# HEALTHY MINERAL SUNSCREEN NO SHINE - NO TINT- titanium dioxide, zinc oxide cream Zen Dermatology, Inc.

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# **Active Ingredients:**

Titanium Dioxide 8% Zinc Oxide 3.8%

# **Purpose:**

Sunscreen

#### **Uses:**

Helps prevents 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. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. Keep out of the reach of children. If swallowed, get medical help or contact a poison control center right away.

# Warnings:

Keep out of the reach of children

#### **Directions:**

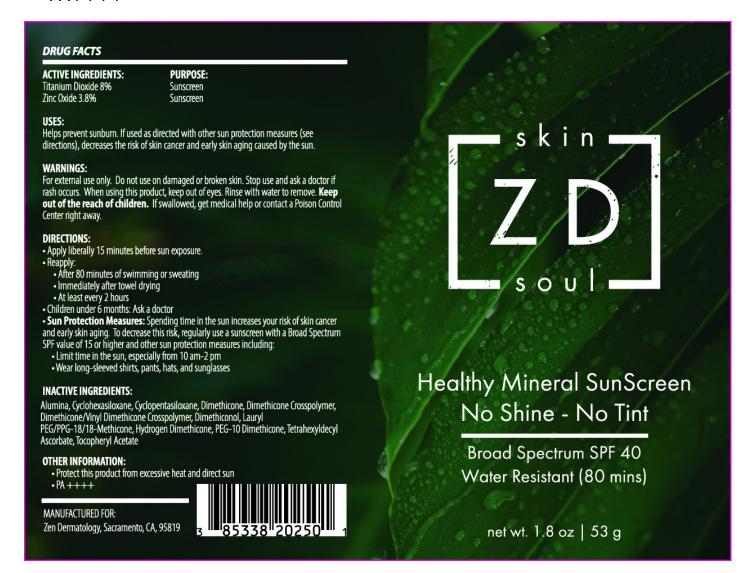
• Apply liberally 15 minutes before sun exposure. • Reapply: • After 80 minutes of swimming or sweating • Immediately after towel drying • At least every 2 hours • Children under 6 months: Ask a doctor • Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: •Limit time in the sun, especially from 10 am-2 pm •Wear long-sleeved shirts, pants, hats, and sunglasses

# **Inactive Ingredients:**

Alumina, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Lauryl PEG/PPG-18/18 Methicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate

#### Other Information:

- Protect this product from excessive heat and direct sun.
- PA++++



### **HEALTHY MINERAL SUNSCREEN NO SHINE - NO TINT**

titanium dioxide, zinc oxide cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85338-202	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	80 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	38 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
ALUMINA (UNII: LMI26O6933)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
DIMETHICONE (UNII: 92RU3N3Y10)	

l	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:85338- 202-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/17/2024		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M020	04/17/2024		

# Labeler - Zen Dermatology, Inc. (113127065)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Fragrance Manufacturing Inc.		793406000	manufacture(85338-202)

Establishment					
Name	Address	ID/FEI	Business Operations		
Custom Analytics LLC		144949372	analysis (85338-202)		

Revised: 3/2025 Zen Dermatology, Inc.