

SAFETY DATA SHEET

Distributor's Name: Crown Laboratories, Inc.
Street Address: 349 Lafe Cox Drive
City, State, Zip Code: Johnson City, TN 37604
Emergency Telephone Number: Contact poison control center

SECTION 1: IDENTIFICATION

Product Name:	Dermasorb XM (39% Urea Cream)
Synonyms:	39% Urea Cream, NDC 0316-0204-01; NDC 0316-1035-01
CAS #:	Not applicable
Chemical Family:	Prescription Cream
Formula:	Urea, Dimethyl Isosorbide, Emulsifying Wax, Glycerin, Isopropyl Myristate, Purified Water, Sorbitol, Tridecyl Stearate and Neopentyl Glycol Dicaprylate/Dicaprate, and Tridecyl Trimellitate

SECTION 2: HAZARD IDENTIFICATION

Health (Acute-Chronic):	1
Flammability:	0
Reactivity:	0
Environment (Air-Water-Soil):	1-1-1
Special Hazards:	None
Protective Equipment:	Eye and hand wash

RATINGS	
Minimal	0
Slight	1
Moderate	2
Severe	3
Extreme	4

SECTION 3: COMPOSITION / INGREDIENT INFORMATION

NAME	CAS#	CARCINOGEN			HAZARD DATA	
		IARC	NTP	OSHA	ACGIH TLV	OSHA PEL
Urea	57-13-6	no	no	no	not established	
Purified Water	7732-18-5	no	no	no	not established	
Dimethyl Isosorbide	5306-85-4	no	no	no	not established	
Emulsifying Wax	N/A	no	no	no	not established	
Glycerin	56-81-5	no	no	no	not established	
Isopropyl Myristate	110-27-0	no	no	no	not established	
Sorbitol	50-70-4	no	no	no	not established	
Tridecyl Stearate	31556-45-3	no	no	no	not established	
Neopentyl Glycol Dicaprylate/Dicaprate	70693-32-2	no	no	no	not established	
Tridecyl Trimellitate	94109-09-8	no	no	no	not established	

SECTION 4: FIRST AID PROCEDURES

Eyes:	Flush eyes with large amounts of water for at least 15 minutes. If redness or irritation persists, contact a doctor
Skin:	If irritation develops, wash thoroughly with soap and water.
Ingestion:	Contact Poison Control Center. Never give anything by mouth to an unconscious person.
Inhalation:	If small amounts of this product are inhaled, specific treatment is generally not expected to be necessary. If exposed to excessive levels or if exposure causes adverse symptoms, remove to fresh air and seek immediate medical attention

CALL A PHYSICIAN or
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, water fog, or foam as appropriate
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: ACCIDENTIAL RELEASE MEASURES

Respiratory Protection:	General ventilation
Skin Protection:	Normal hygiene
Eye Protection:	Safety goggles or shield
Other Protective Clothing or Equipment:	As needed to prevent repeated/prolonged contact

SECTION 7: HANDLING AND STORAGE

Handling/Storage Precautions:	Keep container closed when not in use. Store in cool, dry area. Keep away from heat.
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.
Material Release or Spill:	Assure slippery conditions are nullified. Collect small spills with clean towel or mop. For larger spills, wear protective gear, collect in suitable container, wash spill area with water
Waste Disposal Methods:	Assure disposal is performed in accordance with applicable local, state and federal regulations.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

See Section 3 for Permissible Exposure Limits (PELs); Threshold Limit Values (TLVs)

See Section 6 for recommended Personal Protective Equipment (PPE)

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor:	White Cream, fragrance free, but may have slight ammonia odor
Molecular Weight:	Not applicable
pH:	8 - 10
Refractive Index @ 20° C:	Not determined
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:	Unknown
Solubility in Oil:	Not determined
Solubility in Other:	Not determined
Specific Gravity (H ₂ O=1):	~ 1.08
% 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, strong bases and sources of heat
Hazardous Combustion or Decomposition Products:	May emit ammonia fumes

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
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 applicable
UN/NA #:	Not applicable
Hazard Classification:	Not applicable
DOT Name:	Not applicable
Shipping Instructions:	Not applicable

SECTION 15: REGULATORY INFORMATION

Refer to the following references:	OSHA	Not applicable
	Regulations:	Not applicable
	DOT Regulations:	Not applicable
	EPA Regulations:	Not applicable
	Other:	None

SECTION 16: OTHER INFORMATION

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Date of Preparation/Change: November 18, 2013	Revision # 1	Replaces N/A
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