## TINTED MINERAL SUNSCREEN- titanium dioxide, zinc oxide cream **ESTHETICS BY RIKI LLC**

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#### 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 (Cl 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
- Cleanse thoroughly at nighttime
- PA +++

Esthetics by Riki | 505-980-5855 6501 Wyoming Blvd NE C-100, Albuquerque, NM 87109



## SKIN COEUR BY RIKI RAE

IT'S NOT JUST SKIN CARE. IT'S SKIN LOVE

## TINTED MINERAL SUNSCREEN

SPF 40 **BROAD SPECTRUM** WATER RESISTANT (80 MINS)

1.8 oz | 53 g

## TINTED MINERAL SUNSCREEN

titanium dioxide, zinc oxide cream

#### **Product Information**

NDC:85604-203 **Product Type** HUMAN OTC DRUG Item Code (Source)

**TOPICAL Route of Administration** 

## **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	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
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
VINYLDIMETHYL/TRIMETHYLSILOXYSILICATE STEARYL DIMETHICONE CROSSPOLYMER (UNII: 01S784FLCO)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
ALUMINA (UNII: LMI26O6933)	
CI 77499 (UNII: XM0M87F357)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
CI 77491 (UNII: 1K09F3G675)	
CI 77492 (UNII: EX43802MRT)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:85604- 203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/16/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/16/2020	

# Labeler - ESTHETICS BY RIKI LLC (090593509)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Fragrance Manufacturing Inc		793406000	manufacture(85604-203)	

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Custom Analytics LLC		144949372	analysis (85604-203)	

Revised: 6/2025 ESTHETICS BY RIKI LLC