

SAFETY DATA SHEET

1. Identification

Product identifier	Cerave® Hydrocortisone Anti-Itch Cream		
Other means of identification	Not available.		
Recommended use	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.		
Recommended restrictions	None known.		
Manufacturer/Importer/Supplier/Distributor information			
Company name	Valeant Pharmaceuticals International, Inc.		
Address	2150 St. Elzéar Blvd. West Laval, Quebec H7L 4AB Canada		
Telephone	Customer Support	1-800-321-4576	
E-mail	Not available.		
Emergency phone number	3E Emergency Response Hotline	1-866-951-9833	

2. Hazard(s) identification

Physical hazards	Not classified.		
Health hazards	Acute toxicity, oral	Category 4	
	Acute toxicity, inhalation	Category 4	
	Serious eye damage/eye irritation	Category 2	
Environmental hazards	Not classified.		
OSHA defined hazards	Not classified.		
Label elements			



Signal word	Warning		
Hazard statement	Harmful if swallowed. Causes serious eye irritation. Harmful if inhaled.		
Precautionary statement			
Prevention	Avoid breathing mist or vapor. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves. Wear eye/face protection.		
Response	If swallowed: Call a poison center/doctor if you feel unwell. If on skin: Wash with plenty of water. If inhaled: Remove person to fresh air and keep comfortable for breathing. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.		
Storage	Store away from incompatible materials.		
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.		
Hazard(s) not otherwise classified (HNOC)	None known.		
Supplemental information	21.69% of the mixture consists of component(s) of unknown acute oral toxicity. 23.2% of the mixture consists of component(s) of unknown acute inhalation toxicity.		

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
HYDROCORTISONE		50-23-7	1 - < 3

Chemical name	Common name and synonyms	CAS number	%
ALOE BARBADENSIS (ALOE VERA) LEAF JUICE		85507-69-3	*
AVENA SATIVA (OAT) KERNEL EXTRACT		84012-26-0	*
BENZYL ALCOHOL		100-51-6	*
CARBOMER		9003-01-4	*
CERAMIDES		100403-19-8	*
CETEARYL ALCOHOL		67762-27-0	*
CHOLESTEROL		57-88-5	*
CHRYSANTHEMUM PARTHENIUM (FEVERFEW) EXTRACT		20554-84-1	*
Citric Acid		77-92-9	*
CYCLOMETHICONE		556-67-2	*
CYCLOPENTASILOXANE		541-02-6	*
DIMETHYL MEA		108-01-0	*
ETHYLHEXYLGLYCERIN		70445-33-9	*
FATTY ACIDS, C16-18, C12-18-ALKYL ESTERS		95912-87-1	*
GLYCERIN		56-81-5	*
ISOPROPYL MYRISTATE		110-27-0	*
ISOSTEARYL NEOPENTANOATE		58958-60-4	*
METHYL PARABEN		99-76-3	*
NIACINAMIDE		98-92-0	*
PEG-40 STEARATE		9004-99-3	*
PHENOXYETHANOL		122-99-6	*
PHYTOSPHINGOSINE		554-62-1	*
POTASSIUM LACTATE		85895-78-9	*
SODIUM HYALURONATE		9067-32-7	*
SODIUM LAUROYL LACTYLATE		13557-75-0	*
WATER		7732-18-5	*
XANTHAN GUM		11138-66-2	*

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

4. First-aid measures

Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Call a POISON CENTER or doctor/physician if you feel unwell.
Skin contact	Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Wash contaminated clothing before reuse.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Get medical advice/attention if you feel unwell.
Most important symptoms/effects, acute and delayed	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before reuse.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Not established.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of vapors and spray mists. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Avoid inhalation of vapors and spray mists. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Do not taste or swallow. When using, do not eat, drink or smoke. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Storage temperature: between 22-25°C (66-77°F) Store in original tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
GLYCERIN (CAS 56-81-5)	PEL	5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.

US. Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value
BENZYL ALCOHOL (CAS 100-51-6)	TWA	44.2 mg/m ³
		10 ppm

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	No special controls required during normal clinical use. When handling bulk product Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Eye wash facilities and emergency shower must be available when handling this product.

Individual protection measures, such as personal protective equipment

Eye/face protection	No eye protection required under conditions of intended use. When handling bulk product: Face shield is recommended. Wear safety glasses with side shields (or goggles).
Skin protection	
Hand protection	No hand protection required under conditions of intended use. When handling bulk product: Wear appropriate chemical resistant gloves.
Other	No special precautions needed under conditions of intended use. When handling bulk product: Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended.
Respiratory protection	No respiratory protection required under conditions of intended use. When handling bulk product: In case of insufficient ventilation, wear suitable respiratory equipment.
Thermal hazards	None known.
General hygiene considerations	Keep away from food and drink. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Appearance

Physical state	Liquid.
Form	Cream.
Color	White to off-white
Odor	Not available.
Odor threshold	Not available.
pH	4 - 5
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	0.00001 hPa estimated
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.

Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Harmful if inhaled.
Skin contact	No adverse effects due to skin contact are expected.
Eye contact	Causes serious eye irritation.
Ingestion	Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.

