

# MATERIAL SAFETY DATA SHEET

## SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME:	Fluorouracil Topical Cream USP, 5%	PRODUCT No.:	51672-4118-5 (5g tube), 51672-4118-2 (25g tube), 51672-4118-6 (40g tube)
CAS #:	[51-21-8]	FORMULA:	C <sub>4</sub> H <sub>3</sub> FN <sub>2</sub> O <sub>2</sub>
SUBSTANCE CLASS:	Antineoplastic	M.W.:	130.08

## SECTION 2: PHYSICAL/CHEMICAL DATA

BOILING POINT:	Unspecified
PHYSICAL STATE (liquid/solid/gas):	Cream
SPECIFIC GRAVITY (H <sub>2</sub> O=1):	Unspecified
EVAPORATION RATE (Butyl Acetate=1):	Unspecified
SOLUBILITY:	Sparingly soluble in water Slightly soluble in alcohol Practically insoluble in chloroform and in ether
APPEARANCE:	White smooth cream
ODOR DESCRIPTION:	Not Known.

## SECTION 3: FIRE AND EXPLOSION HAZARD DATA

FLASH POINT:	Unspecified
EXTINGUISHING MEDIA:	In case of fire, use waterspray, foam or dry chemical.
SPECIAL FIRE FIGHTING PROCEDURES:	In case of fire, use full firefighting turnout (bunker) gear and self and self-contained breathing apparatus (SCBA). Keep personnel upwind and away from fire. Move container from fire area if you can do it without risk. Do not scatter spilled material with high-pressure water streams. Dike fire-control water for later disposal.
UNUSUAL FIRE AND EXPLOSION HAZARDS:	N/A
HAZARDOUS COMBUSTION PRODUCTS:	Hydrogen fluoride, phosgene, CO, CO <sub>2</sub> and oxides of nitrogen and sulfur may be generated in a fire.

## SECTION 4: STABILITY AND REACTIVITY DATA

CHEMICAL STABILITY:	Stable
CONDITIONS TO AVOID:	In case of fire and/or explosion, do not breathe fumes.
INCOMPATIBILITY WITH OTHER MATERIALS:	Strong oxidizers, strong bases
HAZARDOUS DECOMPOSITION PRODUCTS:	On combustion, product is decomposed and toxic fumes are emitted: hydrogen fluoride, carbon, nitrogen and sulfur oxides and phosgene are possible.
HAZARDOUS POLYMERIZATION:	Hazardous polymerization has not been reported to occur under normal temperatures and pressures.

## SECTION 5: HEALTH HAZARD DATA

EMERGENCY OVERVIEW	<p><b>Eye:</b> Risk of serious damage to eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice</p> <p><b>Skin Contact:</b> Causes burns. After contact with skin, wash immediately with plenty soap and water.</p> <p><b>Skin Absorption:</b> Very toxic in contact with skin.</p> <p><b>Ingestion:</b> Very toxic if swallowed. If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label.</p> <p><b>Chronic Effects/Carcinogenicity:</b> Overexposure may cause reproductive and developmental disorders. Laboratory experiments have shown mutagenic effects. Target organs include the blood, heart, bone marrow, GI and immune systems. Consult package insert of Physician's Desk Reference for complete details.</p>
FIRST AID MEASURES	
Eye:	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Skin:	After contact with skin, wash immediately with plenty soap and water.
Ingestion:	If swallowed, do not induce vomiting: seek medical advice immediately and show the container or label.
Inhalation:	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

## SECTION 6: SPILL OR LEAK PROCEDURES

STEPS TO BE TAKEN IF MATERIAL IS RELEASED OR	Wear suitable protective clothing. Scoop cream into suitable container for disposal.
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**SPILLED:**

**WASTE DISPOSAL METHOD:** Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Observe all federal, state and local environmental regulations.

**SECTION 7: HANDLING AND STORAGE**

**HANDLING:** Avoid direct contact with this material. Wash thoroughly after handling to avoid accidental transfer of the compound to food that may be subsequently ingested. Keep hands away from face when handling compound. Do not get compound on skin or on clothing. Keep container closed when not in use. Avoid contact with eyes.

**STORAGE:** Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

**SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION**

**ENGINEERING CONTROLS:** Once packaged, none required. Manufacturing and packaging operations should be designed so as to offer no significant exposure to fluorouracil topical cream USP, 5%.

**PERSONAL PROTECTION:** **Eye Protection:** Avoid contact with eyes. Wear eye/face protection. Full-face protection required if potential exists for direct exposure to dusts or splashes during manufacturing or packaging operations. Once packaged, none required.

**Skin Protection:** Avoid contact with skin. For manufacturing and packaging operations, wear suitable protective clothing and wear suitable gloves. Once packaged, not required but impervious gloves recommended when diluting or administering this product. Once compounded as a cream, none required.

**RESPIRATORY PROTECTION :**

**SECTION 9: TOXICOLOGICAL INFORMATION**

Data for 5-fluorouracil (5-FU) active ingredient:

LD<sub>50</sub> Rat Oral 234 mg/kg

LD<sub>50</sub> Dogs Oral 39 mg/kg

**Toxicology Text**

5-FU is extremely destructive to tissue of the mucous membranes, respiratory tract, skin and eyes. 5-FU causes photosensitivity. Laboratory experiments indicate that 5-FU may cause mutagenic, developmental and /or reproductive effects. The most frequent adverse reactions to Fluorouracil occur locally and are often related to an extension of the pharmacological activity of the drug. These include burning, crusting, allergic contact dermatitis, erosions, erythema, hyperpigmentation, irritation, pain, photosensitivity, pruritus, scarring, rash, soreness and ulceration. Ulcerations, other local reactions, cases of miscarriage and a birth defect (ventricular septal defect) have been reported when Fluorouracil was applied to mucous membrane areas. Leukocytosis is the most frequent hematological side effect.

**SECTION 10: TRANSPORTATION INFORMATION**

Not a regulated material. Ship according to DOT and/ or IATA regulations.

## **SECTION 11: REGULATORY INFORMATION**

### **TSCA**

This material is a pharmaceutical agent and as such is regulated by the United States Food and Drug Administration (FDA).

### **CERCLA**

Not listed.

### **SARA Title III**

5-FU is listed on EPA Extremely Hazardous Substance .

### **SARA 313**

Not listed.

## **SECTION 12: CONTACT INFORMATION**

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## **DISCLAIMER**

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