

Creation Date 22-Sep-2009 Revision Date 29-Feb-2016 Revision Number 3

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

1.1. Product identification

Product Description: 5-Fluorouracil

Cat No.: 228440000; 228440010; 228440050; 228440250; 228441000

Synonyms 5-Fluoro-2,4(1H,3H)-pyrimidinedione

CAS-No 51-21-8
EC-No. 200-085-6
Molecular Formula C4 H3 F N2 O2

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

Recommended Use Laboratory chemicals.
Uses advised against No Information available

1.3. Details of the supplier of the safety data sheet

Company Acros Organics BVBA

Janssen Pharmaceuticalaan 3a

2440 Geel, Belgium

E-mail address begel.sdsdesk@thermofisher.com

1.4. Emergency telephone number

For information **US** call: 001-800-ACROS-01 / **Europe** call: +32 14 57 52 11 Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99 **CHEMTREC** Tel. No.**US**:001-800-424-9300 / **Europe**:001-703-527-3887

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

CLP Classification - Regulation (EC) No 1272/2008

Physical hazards

Based on available data, the classification criteria are not met

Health hazards

Category 3 Acute oral toxicity Acute dermal toxicity Category 4 Acute Inhalation Toxicity - Dusts and Mists Category 4 Category 2 Skin Corrosion/irritation Serious Eye Damage/Eye Irritation Category 2 Germ Cell Mutagenicity Category 2 Category 2 Reproductive Toxicity Specific target organ toxicity - (single exposure) Category 3

Environmental hazards

Based on available data, the classification criteria are not met

2.2. Label elements

5-Fluorouracil Revision Date 29-Feb-2016



Signal Word

Danger

Hazard Statements

H301 - Toxic if swallowed

H312 - Harmful in contact with skin

H332 - Harmful if inhaled

H315 - Causes skin irritation

H319 - Causes serious eye irritation

H335 - May cause respiratory irritation

H341 - Suspected of causing genetic defects

H361d - Suspected of damaging the unborn child

Precautionary Statements

P280 - Wear protective gloves/ protective clothing/ eye protection/ face protection

P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

P304 + P340 - IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing

P312 - Call a POISON CENTER or doctor/ physician if you feel unwell

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

2.3. Other hazards

No information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Component	CAS-No	EC-No.	Weight %	CLP Classification - Regulation (EC) No 1272/2008
Fluorouracil	51-21-8	EEC No. 200-085-6	99	STOT SE 3 (H335) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Muta. 2 (H341) Repr. 2 (H361d) Acute Tox. 3 (H301) Acute Tox. 4 (H312) Acute Tox. 4 (H332)

Full text of Hazard Statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

General Advice Show this safety data sheet to the doctor in attendance. Immediate medical attention is

required.

Eye Contact In the case of contact with eyes, rinse immediately with plenty of water and seek medical

5-Fluorouracil Revision Date 29-Feb-2016

advice.

Skin Contact Wash off immediately with plenty of water for at least 15 minutes. Immediate medical

attention is required.

Ingestion Do not induce vomiting. Call a physician or Poison Control Center immediately.

Inhalation Move to fresh air. If not breathing, give artificial respiration. Do not use mouth-to-mouth

method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Immediate medical attention is required.

Protection of First-aiders Ensure that medical personnel are aware of the material(s) involved, take precautions to

protect themselves and prevent spread of contamination.

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

None reasonably foreseeable.

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

Notes to Physician Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Extinguishing media which must not be used for safety reasons

No information available.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors.

Hazardous Combustion Products

Nitrogen oxides (NOx), Carbon monoxide (CO), Carbon dioxide (CO₂), Hydrogen fluoride.

5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear. Thermal decomposition can lead to release of irritating gases and vapors.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Use personal protective equipment. Avoid dust formation. Keep people away from and upwind of spill/leak. Evacuate personnel to safe areas.

6.2. Environmental precautions

Should not be released into the environment.

6.3. Methods and material for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation.

6.4. Reference to other sections

5-Fluorouracil Revision Date 29-Feb-2016

Refer to protective measures listed in Sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Wear personal protective equipment. Do not get in eyes, on skin, or on clothing. Avoid dust formation. Use only under a chemical fume hood. Do not breathe vapors/dust. Do not ingest.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing before re-use. Wash hands before breaks and at the end of workday.

7.2. Conditions for safe storage, including any incompatibilities

Keep in a dry, cool and well-ventilated place. Keep container tightly closed.

To maintain product quality. Keep away from direct sunlight.

7.3. Specific end use(s)

Use in laboratories

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies

Biological limit values

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Monitoring methods

BS EN 14042:2003 Title Identifier: Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.

