

Safety Data Sheet



Section 1: Identification

Product identifier

- Product Name** • **Elidel Cream, 1%**
- Synonyms** • Pimecrolimus
- Product Code** • NDC 0187-5100-01; NDC 0187-5101-02; NDC 0187-5102-03
- Product Description** • Indicated for use in inflammatory skin diseases (atopic dermatitis, allergic contact dermatitis, irritant contact dermatitis, chronic plaque psoriasis)

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

- Recommended use** • Finished Pharmaceutical Product
- Restrictions on use** • Refer to the product insert and/or prescribing information for restrictions on use and contraindications. KEEP OUT OF REACH OF CHILDREN

Details of the supplier of the safety data sheet

- Manufacturer** • Valeant Pharmaceuticals North America, LLC

Bridgewater, NJ 08807
United States
valeant.com

- Telephone (General)** • 1-800-321-4567

Emergency telephone number

- Manufacturer** • 1-866-951-9833 - 3E's Emergency Response Hotline

Section 2: Hazard Identification

UN GHS

According to Third Revised Edition

Classification of the substance or mixture

- UN GHS**
- Skin Mild Irritation 3 - H316
 - Reproductive Toxicity 1B - H360
 - Acute Toxicity Dermal 4 - H312
 - Acute Toxicity Oral 4 - H302
 - Carcinogenicity 2 - H351
 - Eye Mild Irritation 2B - H320

Label elements

UN GHS

DANGER



- Hazard statements** • KEEP OUT OF REACH OF CHILDREN
H316 - Causes mild skin irritation

H302 - Harmful if swallowed
 H312 - Harmful in contact with skin
 H320 - Causes eye irritation
 H351 - Suspected of causing cancer.

Precautionary statements

- Prevention**
- P202 - Do not handle until all safety precautions have been read and understood.
 - P264 - Wash thoroughly after handling.
 - P233 - Keep container tightly closed.
 - P201 - Obtain special instructions before use.
 - P281 - Use personal protective equipment as required.
 - P264 - Wash : thoroughly after handling.
 - P280 - Wear protective gloves and eye/face protection , .
- Response**
- P308+P313 - IF exposed or concerned: Get medical advice/attention.
 - P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 - P337+P313 - If eye irritation persists: Get medical advice/attention.
 - P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
 - P332+P313 - If skin irritation occurs: Get medical advice/attention.
 - P301+P312 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician if you feel unwell.
 - P370+P378 - In case of fire: Use appropriate media water spray, foam, dry chemicals, or carbon dioxide for extinction.
 - P363 - Wash contaminated clothing before reuse.
- Storage/Disposal**
- KEEP OUT OF REACH OF CHILDREN
 - P501 - Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.
- Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.

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
Benzyl alcohol	CAS:100-51-6	< 5%	UN GHS: Acute Tox. Inhal. 4; Acute Tox. Oral 4
Cetyl alcohol	CAS:36653-82-4	< 5%	UN GHS: Eye Irrit. 2A; Skin Irrit. 2
Mono- and di-glycerides	CAS:67701-32-0	< 5%	UN GHS: NDA
Oleyl alcohol	CAS:143-28-2	10% TO 25%	UN GHS: NDA
Pimecrolimus	CAS:137071-32-0	1%	UN GHS: Skin Irrit. 2; Carcin. 2; Repro. Tox. 1B
Propylene glycol	CAS:57-55-6	< 10%	UN GHS: Eye Irrit. 2B; Skin Irrit. 3
Purified water	CAS:7732-18-5	> 50%	UN GHS: NDA
Sodium cetostearyl sulfate	CAS:68955-20-4	< 5%	UN GHS: Flam. Sol. 2; Skin Corr./Irrit. 2; Eye Dam./Irrit. 2
Stearyl alcohol	CAS:112-92-5	< 5%	UN GHS: NDA

Triglycerides, medium chain	CAS:73398-61-5	10% TO 25%	UN GHS: NDA
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See Section 11 for Toxicological Information.

Section 4: First-Aid Measures

Description of first aid measures

- Inhalation**
- Normal use of this product does not pose an inhalation hazard. However, should respiratory tract irritation develop, discontinue use and remove to fresh air. Get medical attention if irritation or other symptoms develop or persist.
- Skin**
- Wash skin with soap and water. If skin irritation occurs: Get medical advice/attention. Wash clothing separately 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 swallowed, wash out mouth with water provided person is conscious. Seek medical attention.

