

DERMATONE SPF 30 MINERAL SUNSCREEN- zinc oxide lotion
Dermatone Labs LLC

Dermatone SPF 30 Mineral Sunscreen Lotion

Active ingredients

Avobenzone 3.0%

Homosalate 15.0%

Octisalate 5.0%

Octocrylene 10.0%

Uses

- Helps prevent sunburn, higher SPF gives more sunburn protection
- retains SPF after XX minutes of activity in the water or sweating
- provides moderate protection against sunburn
- 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.

Highly Flammable: Do not apply or use product near heat, flame, or while smoking.

When using this product:

- keep out of eyes. Rinse with water to remove.
- Keep away from face to avoid breathing it.
- Do not puncture or incinerate, Contents under pressure
- Do not store at temperature above 120°F

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

When using this product:

- keep out of eyes. Rinse with water to remove.
- Keep away from face to avoid breathing it.
- Do not puncture or incinerate, Contents under pressure
- Do not store at temperature above 120°F

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

Behenyl Alcohol

BHT

Butyloctyl Salicylate

Caprylyl Methicone

Dimethicone

Dimethyl Capramide

Disodium EDTA

Ethylhexyl Stearate

Ethylhexylglycerin

Glyceryl Stearate

Hydrated Silica

PEG-100 Stearate

Phenoxyethanol

Polyester-8

Sodium Polyacrylate

Styrene/ Acrylate Copolymer

Trideceth-6

Trimethylsiloxysilicate

VP/Hexadecene Copolymer

Water

Xanthan Gum

DIRECTIONS

- Apply liberally 15 minutes before sun exposure.

- Reapply:

after 80 minutes of swimming or sweating

immediately after towel drying

at least every 2 hours

- Hold container 4 to 6 inches from the skin to apply.
- Do not spray directly into face. Spray on hands then apply to face.
- Do not apply in windy conditions.
- Use in a well-ventilated area.
- For sunscreen use
- apply to all areas of the skin exposed to the sun.
- Reapply as needed or after towel drying, swimming, or sweating.

Sunscreen

Non Printing Area

MINERAL
SPF
30
Dermatone®
SUNSCREEN LOTION

Broad Spectrum SPF 30
Moisturizing & Non-Greasy
Reef Safe

2 FL OZ / 59 mL

Drug Facts

Active Ingredient
Zinc Oxide 20.0%

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.

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



Non Printing Area

FRONT

BACK

DERMATONE SPF 30 MINERAL SUNSCREEN

zinc oxide lotion

Product Information							
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:54414-052			
Route of Administration		TOPICAL					
Active Ingredient/Active Moiety							
Ingredient Name			Basis of Strength	Strength			
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)			ZINC OXIDE	20 g in 100 mL			
Inactive Ingredients							
Ingredient Name				Strength			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)							
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)							
COCO-CAPRYLATE (UNII: 4828G836N6)							
DEHYDROACETIC ACID (UNII: 2KAG279R6R)							
GLYCERIN (UNII: PDC6A3C0OX)							
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)							
SUCROSE LAURATE (UNII: 05Q7CD0E49)							
XANTHAN GUM (UNII: TTV12P4NEE)							
SUCROSE STEARATE/PALMITATE ESTER (75% MONO ESTER) (UNII: L98X941W2B)							
CYNARA SCOLYMUS LEAF (UNII: B71UA545DE)							
NIACINAMIDE (UNII: 25X51I8RD4)							
PANTHENOL (UNII: WV9CM0O67Z)							
SACCHARIDE ISOMERATE (UNII: W8K377W98I)							
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)							
HEXASODIUM PHYTATE (UNII: ZBX50UG81V)							
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)							
TURMERIC (UNII: 856YO1Z64F)							
TOCOPHEROL (UNII: R0ZB2556P8)							
WATER (UNII: 059QF0KO0R)							
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)							
PROPYLPARABEN (UNII: Z8IX2SC1OH)							
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)							
SORBITOL (UNII: 506T60A25R)							
STEARIC ACID (UNII: 4ELV7Z65AP)							
BENZYL ALCOHOL (UNII: LKG8494WBH)							
Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:54414-052-01	59 mL in 1 TUBE; Type 0: Not a Combination Product	06/26/2022				
Marketing Information							
Marketing		Application Number or Monograph		Marketing Start		Marketing End	

Category	Citation	Date	Date
OTC Monograph Drug	M020	06/26/2022	

Labeler - Dermatone Labs LLC (100928460)

Registrant - Inspec Solutions LLC. (081030372)

Establishment

Name	Address	ID/FEI	Business Operations
Inspec Solutions LLC.		081030372	manufacture(54414-052)

Revised: 4/2025 Dermatone Labs LLC