

MATERIAL SAFETY DATA SHEET

Manufacturer's Name: ALTANA INC.
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PHARMADERM DIVISION
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SECTION 1: IDENTITY

Product Name: Hydrocortisone Cream USP, 0.5%, 1% and 2.5%
Synonyms: None.
CAS #: None.
Chemical Family: Adrenocortical Cream
Formula: Hydrocortisone, Glycerin, Potassium Sorbate, Benzyl Alcohol, Lactic Acid 88%, Purified Water, Paraffin, Stearyl Alcohol, Glyceryl Monostearate, Isopropyl Palmitate, Polyoxyl 40 Stearate, and Sorbitan Monostearate.

SECTION 2: SAFETY and HAZARD RATINGS

Health (Acute-Chronic):	1-1	<div><u>RATINGS</u></div> <div>Minimal0</div> <div>Slight1</div> <div>Moderate2</div> <div>Severe3</div> <div>Extreme4</div>
Flammability:	0	
Reactivity:	0	
Environment (Air-Water-Soil):	0-1-0	
Special Hazards:	Not indicated.	
Protective Equipment:	General ventilation, eye and hand wash. (Not under standard application.)	

SECTION 3: EMERGENCY and FIRST AID PROCEDURES

Eyes: Flush eyes with plenty of water for at least 15 minutes.
Skin: Wash thoroughly with soap and water.
Ingestion: Give two glasses of water and induce vomiting if directed by medical personnel. Never give anything by mouth to an unconscious person.
Inhalation: Remove to fresh air. If breathing is difficult, give oxygen. If breathing has stopped, give artificial respiration.

CALL A PHYSICIAN
CONTACT A POISON CONTROL CENTER

SECTION 4: INGREDIENTS

NAME	CAS#	%	CARCINOGEN			HAZARD DATA	
			IARC	NTP	OSHA	ACGIH TLV	OSHA PEL
Hydrocortisone	50-23-7		no	no	no	not established	
Glycerin	56-81-5		no	no	no	not established	
Potassium Sorbate	590-00-1		no	no	no	not established	
Benzyl Alcohol	100-51-6		no	no	no	not established	
Lactic Acid	50-21-5		no	no	no	not established	
Purified Water	7732-18-5		no	no	no	not established	
Paraffin	64742-43-4		no	no	no	not established	
Stearyl Alcohol	112-92-5		no	no	no	not established	
Glyceryl Monostearate	123-94-4		no	no	no	not established	
Isopropyl Palmitate	142-91-6		no	no	no	not established	
Polyoxyl 40 Stearate	9004-99-3		no	no	no	not established	
Sorbitan Monostearate	1338-41-6		no	no	no	not established	

SECTION 5: FIRE and EXPLOSION HAZARD DATA

Flash Point:	Not determined.
Auto-ignition Temperature °F:	Not determined.
Flammable Limits in Air by Volume LEL:	Not determined.
UEL:	Not determined.
Extinguishing Media:	Foam, Dry chemical, Carbon dioxide.
Special Fire Fighting Procedures:	Use self-contained breathing apparatus when firefighting.
Unusual Fire and Explosion Hazards:	Do not store or mix with strong oxidizers or acids.

SECTION 6: REACTIVITY DATA (PHYSICAL HAZARDS)

Stability:	<input checked="" type="checkbox"/> Stable <input type="checkbox"/> Unstable
Conditions and Chemicals to Avoid:	Avoid strong oxidants, strong acids, alkalies and extreme heat.
Hazardous Combustion or Decomposition Products:	Carbon dioxide, Carbon monoxide.
Hazardous Polymerization:	<input type="checkbox"/> May Occur <input checked="" type="checkbox"/> Will Not Occur

SECTION 7: HEALTH HAZARDS**Primary Route(s) of Entry:**
Signs and Symptoms of Exposure

- a. Overexposure Effects:
b. Chronic Effects:

1. Inhalation:
2. Eyes:
3. Skin:
4. Ingestion:
5. Medical Conditions

Potentially Aggravated:

Dermal, Ingestion.