Most important symptoms and effects, both acute and delayed

- No data available

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**
- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

Special hazards arising from the substance or mixture

- Unusual Fire and Explosion Hazards**
- No data available
- Hazardous Combustion Products**
- No data available

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.

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

- Personal Precautions**
- Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Evacuate immediate area. Ventilate enclosed areas.
- Emergency Procedures**
- ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Keep unauthorized personnel away. Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for

disposal.

Environmental precautions

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

Methods and material for containment and cleaning up

Containment/Clean-up Measures

- Isolate hazard area. Prevent from entering drains and sewers. Cover with vermiculite or other suitable inert material, pick up and place in closed containers. Transport outdoors and hold for waste disposal. Ventilate area and wash spill site after material pickup is complete. Refer to Section 13 for appropriate disposal procedures.

Reference to other sections

- Refer to Section 8 - Exposure Controls/Personal Protection and Section 13 - Disposal Considerations.

Section 7 - Handling and Storage

Precautions for safe handling

Handling

- Keep away from fire - No Smoking. Keep away from heat and sparks.

Conditions for safe storage, including any incompatibilities

Storage

- Keep tightly closed and store in upright position. Store at room temperature 15-30C (59-86F). Solution is flammable, keep away from heat or flame. 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 Supplemental

ACGIH

- Sodium hydroxide (1310-73-2): **TLV Basis - Critical Effects:** (eye, skin and upper respiratory tract irritation)

Exposure controls

Engineering

Measures/Controls

- NO SPECIAL CONTROLS ARE REQUIRED UNDER CONDITIONS OF INTENDED USE. Local exhaust ventilation should be provided when handling bulk product.

Personal Protective Equipment

Pictograms



Respiratory

- Where risk assessment shows that air-purifying respirators are appropriate, a NIOSH (US) or CEN (EU) -certified air-purifying respirator equipped with HEPA and organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

Eye/Face

- Avoid contact with the eye. No special controls or personal protection required under conditions of intended use. In the event of a spill, appropriate eye protection should be worn.

Hands

- Wear protective gloves .

Skin/Body

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

General Industrial Hygiene

- Handle in accordance with good industrial hygiene and safety practice. Do not eat,

Considerations

drink or smoke during work. Avoid contact with skin, eyes or clothing. Wash thoroughly after handling.

Environmental Exposure Controls

- No special controls are required under conditions of intended use. In the event of a bulk spill, prevent spilled material from entering storm sewers or drains, waterways, and contact with the soil.

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid Cream	Appearance/Description	Not relevant
Color	White to off-white.	Odor	Not relevant
General Properties			
Boiling Point	Not relevant	Decomposition Temperature	Not relevant
Heat of Decomposition	Not relevant	pH	Not relevant
Specific Gravity/Relative Density	Not relevant	Density	Not relevant
Water Solubility	insoluble	Solvent Solubility	methanol; ethanol
Volatility			
Vapor Pressure	No data available	Vapor Density	No data available
Evaporation Rate	No data available		
Flammability			
Flash Point	No data available	UEL	No data available
LEL	No data available	Flammability (solid, gas)	Not relevant
Environmental			
Half-Life	Not relevant	Octanol/Water Partition coefficient	Not relevant
Coefficient of water/oil distribution	Not relevant	Bioaccumulation Factor	Not relevant
Bioconcentration Factor	Not relevant	Biochemical Oxygen Demand BOD/BOD5	Not relevant
Chemical Oxygen Demand	Not relevant	Persistence	Not relevant
Degradation	Not relevant		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and humidities.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Heat, direct sunlight.

Incompatible materials

- No data available

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information

Information on toxicological effects

Other Material Information • Toxicological information refers to raw materials only. Concentrations and toxicological effects may be substantially reduced in the product.