Information on toxicological effects

Acute toxicity Harmful if inhaled. Harmful if swallowed.

Components	Species	Test Results
BENZYL ALCOHOL (CAS 100-51-6)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	2000 mg/kg
<i>Inhalation</i>		
LC100	Rat	200 - 300 mg/l, 8 Hours
LC50	Rat	1000 mg/l, 8 Hours
<i>Oral</i>		
LD50	Mouse	1580 mg/kg
	Rabbit	1940 mg/kg
	Rat	1230 - 3100 mg/kg
<i>Other</i>		
LD50	Guinea pig	> 400 mg/kg
	Mouse	324 mg/kg
	Rat	53 mg/kg
Citric Acid (CAS 77-92-9)		
Acute		
<i>Oral</i>		
LD50	Mouse	5040 mg/kg
	Rat	6730 mg/kg
<i>Other</i>		
LD50	Mouse	42 mg/kg
	Rabbit	330 mg/kg
	Rat	883 mg/kg
ISOPROPYL MYRISTATE (CAS 110-27-0)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	5 g/kg
<i>Oral</i>		
LD50	Mouse	49700 mg/kg

Components	Species	Test Results
METHYL PARABEN (CAS 99-76-3)		
Acute		
<i>Oral</i>		
LD50	Dog	3000 mg/kg
	Guinea pig	3 g/kg
	Mouse	8 g/kg
	Rabbit	6 g/kg
<i>Other</i>		
LD50	Mouse	0.96 g/kg
	Rat	> 0.5 g/kg
NIACINAMIDE (CAS 98-92-0)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 2000 mg/kg
<i>Oral</i>		
LD50	Mouse	2500 mg/kg
	Rat	3500 mg/kg
<i>Other</i>		
LD50	Mouse	1800 mg/kg
	Rat	1680 mg/kg
PHENOXYETHANOL (CAS 122-99-6)		
Acute		
<i>Oral</i>		
LD50	Mouse	16500 mg/kg
	Rat	1260 mg/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation	Health injuries are not known or expected under normal use.
Serious eye damage/eye irritation	Causes serious eye irritation.
Respiratory or skin sensitization	
Respiratory sensitization	Not available.
Skin sensitization	This product is not expected to cause skin sensitization.
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
IARC Monographs. Overall Evaluation of Carcinogenicity	
CARBOMER (CAS 9003-01-4)	3 Not classifiable as to carcinogenicity to humans.
CHOLESTEROL (CAS 57-88-5)	3 Not classifiable as to carcinogenicity to humans.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	
Not listed.	
Reproductive toxicity	This product is not expected to cause reproductive or developmental effects.
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not available.
Chronic effects	Prolonged inhalation may be harmful.

12. Ecological information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
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Components	Species	Test Results
BENZYL ALCOHOL (CAS 100-51-6)		
Aquatic		
Fish	LC50	Bluegill (<i>Lepomis macrochirus</i>)
		10 mg/l, 96 hours
GLYCERIN (CAS 56-81-5)		
Aquatic		
Fish	LC50	Rainbow trout,donaldson trout (<i>Oncorhynchus mykiss</i>)
		51000 - 57000 mg/l, 96 hours
PHENOXYETHANOL (CAS 122-99-6)		
Aquatic		
Fish	LC50	Fathead minnow (<i>Pimephales promelas</i>)
		337 - 352 mg/l, 96 hours
XANTHAN GUM (CAS 11138-66-2)		
Aquatic		
Fish	LC50	Rainbow trout,donaldson trout (<i>Oncorhynchus mykiss</i>)
		320 - 560 mg/l, 96 hours

* Estimates for product may be based on additional component data not shown.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Partition coefficient n-octanol / water (log Kow)

BENZYL ALCOHOL	1.1
CYCLOPENTASILOXANE	5.2
GLYCERIN	-1.76
NIACINAMIDE	-0.37
PHENOXYETHANOL	1.16

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. One or more components are not listed on TSCA.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

PHENOXYETHANOL (CAS 122-99-6) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
 Delayed Hazard - No
 Fire Hazard - No
 Pressure Hazard - No
 Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No**SARA 313 (TRI reporting)**

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

PHENOXYETHANOL (CAS 122-99-6)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.**US state regulations****US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

US. Massachusetts RTK - Substance List

BENZYL ALCOHOL (CAS 100-51-6)

DIMETHYL MEA (CAS 108-01-0)

GLYCERIN (CAS 56-81-5)

US. New Jersey Worker and Community Right-to-Know Act

DIMETHYL MEA (CAS 108-01-0)

GLYCERIN (CAS 56-81-5)

PHENOXYETHANOL (CAS 122-99-6)

US. Pennsylvania Worker and Community Right-to-Know Law

BENZYL ALCOHOL (CAS 100-51-6)

DIMETHYL MEA (CAS 108-01-0)

GLYCERIN (CAS 56-81-5)

PHENOXYETHANOL (CAS 122-99-6)

US. Rhode Island RTK

PHENOXYETHANOL (CAS 122-99-6)

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 10-16-2014

Version # 01

Disclaimer Valeant cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.