



## Safety Data Sheet

### Section 1: Identification

#### Product identifier

**Product Name** • **EFUDEX® Topical Cream, 5%(5-fluorouracil)**

**Product Code** • NDC 0187-3204-47

#### Relevant identified uses of the substance or mixture and uses advised against

**Recommended use** • Used to treat solar keratosis or actinic keratosis.

#### Details of the supplier of the safety data sheet

**Manufacturer** • Valeant Pharmaceuticals North America, LLC

2150 St. Elzear West  
Laval H7L 4A8  
Canada  
valeant.com

**Telephone (General)** • 1-800-321-4576

#### Emergency telephone number

**Manufacturer** • 1-800-535-5053 - US - Infotrac

**Manufacturer** • +1 352-323-3500 - International - Infotrac

### Section 2: Hazard Identification

#### UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

#### Classification of the substance or mixture

**UN GHS**

- Acute Toxicity Oral 3
- Carcinogenicity 1A
- Eye Irritation 2
- Reproductive Toxicity 1B
- Skin Irritation 2
- Specific Target Organ Toxicity Repeated Exposure 2

#### Label elements

**UN GHS**

#### DANGER



**Hazard statements** • Toxic if swallowed  
 Causes skin irritation  
 Causes serious eye irritation  
 May cause cancer.  
 May damage fertility or the unborn child.  
 May cause damage to organs through prolonged or repeated exposure.

## Precautionary statements

- Prevention**
- Do not handle until all safety precautions have been read and understood.
  - Do not breathe dust, fume, gas, mist, vapours and/or spray.
  - Wash thoroughly after handling.
  - Do not eat, drink or smoke when using this product.
  - Use personal protective equipment as required.

- Response**
- IF exposed or concerned: Get medical advice/attention.
  - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
  - IF ON SKIN: Wash with plenty of soap and water.
  - If skin irritation occurs: Get medical advice/attention.
  - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  - If eye irritation persists: Get medical advice/attention.
  - Take off contaminated clothing and wash before reuse.

- Storage/Disposal**
- KEEP OUT OF REACH OF CHILDREN
  - Keep tightly closed. Store at room temperature 20-25°C (68-77°F), to maintain product integrity. Use before date marked on carton and/or container.
  - Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

## Other hazards

- UN GHS**
- No data available

## Section 3 - Composition/Information on Ingredients

### Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

### Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Uracil, 5-fluoro-	CAS:51-21-8 EINECS:200-085-6	5%	UN GHS: NDA
Propylene glycol	CAS:57-55-6 EINECS:200-338-0	10% TO 15%	UN GHS: Skin Irrit. 3; Eye Irrit. 2B
Methyl paraben	CAS:99-76-3 EINECS:202-785-7	< 0.1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Propyl paraben	CAS:94-13-3 EINECS:202-307-7	< 0.1%	UN GHS: NDA
Water	CAS:7732-18-5 EINECS:231-791-2	< 50%	UN GHS: not classified
Polysorbate 60	CAS:9005-67-8	< 10%	UN GHS: NDA
Stearyl alcohol	CAS:112-92-5 EINECS:204-017-6	10% TO 20%	UN GHS: NDA
Petrolatum, White	CAS:8009-03-8 EINECS:232-373-2	20% TO 25%	UN GHS: not classified

The exact percentage of composition has been withheld as a trade secret.

## Section 4: First-Aid Measures

### Description of first aid measures

- Inhalation**
- IF INHALED: Call a POISON CENTER or doctor/physician if you feel unwell.
- Skin**
- IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse.
- Eye**
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
- Ingestion**
- Call a physician or poison control center immediately.

### Most important symptoms and effects, both acute and delayed

- Stomach pain, diarrhea, vomiting, fever, or chills may indicate an enzyme deficiency. Eliminate all contact with Carac and contact a physician immediately. Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects. Refer to Section 11 - Toxicological Information.

