

Safety Data Sheet

Section 1: Identification

Product identifier

Product Name • CERAVE® SA Renewing Cream

Product Code • 301872481301

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 • Skin Mild Irritation 3
Eye Irritation 2

Label elements

UN GHS

WARNING



Hazard statements • Causes serious eye irritation
Causes mild skin irritation

Precautionary statements

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

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 • Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

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
Ammonium Lactate	CAS:515-98-0 EINECS:208-214-8	N/A	UN GHS: NDA
Behentrimonium methosulfate	CAS:81646-13-1 EINECS:279-791-1	N/A	UN GHS: NDA
Carbomer	CAS:9007-20-9	N/A	UN GHS: NDA
Ceramides	CAS:100403-19-8 EINECS:309-560-3	N/A	UN GHS: NDA
Cetearyl alcohol	CAS:67762-27-0 EINECS:267-008-6	N/A	UN GHS: NDA
Cetyl Alcohol	CAS:36653-82-4 EINECS:253-149-0	N/A	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Cholecalciferol	CAS:67-97-0 EINECS:200-673-2	N/A	UN GHS: Acute Tox. Oral 3; Acute Tox. Dermal 3; Acute Tox. Inhal. 2; STOT RE 1
Cholesterol	CAS:57-88-5 EINECS:200-353-2	N/A	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Carc. 1A
Dimethicone	CAS:9006-65-9	N/A	UN GHS: NDA
Edetate disodium	CAS:6381-92-6	N/A	UN GHS:
Glycerin	CAS:56-81-5 EINECS:200-289-5	N/A	UN GHS: Skin Irrit. 3; Eye Irrit. 2B
Glycerol monostearate	CAS:11099-07-3 EINECS:234-325-6	N/A	UN GHS: NDA
Hyaluronic acid, sodium salt	CAS:9067-32-7	N/A	UN GHS: NDA

Methylparaben	CAS:99-76-3 EINECS:202-785-7	N/A	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Niacinamide	CAS:98-92-0 EINECS:202-713-4	N/A	UN GHS: NDA
PEG-100 Stearate	CAS:9004-99-3	N/A	UN GHS: NDA
Phenoxyethanol	CAS:122-99-6 EINECS:204-589-7	N/A	UN GHS: Eye Irrit. 2A; Acute Tox. Oral 4
phytospingosine	CAS:554-62-1	N/A	UN GHS: NDA
Propylparaben	CAS:94-13-3 EINECS:202-307-7	N/A	UN GHS: NDA
Salicylic acid	CAS:69-72-7 EINECS:200-712-3	N/A	UN GHS: Skin Corr. 1; Skin Irrit. 2; Eye Dam. 1; Eye Irrit. 2A
Sodium Lauroyl Lactylate	CAS:13557-75-0 EINECS:236-942-6	N/A	UN GHS: NDA
Triethanolamine	CAS:102-71-6 EINECS:203-049-8	N/A	UN GHS: Skin Irrit. 3; Eye Irrit. 2A; Skin Sens. 1B; Acute Tox. Oral 5; STOT SE 3: Resp. Irrit.
Water	CAS:7732-18-5 EINECS:231-791-2	N/A	UN GHS: Classification Criteria Not Met
White mineral oil	CAS:8042-47-5 EINECS:232-455-8	N/A	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Xanthan gum	CAS:11138-66-2 EINECS:234-394-2	N/A	UN GHS: NDA

N/A - Designates that the chemical percentage of composition is not available as it is considered proprietary information.

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

- For accidental and non-therapeutic exposures, immediately flush skin with large amounts of water. Remove contaminated clothing. If irritation (redness, rash, blistering) develops, get medical attention. 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

- 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

Other information

- Have the product container or label with you when calling a poison control center or

doctor, or going for treatment.

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	OSHA
Triethanolamine (102-71-6)	TWAs	5 mg/m ³ TWA	5 mg/m ³ TWAEV	Not established
Glycerin (56-81-5)	TWAs	Not established	10 mg/m ³ TWAEV (mist)	15 mg/m ³ TWA (mist, total particulate); 5 mg/m ³ TWA (mist, respirable fraction)

Exposure controls

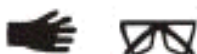
Engineering Measures/Controls

- 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 odor.	Odor Threshold	No data available
General Properties			
Boiling Point	No data available	Melting Point/Freezing 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	No data available	Vapor Density	No data available
Evaporation Rate	No data available		
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

GHS Properties	Classification
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Eye Irritation 2
Acute toxicity	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	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
Germ Cell Mutagenicity	UN GHS • Classification criteria not met

Potential Health Effects

Inhalation

Acute (Immediate)

- Under normal conditions of use, no health effects are expected.

Chronic (Delayed)

- Under normal conditions of use, no health effects are expected.

