

PROTECT MINERAL STICK CLEAR- titanium dioxide, zinc oxide stick
Melinda Menezes, M.D., Inc.

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:
 Melinda Menezes, MD Inc. Lihue, HI 96766



PROTECT
 Mineral Protection Stick

CLEAR

broad spectrum spf 45
 water resistant (80 minutes)
 sunscreen

net wt. 1 oz / 30 g

DRUG
ACTIVE
 Titanium Dioxide
 Zinc Oxide

USES: For use with other Direct Protection and ear

WARNING: Do not use on damaged skin. Consult a doctor if you have a skin condition. Keep out of reach of children. Get medical attention if you get an allergic reaction.

DIRECTIONS: Apply liberally to the face and neck. Reapply every 2 hours, or more often if swimming, drying, or sweating. For best results, use with other Direct Protection products. For long-term protection, use with other Direct Protection products.

PROTECT MINERAL STICK CLEAR

titanium dioxide, zinc oxide stick

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:85314-219(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 |
|--|----------|
| CITRIC ACID (UNII: 2968PHW8QP) | |
| HEXYLDECYL LAURATE (UNII: 0V595C1P6M) | |
| CETEARYL ISONONANOATE (UNII: P5O01U99NI) | |
| ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD) | |
| HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX (UNII: 42DG15CHXV) | |
| PEG-8 (UNII: B697894SGQ) | |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| ZINGIBER OFFICINALE (GINGER) ROOT OIL (UNII: SAS9Z1SVUK) | |
| ASCORBYL PALMITATE (UNII: QN83US2B0N) | |
| ETHYLHEXYL PALMITATE (UNII: 2865993309) | |

| |
|--|
| HEXYLDECANOL (UNII: 151Z7P1317) |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8) |
| TOCOPHEROL (UNII: R0ZB2556P8) |
| PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: O4446S9CRA) |
| ALUMINUM STEARATE (UNII: U6XF9NP8HM) |
| PEG/PPG-15/15 DIMETHICONE (UNII: 184IZ28A2G) |
| CERESIN (UNII: Q1LS2UJO3A) |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) |
| STEARIC ACID (UNII: 4ELV7Z65AP) |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) |
| C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ) |
| ALUMINA (UNII: LMI26O6933) |
| CETYL DIMETHYLBUTYL ETHER (UNII: 7LAB1GXG9G) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:85314-219-30 | 30 g in 1 CYLINDER; Type 0: Not a Combination Product | 08/08/2024 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020 | 08/08/2024 | |

Labeler - Melinda Menezes, M.D., Inc. (022910406)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|---------------------|
| Custom Analytics LLC | | 144949372 | analysis(85314-219) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|------------------------|
| Fragrance Manufacturing Inc | | 793406000 | manufacture(85314-219) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|---------------------|
| Fallien Cosmeceuticals Ltd. | | 958388357 | relabel(85314-219) |