Safety Data Sheet



Section 1: Identification

Product identifier

Product Name

Cortaid Maximum Strength Cream/OTC

Product Code

• 301875520052; 301875521011

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

Recommended use

 Skin care product. Temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to: eczema, insect bites, poison ivy, poison oak, or poison sumac, soaps, detergents, cosmetics, jewelry, seborrheic dermatitis or psoriasis.

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 • Eye Mild Irritation 2B

Label elements

UN GHS

WARNING

Hazard statements . May cause eye irritation

Precautionary statements

Prevention • Use personal protective equipment as required.

Wash thoroughly after handling.

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.

Preparation Date: 04/June/2015

Revision Date: 09/June/2015

Page 1 of 9

Format: GHS Language: English (US)

UN GHS

Storage/Disposal • Keep tightly closed. Store at room temperature 20-25°C (68-77°F), to maintain product integrity. Use before date marked on carton and/or container.

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	on	
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Ammonium acryloyldimethyltaurate/VP copolymer	CAS:335383-60-3	N/A	UN GHS: NDA
Carbomer	CAS:9003-01-4	N/A	UN GHS: NDA
Ceteareth-6	CAS:68439-49-6	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
Citric acid	CAS:77-92-9 EINECS:201-069-1	N/A	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5
Dimethicone	CAS:63148-62-9	N/A	UN GHS: NDA
Disodium ETDA	CAS:139-33-3 EINECS:205-358-3	N/A	UN GHS: NDA
Ethylparaben	CAS:120-47-8 EINECS:204-399-4	N/A	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Glycerin	CAS:56-81-5 EINECS:200-289-5	N/A	UN GHS: Skin Irrit. 3; Eye Irrit. 2B
Hydrocortisone	CAS:50-23-7 EINECS:200-020-1	1%	UN GHS: NDA
Methylparaben	CAS:99-76-3 EINECS:202-785-7	N/A	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Mineral Oil	CAS:8042-47-5 EINECS:232-455-8	N/A	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Petrolatum	CAS:8009-03-8 EINECS:232-373-2	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
Propylparaben	CAS:8001-25-0 EINECS:232-277-0	N/A	UN GHS: NDA
Sodium Citrate	CAS:68-04-2 EINECS:200-675-3	N/A	UN GHS: Eye Irrit. 2A
Stearyl alcohol	CAS:112-92-5 EINECS:204-017-6	N/A	UN GHS: NDA
VP/Eicosene Co	CAS:28211-18-9	N/A	UN GHS: NDA
Water	CAS:7732-18-5 EINECS:231-791-2	N/A	UN GHS: Classification Criteria Not Met

Preparation Date: 04/June/2015 Revision Date: 09/June/2015 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 specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention.

Skin

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

Eve

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

No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

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

Preparation Date: 04/June/2015 Format: GHS Language: English (US) Revision Date: 09/June/2015 UN GHS Page 3 of 9

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 20-25°C (68-77°F). Use before expiration date marked on carton and/or container.

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/Guidelin	es
	Result	Canada Quebec	OSHA
Glycerin (56-81-5)	TWAs	I TO MO/M3 TVVAEV (MIST)	15 mg/m3 TWA (mist, total particulate); 5 mg/m3 TWA (mist, respirable fraction)

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.

Eve/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

Preparation Date: 04/June/2015 Format: GHS Language: English (US) Revision Date: 09/June/2015 UN GHS Page 4 of 9

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid Cream	Appearance/Description	Smooth cream.
Color	White to off-white.	Odor	Not relevant
Odor Threshold	Not relevant		
General Properties			
Boiling Point	Not relevant	Melting Point	Not relevant
Decomposition Temperature	Not relevant	pH	4.2 to 5
Specific Gravity/Relative Density	Not relevant	Water Solubility	Not relevant
Viscosity	100000 to 900000 Centipoise (cPs, cP) or mPas	Oxidizing Properties:	Not relevant
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	Not relevant		

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 (N/A)	8009-03-8	Acute Toxicity: Intraperitoneal-Mouse LD50 • >50 g/kg

Preparation Date: 04/June/2015 Format: GHS Language: English (US) **UN GHS** Revision Date: 09/June/2015 Page 5 of 9

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 • Eye Mild Irritation 2B

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
Carbomer	9003-01-4	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

Preparation Date: 04/June/2015
Revision Date: 09/June/2015
Page 6 of 9
Format: GHS Language: English (US)
UN GHS

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

		Inve	ntory	
Component	CAS	Canada DSL	EU EINECS	TSCA
Ceteareth-6	68439-49-6	Yes	No	Yes
Glycerin	56-81-5	Yes	Yes	Yes
VP/Eicosene Co	28211-18-9	Yes	No	Yes
Dimethicone	63148-62-9	Yes	No	Yes
Mineral Oil	8042-47-5	Yes	Yes	Yes

Canada

Lal	bo	r
-----	----	---

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

· Ceteareth-6 68439-49-6 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))

Preparation Date: 04/June/2015 Format: GHS Language: English (US) Revision Date: 09/June/2015 **UN GHS**

 Mineral Oil VP/Eicosene Co Dimethicone	8042-47-5 28211-18-9 63148-62-9	Not Listed Not Listed Not Listed
Canada - WHMIS - Classifications of Substances		
Ceteareth-6	68439-49-6	Not Listed
• Glycerin	56-81-5	Uncontrolled product according to WHMIS classification criteria
Mineral Oil	8042-47-5	Uncontrolled product according to WHMIS classification criteria
VP/Eicosene Co	28211-18-9	Not Listed
Dimethicone	63148-62-9	Not Listed

United States - California

ironment .S California - Proposition 65 - Carcinogens List		
Ceteareth-6	68439-49-6 Not Listed	
Glycerin	56-81-5 Not Listed	
Mineral Oil	8042-47-5 Not Listed	
VP/Eicosene Co	28211-18-9 Not Listed	
Dimethicone	63148-62-9 Not Listed	
J.S California - Proposition 65 - Developmental Toxicity		
Ceteareth-6	68439-49-6 Not Listed	
Glycerin	56-81-5 Not Listed	
Mineral Oil	8042-47-5 Not Listed	
VP/Eicosene Co	28211-18-9 Not Listed	
Dimethicone	63148-62-9 Not Listed	
U.S California - Proposition 65 - Reproductive Toxicity - Female		
Ceteareth-6	68439-49-6 Not Listed	
• Glycerin	56-81-5 Not Listed	
• Mineral Oil	8042-47-5 Not Listed	
VP/Eicosene Co	28211-18-9 Not Listed	
Dimethicone	63148-62-9 Not Listed	
U.S California - Proposition 65 - Reproductive Toxicity - Male		
· Ceteareth-6	68439-49-6 Not Listed	
Glycerin	56-81-5 Not Listed	
Mineral Oil	8042-47-5 Not Listed	
VP/Eicosene Co	28211-18-9 Not Listed	
Dimethicone	63148-62-9 Not Listed	

Section 16 - Other Information

Last Revision Date

• 04/June/2015

Preparation Date

• 04/June/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

Preparation Date: 04/June/2015
Revision Date: 09/June/2015
Page 8 of 9
Format: GHS Language: English (US)
UN GHS

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.

Preparation Date: 04/June/2015

Revision Date: 09/June/2015

Format: GHS Language: English (US)

UN GHS