

**STAY AGELESS TINTED MINERAL SUNSCREEN BROAD SPECTRUM SPF 30-
titanium dioxide and zinc oxide cream
REGENA SPA PLC**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Stay Ageless Tinted Mineral Sunscreen Broad Spectrum SPF 30

DRUG FACTS:

ACTIVE INGREDIENTS

Titanium Dioxide 7.75%, Zinc Oxide 10.0%.

Purpose

Sunscreen

USES

Helps prevent sunburn.

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 a doctor** if rash occurs.

Keep out of reach of children.

DIRECTIONS

Apply to all skin exposed to the sun. *Apply liberally and evenly 15 minutes before sun exposure. *Reapply at least every 2 hours. *Use a water-resistant sunscreen if swimming or sweating. *For children under 6 months of age: 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 a.m. - 2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses.

INACTIVE INGREDIENTS

Water (Aqua), Caprylic/Capric Triglyceride, Butyloctyl Salicylate, Glycerin, Dimethicone, Styrene/Acrylates Copolymer, Coco-Caprylate/Caprates, Aluminum Stearate, Carthamus

Tinctorius Oleosomes, Polyhydroxystearic Acid, Aloe Barbadensis Leaf Juice, Polygonum Aviculare Extract, Tocopheryl Acetate, Perilla Frutescens Extract, Vitis Vinifera Fruit Cell Extract, Lepidium Sativum Sprout Extract, Squalane, Cetearyl Alcohol, Isononyl Isononanoate, Coco-Glucoside, Pentylene Glycol, Behenyl Alcohol, Xanthan Gum, Triethoxycaprylylsilane, Arachidyl Glucoside, Simmondsia Chinensis (Jojoba) Seed Oil, Stearic Acid, Sucrose Stearate, Phenethyl Alcohol, Tetrahexyldecyl Ascorbate, Glycerol Caprylate, Ethylene/Propylene/Styrene Copolymer, Sorbitan Oleate, Polyglyceryl-2 Caprate, Propanediol, Alumina, Arachidyl Alcohol, Iron Oxides (CI 77492, CI 77491, CI 77499).

OTHER INFORMATION

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

Regena Spa
Stay Ageless
Tinted Mineral Sunscreen
Broad Spectrum SPF 30
1.75 fl oz (50ml)

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Broad Spectrum SPF30

| | |
|--|----------------|
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| ACTIVE INGREDIENTS: | PURPOSE |
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| USES: Helps prevent sunburn. | |
| WARNINGS: | |
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| DIRECTIONS: Apply to all skin exposed to the sun. Apply liberally and evenly 15 minutes before sun exposure. Reapply at least every 2 hours. Use a water-resistant sunscreen if swimming or sweating. For children under 6 months of age: 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: <ul style="list-style-type: none"> ■ limit time in the sun, especially from 10 a.m. - 2 p.m. ■ wear long-sleeved shirts, pants, hats, and sunglasses. | |
| INACTIVE INGREDIENTS: Water (Aqua), Caprylic/Capric Triglyceride, Butyloctyl Salicylate, Glycerin, Dimethicone, Styrene/Acrylates Copolymer, Coco-Caprylate/Caprate, Aluminum Stearate, Carthamus Tinctorius Oleosomes, Polyhydroxystearic Acid, Aloe Barbadosis Leaf Juice, Polyorgan Avocadoire Extract, Tocopheryl Acetate, Perilla Frutescens Extract, Vitis Vinifera Fruit Cell Extract, Lepidium Sativum Sprout Extract, Squalane, Cetearyl Alcohol, Isononyl Isononanoate, Coco-Glucoside, Pentylene Glycol, Behenyl Alcohol, Xanthan Gum, Triethoxycaprylylsilane, Arachidyl Glucoside, Simmondsia Chinensis (Jojoba) Seed Oil, Stearic Acid, Sucrose Stearate, Phenethyl Alcohol, Tetrahydrodecyl Ascorbate, Glyceryl Caprylate, Ethylene/Propylene/Styrene Copolymer, Sorbitan Oleate, Polyglyceryl-2 Caprate, Propenediol, Alumina, Arachidyl Alcohol, Iron Oxides (CI 77492, CI 77491, CI 77499). | |
| OTHER INFORMATION: Protect the product in this container from excessive heat and direct sun. | |

Distributed By:
Regena Spa PLC.
Surprise AZ 85374
Made in USA

*the above image is a digital representation, actual products may differ slightly.

STAY AGELESS TINTED MINERAL SUNSCREEN BROAD SPECTRUM SPF 30

titanium dioxide and zinc oxide cream

Product Information

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|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:82107-0650 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|------------------|
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 7.75 g in 100 mL |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 10 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| COCOYL CAPRYLOCAPRATE (UNII: 8D9H4QU99H) | |
| ALUMINUM STEARATE (UNII: U6XF9NP8HM) | |
| CARTHAMUS TINCTORIUS SEED OLEOSOMES (UNII: 9S60Q72309) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| GARDEN CRESS SPROUT (UNII: PWQ18YNR62) | |
| SQUALANE (UNII: GW89575KF9) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| ISONONYL ISONONANOATE (UNII: S4V5BS6GCX) | |
| COCO GLUCOSIDE (UNII: ICS790225B) | |
| PENTYLENE GLYCOL (UNII: 50C1307PZG) | |
| DOCOSANOL (UNII: 9G1OE216XY) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) | |
| ARACHIDYL GLUCOSIDE (UNII: 6JVVW35JOOJ) | |
| JOJOBA OIL (UNII: 724GKU717M) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| SUCROSE STEARATE (UNII: 274KW0050M) | |
| PHENYLETHYL ALCOHOL (UNII: ML9LGA7468) | |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ) | |
| GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A) | |
| SORBITAN MONOOLEATE (UNII: 06XEA2VD56) | |
| POLYGLYCERYL-2 CAPRATE (UNII: JX7WXJ41DH) | |
| PROPANEDIOL (UNII: 5965N8W85T) | |
| ALUMINUM OXIDE (UNII: LMI26O6933) | |
| ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| FERROSO FERRIC OXIDE (UNII: XM0M87F357) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:82107-0650-3 | 50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 07/23/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 07/23/2021 | |

Labeler - REGENA SPA PLC (067446051)

Revised: 7/2021

REGENA SPA PLC