

TINTED MINERAL SUNSCREEN- titanium dioxide, zinc oxide cream  
ESTHETIC ACADEMY LLC

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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:  
The Esthetic Academy | La Plata, MD 20646



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:85597-203(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 |
|--------------------------------------------------------------------------------------|----------|
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)                                                |          |
| <b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)                                   |          |
| <b>ALUMINA</b> (UNII: LMI26O6933)                                                    |          |
| <b>CI 77491</b> (UNII: 1K09F3G675)                                                   |          |
| <b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)                               |          |
| <b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)                              |          |
| <b>CI 77499</b> (UNII: XM0M87F357)                                                   |          |
| <b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                                   |          |
| <b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)                                          |          |
| <b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)                                    |          |
| <b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)                                         |          |
| <b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5) |          |
| <b>CI 77492</b> (UNII: EX438O2MRT)                                                   |          |
| <b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)                                  |          |
| <b>LAURYL PEG/PPG-18/18 METHICONE</b> (UNII: ZJ5S27D9NX)                             |          |

### Packaging

| # | Item Code        | Package Description                                       | Marketing Start Date | Marketing End Date |
|---|------------------|-----------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:85597-203-50 | 53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 04/29/2022           |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| OTC Monograph Drug | M020                                     | 04/29/2022           |                    |

**Labeler -** ESTHETIC ACADEMY LLC (099927137)

### Establishment

| Name                 | Address | ID/FEI    | Business Operations |
|----------------------|---------|-----------|---------------------|
| Custom Analytics LLC |         | 144949372 | analysis(85597-203) |

### Establishment

| Name                         | Address | ID/FEI    | Business Operations    |
|------------------------------|---------|-----------|------------------------|
| Fragrance Manufacturing Inc. |         | 793406000 | manufacture(85597-203) |

### Establishment

| Name                        | Address | ID/FEI    | Business Operations |
|-----------------------------|---------|-----------|---------------------|
| Fallien Cosmeceuticals Ltd. |         | 958388357 | relabel(85597-203)  |