Skin

- Acute (Immediate)**
 - Causes skin irritation.
- Chronic (Delayed)**
 - Repeated and prolonged exposure may cause sensitization.

Eye

- Acute (Immediate)**
 - Causes serious eye irritation.
- Chronic (Delayed)**
 - Under normal conditions of use, no health effects are expected.

Ingestion

- Acute (Immediate)**
 - May be harmful if swallowed.
- Chronic (Delayed)**
 - Under normal conditions of use, no health effects are expected.

Carcinogenic Effects			
	CAS	IARC	NTP
Cholesterol	57-88-5	Group 3-Not Classifiable	Not Listed
Salicylic acid	69-72-7	Not Listed	Evidence of Carcinogenicity
Triethanolamine	102-71-6	Group 3-Not Classifiable	Evidence of Carcinogenicity

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	Not Applicable	Not Regulated	Not Applicable	Not Applicable	NDA
TDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	NDA
IMO/IMDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	NDA
IATA/ICAO	Not Applicable	Not Regulated	Not Applicable	Not Applicable	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
Cetyl Alcohol	36653-82-4	Yes	Yes	Yes
Cetearyl alcohol	67762-27-0	Yes	Yes	Yes
Cholecalciferol	67-97-0	Yes	Yes	Yes
Behentrimonium methosulfate	81646-13-1	Yes	Yes	No
Glycerin	56-81-5	Yes	Yes	Yes
Glycerol monostearate	11099-07-3	Yes	Yes	Yes
Niacinamide	98-92-0	Yes	Yes	Yes
PEG-100 Stearate	9004-99-3	Yes	No	Yes
Ammonium Lactate	515-98-0	Yes	Yes	Yes
Salicylic acid	69-72-7	Yes	Yes	Yes
Triethanolamine	102-71-6	Yes	Yes	Yes
White mineral oil	8042-47-5	Yes	Yes	Yes

Canada

Labor

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

• Glycerol monostearate	11099-07-3	Not Listed
• Cetyl Alcohol	36653-82-4	Not Listed
• Triethanolamine	102-71-6	Not Listed
• Glycerin	56-81-5	Restricted (Manufacturers of oral and leave-on products containing Glycerin must ensure the raw material used is within the specifications of an accepted pharmacopoeia with respect to Diethylene glycol (DEG) impurities (e.g. Glycerin Official Monograph in the most current edition of the USP))
• White mineral oil	8042-47-5	Not Listed
• Salicylic acid	69-72-7	Restricted (Permitted at concentrations <=2%)
• Cetearyl alcohol	67762-27-0	Not Listed
• Cholecalciferol	67-97-0	Restricted (Average daily absorption must be <=25 µg per day)
• Niacinamide	98-92-0	Not Listed

• PEG-100 Stearate	9004-99-3	Not Listed
• Ammonium Lactate	515-98-0	Not Listed
• Behentrimonium methosulfate	81646-13-1	Not Listed

Canada - WHMIS - Classifications of Substances

• Glycerol monostearate	11099-07-3	Uncontrolled product according to WHMIS classification criteria
• Cetyl Alcohol	36653-82-4	D2B
• Triethanolamine	102-71-6	Uncontrolled product according to WHMIS classification criteria
• Glycerin	56-81-5	Uncontrolled product according to WHMIS classification criteria
• White mineral oil	8042-47-5	Uncontrolled product according to WHMIS classification criteria
• Salicylic acid	69-72-7	D2A
• Cetearyl alcohol	67762-27-0	Not Listed
• Cholecalciferol	67-97-0	Not Listed
• Niacinamide	98-92-0	Uncontrolled product according to WHMIS classification criteria
• PEG-100 Stearate	9004-99-3	Uncontrolled product according to WHMIS classification criteria
• Ammonium Lactate	515-98-0	Not Listed
• Behentrimonium methosulfate	81646-13-1	Not Listed

Canada - WHMIS - Ingredient Disclosure List

• Glycerol monostearate	11099-07-3	Not Listed
• Cetyl Alcohol	36653-82-4	Not Listed
• Triethanolamine	102-71-6	1 %
• Glycerin	56-81-5	Not Listed
• White mineral oil	8042-47-5	Not Listed
• Salicylic acid	69-72-7	0.1 %
• Cetearyl alcohol	67762-27-0	Not Listed
• Cholecalciferol	67-97-0	Not Listed
• Niacinamide	98-92-0	Not Listed
• PEG-100 Stearate	9004-99-3	1 %
• Ammonium Lactate	515-98-0	Not Listed
• Behentrimonium methosulfate	81646-13-1	Not Listed

Europe

Other

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

• Glycerol monostearate	11099-07-3	Not Listed
• Cetyl Alcohol	36653-82-4	Not Listed
• Triethanolamine	102-71-6	Not Listed
• Glycerin	56-81-5	Not Listed
• White mineral oil	8042-47-5	Not Listed
• Salicylic acid	69-72-7	Not Listed
• Cetearyl alcohol	67762-27-0	Not Listed

