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

Dermatone Mineral SPF 30 Sunscreen Lotion

Active ingredients	**Purpose**
Zinc Oxide 20%	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 Ingredeints

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 tme 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 no use: on damage or broken skin

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: WV9CM0O67Z)	
.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)