Safety Data Sheet



Section 1: Identification

Product identifier

Product Name CeraVe Baby Diaper Cream

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

Recommended use

Diaper cream

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

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 Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

	Coi	mposit	ion
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Allantoin	CAS:7303-80-2	N/A	UN GHS: NDA
Aluminum magnesium hydroxide	CAS:39366-43-3 EINECS:254-430-0	N/A	UN GHS: NDA
Carbomer	CAS:76050-42-5	N/A	UN GHS: NDA
Ceramide	CAS:104404-17-3	N/A	UN GHS: NDA
Ceramide 1	CAS:100403-19-8 EINECS:309-560-3	N/A	UN GHS: NDA
Ceramide 3	CAS:173059-97-7	N/A	UN GHS: NDA
Cetyl PEG/PPG-10/1 Dimethicone	CAS:144243-53-8	N/A	UN GHS: NDA
Cholesterol	CAS:57-88-5 EINECS:200-353-2	N/A	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Carc. 1A
Cyclohexasiloxane	CAS:540-97-6 EINECS:208-762-8	N/A	UN GHS: NDA
Cyclopentasiloxane	CAS:541-02-6 EINECS:208-764-9	N/A	UN GHS: NDA
Dimethicone	CAS:63148-62-9	1%	UN GHS: NDA
Ethylhexylglycerin	CAS:70445-33-9	N/A	UN GHS: Eye Dam. 1
Hexyl laurate	CAS:34316-64-8 EINECS:251-932-1	N/A	UN GHS: NDA
Niacinamide	CAS:98-92-0 EINECS:202-713-4	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
Polyglyceryl-4-isostearate	CAS:91824-88-3	N/A	UN GHS: NDA
Sodium Chloride	CAS:20510-56-9	N/A	UN GHS: NDA
Sodium hyaluronate	CAS:9067-32-7	N/A	UN GHS: NDA
Sodium Lauroyl Lactylate	CAS:13557-75-0 EINECS:236-942-6	N/A	UN GHS: NDA
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
Zinc oxide	CAS:1314-13-2 EINECS:215-222-5	1%	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

 No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.

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Eye

If contact with eyes directly, flush with gently flowing fresh water thoroughly.

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

No data available

Hazards

No data available

Hazardous Combustion Products

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

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Storage

• Store at room temperature 20-25°C (68-77°F).

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

Personal Protective Equipment

Pictograms

 No special controls are required under conditions of intended use. Local exhaust ventilation should be provided when handling bulk product.





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.

Handle in accordance with good industrial hygiene and safety practice.

General Industrial Hygiene Considerations

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	No data available
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

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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		
Zinc oxide (1%)	1314-13-2	Acute Toxicity: Ingestion/Oral-Rat LDLo • >8437 mg/kg
Dimethicone (1%)	63148-62-9	Acute Toxicity: Ingestion/Oral-Rat LDLo • >5 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

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Chronic (Delayed)

No data available

Skin

Acute (Immediate)

Chronic (Delayed)

Not expected to cause skin irritation.

Not expected to cause skin irritation. Not expected to cause sensitization.

Eye

Acute (Immediate)

Chronic (Delayed)

May cause mild irritation.

Repeated and prolonged exposure may cause irritation.

Ingestion

Acute (Immediate)

 Not expected to be an exposure route. However, may cause gastric and intestinal irritation if ingested.

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

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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	Canada NDSL	EU EINECS	TSCA
Aluminum magnesium hydroxide	39366-43-3	No	Yes	Yes	Yes
Cetyl PEG/PPG-10/1 Dimethicone	144243-53- 8	Yes	No	No	No
Cyclohexasiloxane	540-97-6	Yes	No	Yes	Yes
Cyclopentasiloxane	541-02-6	Yes	No	Yes	Yes
Dimethicone	63148-62-9	Yes	No	No	Yes
Hexyl laurate	34316-64-8	Yes	No	Yes	Yes
Niacinamide	98-92-0	Yes	No	Yes	Yes
Polyglyceryl-4- isostearate	91824-88-3	No	No	No	No
Sodium Chloride	20510-56-9	No	No	No	No

Canada

Cycles asterilayers	E44 00 C	Not Listed
Cyclopentasiloxane	541-02-6	Not Listed
Cyclohexasiloxane	540-97-6	Not Listed
Niacinamide	98-92-0	Uncontrolled product according to WHMIS classification criteria
Polyglyceryl-4-isostearate	91824-88-3	Not Listed
Hexyl laurate	34316-64-8	Not Listed
Dimethicone	63148-62-9	Not Listed
Cetyl PEG/PPG-10/1 Dimethicone	144243-53-8	Not Listed
Sodium Chloride	20510-56-9	Not Listed
Aluminum magnesium hydroxide	39366-43-3	Not Listed

United States - California

□ Environment			
U.S California - Proposition 65 - Carcinogens List			
Cyclopentasiloxane	541-02-6	Not Listed	
Cyclohexasiloxane	540-97-6	Not Listed	
Niacinamide	98-92-0	Not Listed	
Polyglyceryl-4-isostearate	91824-88-3	Not Listed	
Hexyl laurate	34316-64-8	Not Listed	
Dimethicone	63148-62-9	Not Listed	
Cetyl PEG/PPG-10/1 Dimethicone	144243-53-8	Not Listed	

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Sodium Chloride	20510-56-9	Not Listed
Aluminum magnesium hydroxide	39366-43-3	Not Listed
U.S California - Proposition 65 - Developmental Toxicity		
Cyclopentasiloxane	541-02-6	Not Listed
Cyclohexasiloxane	540-97-6	Not Listed
Niacinamide	98-92-0	Not Listed
Polyglyceryl-4-isostearate	91824-88-3	Not Listed
Hexyl laurate	34316-64-8	Not Listed
Dimethicone	63148-62-9	Not Listed
Cetyl PEG/PPG-10/1 Dimethicone	144243-53-8	Not Listed
Sodium Chloride	20510-56-9	Not Listed
Aluminum magnesium hydroxide	39366-43-3	Not Listed
U.S California - Proposition 65 - Reproductive Toxicity - Female		
Cyclopentasiloxane	541-02-6	Not Listed
Cyclohexasiloxane	540-97-6	Not Listed
Niacinamide	98-92-0	Not Listed
Polyglyceryl-4-isostearate	91824-88-3	Not Listed
Hexyl laurate	34316-64-8	Not Listed
Dimethicone	63148-62-9	Not Listed
Cetyl PEG/PPG-10/1 Dimethicone	144243-53-8	Not Listed
Sodium Chloride	20510-56-9	Not Listed
Aluminum magnesium hydroxide	39366-43-3	Not Listed
U.S California - Proposition 65 - Reproductive Toxicity - Male		
Cyclopentasiloxane	541-02-6	Not Listed
Cyclohexasiloxane	540-97-6	Not Listed
Niacinamide	98-92-0	Not Listed
Polyglyceryl-4-isostearate	91824-88-3	Not Listed
Hexyl laurate	34316-64-8	Not Listed
Dimethicone	63148-62-9	Not Listed
Cetyl PEG/PPG-10/1 Dimethicone	144243-53-8	Not Listed
Sodium Chloride	20510-56-9	Not Listed
Aluminum magnesium hydroxide	39366-43-3	Not Listed

Section 16 - Other Information

Last Revision Date Preparation Date Disclaimer/Statement of Liability

- 02/June/2015
- 02/June/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.

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