

SAFETY DATA SHEET

1. Identification

Product identifier Fluorouracil Cream USP, 5%

Other means of identification

Product code NDC # 66530-249-40

Recommended use Topical cream used in the treatment of Actinic or Solar Keratosis

Recommended restrictions For Topical Use Only – Not for Ophthalmic, Oral or Intravaginal Use

Pharmaceutical products are exempt from GHS classifications such as OSHA HazCom 2012.

Manufacturer/Importer/Supplier/Distributor information

Supplier

Company Name Spear Dermatology Products Inc
Address 1250 Sussex Turnpike, Suite G
Randolph, NJ 07869
US
Telephone 973-895-6447
Emergency Telephone 866-773-2779

Manufacturer

Company Name CCI
Address 417 Richard Road
Rockledge, FL 32955
US
Telephone 321-636-0717

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Germ cell mutagenicity Category 1
Reproductive toxicity Category 1

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement May cause genetic defects. May damage fertility or the unborn child.

Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.

Response If exposed or concerned: Get medical advice/attention.

Storage Store at a controlled room temperature, 20°- 25° C (68°-77° F.) Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) None known.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Fluorouracil	51-21-8	5

Inactive Ingredient Chemical name	CAS number	%
Propylene glycol	57-55-6	
Polysorbate 60	9005-67-8	
Stearyl alcohol	112-92-5	
Methyl 4-hydroxybenzoate	99-76-3	
Petrolatum	8009-03-8	
Propylparaben	94-13-3	
Hexadecan-1-ol	36653-82-4	

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation. Symptoms may include severe abdominal pain, bloody diarrhea, vomiting, fever, and chills. Physical examination revealed stomatitis, erythematous skin rash, neutropenia, thrombocytopenia, inflammation of the esophagus, stomach, and small bowel.
Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Provide general supportive measures and treat symptomatically. Symptoms may be delayed.
General information	IF exposed or concerned: Get medical advice/attention. If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage**Precautions for safe handling**

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not taste or swallow. When using, do not eat, drink or smoke. Pregnant or breastfeeding women must not handle this product. Should be handled in closed systems, if possible. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Store locked up. Store in original tightly closed container. Store at 20 – 25 °C (68 - 77°F). Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection**Occupational exposure limits****US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)**

Inactive Ingredient	Type	Value	Form
Petrolatum (CAS 8009-03-8)	PEL	5 mg/m3	Mist.

US. ACGIH Threshold Limit Values

Inactive Ingredient	Type	Value	Form
Petrolatum (CAS 8009-03-8)	TWA	5 mg/m3	Inhalable fraction.

US. NIOSH: Pocket Guide to Chemical Hazards

Inactive Ingredient	Type	Value	Form
Petrolatum (CAS 8009-03-8)	STEL	10 mg/m3	Mist.
	TWA	5 mg/m3	Mist.

US. Workplace Environmental Exposure Level (WEEL) Guides

Inactive Ingredient	Type	Value	Form
Propylene glycol (CAS 57-55-6)	TWA	10 mg/m3	Aerosol.

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment**Eye/face protection**

No protection is ordinarily required under normal conditions of use.

Skin protection**Hand protection**

Wear appropriate chemical resistant gloves.

Other

Wear suitable protective clothing. Use of an impervious apron is recommended.

Respiratory protection

No personal respiratory protective equipment normally required.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties**Appearance****Physical state**

Liquid.

Form

Cream.

Color

Not available.

Odor

Not available.

Odor threshold

Not available.

pH

3 - 5

Melting point/freezing point

Not available.

Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Mostly
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	No adverse effects due to inhalation are expected.
Skin contact	No adverse effects due to skin contact are expected.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	May be harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics	Symptoms may include severe abdominal pain, bloody diarrhea, vomiting, fever, and chills. Physical examination revealed stomatitis, erythematous skin rash, neutropenia, thrombocytopenia, inflammation of the esophagus, stomach, and small bowel.
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Information on toxicological effects

Acute toxicity	May be harmful if swallowed.
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Components	Species	Test Results
Fluorouracil (CAS 51-21-8)		
Acute		
<i>Oral</i>		
LD50	Mouse	115 mg/kg
	Rat	230 mg/kg
<i>Other</i>		
LD50	Mouse	81 mg/kg

Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.
Respiratory or skin sensitization	
Respiratory sensitization	Not a respiratory sensitizer.
Skin sensitization	This product is not expected to cause skin sensitization.
Germ cell mutagenicity	May cause genetic defects.
Carcinogenicity	Long-term studies in animals to determine the carcinogenic potential have not been performed; however, no evidence of carcinogenicity was observed in several animal studies following oral or iv administration of the drug for up to 1 year.

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity

Fluorouracil (CAS 51-21-8)	3 Not classifiable as to carcinogenicity to humans.
Petrolatum (CAS 8009-03-8)	3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity	Pregnancy Category: X Can cause adverse reproductive effects - such as birth defects, miscarriages, or infertility. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. May damage fertility or the unborn child.
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not an aspiration hazard.

12. Ecological information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available.
Partition coefficient n-octanol / water (log Kow)	
Propylene glycol (CAS 57-55-6)	-0.92
Propylparaben (CAS 94-13-3)	3.04
Mobility in soil	No data available.
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT	Not regulated as dangerous goods.
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IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information**US federal regulations**

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. This material is not listed on the US TSCA 8(b) Inventory, therefore it may only be used for TSCA Exempt purposes such as R&D or Food, Drug or Cosmetic use.

In accordance with FDA regulation 21 U.S.C. § 360, the National Drug Code (NDC) is 66530-249-40.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**Hazard categories**

Immediate Hazard - No
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Chemical name	CAS number	Reportable quantity	Threshold planning quantity	Threshold planning quantity, lower value	Threshold planning quantity, upper value
Fluorouracil	51-21-8	500		500 lbs	10000 lbs

SARA 311/312 Hazardous chemical Yes

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.
Fluorouracil	51-21-8	5

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

Not listed.

US state regulations**US. Massachusetts RTK - Substance List**

Fluorouracil (CAS 51-21-8)
Petrolatum (CAS 8009-03-8)

US. New Jersey Worker and Community Right-to-Know Act

Fluorouracil (CAS 51-21-8)
Petrolatum (CAS 8009-03-8)
Propylene glycol (CAS 57-55-6)

US. Pennsylvania Worker and Community Right-to-Know Law

Fluorouracil (CAS 51-21-8)
Petrolatum (CAS 8009-03-8)
Propylene glycol (CAS 57-55-6)

US. Rhode Island RTK

Fluorouracil (CAS 51-21-8)

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Fluorouracil (CAS 51-21-8)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision**Issue date** 02-February-2015**Revision date** -**Version #** 01**HMIS® ratings** Health: 1*
Flammability: 0
Physical hazard: 0**NFPA ratings****Disclaimer**

The information contained herein is based upon data considered true and accurate. The manufacturer makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation, and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.