### Indication of any immediate medical attention and special treatment needed

## Section 5: Fire-Fighting Measures

### Extinguishing media

- Suitable Extinguishing Media**
- SMALL FIRES: Dry chemical, CO<sub>2</sub>, water spray or regular foam.
  - LARGE FIRE: Water spray, fog or regular foam.
- Unsuitable Extinguishing Media**
- No data available
- Firefighting Procedures**
- Keep unauthorized personnel away. Stay upwind. Ventilate closed spaces before entering.
  - LARGE FIRES: Move containers from fire area if you can do it without risk.

### Special hazards arising from the substance or mixture

- Unusual Fire and Explosion Hazards**
- No data available
- Hazardous Combustion Products**
- Carbon monoxide, carbon dioxide, hydrogen fluoride and nitrogen oxides.

### Advice for firefighters

- Structural firefighters' protective clothing provides limited protection in fire situations ONLY; it is not effective in spill situations where direct contact with the substance is possible. Wear positive pressure self-contained breathing apparatus (SCBA).

## Section 6 - Accidental Release Measures

### Personal precautions, protective equipment and emergency procedures

- Personal Precautions**
- Evacuate immediate area. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate enclosed areas.
- Emergency Procedures**
- Keep unauthorized personnel away. Stay upwind. Ventilate closed spaces before entering.

### Environmental precautions

- LARGE SPILLS: Prevent entry into waterways, sewers, basements or confined areas.

### Methods and material for containment and cleaning up

**Containment/Clean-up Measures**

- **SMALL SPILLS:** Take up with sand or other non-combustible absorbent material and place into containers for later disposal. Use appropriate Personal Protective Equipment (PPE)

**Section 7 - Handling and Storage**

**Precautions for safe handling**

**Handling**

- Avoid contact with eyes. Avoid prolonged or repeated exposure to skin or mucous membranes, and breathing mists/vapors. Use in a well ventilated area, away from all sources of ignition. Keep container closed. Wash thoroughly with soap and water after handling.

**Conditions for safe storage, including any incompatibilities**

**Storage**

- Keep tightly closed. Store at room temperature 20-25°C (68-77°F), to maintain product integrity. Use before date marked on carton and/or container. Ventilate enclosed areas. **KEEP OUT OF REACH OF CHILDREN**

**Section 8 - Exposure Controls/Personal Protection**

**Control parameters**

**Exposure Limits/Guidelines**

- Refer to the occupational exposure limits / guidelines for the individual product components.

**Exposure controls**

**Engineering Measures/Controls**

- Adequate ventilation systems as needed to control concentrations of airborne contaminants below applicable threshold limit values.

**Personal Protective Equipment**

**Respiratory**

- In case of insufficient ventilation, wear suitable respiratory equipment. Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or symptoms are experienced.

**Eye/Face**

- Wear safety glasses.

**Hands**

- Wear protective gloves .

**Skin/Body**

- Wear protective clothing

**Environmental Exposure Controls**

- Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

**Section 9 - Physical and Chemical Properties**

**Information on Physical and Chemical Properties**

<b>Material Description</b>			
Physical Form	Liquid Cream	Color	No data available. White .
Odor	Not relevant	Odor Threshold	Not relevant
<b>General Properties</b>			
Boiling Point	Not relevant	Melting Point	Not relevant
Decomposition Temperature	Not relevant	pH	5 to 7
Specific Gravity/Relative Density	Not relevant	Water Solubility	Mostly
Viscosity	Not relevant	Explosive Properties	Not relevant
<b>Volatility</b>			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		

### Flammability

Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Flame Extension	Not relevant
Autoignition	Not relevant	Flammability (solid, gas)	Not relevant
<b>Environmental</b>			
Octanol/Water Partition coefficient	Not relevant		

## Section 10: Stability and Reactivity

### Reactivity

- No dangerous reactions known.

### Chemical stability

- Stable when stored at room temperature 20-25°C (68-77°F). Use before expiration date marked on carton and/or container.

