Safety Data Sheet



Section 1: Identification

Product identifier

Product Name • Velvachol® Cream

Product Code • 301871678146

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

Recommended use • Skin care product.

Restrictions on use• Use in accordance with product literature.

Details of the supplier of the safety data sheet

• Valeant Pharmaceuticals North America, LLC

Bridgewater, NJ 08807 United States

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

Consumer product: This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

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

• Eye Irritation 2 Skin Mild Irritation 3

Label elements

UN GHS

WARNING



Hazard statements • Causes serious eye irritation May cause mild skin irritation

Precautionary statements

Prevention • Wash thoroughly after handling. Wear eye/face protection , .

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Wear protective gloves.

Response • 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. IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.

Storage/Disposal • Store at room temperature 15-30C (59-86F).

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

		Co	mposition
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Cetyl alcohol	CAS:36653-82-4 EINECS:253-149-0	*	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Stearyl alcohol	CAS:112-92-5 EINECS:204-017-6	*	UN GHS: NDA
Petrolatum	CAS:8009-03-8 EINECS:232-373-2	*	UN GHS: NDA
Light mineral oil	CAS:8042-47-5 EINECS:232-455-8	*	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Cholesterol	CAS:57-88-5 EINECS:200-353-2	*	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Carc. 1A
Butylparaben	CAS:94-26-8 EINECS:202-318-7	*	UN GHS: NDA
Propylparaben		*	UN GHS: NDA
Water	CAS:7732-18-5 EINECS:231-791-2	*	UN GHS: not classified
Sodium Lauryl Sulfate	CAS:151-21-3 EINECS:205-788-1	*	UN GHS: NDA
Methylparaben	CAS:99-76-3 EINECS:202-785-7	*	UN GHS: Skin Irrit. 2; Eye Irrit. 2A

^{*}Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

• No adverse effects anticipated by breathing small amounts. If large amounts are inhaled, remove to fresh air.

Skin

IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical

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advice/attention.

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

Ingestion

Call a physician or poison control center.

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 • Carbon dioxide, dry chemical powder, appropriate foam or water fog.

Unsuitable Extinguishing

No data available

Media

Firefighting Procedures

As in any fire, wear self-contained breathing apparatus and full protective gear.

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

No data available

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions

 No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

Emergency Procedures

 Ventilate area. 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. Minimize contact of spilled material with soils to prevent runoff to surface waterways. Dispose of in accordance with Section 13.

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

No data available

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

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handling.

Conditions for safe storage, including any incompatibilities

Storage

• Store at room temperature 15-30C (59-86F).

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines

 Refer to the occupational exposure limits / guidelines for the individual product components.

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

• In the event of a bulk spill, and where risk assessment shows that air-purifying respirators are appropriate, a NIOSH (US) or CEN (EU) -certified air-purifying respirator equipped with 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

Wear eye/face protection , .

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 Considerations

Handle in accordance with good industrial hygiene and safety practice.

Environmental Exposure Controls

No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid Cream	Color	white
Odor	No data available	Odor Threshold	No data available
General Properties			
Boiling Point	No data available	Melting Point	No data available
Decomposition Temperature	No data available	рН	5.5 to 7.5
Specific Gravity/Relative Density	No data available	Water Solubility	Partially soluble
Viscosity	No data available		
Volatility		-	
Vapor Pressure	No data available	Vapor Density	No data available
Evaporation Rate	No data available		
Flammability	-	-	•

Flash Point	170 C(338 F)	UEL	No data available
LEL	No data available	Autoignition	No data available
Flammability (solid, gas)	No data available		
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

• Stable under normal temperatures and pressures.

Chemical stability

Stable under normal temperatures and pressures.

Possibility of hazardous reactions

No data available

Conditions to avoid

Excessive heat above 90°F for prolonged periods.

Incompatible materials

No data available

Hazardous decomposition products

No data available

Section 11 - Toxicological Information

Information on toxicological effects

GHS Properties	Classification
Acute toxicity	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
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 Irritation 2

Potential Health Effects

Inhalation

Acute (Immediate)

• No data available

Chronic (Delayed)

• No data available

Skin

Acute (Immediate)

Chronic (Delayed)

May cause mild irritation.

