Safety Data Sheet

Section 1: Identification

<table>
<thead>
<tr>
<th>Product identifier</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Name</strong></td>
<td>Elidel Cream, 1%</td>
</tr>
<tr>
<td><strong>Synonyms</strong></td>
<td>Pimecrolimus</td>
</tr>
<tr>
<td><strong>Product Code</strong></td>
<td>NDC 0187-5100-01; NDC 0187-5101-02; NDC 0187-5102-03</td>
</tr>
<tr>
<td><strong>Product Description</strong></td>
<td>Indicated for use in inflammatory skin diseases (atopic dermatitis, allergic contact dermatitis, irritant contact dermatitis, chronic plaque psoriasis)</td>
</tr>
</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th>UN GHS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Mild Irritation 3 - H316</td>
<td></td>
</tr>
<tr>
<td>Reproductive Toxicity 1B - H360</td>
<td></td>
</tr>
<tr>
<td>Acute Toxicity Dermal 4 - H312</td>
<td></td>
</tr>
<tr>
<td>Acute Toxicity Oral 4 - H302</td>
<td></td>
</tr>
<tr>
<td>Carcinogenicity 2 - H351</td>
<td></td>
</tr>
<tr>
<td>Eye Mild Irritation 2B - H320</td>
<td></td>
</tr>
</tbody>
</table>

**Label elements**

<table>
<thead>
<tr>
<th>UN GHS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DANGER</strong></td>
<td></td>
</tr>
</tbody>
</table>

**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.

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.
• 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.

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Identifiers</th>
<th>%</th>
<th>Classifications According to Regulation/Directive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>CAS:100-51-6</td>
<td>&lt; 5%</td>
<td>UN GHS: Acute Tox. Inhal. 4; Acute Tox. Oral 4</td>
</tr>
<tr>
<td>Cetyl alcohol</td>
<td>CAS:36653-82-4</td>
<td>&lt; 5%</td>
<td>UN GHS: Eye Irrit. 2A; Skin Irrit. 2</td>
</tr>
<tr>
<td>Mono- and di-glycerides</td>
<td>CAS:67701-32-0</td>
<td>&lt; 5%</td>
<td>UN GHS: NDA</td>
</tr>
<tr>
<td>Oleyl alcohol</td>
<td>CAS:143-28-2</td>
<td>10% TO 25%</td>
<td>UN GHS: NDA</td>
</tr>
<tr>
<td>Pimecrolimus</td>
<td>CAS:137071-32-0</td>
<td>1%</td>
<td>UN GHS: Skin Irrit. 2; Carcin. 2; Repro. Tox. 1B</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>CAS:57-55-6</td>
<td>&lt; 10%</td>
<td>UN GHS: Eye Irrit. 2B; Skin Irrit. 3</td>
</tr>
<tr>
<td>Purified water</td>
<td>CAS:7732-18-5</td>
<td>&gt; 50%</td>
<td>UN GHS: NDA</td>
</tr>
<tr>
<td>Sodium cetostearyl sulfate</td>
<td>CAS:68955-20-4</td>
<td>&lt; 5%</td>
<td>UN GHS: Flam. Sol. 2; Skin Corr./Irrit. 2; Eye Dam./Irrit. 2</td>
</tr>
<tr>
<td>Stearyl alcohol</td>
<td>CAS:112-92-5</td>
<td>&lt; 5%</td>
<td>UN GHS: NDA</td>
</tr>
</tbody>
</table>
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...
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 15-30°C (59-86°F). 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

<table>
<thead>
<tr>
<th>Material Description</th>
<th>Physical Form</th>
<th>Appearance/Description</th>
<th>Odor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Liquid</td>
<td></td>
<td></td>
</tr>
<tr>
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<td>Cream</td>
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<table>
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<th>General Properties</th>
<th>Physical Form</th>
<th>Appearance/Description</th>
<th>Odor</th>
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<td>Liquid</td>
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<td></td>
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<td></td>
<td>Cream</td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
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<td>pH</td>
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<td>Density</td>
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<td>Solvent Solubility</td>
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</table>

