

Issuing Date 21-Nov-2013

Revision Date 21-Nov-2013

Revision Number 0

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

Chemical Name	CAS-No	Weight %	Trade secret
Eflornithine hydrochloridemonohydrate	96020-91-6	13.9	*
Octadecanoic acid, 2,3-dihydroxypropyl ester	123-94-4	7.1	*
White mineral oil	8042-47-5	1.9	*

* 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.

Explosion Data**Sensitivity to Mechanical Impact** None.**Sensitivity to Static Discharge** None.**Protective Equipment and Precautions for Firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

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****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°–30°C (59°–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**

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Octadecanoic acid, 2,3-dihydroxypropyl ester 123-94-4	TWA: 10 mg/m ³ except stearates of toxic metals	-	-
White mineral oil 8042-47-5	TWA: 5 mg/m ³ inhalable fraction excluding metal working fluids, highly & severely refined	TWA: 5 mg/m ³ (vacated) TWA: 5 mg/m ³	IDLH: 2500 mg/m ³ TWA: 5 mg/m ³ STEL: 10 mg/m ³

Appropriate engineering controls**Engineering Measures** Showers
Eyewash stations
Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/Face Protection	None required under normal usage. If direct contact possible: Safety glasses with side-shields.
Skin and Body Protection	None required under normal usage. Repeated or prolonged contact: Protective gloves.
Respiratory Protection	If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.
Hygiene Measures	Handle in accordance with good industrial hygiene and safety practice. Do not eat, drink or smoke when using this product. Keep away from food, drink and animal feeding stuffs. Wash hands before breaks and immediately after handling the product. Provide regular cleaning of equipment, work area and clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES**Information on basic physical and chemical properties**

Physical State	Cream	Appearance	White to off-white
Odor	No information available	Odor Threshold	No information available

Property	Values	Remarks/ - Method
pH	3.5 - 4.3	None known
Melting Point/Range	No data available	None known
Boiling Point/Boiling Range	No data available	None known
Flash Point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limits in Air		
upper flammability limit	No data available	
lower flammability limit	No data available	
Vapor Pressure	No data available	None known
Vapor Density	No data available	None known
Relative Density	No data available	None known
Specific Gravity	No data available.	None known
Water Solubility	No data available	None known
Solubility in other solvents	No data available	None known
Partition coefficient: n-octanol/water	No data available	None known
Autoignition Temperature	No data available	None known
Decomposition Temperature	No data available	None known
Viscosity	No data available	None known

Flammable Properties	Not flammable
Explosive Properties	No data available
Oxidizing Properties	No data available

Other information

VOC Content (%)	No data available
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10. STABILITY AND REACTIVITY**Reactivity**

No data available.

Chemical stability

Stable under recommended storage conditions.

Possibility of hazardous reactions

None under normal processing.

Conditions to avoid

Heat, flames and sparks.

Incompatible materials

Oxidizing agents. Bases.

Hazardous decomposition products

Carbon oxides.

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.

Carcinogenicity 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.

Chemical Name	ACGIH	IARC	NTP	OSHA
White mineral oil	A2			

Reproductive Toxicity

In a dermal fertility 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, eflornithine 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 eflornithine 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 eflornithine 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 viscera 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® (eflornithine 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 eflornithine 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.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
White mineral oil 8042-47-5		LC50 96 h: > 10000 mg/L (Lepomis macrochirus)		
Cetylstearyl alcohol 8005-44-5				EC50 48 h: = 1666 mg/L (Daphnia magna)
1-Octadecanol 112-92-5	EC50 96 h: = 235 mg/L (Desmodesmus subspicatus)	LC50 96 h: > 10000 mg/L (Brachydanio rerio)	-	EC50 48 h: = 1666 mg/L (Daphnia magna)

2-Phenoxyethanol 122-99-6	EC50 72 h: > 500 mg/L (Desmodosmus 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(dimethylsilylene)] 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.

Chemical Name	Log Pow
White mineral oil	6.006

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

TSCA Exempt
DSL Exempt

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

Acute Health Hazard No

Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

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

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
White mineral oil	X	X	X		X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. OTHER INFORMATION

NFPA	Health Hazard 0	Flammability 0	Instability 0	Physical and Chemical Hazards - Personal Protection X
HMIS	Health Hazard 0	Flammability 0	Physical Hazard 0	

Prepared By Product Stewardship
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Issuing Date 21-Nov-2013
Revision Date 21-Nov-2013
Revision Note Initial Release.

General Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

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End of Safety Data Sheet