

## SAFETY DATA SHEET

**Manufacturer's Name:** Crown Laboratories, Inc  
**Street Address:** 349 Lafe Cox Drive  
**City, State, Zip Code:** Johnson City, TN 37604  
**Emergency Telephone No.:** Contact poison control center

**Distributor's Name:** Ascend Laboratories  
**Street Address:** 180 Summit Avenue, Suite 200  
**City, State, Zip Code:** Montvale, NJ 07645

### SECTION 1: IDENTIFICATION

Product Name:	Triamcinolone Acetonide Cream USP, 0.025%, 0.1%, 0.5 %.
Synonyms:	Triamcinolone Acetonide Cream USP, 0.025%; NDC 67877-317-15, NDC 67877-317-45, NDC 67877-317- 80; 0.1%.; NDC 67877-215-15, NDC 67877-251-30, NDC 67877251-45, NDC 67877-251-80; 0.5%; NDC 67877-318-15;
CAS #:	Not applicable.
Chemical Family:	Topical corticosteroid pharmaceutical cream.
Formula:	Triamcinolone Acetonide USP (Micronized), Purified Water, Emulsifying Wax NF, Mineral Oil, Propylene Glycol, Sorbitol Solution, Cetylpalmitate, Sorbic Acid, and Potassium Sorbate.

### SECTION 2: HAZARD IDENTIFICATION

**According to Regulations of 2012 OSHA Hazard Communications Standard; 29 CFR Part 1910.1200**

#### Classification of the product

No need for classification according to GHS criteria for this product.

#### Labeling elements

This product does not require a hazard warning label in accordance with GHS criteria.

#### Hazards not otherwise classified

No specific dangers are known, if the directions for use and storage on the label are followed.

#### Emergency overview

No particular hazards are known. Avoid ingestion and contact with eyes (could be an irritant to the eyes.)

SECTION 3: COMPOSITION / INGREDIENT INFORMATION							
NAME	CAS#	%	IARC	CARCINOGEN		HAZARD DATA	
				NTP	OSHA	ACGIH TLV	OSHA PEL
Triamcinolone Acetonide	76-25-5		no	no	no	not established	
Purified Water	7732-18-5		no	no	no	not established	
Emulsifying Wax	NA		no	no	no	not established	
Mineral Oil	8012-95-1		no	no	no	not established	
Propylene Glycol	57-55-6		no	no	no	not established	
Sorbitol Solution	50-70-4		no	no	no	not established	
Cetylpalmitate	540-10-3		no	no	no	not established	
Sorbic Acid	110-44-1		no	no	no	not established	
Potassium Sorbate	590-00-01		no	no	no	not established	

SECTION 4: FIRST AID PROCEDURES	
Eyes:	Flush eyes with plenty of water for at least 15 minutes. If irritation develops, seek medical attention.
Skin:	Wash thoroughly with soap and water. If irritation develops, discontinue use and seek medical attention.
Ingestion:	Give two glasses of water and induce vomiting. Never give anything by mouth to an unconscious person. Contact Poison Control Center.
Inhalation:	Very unlikely to occur, however, if it were to occur, remove to fresh air. If breathing is difficult, give oxygen. If breathing has stopped, give artificial respiration. If exposed to excessive levels or if exposure causes adverse symptoms seek immediate medical attention
<p><b>CALL A PHYSICIAN</b>  <b>CONTACT A POISON CONTROL CENTER</b></p>	

SECTION 5: FIRE FIGHTING MEASURES	
Flash Point:	Not applicable.
Auto-ignition Temperature °F:	Not applicable.
Flammable Limits in Air by Volume LEL:	Not applicable.
UEL:	Not applicable.
Extinguishing Media:	Alcohol foam, Dry chemical, Carbon dioxide.
Special Fire Fighting Procedures:	Use self-contained breathing apparatus and protective clothing.
Unusual Fire and Explosion Hazards:	May react with acids, bases and extreme heat.

SECTION 6: ACCIDENTAL RELEASE MEASURES	
Respiratory Protection:	General ventilation.
Skin Protection:	Normal hygiene.
Eye Protection:	Normal hygiene.
Other Protective Clothing or Equipment:	As needed to prevent repeated/prolonged contact.
Environmental Precautions:	This product is not regulated by RCRA. This product is not regulated by CERCLA (Superfund).

