1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

GHS product identifier

Product Name VANIQA® (eflornithine hydrochloride) Cream, 13.9%

Other means of identification

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended Use Dermatological use in treatment of excessive facial hair.

Uses advised against No information available

Supplier’s details

Supplier Address Allergan, Inc.
2525 Dupont
Irvine, CA
TEL: 1-714-246-4500

Emergency telephone number

Emergency Telephone Number Chemtrec 1-800-424-9300

2. HAZARDS IDENTIFICATION

Classification

This chemical is not considered hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

Not classified

GHS Label elements, including precautionary statements

Emergency Overview

Signal Word None

Hazard Statements
- None

The product contains no substances which at their given concentration are considered to be hazardous to health

Appearance White to off-white

Physical State Cream.

Odor No information available

Precautionary Statements

Prevention
- None
General Advice
• None

Storage
• None

Disposal
• None

Hazard Not Otherwise Classified (HNOC)
Not applicable

Other information
May cause allergic reactions in susceptible individuals. Contact with eyes may cause irritation. Prolonged or repeated contact may dry skin and cause irritation.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS-No</th>
<th>Weight %</th>
<th>Trade secret</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eflornithine hydrochloride monohydrate</td>
<td>96020-91-6</td>
<td>13.9</td>
<td>*</td>
</tr>
<tr>
<td>Octadecanoic acid, 2,3-dihydroxypropyl ester</td>
<td>123-94-4</td>
<td>7.1</td>
<td>*</td>
</tr>
<tr>
<td>White mineral oil</td>
<td>8042-47-5</td>
<td>1.9</td>
<td>*</td>
</tr>
</tbody>
</table>

* Where range is displayed, the exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of necessary first-aid measures
Eye Contact
Rinse thoroughly with plenty of water, also under the eyelids. If irritation persists, call a physician.

Skin Contact
Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.

Inhalation
Move to fresh air. If symptoms persist, call a physician.

Ingestion
Do NOT induce vomiting. Clean mouth with water and afterwards drink plenty of water. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician.

Most important symptoms/effects, acute and delayed

Most Important Symptoms/Effects
No information available.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to Physician
Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media
CAUTION: Use of water spray when fighting fire may be inefficient.

Specific Hazards Arising from the Chemical
Emits toxic fumes under fire conditions.
6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions
Use personal protective equipment. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation.

Environmental Precautions
See Section 12 for additional Ecological Information

Methods and materials for containment and cleaning up

Methods for Containment
Prevent further leakage or spillage if safe to do so.

Methods for Cleaning Up
Soak up with inert absorbent material. Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation.

Conditions for safe storage, including any incompatibilities

Storage
Keep container tightly closed when not in use. Do not handle or store near flame, heat, light, oxidants and bases. Store at 25°C (77°F), excursions permitted to 15°C–30°C (59°F–86°F). Do not freeze. Keep out of the reach of children.

Incompatible Products
Oxidizing agents. Bases.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

Exposure Guidelines

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH IDLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Octadecanoic acid, 2,3-dihydroxypropyl ester</td>
<td>TWA: 10 mg/m³ except</td>
<td></td>
<td></td>
</tr>
<tr>
<td>123-94-4</td>
<td>stearates of toxic metals</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White mineral oil</td>
<td>TWA: 5 mg/m³ inhalable fraction</td>
<td></td>
<td>IDLH: 2500 mg/m³</td>
</tr>
<tr>
<td>8042-47-5</td>
<td>(vacated) TWA: 5 mg/m³</td>
<td></td>
<td>TWA: 5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>highly &amp; severely refined</td>
<td></td>
<td>STEL: 10 mg/m³</td>
</tr>
</tbody>
</table>

Appropriate engineering controls

Engineering Measures
Showers
Eyewash stations
Ventilation systems
9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
<th>Remarks/ Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>3.5 - 4.3</td>
<td>None known</td>
</tr>
<tr>
<td>Melting Point/Range</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Boiling Point/Boiling Range</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Flash Point</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Flammability Limits in Air</td>
<td></td>
<td></td>
</tr>
<tr>
<td>upper flammability limit</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>lower flammability limit</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Vapor Density</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Relative Density</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>No data available.</td>
<td>None known</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Solubility in other solvents</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Autoignition Temperature</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Decomposition Temperature</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Flammable Properties</td>
<td>Not flammable</td>
<td></td>
</tr>
<tr>
<td>Explosive Properties</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Oxidizing Properties</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Other information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VOC Content (%)</td>
<td>No data available</td>
<td></td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Reactivity

No data available.

