



## FLUOROURACIL TOPICAL CREAM SAFETY DATA SHEET

NORTH AMERICA GHS

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

### 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

#### Product Identifier

**Product name:** Fluorouracil Topical Cream

**Synonyms:** Fluorouracil Topical Cream 5%

#### Intended Use of the Product

**Use of the substance/mixture:** Topical Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

#### Name, Address, and Telephone of the Responsible Party

##### Supplier:

Mylan N.V.  
Building 4, Trident Place  
Mosquito Way  
Hatfield,  
Hertfordshire  
AL10 9UL, United Kingdom  
+44 (0)1707 853000

[www.mylan.com](http://www.mylan.com)

##### Contact e-mail:

[SDScontact@Mylan.com](mailto:SDScontact@Mylan.com)

##### Emergency Telephone Number

**Emergency number**

: For Hazardous Materials Incident  
Spill, Leak, Fire, Exposure, or Accident  
Call CHEMTREC (24 Hours)  
Worldwide +1 703-741-5970

For reporting adverse health events, call:  
+1 877-446-3679

### 2. HAZARDS IDENTIFICATION

*Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.*

**Patients/Consumers:** Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

#### Classification of the Substance or Mixture

##### Classification (GHS-US)

Acute Tox. 4 (Oral) H302

Muta. 1B H340

Repr. 1B H360

#### Label Elements

##### GHS-US labeling

**Hazard pictograms (GHS-US)**



**Signal word (GHS-US)**

: Danger

**Hazard statements (GHS-US)**

: H302 - Harmful if swallowed  
H340 - May cause genetic defects  
H360 - May damage fertility or the unborn child

**Precautionary statements (GHS-US)** :

- P201 - Obtain special instructions before use.
- P202 - Do not handle until all safety precautions have been read and understood.
- P264 - Wash hands, forearms, and exposed areas thoroughly after handling.
- P270 - Do not eat, drink or smoke when using this product.
- P280 - Wear eye protection, protective clothing, protective gloves.
- P301+P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
- P308+P313 - If exposed or concerned: Get medical advice/attention.
- P330 - If swallowed, rinse mouth.
- P405 - Store locked up.
- P501 - Dispose of contents/container according to local, regional, national, territorial, provincial, and international regulations.

### **Other Hazards**

H402 - Aquatic Acute 3 - Harmful to aquatic life

P273 - Avoid release to the environment

### **Unknown acute toxicity (GHS-US)**

Not available

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### **Mixture**

<b>Name</b>	<b>Product identifier</b>	<b>% (w/w)</b>	<b>Classification (GHS-US)</b>
1,2-Propylene glycol	(CAS No) 57-55-6	7 - 13	Aquatic Acute 3, H402
Fluorouracil	(CAS No) 51-21-8	3 - 7	Acute Tox. 3 (Oral), H301 Acute Tox. 4 (Dermal), H312 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Muta. 1B, H340 Repr. 1B, H360 STOT SE 3, H335

Full text of H-phrases: see section 16

## 4. FIRST AID MEASURES

*This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited, however, the following guidance may be used as needed.*

### **Description of First Aid Measures**

**General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

**Inhalation:** The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

**Skin Contact:** Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

**Eye Contact:** The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

**Ingestion:** Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention.

### **Most Important Symptoms and Effects Both Acute and Delayed**

**General:** Please refer to the package insert for more detailed information. Harmful if swallowed.

**Inhalation:** None expected under normal conditions of use.

**Skin Contact:** Absorbed through the skin. May cause mild skin irritation.

**Eye Contact:** May cause eye irritation.

**Ingestion:** Potent pharmaceutical- ingestion is harmful and may have adverse effects.

**Chronic symptoms:** Repeated or prolonged skin contact may cause dermatitis and defatting. May damage fertility. May damage the unborn child. May cause heritable genetic damage.

### **Indication of Any Immediate Medical Attention and Special Treatment Needed**

If exposed or concerned, get medical advice and attention.

## 5. FIREFIGHTING MEASURES

### **Extinguishing Media**

**Suitable extinguishing media:** Not flammable. Use extinguishing media appropriate for surrounding fire.

**Unsuitable extinguishing media:** None known.

### **Special Hazards Arising From the Substance or Mixture**

**Fire hazard:** Not flammable.

**Explosion hazard:** Product is not explosive.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

**Advice for Firefighters**

**Precautionary measures fire:** Exercise caution when fighting any chemical fire.

**Firefighting instructions:** Use water spray or fog for cooling exposed containers.

**Protection during firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Hazardous Combustion Products:** Carbon oxides (CO, CO<sub>2</sub>).

