

TINTED FACIAL MINERAL SUNSCREEN- titanium dioxide, zinc oxide cream
ORAIOS BEAUTY LLC

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 broken or damaged 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 reach of children. If swallowed, get medical help or contact a poison control center right away.

Warnings:

Keep out of reach of children

Directions:

Apply liberally 15 minutes before sun exposure. Use a water-resistant product if swimming or sweating. Reapply 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 a.m. - 2 p.m. 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 +++

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 (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 +++



Tinted Facial Mineral Sunscreen

Broad Spectrum SPF 40
Water Resistant (80 minutes)

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



MANUFACTURED FOR:
Oraios Beauty LLC | Lemont, IL 60439
www.oraiosbeauty.com



3 85939 20350 1

Net Wt. 1.8 oz / 53 g

TINTED FACIAL MINERAL SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85939-203
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
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)				
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)				
CI 77491 (UNII: 1K09F3G675)				
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)				
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
CI 77492 (UNII: EX438O2MRT)				
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)				
ALUMINA (UNII: LMI26O6933)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)				
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)				
CI 77499 (UNII: XM0M87F357)				
CYCLOHEXASILOXANE (UNII: XHK3U310BA)				
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85939-203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/04/2022	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M020	02/04/2022	

Labeler - ORAIOS BEAUTY LLC (126239175)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85939-203)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85939-203)