

# SAFETY DATA SHEET

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## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

### Product identifier

**Product Name** Hydrocortisone Cream with Aloe 1%

### Other means of identification

**Synonyms** None

### Recommended use of the chemical and restrictions on use

**Recommended Use** Antibiotic, Liquid or Cream, Non-Aerosol

**Uses advised against** No information available

### Details of the supplier of the safety data sheet

**Supplier Name** Actavis  
**Supplier Address** 400 Interpace Parkway  
Parsippany  
NJ  
07054  
US  
**Supplier Phone Number** Phone:800-432-8534  
Contact Phone973-889-6975  
**Supplier Email** rhooper@actavis.com  
**Emergency telephone number**

## 2. HAZARDS IDENTIFICATION

### Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Reproductive toxicity	Category 1A
Specific target organ toxicity (repeated exposure)	Category 2

### GHS Label elements, including precautionary statements

#### Emergency Overview

<b>Signal word</b>	<b>Danger</b>
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**Hazard Statements**

May damage fertility or the unborn child  
May cause damage to organs through prolonged or repeated exposure

**Appearance** White**Physical State** Semi-Solid Liquid**Odor** Waxy**Precautionary Statements - Prevention**

Obtain special instructions before use  
Do not handle until all safety precautions have been read and understood  
Use personal protective equipment as required  
Do not breathe dust/fume/gas/mist/vapors/spray

**Precautionary Statements - Response**

IF exposed or concerned: Get medical advice/attention

**Precautionary Statements - Storage**

Store locked up

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**Hazards not otherwise classified (HNOC)**

Not applicable

**Unknown Toxicity**

10% of the mixture consists of ingredient(s) of unknown toxicity

**Other information**

No information available

**Interactions with Other Chemicals**

No information available.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight-%	Trade Secret
Supplier Trade Secret	Proprietary	1 - 5	*
Supplier Trade Secret	Proprietary	1 - 5	*
Supplier Trade Secret	Proprietary	1 - 5	*
Supplier Trade Secret	Proprietary	1 - 5	*
Supplier Trade Secret	Proprietary	1 - 5	*

\*The exact percentage (concentration) of composition has been withheld as a trade secret

## 4. FIRST AID MEASURES

### First aid measures

#### General Advice

Show this safety data sheet to the doctor in attendance.

#### Eye Contact

Rinse thoroughly with plenty of water, also under the eyelids. If symptoms persist, call a physician.

#### Skin Contact

Wash with soap and water.

#### Inhalation

Remove to fresh air.

#### Ingestion

Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person.

### Most important symptoms and effects, both acute and delayed

**Most Important Symptoms and Effects** No information available.

### Indication of any immediate medical attention and special treatment needed

#### Notes to Physician

Treat symptomatically.

## 5. FIRE-FIGHTING MEASURES

### Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

### Unsuitable extinguishing media

CAUTION: Use of water spray when fighting fire may be inefficient.

### Specific Hazards Arising from the Chemical

No information available.

#### Uniform Fire Code

Sensitizer: Liquid

### Hazardous Combustion Products

Carbon oxides.

### Explosion Data

**Sensitivity to Mechanical Impact** No.

**Sensitivity to Static Discharge** No.

### Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

## 6. ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures

**Personal Precautions** Avoid contact with eyes. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas.

**Other Information** Refer to protective measures listed in Sections 7 and 8.

### Environmental Precautions

**Environmental Precautions** Refer to protective measures listed in Sections 7 and 8.

### Methods and material for containment and cleaning up

**Methods for Containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Soak up with inert absorbent material. Pick up and transfer to properly labeled containers.

## 7. HANDLING AND STORAGE

### Precautions for safe handling

**Handling** Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.

### Conditions for safe storage, including any incompatibilities

**Storage** Keep container tightly closed. Store locked up.

**Incompatible Products** None known based on information supplied.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

**Exposure Guidelines** This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies

### Appropriate engineering controls

**Engineering Measures** Showers  
Eyewash stations  
Ventilation systems

### Individual protection measures, such as personal protective equipment

**Eye/Face Protection** No special protective equipment required.

**Skin and Body Protection** Wear protective gloves and protective clothing.

**Respiratory Protection**

No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

**Hygiene Measures**

Handle in accordance with good industrial hygiene and safety practice. Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical and Chemical Properties**

<b>Physical State</b>	Semi-Solid, Liquid	<b>Odor</b>	Waxy
<b>Appearance</b>	White	<b>Odor Threshold</b>	No information available
<b>Color</b>	No information available		

<b><u>Property</u></b>	<b><u>Values</u></b>	<b><u>Remarks</u></b>	<b><u>Method</u></b>
pH		None known	
Melting / freezing point	No data available	None known	
Boiling point / boiling range	No data available	None known	
Flash Point	No data available	None known	
Evaporation Rate	No data available	None known	
Flammability (solid, gas)	No data available	None known	
Flammability Limit in Air			
Upper flammability limit	No data available		
Lower flammability limit	No data available		
Vapor pressure	No data available	None known	
Vapor density	No data available	None known	
Specific Gravity	No data available	None known	
Water Solubility	No information available	None known	
Solubility in other solvents	No data available	None known	
Partition coefficient: n-octanol/water	No data available	None known	
Autoignition temperature	No data available	None known	
Decomposition temperature	No data available	None known	
Kinematic viscosity	No data available	None known	
Dynamic viscosity	No data available	None known	
Explosive properties	No data available		
Oxidizing Properties	No data available		

**Other Information**

<b>Softening Point</b>	No data available
<b>VOC Content (%)</b>	No data available
<b>Particle Size</b>	No data available
<b>Particle Size Distribution</b>	

## 10. STABILITY AND REACTIVITY

### Reactivity

No data available.