May cause reversible suppression of hypothalamic-pituitary-adrenal (HPA) axis, manifestations of Cushing's syndrome, hyperglycemia and glucosuria. May cause allergic reaction and skin irritation in sensitive individuals.

None expected under normal condition of use.

Topical forms will cause moderate irritation. Not for ophthalmic use.

May result in absorption corticosteroid. No effects expected under normal conditions of use.

May result in absorption of corticosteroid. May induce low toxicity.

Skin conditions. Systemic effects may be produced.

SECTION 8: SPECIAL PRECAUTIONS and SPILL/LEAK PROCEDURES

Precautions to be Taken in
Handling/Storage:

Keep container closed when not in use. Store at controlled room temperature 15°-30°C (59°-86°F). Avoid strong oxidants, strong acids, alkalies and extreme heat.

Hygienic Practices:

Wash thoroughly after handling. Use normal hygiene to protect hands, eyes and skin.

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 9: SPECIAL PROTECTION INFORMATION

Respiratory Protection:

General ventilation.

Skin Protection:

Normal hygiene.

Eye Protection:

Normal hygiene.

Other Protective Clothing or Equipment:

As needed to prevent repeated/prolonged contact.

SECTION 10: CONTAINERS and LABELING

Special Precautions:	Keep container closed when not in use. Store at controlled room temperature 15°-30°C (59°-86°F). Avoid strong oxidants, strong acids, alkalies and extreme heat.
Recommended Container:	As supplied (not sold in bulk quantity).
Protect the Container by:	Avoid physical damage and heat.
Container Should be Handled in an Area With:	Adequate general ventilation.
The Empty Container is:	Not reusable.
Precautionary Label:	Federal law prohibits dispensing without a prescription. For external use only. Not for ophthalmic use. (See package insert.)
Warning Placard:	Keep out of reach of children. Not to be used on children under 2 years of age.
IMO Hazard Class #:	Not applicable.
UN/NA #:	Not applicable.
Hazard Classification:	Not applicable.
DOT Name:	Not applicable.
Shipping Instructions:	Keep away from oxidizers, strong acids, alkalies, and heat.

SECTION 11: ENVIRONMENTAL RISKS

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

SECTION 12: REGULATORY INFORMATION

Refer to the following references:	OSHA Regulations:	If respirator used, 29 CFR 1910.134
	DOT Regulations:	Not applicable.
	EPA Regulations:	Not applicable.
	Other:	FDA: 21 CFR 330.5
		NDC: 0.5% (OTC) 0168-0014-31
		1% (OTC) 0168-0154-08, 0168-0154-31
		1% (R _x) 0168-0015-31, 0168-0015-16
		2.5% (R _x) 0168-0080-31, 0168-0080-16
		Federal law prohibits dispensing hydrocortisone in strengths above 1% without prescription.

SECTION 13: PHYSICAL DATA

Appearance and Odor:	A white cream with slight fatty odor.
Molecular Weight:	Not applicable.
pH:	Not indicated.
Refractive Index @ 20°C:	Not determined.
Viscosity:	Not determined.
Boiling Point:	135°C (275°F)
Freezing/Melting Point:	60°C (140°F)
Congeaing Point:	Not indicated.
Vapor Pressure (mm Hg @ 20°C):	Not indicated.
Vapor Density (Air=1):	Not indicated.
Solubility in Water:	Miscible.
Specific Gravity @ 50°C:	Not indicated.
% Volatile by Volume:	~ 63
Evaporation Rate (Ether=1):	0.07

Date of Preparation/Change:
March 15, 2005

Revision # 3

Replaces
October 16, 2000

The information presented herein relates to the specific material described and may not be valid for this material used in combination with any other materials or in any process. This information is, to the best of our knowledge, accurate and reliable on the date compiled. We make no representation, warranty or guarantee as to its accuracy, reliability or completeness.

It is the reader's responsibility to ascertain whether the information supplied is suitable and complete for that person's specific uses. This Material Safety Data Sheet was prepared for ALTANA INC. by:

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