Not expected to cause sensitization. May cause skin irritation.

Eye

Acute (Immediate)

Chronic (Delayed)

Causes serious eye irritation.

Repeated and prolonged exposure may cause irritation.

Ingestion

Acute (Immediate)

May be harmful if swallowed.

Chronic (Delayed)

No data available

		Carcinogenic Effects
	CAS	IARC
Cholesterol	57-88-5	Group 3-Not Classifiable

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	Not regulated	NDA	NDA	NDA
IMO/IMDG	NDA	Not regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not regulated	NDA	NDA	NDA

Special precautions for user • No data available

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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

		Inve	ntory	
Component	CAS	Canada DSL	EU EINECS	TSCA
Cetyl alcohol	36653-82-4	Yes	Yes	Yes
Stearyl alcohol	112-92-5	Yes	Yes	Yes
Butylparaben	94-26-8	Yes	Yes	Yes
Methylparaben	99-76-3	Yes	Yes	Yes
Propylparaben	94-13-3	Yes	Yes	Yes
Cholesterol	57-88-5	Yes	Yes	Yes
Petrolatum	8009-03-8	Yes	Yes	Yes
Water	7732-18-5	Yes	Yes	Yes
Light mineral oil	8042-47-5	Yes	Yes	Yes

Canada

bor		
Canada - List of Prohibited and Restricted Cosmetic	•	•
Methylparaben	99-76-3	Not Listed
Propylparaben	94-13-3	Not Listed
Stearyl alcohol	112-92-5	Not Listed
Cetyl alcohol	36653-82-4	Not Listed
Petrolatum	8009-03-8	Not Listed
Light mineral oil	8042-47-5	Not Listed
Cholesterol	57-88-5	Not Listed
Butylparaben	94-26-8	Not Listed
• Water	7732-18-5	Not Listed
Canada - WHMIS - Classifications of Substances		
Methylparaben	99-76-3	Not Listed
Propylparaben	94-13-3	Not Listed
		Uncontrolled product
Stearyl alcohol	112-92-5	according to WHMIS
		classification criteria
Cetyl alcohol	36653-82-4	D2B
		Uncontrolled product
Petrolatum	8009-03-8	according to WHMIS
		classification criteria
Light mineral oil	8042-47-5	Uncontrolled product according to WHMIS
- Light Hillicial Oll	0042-47-3	classification criteria
Cholesterol	57-88-5	Not Listed
Butylparaben	94-26-8	Not Listed
σατγιραιασοίτ	54-20-0	Uncontrolled product
• Water	7732-18-5	according to WHMIS
	.702 10 0	classification criteria

Methylparaben	99-76-3	Not Listed
Propylparaben	94-13-3	Not Listed
Stearyl alcohol	112-92-5	Not Listed
Cetyl alcohol	36653-82-4	Not Listed
Petrolatum	8009-03-8	Not Listed
Light mineral oil	8042-47-5	Not Listed
Cholesterol	57-88-5	Not Listed
Butylparaben	94-26-8	Not Listed
Water	7732-18-5	Not Listed

