

SILK SCREEN TINTED- titanium dioxide, zinc oxide cream
Skin Science Institute Inc

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 • 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 +++ | |

MANUFACTURED FOR:
Skin Science Institute, LLC | North Palm Beach, FL 33408
www.skincareinstitute.us É (561) 201-6398



TINTED MINERAL SUNSCREEN

Broad Spectrum SPF 40
Water Resistant (80 minutes)

Reef Friendly • Cruelty-Free
Non-Comedogenic

Net Wt. 1.8 oz / 53 g

SILK SCREEN TINTED

titanium dioxide, zinc oxide cream

| Product Information | | | |
|--|----------------|--------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:85644-203(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 |
|--|----------|
| CYCLOHEXASILOXANE (UNII: XHK3U310BA) | |
| CYCLOPENTASILOXANE (UNII: 0THT5PCI0R) | |
| DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6) | |
| CI 77491 (UNII: 1K09F3G675) | |
| CI 77499 (UNII: XM0M87F357) | |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ) | |
| ALUMINA (UNII: LMI26O6933) | |
| DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y) | |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| CI 77492 (UNII: EX438O2MRT) | |
| HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N) | |
| PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX) | |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:85644-203-50 | 53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 03/20/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020 | 03/20/2023 | |

Labeler - Skin Science Institute Inc (800955614)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|---------------------|
| Custom Analytics LLC | | 144949372 | analysis(85644-203) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|------------------------|
| Fragrance Manufacturing INC | | 793406000 | manufacture(85644-203) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|---------------------|
| Fallien Cosmeceuticals Ltd. | | 958388357 | relabel(85644-203) |