

**SHEER TINTED SUNSCREEN- titanium dioxide, zinc oxide cream**  
**SARA ELIZABETH SKINCARE**

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**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.

**Warning:**

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:      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 (CI77491), 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  
PA+++



SARA ELIZABETH

sheer tinted sunscreen  
spf40  
soft mineral primer  
broad spectrum (uva/uvb)  
water resistant (80 Minutes)

Net Wt. 1.8 oz/53 g

SHEER TINTED SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85968-203
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
<b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)	
<b>CI 77499</b> (UNII: XM0M87F357)	
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)	
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)	
<b>CI 77491</b> (UNII: 1K09F3G675)	
<b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>LAURYL PEG/PPG-18/18 METHICONE</b> (UNII: ZJ5S27D9NX)	
<b>CI 77492</b> (UNII: EX438O2MRT)	
<b>ALUMINA</b> (UNII: LMI26O6933)	
<b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)	
<b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85968-203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/04/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/04/2016	

**Labeler -** SARA ELIZABETH SKINCARE (605215214)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85968-203)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85968-203)