

FACIAL MINERAL SUNSCREEN MINERAL PROTECTION- titanium dioxide, zinc oxide cream
CAPE COD SKIN CARE CO. INC.



Facial Mineral Sunscreen Mineral Protection

Tinted

SPF 40 BROAD SPECTRUM
 WATER RESISTANT (80 MINUTES)

Zinc Oxide | Titanium Dioxide

NET WT. 1.8 OZ / 53 G

DRUG FACTS	
ACTIVE INGREDIENT: Titanium Dioxide 8% Zinc Oxide 3.8%	PURPOSE: Sunscreen Sunscreen
USES: Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early 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 reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
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, Iron Oxide (CI 77491), 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 · May stain some fabrics · PA+++	
MANUFACTURED FOR: Cape Cod Skin Care® Cotuit, MA 02635 www.capecodskincare.com · (508) 420-5100	

FACIAL MINERAL SUNSCREEN MINERAL PROTECTION

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85627-203(NDC:58892-203)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	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
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
CI 77499 (UNII: XM0M87F357)	
CI 77491 (UNII: 1K09F3G675)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALUMINA (UNII: LMI26O6933)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
CI 77492 (UNII: EX438O2MRT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85627-203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/03/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/03/2017	

Labeler - CAPE COD SKIN CARE CO. INC. (042396858)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85627-203)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc		793406000	manufacture(85627-203)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85627-203)