MDHS14/3 General methods for sampling and gravimetric analysis of respirable and inhalable dust

Derived No Effect Level (DNEL)	No information available			
Route of exposure	Acute effects (local)	Acute effects	Chronic effects	Chronic effects
		(systemic)	(local)	(systemic)
Oral				
Dermal				
Inhalation				

Predicted No Effect Concentration No information available. (PNEC)

8.2. Exposure controls

5-Fluorouracil Revision Date 29-Feb-2016

Engineering Measures

Ensure adequate ventilation, especially in confined areas. Ensure that evewash stations and safety showers are close to the workstation location.

Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

Personal protective equipment

Eye Protection Goggles (European standard - EN 166)

Hand Protection Protective gloves

Glove material Nitrile rubber Neoprene Natural rubber PVC Breakthro See manu recomme		EU standard EN 374	Glove comments (minimum requirement)
---	--	-----------------------	---

Skin and body protection Long sleeved clothing

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

Respiratory Protection When workers are facing concentrations above the exposure limit they must use

appropriate certified respirators.

To protect the wearer, respiratory protective equipment must be the correct fit and be used

and maintained properly

Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits Large scale/emergency use

are exceeded or if irritation or other symptoms are experienced

Recommended Filter type: Particulates filter conforming to EN 143 Small scale/Laboratory use

Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure

limits are exceeded or if irritation or other symptoms are experienced.

Recommended half mask:- Particle filtering: EN149:2001 When RPE is used a face piece Fit Test should be conducted

Environmental exposure controls No information available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance White Powder Solid **Physical State**

Odor Odorless

No data available **Odor Threshold**

4.5-5.0 Hq 1 % aq. solution

278 - 282 °C / 532.4 - 539.6 °F **Melting Point/Range**

Softening Point No data available

190 - 200 °C / 374 - 392 °F **Boiling Point/Range** @ 0.1 mmHg

Flash Point No information available Method - No information available

Not applicable **Evaporation Rate** Solid

No information available Flammability (solid,gas)

No data available **Explosion Limits**

Vapor Pressure No information available

Vapor Density Not applicable Solid

Specific Gravity / Density No data available **Bulk Density** No data available **Water Solubility** 12.2 g/L (20°C)

5-Fluorouracil Revision Date 29-Feb-2016

Solubility in other solvents No information available

Partition Coefficient (n-octanol/water)

Autoignition TemperatureNot applicableDecomposition Temperature280 °C

Viscosity Not applicable Solid

Explosive PropertiesOxidizing Properties
No information available
No information available

9.2. Other information

Molecular Formula C4 H3 F N2 O2

Molecular Weight 130.08

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

None known, based on information available

10.2. Chemical stability

Light sensitive

10.3. Possibility of hazardous reactions

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous Reactions None under normal processing.

10.4. Conditions to avoid

Exposure to light. Incompatible products.

10.5. Incompatible materials

Strong oxidizing agents. Strong bases.

10.6. Hazardous decomposition products

Nitrogen oxides (NOx). Carbon monoxide (CO). Carbon dioxide (CO2). Hydrogen fluoride.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Product Information

(a) acute toxicity;

OralCategory 3DermalCategory 4InhalationCategory 4

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation		
Fluorouracil	LD50 = 230 mg/kg (Rat)				

(b) skin corrosion/irritation; Category 2

(c) serious eye damage/irritation; Category 2

(d) respiratory or skin sensitization;

Respiratory SkinNo data available
No data available

(e) germ cell mutagenicity; Category 2

Substances which cause concern for man owing to possible mutagenic effects but for which

5-Fluorouracil Revision Date 29-Feb-2016

the available information is not adequate for making a satisfactory assessment

(f) carcinogenicity; No data available

There are no known carcinogenic chemicals in this product

(g) reproductive toxicity;

Reproductive Effects Teratogenicity Category 2

May impair fertility. May cause harm to the unborn child. Teratogenic effects have occurred in experimental animals.

(h) STOT-single exposure; Category 3

Results / Target organs Respiratory system.

(i) STOT-repeated exposure; No data available

Target Organs None known.

(j) aspiration hazard; Not applicable

Solid

Other Adverse Effects The toxicological properties have not been fully investigated.

Symptoms / effects,both acute and No information available

delayed

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity effects Do not empty into drains.

12.2. Persistence and degradability

Persistence Soluble in water, Persistence is unlikely, based on information available.

12.3. Bioaccumulative potential Bioaccumulation is unlikely

12.4. Mobility in soil The product is water soluble, and may spread in water systems Will likely be mobile in the

environment due to its water solubility. Highly mobile in soils

12.5. Results of PBT and vPvB

assessment

No data available for assessment.

