

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

DRUG FACTS (cont)

• 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 (CI77491), 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+++



CAPE COD SKIN CARE®

FACIAL MINERAL SUNSCREEN

MINERAL PROTECTION

SPF 40 BROAD SPECTRUM
 WATER RESISTANT (80 MINUTES)

NET WT. 3 OZ / 85 G

DRUG FACTS

ACTIVE INGREDIENTS: 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 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.

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

Distributed By:
 Cape Cod Skin Care
 Cotuit, MA 02635



FACIAL MINERAL SUNSCREEN MINERAL PROTECTION			
titanium dioxide, zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85627-201(NDC:58892-201)
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	38 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	80 mg in 1 g
Inactive Ingredients			
Ingredient Name			Strength

CYCLOHEXASILOXANE (UNII: XHK3U310BA)
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)
CI 77491 (UNII: 1K09F3G675)
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
DIMETHICONE (UNII: 92RU3N3Y1O)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
CI 77499 (UNII: XM0M87F357)
ALUMINA (UNII: LMI26O6933)
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
CI 77492 (UNII: EX438O2MRT)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85627-201-85	85 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/21/2023	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M020	04/21/2023		

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Custom Analytics LLC		144949372	analysis(85627-201)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Fragrance Manufacturing Inc		793406000	manufacture(85627-201)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Fallien Cosmeceuticals Ltd.		958388357	relabel(85627-201)	