

Safety Data Sheet



Section 1: Identification

Product identifier

Product Name • Cerave Healing Ointment

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

Manufacturer • 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

UN GHS • Classification criteria not met

Label elements

UN GHS

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
Dimethicone	CAS:9006-65-9	*	UN GHS:
Mineral oil	CAS:8012-95-1 EINECS:232-384-2	*	UN GHS: NDA
Ozokerite	CAS:12198-93-5	*	UN GHS:
Paraffin	CAS:8002-74-2 EINECS:232-315-6	*	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Petrolatum	CAS:8009-03-8 EINECS:232-373-2	46.499%	UN GHS: NDA

Other inactive ingredients <1%(<0.1% concentration for potential carcinogens, reproductive toxins, respiratory tract sensitizers, and mutagens): Carbomer, Cholesterol, Ceramides, phytosphingosine, Sodium hyaluronate, Sodium Lauroyl Lactylate, Xanthan gum.

**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 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 advice/attention.

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 Media • No data available

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 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 Limits/Guidelines					
	Result	ACGIH	Canada Quebec	NIOSH	OSHA
Paraffin (8002-74-2)	TWAs	2 mg/m3 TWA (fume)	2 mg/m3 TWAEV (fume)	2 mg/m3 TWA (fume)	Not established
Mineral oil (8012-95-1)	STELs	Not established	10 mg/m3 STEV (mist)	10 mg/m3 STEL	Not established
	TWAs	5 mg/m3 TWA (excluding metal working fluids, highly & severely refined, inhalable fraction)	5 mg/m3 TWAEV (mist)	5 mg/m3 TWA	5 mg/m3 TWA

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

- No special personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye/face protection should be worn.

Hands

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear rubber or nitrile 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 Ointment	Appearance/Description	Translucent ointment.
Color	Translucent to white.	Odor	No odor.
Odor Threshold	Not relevant		
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	No data available	pH	No data available
Specific Gravity/Relative Density	No data available	Water Solubility	No data available
Viscosity	No data available		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity**Reactivity**

- No dangerous reactions known.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- No data available

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information**Information on toxicological effects**

Components		
Petrolatum (46.499%)	8009-03-8	Acute Toxicity: Intraperitoneal-Mouse LD50 • >50 g/kg

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 • Classification criteria not met
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 • Classification criteria not met

Potential Health Effects**Inhalation**

- Acute (Immediate)** • No data available
- Chronic (Delayed)** • No data available

Skin

- Acute (Immediate)** • Not expected to cause skin irritation.
- Chronic (Delayed)** • Not expected to cause skin irritation. Not expected to cause sensitization.

Eye

- Acute (Immediate)** • May cause mild irritation.
- Chronic (Delayed)** • 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

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

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA

Dimethicone	9006-65-9	Yes	No	No
Mineral oil	8012-95-1	Yes	Yes	Yes
Ozokerite	12198-93-5	Yes	No	No
Paraffin	8002-74-2	Yes	Yes	Yes
Petrolatum	8009-03-8	Yes	Yes	Yes

Canada

Labor

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

• Dimethicone	9006-65-9	Not Listed
• Petrolatum	8009-03-8	Not Listed
• Paraffin	8002-74-2	Not Listed
• Mineral oil	8012-95-1	Not Listed
• Ozokerite	12198-93-5	Not Listed

Canada - WHMIS - Classifications of Substances

• Dimethicone	9006-65-9	Not Listed
• Petrolatum	8009-03-8	Uncontrolled product according to WHMIS classification criteria
• Paraffin	8002-74-2	Uncontrolled product according to WHMIS classification criteria
• Mineral oil	8012-95-1	Uncontrolled product according to WHMIS classification criteria
• Ozokerite	12198-93-5	Not Listed

Canada - WHMIS - Ingredient Disclosure List

• Dimethicone	9006-65-9	Not Listed
• Petrolatum	8009-03-8	Not Listed
• Paraffin	8002-74-2	Not Listed
• Mineral oil	8012-95-1	1 %
• Ozokerite	12198-93-5	Not Listed

Europe

Other

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

• Dimethicone	9006-65-9	Not Listed
• Petrolatum	8009-03-8	Carc.Cat.2; R45
• Paraffin	8002-74-2	Not Listed
• Mineral oil	8012-95-1	Not Listed
• Ozokerite	12198-93-5	Not Listed

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

• Dimethicone	9006-65-9	Not Listed
• Petrolatum	8009-03-8	T R:45 S:53-45
• Paraffin	8002-74-2	Not Listed
• Mineral oil	8012-95-1	Not Listed
• Ozokerite	12198-93-5	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Notes - Substances and Preparations

• Dimethicone	9006-65-9	Not Listed
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• Petrolatum	8009-03-8	N
• Paraffin	8002-74-2	Not Listed
• Mineral oil	8012-95-1	Not Listed
• Ozokerite	12198-93-5	Not Listed

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

• Dimethicone	9006-65-9	Not Listed
• Petrolatum	8009-03-8	S:53-45
• Paraffin	8002-74-2	Not Listed
• Mineral oil	8012-95-1	Not Listed
• Ozokerite	12198-93-5	Not Listed

United States**Environment****U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

• Dimethicone	9006-65-9	Not Listed
• Petrolatum	8009-03-8	Not Listed
• Paraffin	8002-74-2	Not Listed
• Mineral oil	8012-95-1	Not Listed
• Ozokerite	12198-93-5	Not Listed

United States - California**Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Dimethicone	9006-65-9	Not Listed
• Petrolatum	8009-03-8	Not Listed
• Paraffin	8002-74-2	Not Listed
• Mineral oil	8012-95-1	Not Listed
• Ozokerite	12198-93-5	Not Listed

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

• Dimethicone	9006-65-9	Not Listed
• Petrolatum	8009-03-8	Not Listed
• Paraffin	8002-74-2	Not Listed
• Mineral oil	8012-95-1	Not Listed
• Ozokerite	12198-93-5	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Dimethicone	9006-65-9	Not Listed
• Petrolatum	8009-03-8	Not Listed
• Paraffin	8002-74-2	Not Listed
• Mineral oil	8012-95-1	Not Listed
• Ozokerite	12198-93-5	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Dimethicone	9006-65-9	Not Listed
• Petrolatum	8009-03-8	Not Listed
• Paraffin	8002-74-2	Not Listed
• Mineral oil	8012-95-1	Not Listed
• Ozokerite	12198-93-5	Not Listed

Section 16 - Other Information

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| Last Revision Date | <ul style="list-style-type: none"> • 26/May/2015 |
| Preparation Date | <ul style="list-style-type: none"> • 26/May/2015 |
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