**Other information:** Refer to Section 9 for flammability properties.

<b>6. ACCIDENTAL RELEASE MEASURES</b>
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*This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited, however, the following guidance may be used as needed.*

**Personal Precautions, Protective Equipment and Emergency Procedures**

**General measures:** Do not get in eyes, on skin, or on clothing.

**For Non-Emergency Personnel**

**Protective equipment:** Use appropriate personal protection equipment (PPE).

**Emergency procedures:** Evacuate unnecessary personnel.

**For Emergency Personnel**

**Protective equipment:** Equip cleanup crew with proper protection.

**Environmental Precautions**

Prevent entry to sewers and public waters.

**Methods and Material for Containment and Cleaning Up**

**Methods for cleaning up:** For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal.

**Reference to Other Sections**

See heading 8, Exposure Controls and Personal Protection.

<b>7. HANDLING AND STORAGE</b>
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**Precautions for Safe Handling**

**Patients/Consumers:** Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

**Hygiene measures:** This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

**Conditions for Safe Storage, Including Any Incompatibilities**

**Storage conditions:** Store in a dry, cool and well-ventilated place. Protect from heat and direct sunlight.

**Specific End Use(s)**

Topical Pharmaceutical. Refer to product insert for usage instructions and product information.

<b>8. EXPOSURE CONTROLS/PERSONAL PROTECTION</b>
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*This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited, however, the following guidance may be used as needed.*

**Control Parameters****1,2-Propylene glycol (57-55-6)**

Ontario	OEL TWA (mg/m <sup>3</sup> )	155 mg/m <sup>3</sup>
Ontario	OEL TWA (ppm)	50 ppm

**Exposure Controls**

**Appropriate engineering controls:** Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

**Personal protective equipment:** Not generally required. The use of personal protective equipment may be necessary as conditions warrant. Gloves. Safety glasses. Protective clothing.

**Hand protection:** Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.

**Eye protection:** In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

**Skin and body protection:** In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

**Respiratory protection:** When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

<b>9. PHYSICAL AND CHEMICAL PROPERTIES</b>
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**Information on Basic Physical and Chemical Properties**

**Physical state** : Liquid  
**Appearance** : Soft, white cream  
**Odor** : Odorless

Odor threshold	: Not available
pH	: Not available
Relative evaporation rate (butyl acetate=1)	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition Temperature	: Not available
Flammability (solid, gas)	: Not available
Lower flammable limit	: Not available
Upper flammable limit	: Not available
Vapor pressure	: Not available
Relative vapor density at 20 °C	: Not available
Relative density	: Not available
Specific gravity density	: Not available
Solubility	: Not available
Log Pow	: Not available
Log Kow	: Not available
Viscosity, kinematic	: Not available
Viscosity, dynamic	: Not available
Explosion data - sensitivity to mechanical impact	: Not available
Explosion data - sensitivity to static discharge	: Not available

## 10. STABILITY AND REACTIVITY

**Reactivity** Hazardous reactions will not occur under normal conditions.

**Chemical Stability** Stable under normal conditions.

**Possibility of Hazardous Reactions** Hazardous polymerization will not occur.

**Conditions to Avoid** Direct sunlight. Extremely high or low temperatures.

**Incompatible Materials** Strong oxidizers. Strong bases. Strong acids.

**Hazardous Decomposition Products** Decomposition will not occur under normal conditions.

## 11. TOXICOLOGICAL INFORMATION

### Information on Toxicological Effects - Product

**Acute toxicity:** Harmful if swallowed.

**LD50 and LC50 Data:** Not available

**Respiratory or skin sensitization:** Not classified

**Germ cell mutagenicity:** May cause genetic defects.

**Teratogenicity:** Not available

**Carcinogenicity:** Not classified

**Specific target organ toxicity (repeated exposure):** Not classified

**Reproductive toxicity:** May damage fertility or the unborn child.

**Specific target organ toxicity (single exposure):** Not classified

**Aspiration hazard:** Not classified

### Information on Toxicological Effects - Ingredient(s)

#### LD50 and LC50 Data

#### 1,2-Propylene glycol (57-55-6)

LD50 oral rat	20000 mg/kg
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LD50 dermal rabbit	20800 mg/kg
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#### Fluorouracil (51-21-8)

IARC group	3
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## 12. ECOLOGICAL INFORMATION

### Toxicity

#### 1,2-Propylene glycol (57-55-6)

LC50 fish 1	51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
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EC50 Daphnia 1	10000 mg/l (Exposure time: 24 h - Species: Daphnia magna)
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EC50 other aquatic organisms 1	19000 mg/l (Exposure time: 96 h - Species: Pseudokirchneriella subcapitata)
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LC50 fish 2	41 (41 - 47) mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
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EC50 Daphnia 2	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
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### Persistence and Degradability

