizing properties: N.A./N.A.
N.A./N.A. = Not Available/Not Applicable due to the nature of the product

9.2. Other information.

SECTION 10: STABILITY AND REACTIVITY.

10.1 Reactivity.

The product does not present hazards by their reactivity.

10.2 Chemical stability.

Unstable in contact with:

- Bases.

10.3 Possibility of hazardous reactions.

Neutralization can occur on contact with bases.

10.4 Conditions to avoid.

- Avoid contact with bases.

10.5 Incompatible materials.

Avoid the following materials:

- Bases.

10.6 Hazardous decomposition products.

Depending on conditions of use, can be generated the following products:

- Corrosive vapors or gases.

SECTION 11: TOXICOLOGICAL INFORMATION.

11.1 Information on toxicological effects.

Repeated or prolonged contact with the product can cause the elimination of oil from the skin, giving rise to non-allergic contact dermatitis and absorption of the product through the skin.

Splatters in the eyes can cause irritation and reversible damage.

Toxicological information.

Name	Acute toxicity			
	Type	Test	Kind	Value
5-Fluorouracil CAS No: 51-21-8 EC No: 200-085-6	Oral	DL50	Rat	230 mg/kg
	Dermal			
	Inhalation			

a) acute toxicity;

Product classified:

Acute toxicity (Oral), Category 4: Harmful if swallowed.

b) skin corrosion/irritation;

Not conclusive data for classification.

c) serious eye damage/irritation;

Not conclusive data for classification.

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d) respiratory or skin sensitisation;
Not conclusive data for classification.

e) germ cell mutagenicity;
Not conclusive data for classification.

f) carcinogenicity;
Product classified:
Carcinogen, Category 2: Suspected of causing cancer.

g) reproductive toxicity;
Not conclusive data for classification.

h) STOT-single exposure;
Not conclusive data for classification.

i) STOT-repeated exposure;
Not conclusive data for classification.

j) aspiration hazard;
Not conclusive data for classification.

SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.

Name	Ecotoxicity			
	Type	Test	Kind	Value
5-Fluorouracil CAS No: 51-21-8 EC No: 200-085-6	Fish	LC50	Oncorhynchus mykiss	>1 g/l (48 h)
	Aquatic invertebrates			
	Aquatic plants			

12.2 Persistence and degradability.

No information is available about persistence and degradability of the product.

12.3 Bioaccumulative potential.

Information about the bioaccumulation.

Name	Bioaccumulation			
	Log Pow	BCF	NOECs	Level
5-Fluorouracil N. CAS: 51-21-8 EC No: 200-085-6	-0,89	-	-	Very low

12.4 Mobility in soil.

No information is available about the mobility in soil.
The product must not be allowed to go into sewers or waterways.
Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment.

No information is available about the results of PBT and vPvB assessment of the product.

12.6 Other adverse effects.

No information is available about other adverse effects for the environment.

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SECTION 13 DISPOSAL CONSIDERATIONS.

13.1 Waste treatment methods.

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.

Follow the provisions of Directive 2008/98/EC regarding waste management.

SECTION 14: TRANSPORT INFORMATION.

Transport following ADR rules for road transport, RID rules for railway, ADN for inner waterways, IMDG for sea, and ICAO/IATA for air transport.

Land: Transport by road: ADR, Transport by rail: RID.

Transport documentation: Consignment note and written instructions

Sea: Transport by ship: IMDG.

Transport documentation: Bill of lading

Air: Transport by plane: ICAO/IATA.

Transport document: Airway bill.

14.1 UN number.

UN No: UN2811

14.2 UN proper shipping name.

Description: UN 2811, TOXIC SOLID, ORGANIC, N.O.S. (CONTAINS 5-FLUOROURACIL), 6.1, PG III, (E)

14.3 Transport hazard class(es).

Class(es): 6.1

14.4 Packing group.

Packing group: III

14.5 Environmental hazards.

Marine pollutant: No

14.6 Special precautions for user.

Labels: 6.1



Hazard number: 60

ADR LQ: 5 kg

Provisions concerning carriage in bulk ADR:

VC1 Carriage in bulk in sheeted vehicles, sheeted containers or sheeted bulk containers is permitted.

VC2 Carriage in bulk in closed vehicles, closed containers or closed bulk containers is permitted.

AP7 Carriage in bulk shall only be as a full load.

Transport by ship, FEm – Emergency sheets (F – Fire, S - Spills): F-A,S-A

Proceed in accordance with point 6.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code.

The product is not transported in bulk.

SECTION 15: REGULATORY INFORMATION.

15.1 Safety, health and environmental regulations/legislation specific for the substance.

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The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.

See annex I of the Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances and the Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals and its subsequent updates.

The product is not affected by Directive 2012/18/EU (SEVESO III).

The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

15.2 Chemical safety assessment.

There has been no evaluation a chemical safety assessment of the product.

SECTION 16: OTHER INFORMATION.

Classification codes:

Acute Tox. 4 [Oral] : Acute toxicity (Oral), Category 4
Carc. 2 : Carcinogen, Category 2

Sections changed compared with the previous version:

1,2,14,16

It is advisable to carry out basic training with regard to health and safety at work in order to handle this product correctly.

Labelling in accordance with Directive 67/548/EEC:

Symbols:



R Phrases:

R22 Harmful if swallowed.
R40 Limited evidence of a carcinogenic effect.

S Phrases:

S22 Do not breathe dust.
S24/25 Avoid contact with skin and eyes.
S36/37 Wear suitable protective clothing and gloves.

Contains:

5-Fluorouracil

Abbreviations and acronyms used:

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
BCF: Bioconcentration factor.
CEN: European Committee for Standardization.
EC50: Half maximal effective concentration.
PPE: Personal protection equipment.
IATA: International Air Transport Association.
IMDG: International Maritime Code for Dangerous Goods.
LC50: Lethal concentration, 50%.
LD50: Lethal dose, 50%.
Log Pow: Logarithm of the partition octanol-water.
NOEC: No observed effect concentration.
RID: Regulations Concerning the International Transport of Dangerous Goods by Rail.

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Key literature references and sources for data:

<http://eur-lex.europa.eu/homepage.html>

<http://echa.europa.eu/>

Regulation (EU) 2015/830.

Regulation (EC) No 1907/2006.

Regulation (EU) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.