<table>
<thead>
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<td></td>
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<td>Cream</td>
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<table>
<thead>
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<th>Odor</th>
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</thead>
<tbody>
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<td>Liquid</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Cream</td>
<td></td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Flash Point</th>
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<th>UEL</th>
<th>No data available</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEL</td>
<td>No data available</td>
<td>Flammability (solid, gas)</td>
<td>Not relevant</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Environmental</th>
<th>Physical Form</th>
<th>Appearance/Description</th>
<th>Odor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Liquid</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cream</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Half-Life</th>
<th>Not relevant</th>
<th>Octanol/Water Partition coefficient</th>
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</thead>
<tbody>
<tr>
<td>Coefficient of water/oil distribution</td>
<td>Not relevant</td>
<td>Bioaccumulation Factor</td>
<td>Not relevant</td>
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<tr>
<td>Bioconcentration Factor</td>
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<td>Biochemical Oxygen Demand BOD/BOD5</td>
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</tr>
<tr>
<td>Chemical Oxygen Demand</td>
<td>Not relevant</td>
<td>Persistence</td>
<td>Not relevant</td>
</tr>
<tr>
<td>Degradation</td>
<td>Not relevant</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>CAS</th>
<th>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</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cetyl alcohol (&lt; 5%)</td>
</tr>
<tr>
<td>Stearyl alcohol (&lt; 5%)</td>
</tr>
<tr>
<td>Oleyl alcohol (10% TO 25%)</td>
</tr>
<tr>
<td>Propylene glycol (&lt; 10%)</td>
</tr>
<tr>
<td>Benzyl alcohol (&lt; 5%)</td>
</tr>
<tr>
<td>Pimecrolimus (1%)</td>
</tr>
</tbody>
</table>

**GHS Properties**

- **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

*Revision Date: 23/July/2014*
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.
Section 14 - Transport Information

<table>
<thead>
<tr>
<th>UN number</th>
<th>UN proper shipping name</th>
<th>Transport hazard class (es)</th>
<th>Packing group</th>
<th>Environmental hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOT</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
</tr>
<tr>
<td>TDG</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
</tr>
<tr>
<td>IMO/IMDG</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
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<tr>
<td>ADN</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
</tr>
<tr>
<td>ADR/RID</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
</tr>
<tr>
<td>IATA/ICAO</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
</tr>
</tbody>
</table>

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

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

Canada

Preparation Date: 23/July/2014
Revision Date: 23/July/2014
Format: GHS Language: English (US)
UN GHS
### Labor

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stearyl alcohol</td>
<td>112-92-5</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Cetyl alcohol</td>
<td>36653-82-4</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>Not Listed</td>
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<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

*Restrict (Permitted at total concentrations <=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 >=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."

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td></td>
</tr>
<tr>
<td>Triglycerides, medium chain</td>
<td>73388-61-5</td>
<td>Not Listed</td>
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<tr>
<td>Oleyl alcohol</td>
<td>143-28-2</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Mono- and di-glycerides</td>
<td>67701-32-0</td>
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<tr>
<td>Purified water</td>
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</tr>
<tr>
<td>Pimecrolimus</td>
<td>137071-32-0</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Sodium cetostearyl sulfate</td>
<td>68955-20-4</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

#### Canada - WHMIS - Classifications of Substances

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stearyl alcohol</td>
<td>112-92-5</td>
<td>Uncontrolled product according to WHMIS classification criteria</td>
</tr>
<tr>
<td>Cetyl alcohol</td>
<td>36653-82-4</td>
<td>D2B</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>Uncontrolled product according to WHMIS classification criteria 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)</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td></td>
</tr>
</tbody>
</table>
### Canada - WHMIS - Ingredient Disclosure List

- 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

### 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, 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

**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; 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
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

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  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

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
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.