

Safety Data Sheet

Section 1: Identification

Product identifier

- Product Name** • **CaraC (5-fluorouracil cream)**
Product Code • NDC 0187-5200-30

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
Carbomer homopolymer 980	CAS:9007-20-9	< 1%	UN GHS: NDA
Glycerine	CAS:56-81-5 EINECS:200-289-5	< 10%	UN GHS: Skin Irrit. 3; Eye Irrit. 2B
Polyethylene glycol #400	CAS:25322-68-3	5% TO 15%	UN GHS: NDA
Uracil, 5-fluoro-	CAS:51-21-8 EINECS:200-085-6	0.5%	UN GHS: NDA
Polysorbate 80	CAS:9005-65-6	< 5%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Sorbitan, monooleate	CAS:1338-43-8 EINECS:215-665-4	< 5%	UN GHS: NDA
Oxtyl hydroxystearate	CAS:148718-35-8	5% TO 15%	UN GHS: NDA
Methyl gluceth-20	CAS:68239-42-9	< 10%	UN GHS: NDA
Stearic acid	CAS:57-11-4 EINECS:200-313-4	< 5%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Muta. 1; Carc. 1A; Repr. 1

5-Fluorouracil (16%) in acrylate polymer	NDA	< 5%	UN GHS: NDA
dimethicone in acrylate polymer	NDA	> 20%	UN GHS: NDA
Trolamine	CAS:102-71-6 EINECS:203-049-8	< 1%	UN GHS: Skin Irrit. 3; Eye Irrit. 2A; Skin Sens. 1B; Acute Tox. Oral 5; STOT SE 3: Resp. Irrit.
Propylene glycol	CAS:57-55-6 EINECS:200-338-0	< 1%	UN GHS: Skin Irrit. 3; Eye Irrit. 2B
Methyl paraben	CAS:99-76-3 EINECS:202-785-7	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Propyl paraben	CAS:94-13-3 EINECS:202-307-7	< 1%	UN GHS: NDA
Water	CAS:7732-18-5 EINECS:231-791-2	> 30%	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

- If Carac is accidentally ingested, induce vomiting and gastric lavage. 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, CO₂, 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

- No data available

Hazards

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 Limits/Guidelines				
	Result	ACGIH	Canada Quebec	OSHA
Trolamine (102-71-6)	TWAs	5 mg/m3 TWA	5 mg/m3 TWAEV	Not established
Glycerine (56-81-5)	TWAs	Not established	10 mg/m3 TWAEV (mist)	15 mg/m3 TWA (mist, total particulate); 5 mg/m3 TWA (mist, respirable fraction)

Exposure Limits Supplemental ACGIH

- Trolamine (102-71-6): TLV Basis - Critical Effects: (eye and skin irritation)

