

DERMATONE MINERAL SPF 30- zinc oxide 20% lotion
Dermatone Labs LLC

Dermatone Mineral SPF 30 Sunscreen Lotion

Active ingredients

Zinc Oxide 20%

Purpose

Sunscreen

Uses

- Helps prevent sunburn, higher SPF gives more sunburn protection
- if used as directed with other sun protection measures (**see Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

WARNINGS

For external use only.

When using this product:

Stop use and ask a doctor if rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Inactive Ingredieints

WATER
CAPRYLIC/CAPRIC TRIGLYCERIDE
COCO-CAPRYLATE
BUTYLOCTYL SALICYLATE
NIACINAMIDE
POLYHYDROXYSTEARIC ACID
GLYCERIN
PANTHENOL
.ALPHA.-TOCOPHEROL ACETATE
SUCROSE PALMITATE
XANTHAN GUM
CITRIC ACID
SACCHARIDE ISOMERATE
SUCROSE TRISTEARATE
SODIUM STEAROYL GLUTAMATE
BENZYL ALCOHOL
DEHYDROACETIC ACID
SODIUM PHYTATE

DIRECTIONS

- Apply liberally 15 minutes before sun exposure.

- Reapply at least every 2 hours
- apply to all areas of the skin exposed to the sun.
- Reapply as needed or after towel drying, swimming, or sweating.
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. - 2. p.m.
 - wear a long-sleeve shirt, pants, hats, and sunglasses.
 - children under 6 months: Ask a doctor.

Do not use: on damage or broken skin

Non Printing Area

MINERAL

SPF

30

SUNSCREEN LOTION

Broad Spectrum SPF 30
Moisturizing & Non-Greasy
Reef Safe

2 FL OZ / 59 mL

Dermatone®

Drug Facts

Active Ingredient	Purpose
Zinc Oxide 20.0%	Sunscreen

Uses: Helps prevent sunburn • Higher SPF gives more sunburn protection. If used as directed with other sun protection measures (see directions), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only.

Do not use on damaged or broken skin.

When using the product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash or irritation develops and lasts.

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions • Apply liberally to face and neck 15 minutes before sun exposure and as needed. • Reapply at least every 2 hours. • Use a water-resistant sunscreen if swimming or sweating. • Children under 6 months: Ask a doctor.

Sun Protection Measures • Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad-spectrum SPF of 15 or higher and other sun protection measures including: • Limit time in the sun, especially from 10AM-2PM. • Wear long-sleeve shirts, pants, hats, and sunglasses.

Other Information Protect this product from excessive heat and direct sun.

Inactive Ingredients Water, Caprylic/Capric Triglyceride, Coco-Caprylate, Butyloctyl Salicylate, Niacinamide, Polyhydroxystearic Acid, Glycerin, Panthenol, Tocopheryl Acetate, Sucrose Palmitate, Glyceryl Stearate, Xanthan Gum, Citric Acid, Saccharide Isomerate, Sucrose Tristearate, Sodium Stearoyl Glutamate, Benzyl Alcohol, Dehydroacetic Acid, Sodium Phytate

Questions? Call 1-203-858-2663

Distributed by Dermatone Labs, LLC
Southport, CT 06890 • www.dermatone.com


MADE IN THE USA
With US and
Imported Materials


Dermatone®



DERMATONE MINERAL SPF 30

zinc oxide 20% lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54414-030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	20 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
NIACINAMIDE (UNII: 25X51I8RD4)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
GLYCERIN (UNII: PDC6A3C0OX)	
PANTHENOL (UNII: WW9CM0O67Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SUCROSE PALMITATE (UNII: 3OSQ643ZK5)	
GLYCERYL STEARATE (UNII: 230OU9XXE4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CITRIC ACID (UNII: 2968PHW8QP)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
SUCROSE TRISTEARATE (UNII: 71I93STU5M)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
SODIUM PHYTATE (UNII: 88496G1ERL)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54414-030-02	89 mL in 1 CONTAINER; Type 0: Not a Combination Product	08/21/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/21/2025	

Labeler - Dermatone Labs LLC (100928460)

Registrant - Inspec Solutions LLC (081030372)

Establishment

Name	Address	ID/FEI	Business Operations
Inspec Solutions LLC.		081030372	manufacture(54414-030)

Revised: 8/2025

Dermatone Labs LLC