

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

SECTION 1: IDENTIFICATION

Product Name:	Hydrocortisone 0.5% and Idochlorhydroxyquin 3% Cream
Synonyms:	Ala Quin; Dermasorb AF; NDC 0316-0123-01; NDC 0316-0123-05; NDC 0316-0123-80; NDC 0316-0203-01; NDC 0316-1025-01
CAS #:	Not applicable.
Chemical Family:	Topical corticosteroid pharmaceutical cream.
Formula:	Hydrocortisone USP, Idochlorhydroxyquin USP, Polysorbate 80, Purified Water, Cetyl Alcohol, Glycerin, Stearyl Alcohol, Sodium Lauryl Sulfate, Cetyl Palmitate, and Sorbic Acid.

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

					CARCINOGEN	HAZARD DATA
NAME	CAS#	IARC	NTP	OSHA	ACGIH TLV	OSHA PEL
Idochlorhydroxyquin	130-26-7	No	No	No	NE	NE
Hydrocortisone	50-23-7	No	No	No	NE	NE
Purified Water	7732-18-5	No	No	No	NE	NE
Cetyl Alcohol	36653-82-4	No	No	No	NE	NE
Glycerin	56-81-5	No	No	No	NE	NE
Stearyl Alcohol	112-92-5	No	No	No	NE	NE
Polysorbate 80	9005-65-6	No	No	No	NE	NE
Sodium Lauryl Sulfate	151-21-3	No	No	No	NE	NE
Cetyl Palmitate	95912-87-1	No	No	No	NE	NE
Sorbic Acid	110-44-1	No	No	No	NE	NE

NE = 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. 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

CALL A PHYSICIAN
CONTACT A POISON CONTROL CENTER

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:	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:	No special precautions necessary. 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

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:	Not determined
Refractive Index @ 20° C:	Not applicable.
Viscosity @ 25° C:	Not applicable.
Boiling Point:	Not determined
Freezing/Melting Point:	Not determined.
Congeaing 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 ₂ O=1):	Not determined; approximately 1 @ 20°C
% Volatile by Volume:	Not determined.
Evaporation Rate (Ether=1):	Not determined.

SECTION 10: STABILITY AND REACTIVITY

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

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:	Keep container closed when not in use. Avoid heat and flame.
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:	Prescription Only. For external use only. Use as directed Not for ophthalmic use.
Warning Placard:	Keep Out of Reach of Children.
IMO Hazard Class #:	Not regulated.
UN/NA #:	Not regulated.
Hazard Classification:	Not regulated.
DOT Name:	Not regulated.
Shipping Instructions:	Keep away from oxidizers and sources of heat.

SECTION 15: REGULATORY INFORMATION

Refer to the following references:	OSHA	If respirator used, 29 CFR 1910.134
	Regulations:	Not applicable.
	DOT Regulations:	Not applicable.
	EPA Regulations:	FDA: 21 CFR 330.5
	Other:	None

SECTION 16: OTHER INFORMATION

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