Chemical stability

Stable under recommended storage conditions.
### 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

- **Product Information**
  - **Inhalation**: There is no data available for this product.
  - **Eye Contact**: There is no data available for this product.
  - **Skin Contact**: There is no data available for this product.
  - **Ingestion**: There is no data available for this product.

#### Symptoms related to the physical, chemical and toxicological characteristics

- **Symptoms**: No information available.

#### Delayed and immediate effects and also chronic effects from short and long term exposure

- **Sensitization**: No information available.
- **Mutagenic Effects**: Eflornithine did not elicit mutagenic effects in an Ames reverse-mutation assay or clastogenicity in primary human lymphocytes, with and without metabolic activation. In a dermal micronucleus assay, eflornithine hydrochloride cream, 13.9%, at doses up to 900 mg/kg (58X the MRHD based on BSA) in rats yielded no evidence of genotoxicity.

  In a 12-month photocarcinogenicity study in hairless albino mice, animals treated with the vehicle alone showed an increased incidence of skin tumors induced by exposure to ultraviolet (UVA/UVB) light, whereas mice treated topically with VANIQA® at doses up to 600 mg/kg [19X the Maximum Recommended Human Dose (MRHD) based on body surface area (BSA)] showed an incidence of skin tumors equivalent to untreated-control animals.

  A 2-year dermal carcinogenicity study in CD-1 mice treated with VANIQA® revealed no evidence of carcinogenicity at daily doses up to 600 mg/kg (950X the MRHD based on AUC comparisons).

  Mineral oils are known to cause cancer because of carcinogenic components (e.g. benzene). The mineral oil in this product is highly refined and should not be considered a carcinogen.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil</td>
<td>A2</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Reproductive Toxicity**

In a dermal and early embryonic development study in rats treated with VANIQA®, there were no adverse reproductive effects at doses up to 450 mg/kg (29X the MRHD based on BSA). In a peri- and postnatal study in rats, efornithine administered in the drinking water was associated with maternal toxicity and reduced pup weights at doses of at least 625 mg/kg (40X the MRHD based on BSA) and a slightly reduced fertility index, which was considered to be of questionable biological significance, at 1698 mg/kg (110X the MRHD based on BSA). No effects were seen with an oral dose of 223 mg/kg (14X the MRHD based on BSA). In the latter study, the multiples of the human exposure are likely much higher, since efornithine is well absorbed orally in rats, whereas minimal absorption occurs in humans treated topically.

**Teratogenic**

Teratogenic Effects: Pregnancy Category C:

In the first dermal embryo-fetal development study in rats treated with efornithine hydrochloride cream, 13.9% (in which no precautions were taken to prevent ingestion of drug from application sites), maternal toxicity and fetal effects including reduced numbers of live fetuses, decreased fetal weights, and delayed ossification and development of the visceras were observed at doses of 225 and 450 mg/kg (15X and 29X the MRHD based on BSA, respectively). When the study was repeated under conditions that avoided ingestion from application sites, no maternal, fetal or teratogenic effects were observed at doses up to 450 mg/kg (29X the MRHD based on BSA). In the first study in which no precautions were taken to prevent ingestion, circulating plasma levels were 11- to 14-fold higher than in the second study in which ingestion was prevented.

In a dermal embryo-fetal development study in rabbits treated with VANIQA® (efornithine hydrochloride) cream, 13.9% no adverse maternal or fetal effects occurred at doses up to 90 mg/kg (11X the MRHD based on BSA). Significant dermal irritation, as well as possible ingestion of VANIQA® occurred at 300 mg/kg/day (36X the MRHD based on BSA) and was associated with maternal deaths, abortions, increased fetal resorptions, and reduced fetal weights.

Fetotoxicity in the absence of maternal toxicity has been reported in oral studies with efornithine with fetal no-effect doses of 80 mg/kg in rats and 45 mg/kg in rabbits. In these studies, no evidence of teratogenicity was observed in rats given up to 200 mg/kg or in rabbits given up to 135 mg/kg.