### Possibility of hazardous reactions

- No data available

### Conditions to avoid

- No data available

### Incompatible 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 are possible.

## Section 11 - Toxicological Information

### Information on toxicological effects

Components		
Uracil, 5-fluoro- (5%)	51-21-8	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 230 mg/kg; <b>Multi-dose Toxicity:</b> Ingestion/Oral-Rat TDLo • 2520 mg/kg 12 Week(s)-Intermittent; <b>Endocrine:Changes in spleen weight; Blood:Changes in bone marrow not included above; Related to Chronic Data:Changes in testicular weight;</b> <b>Reproductive:</b> Ingestion/Oral-Mouse TDLo • 245 mg/kg (7-13D preg); <b>Reproductive Effects:Effects on Fertility:Litter size (e.g., # fetuses per litter; measured before birth); Reproductive Effects:Effects on Embryo or Fetus:Fetal death;</b> Ingestion/Oral-Rat TDLo • 35 mg/kg (7-13D preg); <b>Reproductive Effects:Specific Developmental Abnormalities:Musculoskeletal system;</b> <b>Tumorigen / Carcinogen:</b> Intraperitoneal-Mouse TDLo • 1500 mg/kg 50 Week(s)-Intermittent; <b>Tumorigenic:Carcinogenic by RTECS criteria; Lungs, Thorax, or Respiration:Tumors; Blood:Tumors</b>
Propylene glycol (10% TO 15%)	57-55-6	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 20 g/kg; <b>Irritation:</b> Skin-Human • 500 mg 7 Day(s) • Mild irritation
Methyl paraben (< 0.1%)	99-76-3	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 2100 mg/kg
Propyl paraben (< 0.1%)	94-13-3	<b>Acute Toxicity:</b> Ingestion/Oral-Rabbit LDLo • 6 g/kg
Polysorbate 60 (< 10%)	9005-67-8	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • >60 mL/kg
Stearyl alcohol (10% TO 20%)	112-92-5	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • >2000 mg/kg; <b>Irritation:</b> Eye-Rabbit • 100 mg 24 Hour(s) • Mild irritation; Skin-Rabbit • 500 mg 24 Hour(s) • Mild irritation

GHS Properties	Classification
Acute toxicity	UN GHS • Acute Toxicity; Acute Toxicity - Dermal - Data lacking; Acute Toxicity - Inhalation - Classification criteria not met; Acute Toxicity - Oral 3
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Carcinogenicity 1A
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Skin Irritation 2
Skin sensitization	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Specific Target Organ Toxicity Repeated Exposure 2
STOT-SE	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Toxic to Reproduction 1B
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Eye Irritation 2

## Potential Health Effects

### Inhalation

#### Acute (Immediate)

- May affect the bone marrow. May affect the reproductive system. May cause cancer. May cause gastrointestinal disturbances including diarrhea, nausea, and vomiting. May cause severe irritation and eye damage.

#### Chronic (Delayed)

- Repeated and prolonged exposure may affect the bone marrow. Repeated and prolonged exposure may affect the reproductive system. Repeated and prolonged exposure may cause gastrointestinal disturbances including diarrhea, nausea, and vomiting. Repeated and prolonged exposure may cause mutagenic effects.

### Skin

#### Acute (Immediate)

- Causes skin irritation.

#### Chronic (Delayed)

- Repeated and prolonged exposure may cause irritation. Repeated or prolonged exposure to corrosive materials will cause dermatitis.

### Eye

#### Acute (Immediate)

- Causes serious eye irritation.

#### Chronic (Delayed)

- Repeated and prolonged exposure may be harmful.

### Ingestion

#### Acute (Immediate)

- May be harmful if swallowed.

#### Chronic (Delayed)

- No data available

### Carcinogenic Effects

- Adequate long-term studies in animals to evaluate carcinogenic potential have not been conducted with fluorouracil. Studies with the active ingredient of Carac, fluorouracil, have shown positive effects in in vitro and in vivo tests for mutagenicity and on impairment of fertility in in vivo animal studies.