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

Material Description			
Physical Form	Liquid Cream	Color	No data available.
Odor	Not relevant	Odor Threshold	Not relevant
General Properties			
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		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not relevant		
Environmental			
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
Glycerine (< 10%)	56-81-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 12600 mg/kg; Behavioral:General anesthetic; Behavioral:Muscle weakness; Liver:Other changes; Irritation: Eye-Rabbit • 500 mg 24 Hour(s) • Mild irritation; Skin-Rabbit • 500 mg 24 Hour(s) • Mild irritation; Multi-dose Toxicity: Ingestion/Oral-Rat TDLo • 96 g/kg 30 Day(s)-Intermittent; Blood:Changes in leucocyte (WBC) count; Blood:Changes in serum composition (e.g., TP, bilirubin cholesterol); Biochemical:Enzyme inhibition, induction, or change in blood or tissue levels:True cholinesterase; Mutagen: Cytogenetic analysis • Ingestion/Oral-Rat • 1 g/kg; Reproductive: Ingestion/Oral-Rat TDLo • 100 mg/kg (1D male); Reproductive Effects:Effects on Fertility:Post-implantation mortality
Polyethylene glycol #400 (5% TO 15%)	25322-68-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 28 g/kg; Irritation: Eye-Rabbit • 500 mg • Mild irritation; Skin-Rabbit • 500 mg 24 Hour(s) • Mild irritation; Multi-dose Toxicity: Inhalation-Rat TCLo • 567 mg/m ³ 6 Hour(s) 2 Week(s)-Intermittent; Lungs, Thorax, or Respiration:Changes in lung weight; Nutritional and Gross Metabolic:Gross Metabolite Changes:Weight loss or decreased weight gain
Uracil, 5-fluoro- (0.5%)	51-21-8	Acute Toxicity: Ingestion/Oral-Rat LD50 • 230 mg/kg; Multi-dose Toxicity: Ingestion/Oral-Rat TDLo • 2520 mg/kg 12 Week(s)-Intermittent; Endocrine:Changes in spleen weight; Blood:Changes in bone marrow not included above; Related to Chronic Data:Changes in testicular weight; Reproductive: Ingestion/Oral-Mouse TDLo • 245 mg/kg (7-13D preg); Reproductive Effects:Effects on Fertility:Litter size (e.g., # fetuses per litter; measured before birth); Reproductive Effects:Effects on Embryo or Fetus:Fetal death; Ingestion/Oral-Rat TDLo • 35 mg/kg (7-13D preg); Reproductive Effects:Specific Developmental Abnormalities:Musculoskeletal system; Tumorigen / Carcinogen: Intraperitoneal-Mouse TDLo • 1500 mg/kg 50 Week(s)-Intermittent; Tumorigenic:Carcinogenic by RTECS criteria; Lungs, Thorax, or Respiration:Tumors; Blood:Tumors
Polysorbate 80 (< 5%)	9005-65-6	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 25 g/kg; Irritation: Eye-Rabbit • 150 mg • Mild irritation; Tumorigen / Carcinogen: Ingestion/Oral-Rat TDLo • 2163 g/kg 2 Year(s)-Continuous; Tumorigenic:Equivocal tumorigenic agent by RTECS criteria; Endocrine:Adrenal cortex tumors
Sorbitan, monooleate (< 5%)	1338-43-8	Acute Toxicity: Ingestion/Oral-Rat LD50 • >39.8 g/kg; Irritation: Skin-Rabbit • 250 µg • Mild irritation
Stearic acid (< 5%)	57-11-4	Acute Toxicity: Ingestion/Oral-Rat LDLo • 4640 mg/kg; Irritation: Skin-Human • 75 mg 3 Day(s)-Intermittent • Mild irritation; Multi-dose Toxicity: Skin-Rabbit LD50 • >5 g/kg; Tumorigen / Carcinogen: Implant-Mouse TDLo • 400 mg/kg; Tumorigenic:Equivocal tumorigenic agent by RTECS criteria; Kidney, Ureter, and Bladder:Tumors
		Acute Toxicity: Ingestion/Oral-Rabbit LD50 • 2200 mg/kg; Skin-Rabbit LD50 • >20 mL/kg; Irritation: Eye-Rabbit • 20 mg • Severe irritation; Skin-Human • 15 mg 3 Day(s)-Intermittent • Mild irritation; Skin-Rabbit • 560 mg 24 Hour(s) • Mild irritation; Multi-dose Toxicity: Inhalation-Mouse TCLo • 125 mg/m ³ 6 Hour(s) 3 Week(s)-Intermittent; Cardiac:Changes in heart weight; Blood:Pigmented or nucleated red blood cells; Blood:Changes in erythrocyte (RBC) count; Skin-Mouse TDLo • 459900 mg/kg 2 Year(s)-Intermittent; Vascular:Tumors; Skin and Appendages:After topical

Trolamine (< 1%)	102-71-6	<i>exposure:Primary irritation; Tumorigenic:Increased incidence of tumors in susceptible strains; Skin-Rat TDLo • 22750 mg/kg 13 Week(s)-Intermittent; Behavioral:Irritability; Skin and Appendages:After topical exposure:Primary irritation; Skin-Rat TDLo • 45990 mg/kg 2 Year(s)-Intermittent; Kidney, Ureter, and Bladder:Tumors; Skin and Appendages:After topical exposure:Primary irritation; Tumorigenic:Increased incidence of tumors in susceptible strains; Skin-Rat TDLo • 65 g/kg 13 Week(s)-Intermittent; Kidney, Ureter, and Bladder:Changes in kidney weight; Skin and Appendages:After systemic exposure:Dermatitis, other; Nutritional and Gross Metabolic:Gross Metabolite Changes:Weight loss or decreased weight gain; Tumorigen / Carcinogen: Skin-Rat TDLo • 129 g/kg 2 Year(s)-Intermittent; Tumorigenic:Equivocal tumorigenic agent by RTECS criteria; Kidney, Ureter, and Bladder:Tumors</i>
Propylene glycol (< 1%)	57-55-6	Acute Toxicity: Ingestion/Oral-Rat LD50 • 20 g/kg; Irritation: Skin-Human • 500 mg 7 Day(s) • Mild irritation
Methyl paraben (< 1%)	99-76-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2100 mg/kg
Propyl paraben (< 1%)	94-13-3	Acute Toxicity: Ingestion/Oral-Rabbit LDLo • 6 g/kg

