RADIANCE SILKY MINERAL PRIMER SUNSCREEN SPF-42 HONEY- titanium dioxide, zinc oxide solution SANTO REMEDIO LLC

RADIANCE Silky Mineral Primer Sunscreen SPF-42 (HONEY)

Drug Facts

Active ingredients

Titanium Dioxide 6% Zinc Oxide 8%

Purpose

Sunscreen

Uses:

- Helps prevent sunburn.
- Higher SPF gives more sunburn protection.
- Retains SPF after 80 minutes of swimming or sweating.
- If used as as directed with other sun protection measures (see directions), decreases the risk of cancer and early skin aging caused by the sun.

Warnings:

For external use only

Do not use

On damaged or broken skin.

When using this product

• Keep out of eyes. Rinse with water to remove.

Stop use and ask doctor if

• Rash occurs.

Keep out of reach of children.

If swallowed, get medical help, or contact a Poison Control Center right away.

If pregnant or breastfeeding,

Ask a health professional before use.

Directions:

Apply liberally 15 minutes before sun exposure and as needed.

- Reapply:
- After 80 minutes of swimming or sweating
- Immediately after towel drying
- At least every 2 hours
- Children under 6 months of age: ask a doctor.
- Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: **Sun Protection Measures.**
- Limit time in the sun, especially from 10 a.m. 2 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses.

Other information.

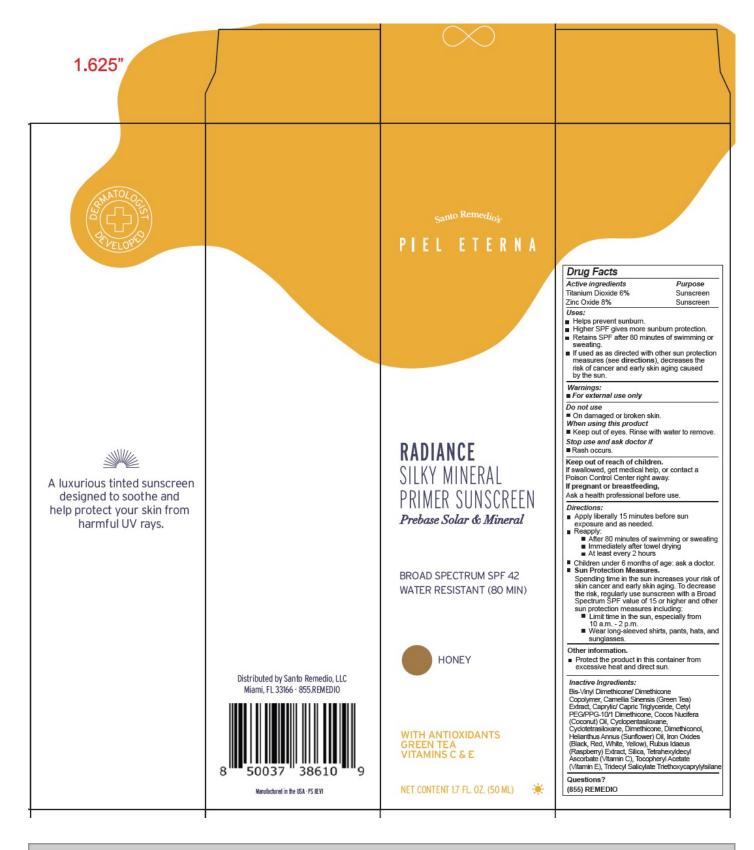
Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients:

Bis-Vinyl Dimethicone/ Dimethicone Copolymer, Camellia Sinensis (Green Tea) Extract, Caprylic/ Capric Triglyceride, Cetyl PEG/PPG-10/1 Dimethicone, Cocos Nucifera (Coconut) Oil, Cyclopentasiloxane, Cyclotetrasiloxane, Dimethicone, Dimethiconol, Helianthus Annus (Sunflower) Oil, Iron Oxides (Black, Red, White, Yellow), Rubus Idaeus (Raspberry) Extract, Silica, Tetrahexyldecyl Ascorbate (Vitamin C), Tocopheryl Acetate (Vitamin E), Tridecyl Salicylate Triethoxycaprylylsilane

Questions? (855) REMEDIO

Package Labeling:



RADIANCE SILKY MINERAL PRIMER SUNSCREEN SPF-42 HONEY

titanium dioxide, zinc oxide solution

| Product Information | | | | |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:81352-521 | |
| Route of Administration | TOPICAL | | | |
| | | | | |

| Active Ingredient/Active Moiety | | | |
|--|--------------------------|---------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 60 mg in 1 mL | |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION | 80 mg in 1 mL | |

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | | |
| COCONUT OIL (UNII: Q9L0O73W7L) | | |
| CYCLOMETHICONE 5 (UNII: 0THT5PCI0R) | | |
| CYCLOMETHICONE 4 (UNII: CZ227117JE) | | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | | |
| HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP) | | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | | |
| RASPBERRY (UNII: 4N14V5R27W) | | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | | |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ) | | |
| .ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | | |
| TRIDECYL SALICYLATE (UNII: AZ Q08K38Z1) | | |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) | | |

| P | Packaging | | | | |
|---|----------------------|--|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:81352-521- 00 | 1 in 1 BOX | 03/06/2023 | | |
| 1 | | 50 mL in 1 BOTTLE; Type 0: Not a Combination Product | | | |

| Marketing Information | | | | |
|-----------------------|---|-------------------------|-----------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC Monograph Drug | M020 | 03/06/2023 | | |
| | | | | |

Labeler - SANTO REMEDIO LLC (117456185)

Revised: 11/2023 SANTO REMEDIO LLC