TINTED FACIAL MINERAL SUNSCREEN SPF 40- titanium dioxide, zinc oxide cream RSL89 LLC

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:

ESTIGLO • San Jose, CA 95124 www.estiglobeauty.com



TINTED FACIAL IINERAL SUNSCREEN SPF 40



with Antioxidants C & E

Sheer Matte Finish

Broad Spectrum SPF 40

Water Resistant (80 minutes)

Net Wt. 1.8 oz / 53 g

TINTED FACIAL MINERAL SUNSCREEN SPF 40

titanium dioxide, zinc oxide cream

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:85508-203 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
DIMETHICONE (UNII: 92RU3N3Y1O)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
CI 77499 (UNII: XM0M87F357)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
BIS-PEG-10 DIMETHICONE/DIMER DILINOLEATE COPOLYMER (UNII: CF5W1YCX11)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CI 77491 (UNII: 1K09F3G675)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
ALUMINA (UNII: LMI26O6933)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
CI 77492 (UNII: EX43802MRT)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85508- 203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/28/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	02/28/2023	

Labeler - RSL89 LLC (050839814)

Establishment					
Name	Address	ID/FEI	Business Operations		
Fragrance Manufacturing INC		793406000	manufacture(85508-203)		

Establishment				
Name	Address	ID/FEI	Business Operations	
Custom Analytics LLC		144949372	analysis (85508-203)	

Revised: 5/2025 RSL89 LLC