**SECTION 7: HANDLING AND STORAGE**

Precautions to be taken in Handling/Storage:	Keep container closed when not in use. Do not handle or store near heat, flame or oxidizers.
Hygienic Practices:	Wash thoroughly after handling. Use normal hygiene to protect hands, eyes and skin. Use general ventilation to protect your lungs. Do not wear contaminated clothing until thoroughly laundered.
When Material is Released or Spilled:	Assure slippery conditions are nullified. Add sand or dirt. Scoop up and remove. Wash area with soap and water. Dispose of in accordance with federal, state and local regulations.
Waste Disposal Methods:	Assure conformity with applicable disposal regulations. Dispose of absorbed material at approved incineration or chemical landfill waste disposal site.

**SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION (continued)**

Primary Route(s) of Entry:	Dermal
<u>Signs and Symptoms of Exposure</u>	
a. Overexposure Effects:	May cause reversible suppression of Hypothalamic-Pituitary-Adrenal Dysfunction, skin irritation and allergic reactions in sensitive individuals.
b. Chronic Effects:	Systemic absorption may cause effects similar to overexposure.
1. Inhalation:	Not likely due to the physical state of the product.
2. Eyes:	Will cause irritation. Not for ophthalmic use.
3. Skin:	System absorption may cause effects similar to overexposure.
4. Ingestion:	May cause hyperglycemia and glycosuria.
5. Medical Conditions Potentially Aggravated:	Hypothalamic-Pituitary-Adrenal axis. May cause allergic reaction and skin irritation.

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

Appearance and Odor:	A white cream that is essentially odorless.
Molecular Weight:	Not applicable.
pH:	4.0-5.5
Refractive Index @ 20° C:	Not applicable.
Viscosity @ 25° C:	No applicable.
Boiling Point:	212°F (100°C)
Freezing/Melting Point:	Not determined.
Congearing Point:	Not determined.
Vapor Pressure (mm Hg @ 20°C):	Not determined.
Vapor Density (Air=1):	Not determined.
Solubility in Water:	Disperses.
Solubility in Alcohol:	Partially soluble.
Solubility in Oil:	Partially soluble.
Solubility in Other:	Not applicable.
Specific Gravity (H <sub>2</sub> O=1):	<1.0 @ 20°C
% Volatile by Volume:	Not determined.
Evaporation Rate (Ether=1):	Not determined.

**SECTION 10: STABILITY AND REACTIVITY**

Stability: Conditions and Chemicals to Avoid:  Hazardous Combustion or Decomposition Products: Hazardous Polymerization:	(X) Stable      ( ) Unstable Avoid strong oxidizers, strong acids, bases and sources of heat. May emit toxic fumes. ( ) May Occur    (X) Will Not Occur
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**SECTION 11: TOXICOLOGICAL INFORMATION**

See Section 4 for First Aid Measures for specific routes of exposure  
 See Section 3 for ingredient information. No numerical measures of toxicity are available

**SECTION 12: ECOLOGICAL INFORMATION**

Aquatic Toxicity:	Not indicated.
Biodegradability:	Not indicated.
Partition Coefficient:	Not indicated.

**SECTION 13: DISPOSAL CONSIDERATIONS**

Assure disposal is performed in accordance with applicable local, state, and federal regulations.

**SECTION 14: TRANSPORTATION INFORMATION**

Special Precautions: Recommended Container: Protect the Container by: Container Should be Handled in an Area with: The Empty Container is: Precautionary Label:  Warning Placard: IMO Hazard Class #: UN/NA #: Hazard Classification: DOT Name: Shipping Instructions:	Keep container closed when not in use. Avoid heat and flame. As supplied (not sold in bulk quantity). Avoid physical damage and heat. Adequate, general ventilation. Not reusable. Prescription Only. For external use Only. Use as directed Not for ophthalmic use. Keep Out of Reach of Children. Not applicable. Not applicable. Not applicable. Not applicable. Keep away from oxidizers and sources of heat.
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**SECTION 15: REGULATORY INFORMATION**

Refer to the following references:

OSHA Regulations:	If respirator used, 29 CFR 1910.134 Not applicable.
DOT Regulations:	Not applicable.
EPA Regulations:	FDA: 21 CFR 330.5
Other:	NDC: 67877-317-15 (15g) 67877-317-45 (45g) 67877-317-80 (80g) 67877-251-15 (15g) 67877-251-30 (30g) 67877-251-45 (45g) 67877-251-45 (80g) 67877-318-15 (15g)

**SECTION 16: OTHER INFORMATION**

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