• Cholecalciferol	67-97-0	T; R24/25-48/25 T+; R26
• Niacinamide	98-92-0	Not Listed
• PEG-100 Stearate	9004-99-3	Not Listed
• Ammonium Lactate	515-98-0	Not Listed
• Behentrimonium methosulfate	81646-13-1	Not Listed

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

• Glycerol monostearate	11099-07-3	Not Listed
• Cetyl Alcohol	36653-82-4	Not Listed
• Triethanolamine	102-71-6	Not Listed
• Glycerin	56-81-5	Not Listed
• White mineral oil	8042-47-5	Not Listed
• Salicylic acid	69-72-7	Not Listed
• Cetearyl alcohol	67762-27-0	Not Listed
• Cholecalciferol	67-97-0	T+ R:24/25-26-48/25 S:(1/2)-28-36/37-45
• Niacinamide	98-92-0	Not Listed
• PEG-100 Stearate	9004-99-3	Not Listed
• Ammonium Lactate	515-98-0	Not Listed
• Behentrimonium methosulfate	81646-13-1	Not Listed

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

• Glycerol monostearate	11099-07-3	Not Listed
• Cetyl Alcohol	36653-82-4	Not Listed
• Triethanolamine	102-71-6	Not Listed
• Glycerin	56-81-5	Not Listed
• White mineral oil	8042-47-5	Not Listed
• Salicylic acid	69-72-7	Not Listed
• Cetearyl alcohol	67762-27-0	Not Listed
• Cholecalciferol	67-97-0	S:(1/2)-28-36/37-45
• Niacinamide	98-92-0	Not Listed
• PEG-100 Stearate	9004-99-3	Not Listed
• Ammonium Lactate	515-98-0	Not Listed
• Behentrimonium methosulfate	81646-13-1	Not Listed

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

• Glycerol monostearate	11099-07-3	Not Listed
• Cetyl Alcohol	36653-82-4	Not Listed
• Triethanolamine	102-71-6	Not Listed
• Glycerin	56-81-5	Not Listed
• White mineral oil	8042-47-5	Not Listed
• Salicylic acid	69-72-7	Not Listed
• Cetearyl alcohol	67762-27-0	Not Listed
• Cholecalciferol	67-97-0	Not Listed
• Niacinamide	98-92-0	Not Listed
• PEG-100 Stearate	9004-99-3	Not Listed
• Ammonium Lactate	515-98-0	Not Listed
• Behentrimonium methosulfate	81646-13-1	Not Listed

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

• Glycerol monostearate	11099-07-3	Not Listed
• Cetyl Alcohol	36653-82-4	Not Listed

• Triethanolamine	102-71-6	Not Listed
• Glycerin	56-81-5	Not Listed
• White mineral oil	8042-47-5	Not Listed
• Salicylic acid	69-72-7	Not Listed
• Cetearyl alcohol	67762-27-0	Not Listed
• Cholecalciferol	67-97-0	Not Listed
• Niacinamide	98-92-0	Not Listed
• PEG-100 Stearate	9004-99-3	Not Listed
• Ammonium Lactate	515-98-0	Not Listed
• Behentrimonium methosulfate	81646-13-1	Not Listed

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

• Glycerol monostearate	11099-07-3	Not Listed
• Cetyl Alcohol	36653-82-4	Not Listed
• Triethanolamine	102-71-6	Not Listed
• Glycerin	56-81-5	Not Listed
• White mineral oil	8042-47-5	Not Listed
• Salicylic acid	69-72-7	Not Listed
• Cetearyl alcohol	67762-27-0	Not Listed
• Cholecalciferol	67-97-0	Not Listed
• Niacinamide	98-92-0	Not Listed
• PEG-100 Stearate	9004-99-3	Not Listed
• Ammonium Lactate	515-98-0	Not Listed
• Behentrimonium methosulfate	81646-13-1	Not Listed

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

• Glycerol monostearate	11099-07-3	Not Listed
• Cetyl Alcohol	36653-82-4	Not Listed
• Triethanolamine	102-71-6	Not Listed
• Glycerin	56-81-5	Not Listed
• White mineral oil	8042-47-5	Not Listed
• Salicylic acid	69-72-7	Not Listed
• Cetearyl alcohol	67762-27-0	Not Listed
• Cholecalciferol	67-97-0	Not Listed
• Niacinamide	98-92-0	Not Listed
• PEG-100 Stearate	9004-99-3	Not Listed
• Ammonium Lactate	515-98-0	Not Listed
• Behentrimonium methosulfate	81646-13-1	Not Listed

Section 16 - Other Information

Revision Date	• 19/August/2015
Last Revision Date	• 19/August/2015
Preparation Date	• 19/August/2015
Disclaimer/Statement of Liability	• 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.