	CAS	
Elidel Cream, 1%		Reproductive: Skin-Rat, adult female • 10 mg/kg 6 Hour(s) 15 Day(s) • Known to cause reproductive effects in humans • Known to cause fertility effects in humans • Known to cause developmental toxicity in humans; Tumorigen / Carcinogen: Ingestion/Oral-Mouse • 45 mg/kg • Suspected human carcinogen • Comments: lymphoma; Skin-Rat • 2 mg/kg • Suspected human carcinogen • Comments: follicular cell adenoma of the thyroid with prolonged exposure
Components		
Cetyl alcohol (< 5%)	36653-82-4	Acute Toxicity: Ingestion/Oral-Rat LD50 • >2000 mg/kg; Irritation: Eye-Rabbit • 82 mg • Mild irritation; Skin-Human • 75 mg 3 Day(s)-Intermittent • Mild irritation; Multi-dose Toxicity: Ingestion/Oral-Dog TDLo • 91 g/kg 13 Week(s)-Intermittent; <i>Behavioral:</i> Tremor; <i>Behavioral:Ataxia;</i> <i>Related to Chronic Data:Death in the Other Multiple Dose data type field;</i> Skin-Human TDLo • 3214.3 mg/kg 3 Day(s)-Intermittent; <i>Skin and Appendages:After topical exposure:Primary irritation</i>
Stearyl alcohol (< 5%)	112-92-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • >2000 mg/kg; Skin-Mammal LD50 • >2000 mg/kg; Irritation: Eye-Rabbit • 100 mg 24 Hour(s) • Mild irritation; Skin-Rabbit • 500 mg 24 Hour(s) • Mild irritation
Oleyl alcohol (10% TO 25%)	143-28-2	Irritation: Eye-Rabbit • 100 mg 24 Hour(s) • Mild irritation; Skin-Human • 75 mg 3 Day(s)-Intermittent • Mild irritation
Propylene glycol (< 10%)	57-55-6	Acute Toxicity: Ingestion/Oral-Rat LD50 • 20 g/kg; Skin-Rabbit LD50 • 20800 mg/kg; Skin-Human TCLo • 10 pph; <i>Skin and Appendages:After topical exposure:Dermatitis, allergic;</i> Irritation: Eye-Rabbit • 100 mg • Mild irritation; Skin-Human • 104 mg 3 Day(s)-Intermittent • Moderate irritation; Multi-dose Toxicity: Ingestion/Oral-Rat TDLo • 84 mL/kg 30 Day(s)-Continuous; <i>Blood:Changes in serum composition (e.g., TP, bilirubin cholesterol); Blood:Changes in leucocyte (WBC) count;</i> <i>Biochemical:Enzyme inhibition, induction, or change in blood or tissue levels:Multiple enzyme effects;</i> Skin-Human TDLo • 4.5 mg/kg 3 Day(s)-Intermittent; <i>Skin and Appendages:After topical exposure:Primary irritation</i>
Benzyl alcohol (< 5%)	100-51-6	Acute Toxicity: Ingestion/Oral-Rat LD50 • 1230 mg/kg; <i>Behavioral:Somnolence (general depressed activity); Behavioral:Excitement; Behavioral:Coma;</i> Skin-Rabbit LD50 • 2000 mg/kg; Irritation: Skin-Man • 16 mg 48 Hour(s) • Mild irritation; Skin-Rabbit • 100 mg 24 Hour(s) • Moderate irritation; Multi-dose Toxicity: Ingestion/Oral-Rat TDLo • 13 g/kg 13 Week(s)-Intermittent; <i>Brain and Coverings:Other degenerative changes;</i> <i>Related to Chronic Data:Death in the Other Multiple Dose data type field;</i> Reproductive: Ingestion/Oral-Mouse TDLo • 6 g/kg (6-13D preg); <i>Reproductive Effects:Effects on Newborn:Growth statistics (e.g., reduced weight gain)</i>
Pimecrolimus (1%)	137071-32-0	Irritation: Skin-Human • .6 % 3 Week(s) • Mild irritation; Multi-dose Toxicity: Ingestion/Oral-Human TDLo • 24 mg/kg 12 Week(s)-Intermittent; <i>Gastrointestinal:Hypermotility, diarrhea; Gastrointestinal:Nausea or vomiting;</i> <i>Behavioral:Headache;</i> Ingestion/Oral-Rat TDLo • 840 mg/kg 4 Week(s)-Intermittent; <i>Blood:Changes in serum composition (e.g., TP, bilirubin cholesterol); Immunological Including Allergic:Decrease in humoral immune response</i>

GHS Properties	Classification
Acute toxicity	UN GHS • Acute Toxicity - Dermal 4; Acute Toxicity - Inhalation - Classification criteria not met; Acute Toxicity - Oral 4
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Carcinogenicity 2
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Skin Mild Irritation 3
Skin sensitization	UN GHS • Classification criteria not met

STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Classification criteria not met
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Eye Mild Irritation 2B

Potential Health Effects

Inhalation

- Acute (Immediate)**
 - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
 - No data available.

Skin

- Acute (Immediate)**
 - Causes mild skin irritation.
- Chronic (Delayed)**
 - Causes mild skin irritation.