Carcinogenic Effects		
	CAS	IARC
Uracil, 5-fluoro-	51-21-8	Group 3-Not Classifiable

### Reproductive Effects

- No adequate and well-controlled studies have been conducted in pregnant women with either topical or parenteral forms of fluorouracil. One birth defect (ventricular septal defect) and cases of miscarriage have been reported when fluorouracil was applied to mucous membrane areas. Multiple birth defects have been reported in the fetus of a patient treated with intravenous fluorouracil. Animal reproduction studies have not been conducted with Carac. Fluorouracil, the active ingredient, has been shown to be teratogenic in mice, rats, and hamsters when administered parenterally at doses greater than or equal to 10, 15, and 33 mg/kg/day, respectively, [4X, 11X and 20X,

respectively, the Maximum Recommended Human Dose (MRHD) based on body surface area (BSA)]. Fluorouracil has been shown to impair fertility after parenteral administration in rats.

## Section 12 - Ecological Information

### Toxicity

- This material has not been tested for environmental effects.

### Persistence and degradability

- No data available

### Bioaccumulative potential

- No data available

### Mobility in Soil

- No data available

### Other adverse effects

## Section 13 - Disposal Considerations

### Waste treatment methods

#### Product waste

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

#### Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

## Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	Not regulated	NDA	NDA	NDA
TDG	NDA	NDA	NDA	NDA	NDA
IMO/IMDG	NDA	Not regulated	NDA	NDA	NDA
ADN	NDA	NDA	NDA	NDA	NDA
ADR/RID	NDA	NDA	NDA	NDA	NDA
IATA/ICAO	NDA	Not regulated	NDA	NDA	NDA

### Special precautions for user

- No data available

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

- No data available

## Section 15 - Regulatory Information

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

#### SARA Hazard Classifications

- No data available

Inventory					
Component	CAS	Canada DSL	Canada NDSL	EU EINECS	TSCA
Propylene glycol	57-55-6	Yes	No	Yes	Yes
Stearyl alcohol	112-92-5	Yes	No	Yes	Yes
Methyl paraben	99-76-3	Yes	No	Yes	Yes
Propyl paraben	94-13-3	Yes	No	Yes	Yes
Petrolatum, White	8009-03-8	Yes	No	Yes	Yes
Polysorbate 60	9005-67-8	Yes	No	No	Yes
Uracil, 5-fluoro-	51-21-8	No	Yes	Yes	Yes
Water	7732-18-5	Yes	No	Yes	Yes

## Canada

### Labor

#### Canada - List of Prohibited and Restricted Cosmetic Ingredients (The Cosmetic Ingredient Hotlist)

• Methyl paraben	99-76-3	Not Listed
• Propyl paraben	94-13-3	Not Listed
• Stearyl alcohol	112-92-5	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Petrolatum, White	8009-03-8	Not Listed
• Polysorbate 60	9005-67-8	Not Listed
• Uracil, 5-fluoro-	51-21-8	Prohibited
• Water	7732-18-5	Not Listed

#### Canada - WHMIS - Classifications of Substances

• Methyl paraben	99-76-3	Not Listed
• Propyl paraben	94-13-3	Not Listed
• Stearyl alcohol	112-92-5	Uncontrolled product according to WHMIS classification criteria
• Propylene glycol	57-55-6	Uncontrolled product according to WHMIS classification criteria
• Petrolatum, White	8009-03-8	Uncontrolled product according to WHMIS classification criteria
• Polysorbate 60	9005-67-8	Not Listed
• Uracil, 5-fluoro-	51-21-8	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria

#### Canada - WHMIS - Ingredient Disclosure List

• Methyl paraben	99-76-3	Not Listed
• Propyl paraben	94-13-3	Not Listed
• Stearyl alcohol	112-92-5	Not Listed
• Propylene glycol	57-55-6	1 %
• Petrolatum, White	8009-03-8	Not Listed
• Polysorbate 60	9005-67-8	Not Listed
• Uracil, 5-fluoro-	51-21-8	Not Listed
• Water	7732-18-5	Not Listed



