

# SHEER TINTED PROTECTION- titanium dioxide, zinc oxide cream

## CLEAR SKIN SOLUTIONS, LLC

### DRUG FACTS

#### ACTIVE INGREDIENTS:

Titanium Dioxide 10%  
Zinc Oxide 3%

#### 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 40 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:

Bismuth Oxchloride, Capric/Caprylic Triglyceride, Caprylhydroxamic Acid, Caprylyl Glycol, Cetearth-20, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Disodium EDTA, Ethylhexyl Hydroxystearate Benzoate, Glycerin, Iron Oxides, Isododecane, Isohexadecane, Melissa Officinalis (Balm Mint) Extract, Mica, Microcrystalline Wax, Octyldodecyl Neopentanoate, PEG-30 Dipolyhydroxystearate, Sodium Chloride, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Tocopherol, Triethanolamine, Triethoxycaprylylsilane, Water

#### OTHER INFORMATION:

- Protect this product from excessive heat and direct sun
- May stain some fabrics

#### MANUFACTURED FOR:

Clear Skin Solutions  
Ardmore, OK 73401  
580-798-3950  
clearskinsolutions.com



CLEAR SKIN  
SOLUTIONS



Sheer  
Tinted Protection  
SPF 50 BROAD SPECTRUM  
WATER RESISTANT (40 MINUTES)

Sunscreen

Net Wt. 1.8 oz / 53 g

## SHEER TINTED PROTECTION

titanium dioxide, zinc oxide cream

### Product Information

|                                |                |                           |                              |
|--------------------------------|----------------|---------------------------|------------------------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:85563-258(NDC:58892-258) |
| <b>Route of Administration</b> | TOPICAL        |                           |                              |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength      |
|---|-------------------|---------------|
| <b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)             | ZINC OXIDE        | 30 mg in 1 g  |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE  | 100 mg in 1 g |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>BISMUTH OXYCHLORIDE</b> (UNII: 4ZR792I587)                 |          |
| <b>ISODODECANE</b> (UNII: A8289P68Y2)                         |          |
| <b>MICA</b> (UNII: V8A1AW0880)                                |          |
| <b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)                |          |
| <b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)           |          |
| <b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)            |          |
| <b>TRIETHANOLAMINE</b> (UNII: 9O3K93S3TK)                     |          |
| <b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)             |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                               |          |
| <b>OCTYLDODECYL NEOPENTANOATE</b> (UNII: X8725R883T)          |          |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)                         |          |
| <b>CAPRYLIC/CAPRIC TRIGLYCERIDE</b> (UNII: C9H2L21V7U)        |          |
| <b>CAPRYLHYDROXAMIC ACID</b> (UNII: UPY805K99W)               |          |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                     |          |
| <b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)          |          |
| <b>CI 77491</b> (UNII: 1K09F3G675)                            |          |
| <b>MELISSA OFFICINALIS LEAF</b> (UNII: 50D2ZE9219)            |          |
| <b>PEG-30 DIPOLYHYDROXYSTEARATE</b> (UNII: 9713Q0S7FO)        |          |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)                     |          |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                          |          |
| <b>ETHYLHEXYL HYDROXYSTEARATE BENZOATE</b> (UNII: 3W8F25684B) |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                            |          |
| <b>CI 77492</b> (UNII: EX438O2MRT)                            |          |
| <b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)                       |          |
| <b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)                  |          |
| <b>CETEARETH-20</b> (UNII: YRC528SWJY)                        |          |
| <b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)                   |          |
| <b>CI 77499</b> (UNII: XM0M87F357)                            |          |

### Packaging

| # | Item Code        | Package Description                                       | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:85563-258-50 | 50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 02/21/2025           |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020                                     | 02/21/2025           |                    |

**Labeler** - CLEAR SKIN SOLUTIONS, LLC (076140083)

### Establishment

| Name                 | Address | ID/FEI    | Business Operations |
|----------------------|---------|-----------|---------------------|
| Custom Analytics LLC |         | 144949372 | analysis(85563-258) |

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| <b>Establishment</b>        |                |               |                            |
|-----------------------------|----------------|---------------|----------------------------|
| <b>Name</b>                 | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
| Fragrance Manufacturing INC |                | 793406000     | manufacture(85563-258)     |

| <b>Establishment</b>        |                |               |                            |
|-----------------------------|----------------|---------------|----------------------------|
| <b>Name</b>                 | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
| Fallien Cosmeceuticals Ltd. |                | 958388357     | relabel(85563-258)         |

Revised: 12/2025

CLEAR SKIN SOLUTIONS, LLC