Eye

- Acute (Immediate)**
 - Causes serious eye irritation.
- Chronic (Delayed)**
 - No data available.

Ingestion

- Acute (Immediate)**
 - May be harmful if swallowed.
- Chronic (Delayed)**
 - No data available.

Other information

- Although a causal relationship has not been established, rare cases of malignancy (e.g., skin and lymphoma) have been reported in patients treated with topical calcineurin inhibitors, including ELIDEL Cream, 1%. Continuous long-term use of topical calcineurin inhibitors, including ELIDEL Cream, 1%, in any age group should be avoided, and application limited to areas of involvement with atopic dermatitis.

Section 12 - Ecological Information

Toxicity

- No data available

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

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

Packaging waste

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

international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	NDA	NDA	NDA	NDA
TDG	NDA	NDA	NDA	NDA	NDA
IMO/IMDG	NDA	NDA	NDA	NDA	NDA
ADN	NDA	NDA	NDA	NDA	NDA
ADR/RID	NDA	NDA	NDA	NDA	NDA
IATA/ICAO	NDA	NDA	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**Other information**

- Limited quantity ground shipment exception applies to retail packages under 1 liter in volume with an outer packaging gross weight less than 30 kg. Lower limits may exist for air shipments. Check applicable regulations.

Section 15 - Regulatory Information**Safety, health and environmental regulations/legislation specific for the substance or mixture****SARA Hazard Classifications** • Acute

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Propylene glycol	57-55-6	Yes	Yes	Yes
Pimecrolimus	137071-32-0	No	No	No
Cetyl alcohol	36653-82-4	Yes	Yes	Yes
Stearyl alcohol	112-92-5	Yes	Yes	Yes
Oleyl alcohol	143-28-2	Yes	Yes	Yes
Benzyl alcohol	100-51-6	Yes	Yes	Yes
Citric acid	77-92-9	Yes	Yes	Yes
Mono- and di-glycerides	67701-32-0	No	Yes	Yes
Triglycerides, medium chain	73398-61-5	Yes	Yes	Yes
Sodium cetostearyl sulfate	68955-20-4	Yes	Yes	Yes
Sodium hydroxide	1310-73-2	Yes	Yes	Yes
Purified water	7732-18-5	Yes	Yes	Yes

Canada

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

• Stearyl alcohol	112-92-5	Not Listed
• Cetyl alcohol	36653-82-4	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Sodium hydroxide	1310-73-2	Not Listed
• Benzyl alcohol	100-51-6	Not Listed
		Restricted (Permitted at total concentrations $\leq 10\%$, with a pH ≥ 3.5 . Preparations containing higher concentrations of AHAs may be permitted for professional use if the manufacturer provides Health Canada with evidence of their safety, pH levels, and the directions for use. The inner and outer labels of all leave-on skin products containing AHAs at concentrations $\geq 3\%$ shall carry cautionary statements to the effect: "Use only as directed", "Avoid contact with the eyes", "If irritation persists, discontinue use and consult a physician", "It is recommended that prior to exposure to the sun, users cover areas where AHAs have been applied, with sunscreen", "Contact of the product with the skin must be of limited frequency and duration." Preparations intended to be diluted in bath water may contain levels of Citric acid $> 10\%$., listed under .alpha.-Hydroxy acids)
• Citric acid	77-92-9	
• Triglycerides, medium chain	73398-61-5	Not Listed
• Oleyl alcohol	143-28-2	Not Listed
• Mono- and di-glycerides	67701-32-0	Not Listed
• Purified water	7732-18-5	Not Listed
• Pimecrolimus	137071-32-0	Not Listed
• Sodium cetostearyl sulfate	68955-20-4	Not Listed

Canada - WHMIS - Classifications of Substances

• Stearyl alcohol	112-92-5	Uncontrolled product according to WHMIS classification criteria
• Cetyl alcohol	36653-82-4	D2B
• Propylene glycol	57-55-6	Uncontrolled product according to WHMIS classification criteria
• Sodium hydroxide	1310-73-2	E (including 0.04% in aqueous solution, 0.08%, 0.4% in aqueous solution, 2%, 2.5%, 4% in aqueous solution, 5%, 10%, 16%, 20%, 40%, 50% in aqueous solution, 8.7N)

• Benzyl alcohol	100-51-6	B3, D2B
• Citric acid	77-92-9	E (including 40%)
• Triglycerides, medium chain	73398-61-5	Not Listed
• Oleyl alcohol	143-28-2	Not Listed
• Mono- and di-glycerides	67701-32-0	Not Listed
• Purified water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
• Pimecrolimus	137071-32-0	Not Listed
• Sodium cetostearyl sulfate	68955-20-4	Not Listed