## United States

### Environment

#### U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs

• Methyl paraben	99-76-3	Not Listed
• Propyl paraben	94-13-3	Not Listed
• Stearyl alcohol	112-92-5	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Petrolatum, White	8009-03-8	Not Listed
• Polysorbate 60	9005-67-8	Not Listed
• Uracil, 5-fluoro-	51-21-8	500 lb EPCRA RQ
• Water	7732-18-5	Not Listed

#### U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs

• Methyl paraben	99-76-3	Not Listed
• Propyl paraben	94-13-3	Not Listed
• Stearyl alcohol	112-92-5	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Petrolatum, White	8009-03-8	Not Listed
• Polysorbate 60	9005-67-8	Not Listed
• Uracil, 5-fluoro-	51-21-8	500 lb lower TPQ; 10000 lb upper TPQ
• Water	7732-18-5	Not Listed

#### U.S. - CERCLA/SARA - Section 313 - Emission Reporting

• Methyl paraben	99-76-3	Not Listed
• Propyl paraben	94-13-3	Not Listed
• Stearyl alcohol	112-92-5	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Petrolatum, White	8009-03-8	Not Listed
• Polysorbate 60	9005-67-8	Not Listed
• Uracil, 5-fluoro-	51-21-8	1.0 % de minimis concentration
• Water	7732-18-5	Not Listed

## United States - California

### Environment

#### U.S. - California - Proposition 65 - Carcinogens List

• Methyl paraben	99-76-3	Not Listed
• Propyl paraben	94-13-3	Not Listed
• Stearyl alcohol	112-92-5	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Petrolatum, White	8009-03-8	Not Listed
• Polysorbate 60	9005-67-8	Not Listed
• Uracil, 5-fluoro-	51-21-8	Not Listed
• Water	7732-18-5	Not Listed

#### U.S. - California - Proposition 65 - Developmental Toxicity

• Methyl paraben	99-76-3	Not Listed
• Propyl paraben	94-13-3	Not Listed
• Stearyl alcohol	112-92-5	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Petrolatum, White	8009-03-8	Not Listed
• Polysorbate 60	9005-67-8	Not Listed

• Uracil, 5-fluoro-	51-21-8	developmental toxicity, initial date 1/1/89
• Water	7732-18-5	Not Listed
<b>U.S. - California - Proposition 65 - Reproductive Toxicity - Female</b>		
• Methyl paraben	99-76-3	Not Listed
• Propyl paraben	94-13-3	Not Listed
• Stearyl alcohol	112-92-5	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Petrolatum, White	8009-03-8	Not Listed
• Polysorbate 60	9005-67-8	Not Listed
• Uracil, 5-fluoro-	51-21-8	Not Listed
• Water	7732-18-5	Not Listed
<b>U.S. - California - Proposition 65 - Reproductive Toxicity - Male</b>		
• Methyl paraben	99-76-3	Not Listed
• Propyl paraben	94-13-3	Not Listed
• Stearyl alcohol	112-92-5	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Petrolatum, White	8009-03-8	Not Listed
• Polysorbate 60	9005-67-8	Not Listed
• Uracil, 5-fluoro-	51-21-8	Not Listed
• Water	7732-18-5	Not Listed

## Section 16 - Other Information

<b>Last Revision Date</b>	<ul style="list-style-type: none"> <li>• 26/March/2015</li> </ul>
<b>Preparation Date</b>	<ul style="list-style-type: none"> <li>• 26/March/2015</li> </ul>
<b>Disclaimer/Statement of Liability</b>	<ul style="list-style-type: none"> <li>• The above information and recommendations contained in the Safety Data Sheet have been compiled from sources believed to be accurate and reliable and to represent the most reasonable current opinion on the subject as of the date the SDS was prepared. No warranty, guaranty, or representation is made as to the correctness or sufficiency of the information. Such data are offered solely for consideration, investigation, and verification but do not purport to be all inclusive and should be used only as a guide. The user of this product must decide what safety measures are necessary to safely use this product, either alone or in combination with other products, and determine its environmental regulatory compliance obligations under any applicable federal or state laws.</li> </ul>