TINTED PRIMER MINERAL SUNSCREEN- titanium dioxide, zinc oxide cream CECILIA EDWARDS

DRUG FACTS

ACTIVE INGREDIENTS: PURPOSE:
Titanium Dioxide 8% Sunscreen
Zinc Oxide 3.8% 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 77491), Lauryl PEG/PPG-18/18 Methicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate

OTHER INFORMATION:

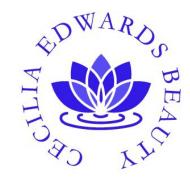
- Protect this product from excessive heat and direct sun
- May stain some fabrics
- PA +++

MANUFACTURED FOR:

Cecilia Edward's Beauty Miami, FL 33156



Reef Friendly • Cruelty-Free • Non-Comedogenic







Broad Spectrum SPF 40
Water Resistant (80 minutes)

Titanium Dioxide, Zinc Oxide and Antioxidants C & E

Net Wt. 1.8 oz / 53 g

TINTED PRIMER MINERAL SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:85640-203

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
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CI 77491 (UNII: 1K09F3G675)	
ALUMINA (UNII: LMI26O6933)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
CI 77492 (UNII: EX43802MRT)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
CYCLOPENTASILOXANE (UNII: OTHT5PCIOR)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
CI 77499 (UNII: XM0M87F357)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:85640- 203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/12/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/12/2022	

Labeler - CECILIA EDWARDS (116365389)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analys is (85640-203)

Establishment				
Name	Address	ID/FEI	Business Operations	
Fragrance Manufacturing INC		793406000	manufacture(85640-203)	

Revised: 7/2025 CECILIA EDWARDS