

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

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 (CI 77491), 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(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 |
|---|----------|
| CI 77499 (UNII: XM0M87F357) | |
| CYCLOPENTASILOXANE (UNII: 0THT5PCI0R) | |
| HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N) | |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) | |
| CI 77491 (UNII: 1K09F3G675) | |
| CYCLOHEXASILOXANE (UNII: XHK3U310BA) | |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0) | |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX) | |
| CI 77492 (UNII: EX438O2MRT) | |
| ALUMINA (UNII: LMI26O6933) | |
| DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y) | |
| DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6) | |

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 |
|----------------------|---------|-----------|---------------------|
| Custom Analytics LLC | | 144949372 | analysis(85968-203) |

Establishment

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

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|---------------------|
| Fallien Cosmeceuticals Ltd. | | 958388357 | relabel(85968-203) |