Not available

### Bioaccumulative Potential

<b>1,2-Propylene glycol (57-55-6)</b>	
BCF fish 1	< 1
<b>13. DISPOSAL CONSIDERATIONS</b>	
<b>Sewage disposal recommendations:</b> Do not dispose of waste into sewer.	
<b>Waste disposal recommendations:</b> Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations.	
<b>14. TRANSPORT INFORMATION</b>	
<i>Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.</i>	
<b>In accordance with ICAO/IATA/DOT/TDG</b>	
Not regulated for transportation as hazardous material or dangerous goods.	
<b>15. REGULATORY INFORMATION</b>	
<b>US Federal Regulations</b>	
<b>Fluorouracil Topical Cream</b>	
<b>SARA Section 311/312 Hazard Classes</b>	Delayed (chronic) health hazard Immediate (acute) health hazard
<b>1,2-Propylene glycol (57-55-6)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>EPA TSCA Regulatory Flag</b>	Y2 - Y2 - indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule.
<b>Fluorouracil (51-21-8)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Listed on SARA Section 302 (Specific toxic chemical listings)	
Listed on SARA Section 313 (Specific toxic chemical listings)	
<b>SARA Section 302 Threshold Planning Quantity (TPQ)</b>	≤ 10000
<b>SARA Section 313 - Emission Reporting</b>	1.0 %
<b>US State Regulations</b>	
<b>Fluorouracil (51-21-8)</b>	
<b>U.S. - California - Proposition 65 - Developmental Toxicity</b>	WARNING: This product contains chemicals known to the State of California to cause birth defects.
<b>1,2-Propylene glycol (57-55-6)</b>	
U.S. - Minnesota - Hazardous Substance List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	
U.S. - Texas - Effects Screening Levels - Long Term	
U.S. - Texas - Effects Screening Levels - Short Term	
<b>Fluorouracil (51-21-8)</b>	
U.S. - Connecticut - Hazardous Air Pollutants - HLVs (30 min)	
U.S. - Connecticut - Hazardous Air Pollutants - HLVs (8 hr)	
U.S. - Delaware - Pollutant Discharge Requirements - Reportable Quantities	
U.S. - Massachusetts - Oil & Hazardous Material List - Groundwater Reportable Concentration - Reporting Category 1	
U.S. - Massachusetts - Oil & Hazardous Material List - Groundwater Reportable Concentration - Reporting Category 2	
U.S. - Massachusetts - Oil & Hazardous Material List - Reportable Quantity	
U.S. - Massachusetts - Oil & Hazardous Material List - Soil Reportable Concentration - Reporting Category 1	
U.S. - Massachusetts - Oil & Hazardous Material List - Soil Reportable Concentration - Reporting Category 2	
U.S. - Massachusetts - Right To Know List	
U.S. - Massachusetts - Toxics Use Reduction Act	
U.S. - New Jersey - Discharge Prevention - List of Hazardous Substances	
U.S. - New Jersey - Environmental Hazardous Substances List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - New Jersey - Special Health Hazards Substances List	
U.S. - New York - Reporting of Releases Part 597 - List of Hazardous Substances	
U.S. - Ohio - Extremely Hazardous Substances - Threshold Quantities	
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	
U.S. - Pennsylvania - RTK (Right to Know) List	

**Canadian Regulations**

<b>Fluorouracil Topical Cream</b>	
WHMIS Classification	Class D Division 2 Subdivision A - Very toxic material causing other toxic effects
	
<b>1,2-Propylene glycol (57-55-6)</b>	
Listed on the Canadian DSL (Domestic Substances List) inventory. Listed on the Canadian Ingredient Disclosure List	
WHMIS Classification	Uncontrolled product according to WHMIS classification criteria
<b>Fluorouracil (51-21-8)</b>	
Listed on Non-Domestic Substances List (NDSL)	
WHMIS Classification	Class D Division 2 Subdivision A - Very toxic material causing other toxic effects Class D Division 2 Subdivision B - Toxic material causing other toxic effects Class D Division 1 Subdivision B - Toxic material causing immediate and serious toxic effects

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all of the information required by CPR.

**16. OTHER INFORMATION**

<b>Indication of Changes</b>	: 9 November 2016
<b>Data sources</b>	: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.
<b>Other information</b>	: This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warnings included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

**GHS Full Text Phrases:**

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Muta. 1B	Germ cell mutagenicity Category 1B
Repr. 1B	Reproductive toxicity Category 1B
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H301	Toxic if swallowed
H302	Harmful 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
H402	Harmful to aquatic life

**Party Responsible For The Preparation Of This Document:**

Mylan Global Environmental, Health, and Safety Department  
Phone Number: 304-599-2595

*This SDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.*