Although VANIQA® was not formally studied in pregnant patients, 22 pregnancies occurred during the trials. Nineteen of these pregnancies occurred while patients were using VANIQA®. Of the 19 pregnancies, there were 9 healthy infants, 4 spontaneous abortions, 5 induced/elective abortions, and 1 birth defect (Down's Syndrome to a 35-year-old). Because there are no adequate and well-controlled studies in pregnant women, the risk/benefit ratio of using VANIQA® in women with unwanted facial hair who are pregnant should be weighed carefully with serious consideration for either not implementing or discontinuing use of VANIQA®.

**STOT - single exposure**
No information available.

**STOT - repeated exposure**
No information available.

**Aspiration Hazard**
No information available.

### Numerical measures of toxicity - Product

#### 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

The environmental impact of this product has not been fully investigated.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Toxicity to Algae</th>
<th>Toxicity to Fish</th>
<th>Toxicity to Microorganisms</th>
<th>Daphnia Magna (Water Flea)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil 8042-47-5</td>
<td></td>
<td>LC50 96 h: &gt; 10000 mg/L (Lepomis macrochirus)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cetylstearyl alcohol 8005-44-5</td>
<td></td>
<td></td>
<td>EC50 48 h: = 1666 mg/L (Daphnia magna)</td>
<td></td>
</tr>
<tr>
<td>1-Octadecanol 112-92-5</td>
<td>EC50 96 h: = 235 mg/L (Desmodesmus subspicatus)</td>
<td>LC50 96 h: &gt; 10000 mg/L (Brachydanio rerio)</td>
<td>-</td>
<td>EC50 48 h: = 1666 mg/L (Daphnia magna)</td>
</tr>
</tbody>
</table>
2-Phenoxyethanol 122-99-6 | EC50 72 h: > 500 mg/L (Desmodesmus subspicatus) | LC50 96 h: 337 - 352 mg/L flow-through (Pimephales promelas) | LC50 96 h: = 366 mg/L static (Pimephales promelas) | LC50 96 h: 220 - 460 mg/L static (Leuciscus idus) | EC50 = 32.4 mg/L 5 min | EC50 = 880 mg/L 17 h | EC50 48 h: > 500 mg/L (Daphnia magna)

Poly[oxy(dimethylsiloxane)] 9016-00-6 | LC50 96 h: > 10000 mg/L static (Lepomis macrochirus) | LC50 96 h: > 10000 mg/L static (Oncorhynchus mykiss)

Persistence and Degradability
No information available.

Bioaccumulation
No information available.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Log Pow</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil</td>
<td>6.006</td>
</tr>
</tbody>
</table>

Other Adverse Effects
No information available.

### 13. DISPOSAL CONSIDERATIONS

**Waste Disposal Methods**
This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

**Contaminated Packaging**
Do not re-use empty containers.

### 14. TRANSPORT INFORMATION

**DOT**
Not regulated

**TDG**
Not regulated

### 15. REGULATORY INFORMATION

**International Inventories**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>TSCA</td>
<td>Exempt</td>
</tr>
<tr>
<td>DSL</td>
<td>Exempt</td>
</tr>
</tbody>
</table>

**Legend**

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

**U.S. Federal Regulations**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

**SARA 311/312 Hazard Categories**

<table>
<thead>
<tr>
<th>Hazard Category</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Health Hazard</td>
<td>No</td>
</tr>
</tbody>
</table>
Clean Water Act
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

U.S. State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>Pennsylvania</th>
<th>Illinois</th>
<th>Rhode Island</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. OTHER INFORMATION

<table>
<thead>
<tr>
<th>NFPA</th>
<th>Health Hazard</th>
<th>Flammability</th>
<th>Instability</th>
<th>Physical and Chemical Hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HMIS</th>
<th>Health Hazard</th>
<th>Flammability</th>
<th>Physical Hazard</th>
<th>Personal Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>X</td>
</tr>
</tbody>
</table>

Prepared By
Product Stewardship
23 British American Blvd.
Latham, NY 12110
1-800-572-6501

Issuing Date
21-Nov-2013
Revision Date
21-Nov-2013
Revision Note
Initial Release.

General Disclaimer
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End of Safety Data Sheet