Canada - WHMIS - Ingredient Disclosure List

• Stearyl alcohol	112-92-5	Not Listed
• Cetyl alcohol	36653-82-4	Not Listed
• Propylene glycol	57-55-6	1 %
• Sodium hydroxide	1310-73-2	1 %
• Benzyl alcohol	100-51-6	1 %
• Citric acid	77-92-9	1 %
• Triglycerides, medium chain	73398-61-5	Not Listed
• Oleyl alcohol	143-28-2	Not Listed
• Mono- and di-glycerides	67701-32-0	Not Listed
• Purified water	7732-18-5	Not Listed
• Pimecrolimus	137071-32-0	Not Listed
• Sodium cetostearyl sulfate	68955-20-4	Not Listed

Europe

Other

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification

• Stearyl alcohol	112-92-5	Not Listed
• Cetyl alcohol	36653-82-4	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Sodium hydroxide	1310-73-2	C; R35
• Benzyl alcohol	100-51-6	Xn; R20/22
• Citric acid	77-92-9	Not Listed
• Triglycerides, medium chain	73398-61-5	Not Listed
• Oleyl alcohol	143-28-2	Not Listed
• Mono- and di-glycerides	67701-32-0	Not Listed
• Purified water	7732-18-5	Not Listed
• Pimecrolimus	137071-32-0	Not Listed
• Sodium cetostearyl sulfate	68955-20-4	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling

• Stearyl alcohol	112-92-5	Not Listed
• Cetyl alcohol	36653-82-4	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Sodium hydroxide	1310-73-2	C R:35 S:(1/2)-26-37/39-45
• Benzyl alcohol	100-51-6	Xn R:20/22 S:(2)-26
• Citric acid	77-92-9	Not Listed
• Triglycerides, medium chain	73398-61-5	Not Listed
• Oleyl alcohol	143-28-2	Not Listed
• Mono- and di-glycerides	67701-32-0	Not Listed
• Purified water	7732-18-5	Not Listed
• Pimecrolimus	137071-32-0	Not Listed

• Sodium cetostearyl sulfate	68955-20-4	Not Listed
EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases		
• Stearyl alcohol	112-92-5	Not Listed
• Cetyl alcohol	36653-82-4	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Sodium hydroxide	1310-73-2	S:(1/2)-26-37/39-45
• Benzyl alcohol	100-51-6	S:(2)-26
• Citric acid	77-92-9	Not Listed
• Triglycerides, medium chain	73398-61-5	Not Listed
• Oleyl alcohol	143-28-2	Not Listed
• Mono- and di-glycerides	67701-32-0	Not Listed
• Purified water	7732-18-5	Not Listed
• Pimecrolimus	137071-32-0	Not Listed
• Sodium cetostearyl sulfate	68955-20-4	Not Listed

United States - California

Environment

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

• Stearyl alcohol	112-92-5	Not Listed
• Cetyl alcohol	36653-82-4	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Sodium hydroxide	1310-73-2	Not Listed
• Benzyl alcohol	100-51-6	Not Listed
• Citric acid	77-92-9	Not Listed
• Triglycerides, medium chain	73398-61-5	Not Listed
• Oleyl alcohol	143-28-2	Not Listed
• Mono- and di-glycerides	67701-32-0	Not Listed
• Purified water	7732-18-5	Not Listed
• Pimecrolimus	137071-32-0	Not Listed
• Sodium cetostearyl sulfate	68955-20-4	Not Listed

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

• Stearyl alcohol	112-92-5	Not Listed
• Cetyl alcohol	36653-82-4	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Sodium hydroxide	1310-73-2	Not Listed
• Benzyl alcohol	100-51-6	Not Listed
• Citric acid	77-92-9	Not Listed
• Triglycerides, medium chain	73398-61-5	Not Listed
• Oleyl alcohol	143-28-2	Not Listed
• Mono- and di-glycerides	67701-32-0	Not Listed
• Purified water	7732-18-5	Not Listed
• Pimecrolimus	137071-32-0	Not Listed
• Sodium cetostearyl sulfate	68955-20-4	Not Listed

Section 16 - Other Information

Last Revision Date • 23/July/2014

Preparation Date • 23/July/2014

Disclaimer/Statement of • The above information and recommendations contained in the Safety Data Sheet have

Liability

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.
