

NON-TINTED MINERAL STICK- titanium dioxide, zinc oxide stick

Shelley Bennett Skincare

DRUG FACTS (continued)

INACTIVE INGREDIENTS: Alumina, Aluminum Hydroxide, Aluminum Stearate, Ascorbic Acid, Ascorbyl Palmitate, C12-15 Alkyl Benzoate, Cetearyl Isononanoate, Cetyl PEG/PPG-15/15 Butyl Ether Dimethicone, Citric Acid, Ethylene Brassylate, Ethylhexyl Palmitate, Helianthus Annuus (Sunflower) Wax, Hexyldecanol, Hexyldecyl Laurate, Lecithin, Ozokerite, PEG-8, Polyglyceryl-3 Diisostearate, Polyhydroxystearic Acid, Propylene Glycol Dicaprylate/Dicaprate, Stearic Acid, Tocopherol, Tocopheryl Acetate, Zingiber Officinale (Ginger) Root Oil

OTHER INFORMATION: • Protect this product from excessive heat and direct sun

MANUFACTURED FOR:
Shelley Bennett Skincare
Monterey, CA 93940
www.shelleyskin.com



NON-TINTED MINERAL
SUNSCREEN STICK

Broad Spectrum SPF 45

Water Resistant (80 minutes)

Net Wt. 1 oz. / 30 g

DRUG FACTS

| ACTIVE INGREDIENTS | PURPOSE |
|-----------------------|-----------|
| Titanium Dioxide 4.0% | Sunscreen |
| Zinc Oxide 5.5% | 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 • **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

NON-TINTED MINERAL STICK

titanium dioxide, zinc oxide stick

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:85326-219(NDC:58892-219) |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------|
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 40 mg in 1 g |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 55 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD) | |
| ALUMINUM STEARATE (UNII: U6XF9NP8HM) | |
| CETEARYL ISONONANOATE (UNII: P5O01U99NI) | |
| CETYL DIMETHYLBUTYL ETHER (UNII: 7LAB1GXC9G) | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| CITRIC ACID (UNII: 2968PHW8QP) | |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) | |
| PEG-8 (UNII: B697894SGQ) | |
| ALUMINA (UNII: LMI26O6933) | |

| |
|--|
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) |
| ZINGIBER OFFICINALE (GINGER) ROOT OIL (UNII: SAS9Z1SVUK) |
| PEG/PPG-15/15 DIMETHICONE (UNII: 184IZ28A2G) |
| HEXYLDECYL LAURATE (UNII: 0V595C1P6M) |
| HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX (UNII: 42DG15CHXV) |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8) |
| PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: O4446S9CRA) |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) |
| ASCORBYL PALMITATE (UNII: QN83US2B0N) |
| C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ) |
| ETHYLHEXYL PALMITATE (UNII: 2865993309) |
| HEXYLDECANOL (UNII: 151Z7P1317) |
| CERESIN (UNII: Q1LS2UJO3A) |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:85326-219-30 | 30 g in 1 CYLINDER; Type 0: Not a Combination Product | 05/27/2024 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020 | 05/27/2024 | |

Labeler - Shelley Bennett Skincare (088733941)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|---------------------|
| Custom Analytics LLC | | 144949372 | analysis(85326-219) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------------|---------|-----------|------------------------|
| Fragrance Manufacturing Inc. | | 793406000 | manufacture(85326-219) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|---------------------|
| Fallien Cosmeceuticals Ltd. | | 958388357 | relabel(85326-219) |