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)**
- Chronic (Delayed)**
- Carcinogenic Effects**
 - May be harmful if swallowed.
 - No data available
 - 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	NTP
Uracil, 5-fluoro-	51-21-8	Group 3-Not Classifiable	Not Listed
Trolamine	102-71-6	Group 3-Not Classifiable	Evidence of Carcinogenicity
Polysorbate 80	9005-65-6	Not Listed	Evidence of Carcinogenicity

- 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
Methyl paraben	99-76-3	Yes	No	Yes	Yes
Propyl paraben	94-13-3	Yes	No	Yes	Yes
Carbomer homopolymer 980	9007-20-9	Yes	No	No	No
Glycerine	56-81-5	Yes	No	Yes	Yes
Methyl gluceth-20	68239-42-9	Yes	No	No	Yes
Oxtyl hydroxystearate	148718-35-8	No	No	No	No
Polyethylene glycol #400	25322-68-3	Yes	No	No	Yes
Sorbitan, monooleate	1338-43-8	Yes	No	Yes	Yes
Polysorbate 80	9005-65-6	Yes	No	No	Yes
Stearic acid	57-11-4	Yes	No	Yes	Yes
Trolamine	102-71-6	Yes	No	Yes	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)

• Stearic acid	57-11-4	Not Listed
• Methyl paraben	99-76-3	Not Listed
• Propyl paraben	94-13-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Carbomer homopolymer 980	9007-20-9	Not Listed
• Sorbitan, monooleate	1338-43-8	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Trolamine	102-71-6	Not Listed

• Glycerine	56-81-5	Restricted (Manufacturers of oral and leave-on products containing Glycerin must ensure the raw material used is within the specifications of an accepted pharmacopoeia with respect to Diethylene glycol (DEG) impurities (e.g. Glycerin Official Monograph in the most current edition of the USP))
• Uracil, 5-fluoro-	51-21-8	Prohibited
• Water	7732-18-5	Not Listed
• Polyethylene glycol #400	25322-68-3	Not Listed
• Oxtyl hydroxystearate	148718-35-8	Not Listed
• Methyl gluceth-20	68239-42-9	Not Listed

Canada - WHMIS - Classifications of Substances

• Stearic acid	57-11-4	Uncontrolled product according to WHMIS classification criteria
• Methyl paraben	99-76-3	Not Listed
• Propyl paraben	94-13-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Carbomer homopolymer 980	9007-20-9	Not Listed
• Sorbitan, monooleate	1338-43-8	Not Listed
• Propylene glycol	57-55-6	Uncontrolled product according to WHMIS classification criteria
• Trolamine	102-71-6	Uncontrolled product according to WHMIS classification criteria
• Glycerine	56-81-5	Uncontrolled product according to WHMIS classification criteria
• Uracil, 5-fluoro-	51-21-8	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
• Polyethylene glycol #400	25322-68-3	Not Listed
• Oxtyl hydroxystearate	148718-35-8	Not Listed
• Methyl gluceth-20	68239-42-9	Not Listed

Canada - WHMIS - Ingredient Disclosure List

• Stearic acid	57-11-4	1 %
• Methyl paraben	99-76-3	Not Listed
• Propyl paraben	94-13-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Carbomer homopolymer 980	9007-20-9	Not Listed
• Sorbitan, monooleate	1338-43-8	Not Listed
• Propylene glycol	57-55-6	1 %
• Trolamine	102-71-6	1 %
• Glycerine	56-81-5	Not Listed
• Uracil, 5-fluoro-	51-21-8	Not Listed
• Water	7732-18-5	Not Listed
• Polyethylene glycol #400	25322-68-3	Not Listed

• Oxytl hydroxystearate	148718-35-8	Not Listed
• Methyl gluceth-20	68239-42-9	Not Listed

United States

Environment

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

• Stearic acid	57-11-4	Not Listed
• Methyl paraben	99-76-3	Not Listed
• Propyl paraben	94-13-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Carbomer homopolymer 980	9007-20-9	Not Listed
• Sorbitan, monooleate	1338-43-8	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Trolamine	102-71-6	Not Listed
• Glycerine	56-81-5	Not Listed
• Uracil, 5-fluoro-	51-21-8	500 lb EPCRA RQ
• Water	7732-18-5	Not Listed
• Polyethylene glycol #400	25322-68-3	Not Listed
• Oxytl hydroxystearate	148718-35-8	Not Listed
• Methyl gluceth-20	68239-42-9	Not Listed