Europe

-	
ner :U - CLP (1272/2008) - Annex VI - Table 3.2 - Classificatio	on
Methylparaben	99-76-3 Not Listed
Propylparaben	94-13-3 Not Listed
• Stearyl alcohol	112-92-5 Not Listed
Cetyl alcohol	36653-82-4 Not Listed
Petrolatum	8009-03-8 Carc.Cat.2; R45
Light mineral oil	8042-47-5 Not Listed
• Cholesterol	57-88-5 Not Listed
Butylparaben	94-26-8 Not Listed
• Water	7732-18-5 Not Listed
EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling	
Methylparaben	99-76-3 Not Listed
Propylparaben	94-13-3 Not Listed
Stearyl alcohol	112-92-5 Not Listed
Cetyl alcohol	36653-82-4 Not Listed
• Petrolatum	8009-03-8 T R:45 S:53-45
Light mineral oil	8042-47-5 Not Listed
Cholesterol	57-88-5 Not Listed
Butylparaben	94-26-8 Not Listed
• Water	7732-18-5 Not Listed
EU - CLP (1272/2008) - Annex VI - Table 3.2 - Notes - Sub	ostances and Preparations
Methylparaben	99-76-3 Not Listed
 Propylparaben 	94-13-3 Not Listed
Stearyl alcohol	112-92-5 Not Listed
Cetyl alcohol	36653-82-4 Not Listed
• Petrolatum	8009-03-8 N
Light mineral oil	8042-47-5 Not Listed
Cholesterol	57-88-5 Not Listed
Butylparaben	94-26-8 Not Listed
• Water	7732-18-5 Not Listed
EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phra	ases
Methylparaben	99-76-3 Not Listed
Propylparaben	94-13-3 Not Listed
Stearyl alcohol	112-92-5 Not Listed
Cetyl alcohol	36653-82-4 Not Listed
Petrolatum	8009-03-8 S:53-45

 Light mineral oil Cholesterol 8042-47-5 Not Listed 57-88-5 Not Listed 	
	il 8042-47-5 Not Listed
	57-88-5 Not Listed
• Butylparaben 94-26-8 Not Listed	94-26-8 Not Listed
Water 7732-18-5 Not Listed	7732-18-5 Not Listed

United States

Methylparaben	99-76-3	Not Listed
Propylparaben	94-13-3	Not Listed
stearyl alcohol	112-92-5	Not Listed
Cetyl alcohol	36653-82-4	Not Listed
Petrolatum	8009-03-8	Not Listed
ight mineral oil	8042-47-5	Not Listed
cholesterol	57-88-5	Not Listed
Butylparaben	94-26-8	Not Listed
Water	7732-18-5	Not Listed

United States - California

vironment U.S California - Proposition 65 - Carcinogens List		
Methylparaben	99-76-3	Not Listed
Propylparaben	94-13-3	Not Listed
Stearyl alcohol	112-92-5	Not Listed
Cetyl alcohol	36653-82-4	Not Listed
Petrolatum	8009-03-8	Not Listed
Light mineral oil	8042-47-5	Not Listed
Cholesterol	57-88-5	Not Listed
Butylparaben	94-26-8	Not Listed
• Water	7732-18-5	Not Listed
U.S California - Proposition 65 - Developmental Toxi	city	
Methylparaben	99-76-3	Not Listed
Propylparaben	94-13-3	Not Listed
Stearyl alcohol	112-92-5	Not Listed
Cetyl alcohol	36653-82-4	Not Listed
Petrolatum	8009-03-8	Not Listed
Light mineral oil	8042-47-5	Not Listed
Cholesterol	57-88-5	Not Listed
Butylparaben	94-26-8	Not Listed
• Water	7732-18-5	Not Listed
U.S California - Proposition 65 - Reproductive Toxici	ty - Female	
Methylparaben	99-76-3	Not Listed
Propylparaben	94-13-3	Not Listed
Stearyl alcohol	112-92-5	Not Listed
Cetyl alcohol	36653-82-4	Not Listed
Petrolatum	8009-03-8	Not Listed
Light mineral oil	8042-47-5	Not Listed
Cholesterol	57-88-5	Not Listed
Butylparaben	94-26-8	Not Listed
Water	7732-18-5	Not Listed

 Methylparaben 	99-76-3	Not Listed
Propylparaben	94-13-3	Not Listed
Stearyl alcohol	112-92-5	Not Listed
Cetyl alcohol	36653-82-4	Not Listed
Petrolatum	8009-03-8	Not Listed
Light mineral oil	8042-47-5	Not Listed
Cholesterol	57-88-5	Not Listed
Butylparaben	94-26-8	Not Listed
• Water	7732-18-5	Not Listed

Section 16 - Other Information

Last Revision Date Preparation Date Disclaimer/Statement of

Liability

- 10/April/2015
- 10/April/2015
- 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.