

TINTED MINERAL SUNSCREEN- titanium dioxide, zinc oxide cream
The Essential Brazilian Spa 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

ACTIVE INGREDIENTS

Titanium Dioxide 8%
Zinc Oxide 3.8%

PURPOSE

Sunscreen
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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
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MANUFACTURED FOR

The Essential Brazilian Spa
Austin, TX 78726

NDC 8549220353



40181 700982


stellar
for teens

tinted mineral sunscreen

broad spectrum spf 40
water resistant (80 minutes)

net wt. 1.8 oz/53 g

TINTED MINERAL SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85492-203(NDC:58892-203)
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
DIMETHICONE (UNII: 92RU3N3Y1O)				
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)				
ALUMINA (UNII: LMI26O6933)				
CI 77491 (UNII: 1K09F3G675)				
CI 77492 (UNII: EX438O2MRT)				
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)				
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)				
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)				
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)				
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)				
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)				
CI 77499 (UNII: XM0M87F357)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
CYCLOHEXASILOXANE (UNII: XHK3U310BA)				
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85492-203-53	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/07/2025	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020		07/07/2025	

Labeler - The Essential Brazilian Spa LLC (106993754)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85492-203)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85492-203)

Establishment			
Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85492-203)