12.6. Other adverse effects

Endocrine Disruptor Information Persistent Organic Pollutant Ozone Depletion Potential This product does not contain any known or suspected endocrine disruptors

This product does not contain any known or suspected substance This product does not contain any known or suspected substance

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from Residues / Unused

Products

Waste is classified as hazardous. Dispose of in accordance with the European Directives

on waste and hazardous waste. Dispose of in accordance with local regulations.

Contaminated Packaging Dispose of this container to hazardous or special waste collection point.

European Waste Catalogue (EWC) According to the European Waste Catalogue, Waste Codes are not product specific, but

application specific.

Other Information Waste codes should be assigned by the user based on the application for which the product

was used. Do not empty into drains.

SECTION 14: TRANSPORT INFORMATION

5-Fluorouracil Revision Date 29-Feb-2016

IMDG/IMO

14.1. UN number UN2811

14.2. UN proper shipping name TOXIC SOLID, ORGANIC, N.O.S

14.3. Transport hazard class(es) 6.1 **14.4. Packing group** III

ADR

14.1. UN number UN2811

14.2. UN proper shipping name TOXIC SOLID, ORGANIC, N.O.S

14.3. Transport hazard class(es) 6.1 14.4. Packing group III

<u>IATA</u>

14.1. UN number UN2811

14.2. UN proper shipping name TOXIC SOLID, ORGANIC, N.O.S

14.3. Transport hazard class(es) 6.1 **14.4. Packing group** III

14.5. Environmental hazardsNo hazards identified

14.6. Special precautions for user No special precautions required

14.7. Transport in bulk according to Not applicable, packaged goods

Annex II of MARPOL73/78 and the

IBC Code

SECTION 15: REGULATORY INFORMATION

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

International Inventories		X = listed									
Component	EINECS	ELINCS	NLP	TSCA	DSL	NDSL	PICCS	ENCS	IECSC	AICS	KECL
Fluorouracil	200-085-6	-		Х	-	Х	Х	Х	-	Χ	Х

National Regulations

Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment.

Take note of Dir 94/33/EC on the protection of young people at work

Take note of Dir 92/85/EC on the protection of pregnant and breastfeeding women at work

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

15.2. Chemical safety assessment

A Chemical Safety Assessment/Report (CSA/CSR) has not been conducted

SECTION 16: OTHER INFORMATION

Full Text of H-/EUH-Statements Referred to Under Section 3

H301 - Toxic if swallowed

H312 - Harmful in contact with skin

H332 - Harmful if inhaled

H315 - Causes skin irritation

H319 - Causes serious eye irritation

H335 - May cause respiratory irritation

5-Fluorouracil Revision Date 29-Feb-2016

H341 - Suspected of causing genetic defects
H361d - Suspected of damaging the unborn child

Legend

CAS - Chemical Abstracts Service

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Commercial Chemical DSL/NDSL - Canadian Domestic Substances List/Non-Domestic

Substances/EU List of Notified Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances IECSC - Chinese Inventory of Existing Chemical Substances KECL - Korean Existing and Evaluated Chemical Substances Substances List

ENCS - Japanese Existing and New Chemical Substances
AICS - Australian Inventory of Chemical Substances
NZIOC - New Zealand Inventory of Chemicals

WEL - Workplace Exposure Limit

ACGIH - American Conference of Governmental Industrial Hygienists

DNEL - Derived No Effect Level

RPE - Respiratory Protective Equipment LC50 - Lethal Concentration 50% NOEC - No Observed Effect Concentration PBT - Persistent, Bioaccumulative, Toxic TWA - Time Weighted Average

IARC - International Agency for Research on Cancer

PNEC - Predicted No Effect Concentration

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50% **POW** - Partition coefficient Octanol:Water **vPvB** - very Persistent, very Bioaccumulative

VOC - Volatile Organic Compounds

ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road

IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code

OECD - Organisation for Economic Co-operation and Development

BCF - Bioconcentration factor

ICAO/IATA - International Civil Aviation Organization/International Air Transport Association

MARPOL - International Convention for the Prevention of Pollution from

Ships **ATE** - Acute Toxicity Estimate

Key literature references and sources for data

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

Training Advice

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Use of personal protective equipment, covering appropriate selection, compatibility, breakthrough thresholds, care, maintenance, fit and standards.

First aid for chemical exposure, including the use of eye wash and safety showers.

 Creation Date
 22-Sep-2009

 Revision Date
 29-Feb-2016

Revision Summary SDS sections updated, 2, 3, 7, 8, 11, 12.

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of Safety Data Sheet