### Chemical stability

Stable under recommended storage conditions.

### Possibility of Hazardous Reactions

None under normal processing.

### Hazardous Polymerization

Hazardous polymerization does not occur.

### Conditions to avoid

None known based on information supplied.

### Incompatible materials

None known based on information supplied.

### Hazardous Decomposition Products

Carbon oxides.

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

#### Product Information

<b>Inhalation</b>	Specific test data for the substance or mixture is not available.
<b>Eye Contact</b>	Specific test data for the substance or mixture is not available.
<b>Skin Contact</b>	Specific test data for the substance or mixture is not available.
<b>Ingestion</b>	Specific test data for the substance or mixture is not available.

#### Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Supplier Trade Secret	= 20000 mg/kg ( Rat )	= 20800 mg/kg ( Rabbit )	-
Supplier Trade Secret	= 3650 mg/kg ( Rat )	-	-
Supplier Trade Secret	= 5000 mg/kg ( Rat )	-	-
Supplier Trade Secret	= 5 g/kg ( Rat )	> 2600 mg/kg ( Rabbit ) > 8000 mg/kg ( Rabbit ) > 2000 mg/kg ( Rat )	-

### Information on toxicological effects

**Symptoms** No information available.

### Delayed and immediate effects as well as chronic effects from short and long-term exposure

**Sensitization** No information available.

**Mutagenic Effects** No information available.

<b>Carcinogenicity</b>	Contains no ingredient listed as a carcinogen.
<b>Reproductive Toxicity</b>	Contains a known or suspected reproductive toxin.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	Causes damage to organs through prolonged or repeated exposure. Based on classification criteria from the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200), this product has been determined to cause systemic target organ toxicity from chronic or repeated exposure. (STOT RE).
<b>Chronic Toxicity</b>	Contains a known or suspected reproductive toxin. Possible risk of irreversible effects. Avoid repeated exposure. Prolonged exposure may cause chronic effects.
<b>Target Organ Effects</b>	Reproductive System.
<b>Aspiration Hazard</b>	No information available.

#### **Numerical measures of toxicity Product Information**

The following values are calculated based on chapter 3.1 of the GHS document

#### **ATEmix (oral)**

81,808.00 mg/kg

#### **ATEmix (dermal)**

64,757.00 mg/kg (ATE)

## **12. ECOLOGICAL INFORMATION**

#### **Ecotoxicity**

The environmental impact of this product has not been fully investigated.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Supplier Trade Secret	96h EC50: = 19000 mg/L (Pseudokirchneriella subcapitata)	96h LC50: = 51600 mg/L (Oncorhynchus mykiss) 96h LC50: 41 - 47 mL/L (Oncorhynchus mykiss) 96h LC50: = 51400 mg/L (Pimephales promelas) 96h LC50: = 710 mg/L (Pimephales promelas)	-	24h EC50: > 10000 mg/L 48h EC50: > 1000 mg/L
Supplier Trade Secret		48h LC50: 1000 - 1500 mg/L (Leuciscus idus)		48h EC50: = 353.54 mg/L

#### **Persistence and Degradability**

No information available.

#### **Bioaccumulation**

Chemical Name	Log Pow
Supplier Trade Secret	1.38
Supplier Trade Secret	6.65

#### **Other adverse effects**

No information available.

### 13. DISPOSAL CONSIDERATIONS

#### Waste treatment methods

#### **Disposal methods**

This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

#### **Contaminated Packaging**

Dispose of contents/containers in accordance with local regulations.

California Hazardous Waste Codes 311

### 14. TRANSPORT INFORMATION

<b>DOT</b>	NOT REGULATED
<b>Proper Shipping Name</b>	NON REGULATED
<b>Hazard Class</b>	N/A

<b>TDG</b>	Not regulated
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<b>MEX</b>	Not regulated
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<b>ICAO</b>	Not regulated
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<b>IATA</b>	Not regulated
<b>Proper Shipping Name</b>	NON REGULATED
<b>Hazard Class</b>	N/A

<b>IMDG/IMO</b>	Not regulated
<b>Hazard Class</b>	N/A

<b>RID</b>	Not regulated
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<b>ADR</b>	Not regulated
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<b>ADN</b>	Not regulated
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### 15. REGULATORY INFORMATION

#### International Inventories

TSCA	Complies
DSL	All components are listed either on the DSL or NDSL.

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

#### US Federal Regulations

#### **SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any





chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

**SARA 311/312 Hazard Categories**

Acute Health Hazard	No
Chronic Health Hazard	Yes
Fire Hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

**CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

**CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

**US State Regulations****California Proposition 65**

This product does not contain any Proposition 65 chemicals.

**U.S. State Right-to-Know Regulations**

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Rhode Island	Illinois
Supplier Trade Secret	X		X		

**International Regulations****Canada****WHMIS Hazard Class**

D2B - Toxic materials

**16. OTHER INFORMATION**

<b>NFPA</b>	<b>Health Hazards</b> 2	<b>Flammability</b> 0	<b>Instability</b> 0	<b>Physical and Chemical Hazards - Personal Protection</b>
<b>HMIS</b>	<b>Health Hazards</b> 1*	<b>Flammability</b> 0	<b>Physical Hazard</b> 0	X

**Chronic Hazard Star Legend** \* = Chronic Health Hazard

**Prepared By** Product Stewardship  
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Latham, NY 12110  
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**Revision Note** No information available



**Disclaimer**

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**End of Safety Data Sheet**