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

• Stearic acid	57-11-4	Not Listed
• Methyl paraben	99-76-3	Not Listed
• Propyl paraben	94-13-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Carbomer homopolymer 980	9007-20-9	Not Listed
• Sorbitan, monooleate	1338-43-8	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Trolamine	102-71-6	Not Listed
• Glycerine	56-81-5	Not Listed
• Uracil, 5-fluoro-	51-21-8	500 lb lower TPQ; 10000 lb upper TPQ
• Water	7732-18-5	Not Listed
• Polyethylene glycol #400	25322-68-3	Not Listed
• Oxytl hydroxystearate	148718-35-8	Not Listed
• Methyl gluceth-20	68239-42-9	Not Listed

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

• Stearic acid	57-11-4	Not Listed
• Methyl paraben	99-76-3	Not Listed
• Propyl paraben	94-13-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Carbomer homopolymer 980	9007-20-9	Not Listed
• Sorbitan, monooleate	1338-43-8	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Trolamine	102-71-6	Not Listed
• Glycerine	56-81-5	Not Listed
• Uracil, 5-fluoro-	51-21-8	1.0 % de minimis concentration
• Water	7732-18-5	Not Listed
• Polyethylene glycol #400	25322-68-3	Not Listed
• Oxytl hydroxystearate	148718-35-8	Not Listed
• Methyl gluceth-20	68239-42-9	Not Listed

United States - California

Environment

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

• Stearic acid	57-11-4	Not Listed
• Methyl paraben	99-76-3	Not Listed
• Propyl paraben	94-13-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Carbomer homopolymer 980	9007-20-9	Not Listed
• Sorbitan, monooleate	1338-43-8	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Trolamine	102-71-6	Not Listed
• Glycerine	56-81-5	Not Listed
• Uracil, 5-fluoro-	51-21-8	Not Listed
• Water	7732-18-5	Not Listed
• Polyethylene glycol #400	25322-68-3	Not Listed
• Oxtyl hydroxystearate	148718-35-8	Not Listed
• Methyl gluceth-20	68239-42-9	Not Listed

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

• Stearic acid	57-11-4	Not Listed
• Methyl paraben	99-76-3	Not Listed
• Propyl paraben	94-13-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Carbomer homopolymer 980	9007-20-9	Not Listed
• Sorbitan, monooleate	1338-43-8	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Trolamine	102-71-6	Not Listed
• Glycerine	56-81-5	Not Listed
• Uracil, 5-fluoro-	51-21-8	developmental toxicity, initial date 1/1/89
• Water	7732-18-5	Not Listed
• Polyethylene glycol #400	25322-68-3	Not Listed
• Oxtyl hydroxystearate	148718-35-8	Not Listed
• Methyl gluceth-20	68239-42-9	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Stearic acid	57-11-4	Not Listed
• Methyl paraben	99-76-3	Not Listed
• Propyl paraben	94-13-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Carbomer homopolymer 980	9007-20-9	Not Listed
• Sorbitan, monooleate	1338-43-8	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Trolamine	102-71-6	Not Listed
• Glycerine	56-81-5	Not Listed
• Uracil, 5-fluoro-	51-21-8	Not Listed
• Water	7732-18-5	Not Listed
• Polyethylene glycol #400	25322-68-3	Not Listed
• Oxtyl hydroxystearate	148718-35-8	Not Listed
• Methyl gluceth-20	68239-42-9	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Stearic acid	57-11-4	Not Listed
• Methyl paraben	99-76-3	Not Listed
• Propyl paraben	94-13-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Carbomer homopolymer 980	9007-20-9	Not Listed
• Sorbitan, monooleate	1338-43-8	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Trolamine	102-71-6	Not Listed
• Glycerine	56-81-5	Not Listed
• Uracil, 5-fluoro-	51-21-8	Not Listed
• Water	7732-18-5	Not Listed
• Polyethylene glycol #400	25322-68-3	Not Listed
• Oxytlyl hydroxystearate	148718-35-8	Not Listed
• Methyl gluceth-20	68239-42-9	Not Listed

Section 16 - Other Information

Last Revision Date

- 26/March/2015

Preparation Date

- 26/March/2015

Disclaimer/Statement of Liability

- 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.