

TINTED MINERAL SUNSCREEN SPF 40- titanium dioxide, zinc oxide cream
DERMATOLOGY ARTS

DRUG FACTS
ACTIVE INGREDIENTS: Titanium Dioxide 8%, Zinc Oxide 3.8%
PURPOSE: 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. 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 44791), Lauryl PEG/PPG-18/18 Hydrogen Dimethicone, 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 IN THE USA FOR: Center for Advanced Dermatology, 301 W Huntington Dr #215, Arcadia CA, 91007



DERMATOLOGY arts

tinted
mineral sunscreen
spf 40

- reef friendly
- no parabens or phthalates
- broad spectrum spf 40
- water resistant (80 mins)

net wt. 1.8 oz / 53 g

TINTED MINERAL SUNSCREEN SPF 40
titanium dioxide, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85344-203
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name		Basis of Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE

Strength	
80 mg in 1 g	
38 mg in 1 g	

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85344-203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/17/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/17/2022	

**Labeler -** DERMATOLOGY ARTS (088517619)

### Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85344-203)

### Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85344-203)