MINERAL CREME SPF 50 MINERAL CREME SPF 50 BROAD SPECTRUM UVA-UVB SUNSCREEN WATER RESISTANT (80 MIN)- titanium dioxide and zinc oxide cream MDSolarSciences

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.

Mineral Crème SPF 50 Mineral Crème SPF 50 Broad Spectrum UVA-UVB Sunscreen Water Resistant (80 min)

Drug Facts

| Active ingredients | Purpose |
|---------------------|-----------|
| Titanium Dioxide 2% | Sunscreen |
| Zinc Oxide 17% | 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 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
 - 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 the risk, regularly use a sunscreen with Broad Spectrum SPF of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10a.m.-2p.m.

• Wear long-sleeved shirts, pants, hats and sunglasses

Other Information

Shake well. Rub in well.

- Protect the product in this container from excessive heat and direct sunlight
- May stain some fabrics
- You may report serious adverse reactions to: Report Reaction LLC PO Box 611, Pompton Plains, NJ 07444

Inactive Ingredients

Dimethicone, Caprylic/Capric Triglyceride, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Butyloctyl Salicylate, Glyceryl Isostearate, Polysilicone-15, Tetrahexyldecyl Ascorbate (Vitamin C), Camellia Sinensis Leaf Extract (Green Tea), Punica Granatum Extract (Pomegranate), Vaccinium Macrocarpon (Cranberry) Fruit Extract, Silica, Polyhydroxystearic Acid, May Contain: (CI 77891, CI 77492, CI 77491, CI 77499)

DISTRIBUTED BY MDSOLARSCIENCES CORP. GREENS FARMS, CT 06838

PRINCIPAL DISPLAY PANEL - 100 ML Tube Carton

MDSOLARSCIENCES[®]

MINERAL CRÈME

Broad Spectrum SPF 50 Water Resistant (80 Min) 100% Mineral Sunscreen

SPF 50

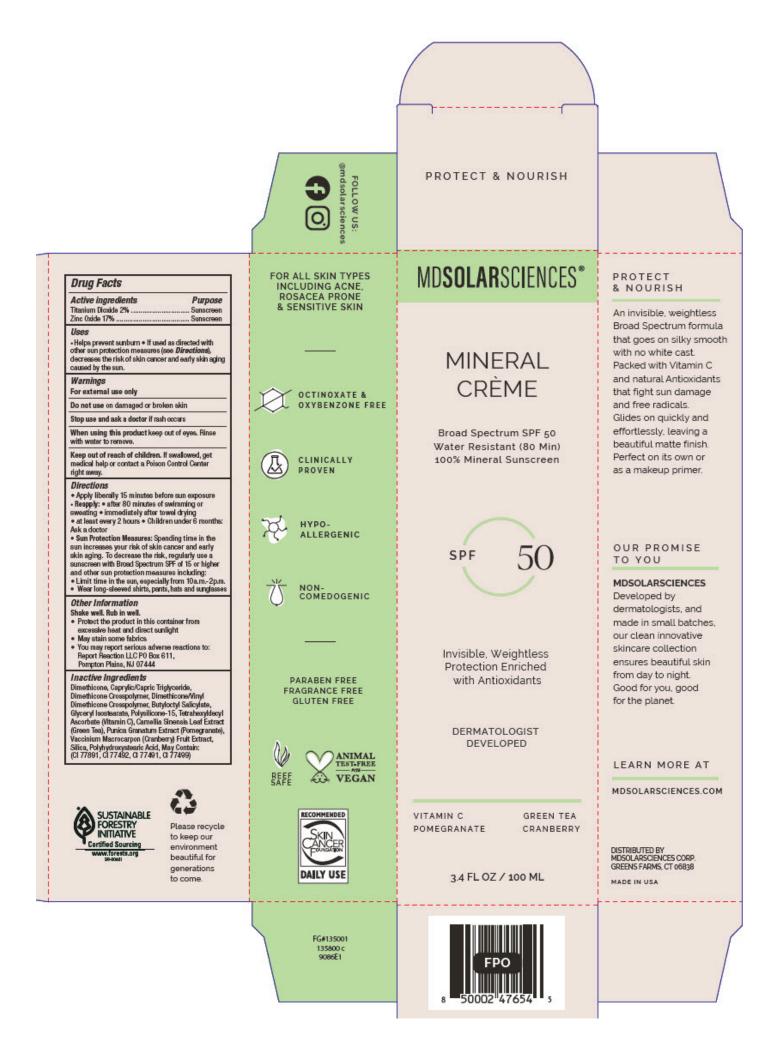
Invisible, Weightless Protection Enriched with Antioxidants

DERMATOLOGIST DEVELOPED

VITAMIN C POMEGRANATE

GREEN TEA CRANBERRY

3.4 FL OZ / 100 ML



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MINERAL CREME SPF 50 MINERAL CREME SPF 50 BROAD SPECTRUM UVA-UVB SUNSCREEN WATER RESISTANT (80 MIN)

titanium dioxide and zinc oxide cream

| Product Information | | | | | | |
|-----------------------------|-------------------------------------|---|------------------------|--------|---------------|--|
| Product Type | HUMAN OTC DRUG | ltem Code | Item Code (Source) NDC | | C:49358-570 | |
| Route of Administration | TOPICAL | | | | | |
| | | | | | | |
| Active Ingredient/Act | ive Moietv | | | | | |
| | Ingredient Name Basis of Strength | | | | h Strength | |
| | | (9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP) Titanium Dioxide | | | 20 mg in 1 mL | |
| Zinc Oxide (UNII: SOI2LOH54 | • • • | • | Zinc Oxide | | 170 mg in 1 m | |
| | | | | | - | |
| Inactive Ingredients | | | | | | |
| | Ingredient Na | me | | | Strengt | |
| Dimethicone (UNII: 92RU3N3) | Y10) | | | | | |
| MEDIUM-CHAIN TRIGLYCER | DES (UNII: C9H2L21V7U) | | | | | |
| DIMETHICONE/DIENE DIMET | | | | | | |
| DIMETHICONE/VINYL DIMET | | SOFT PARTICLE | •) (UNII: 9E4CO0W6C5 | 5) | | |
| BUTYLOCTYL SALICYLATE (| | | | | | |
| GLYCERYL ISOSTEARATE (U | | | | | | |
| POLYSILICONE-15 (UNII: F8D | | | | | | |
| | | | | | | |
| GREEN TEA LEAF (UNII: W2Z) | | | | | | |
| POMEGRANATE JUICE (UNII: | | | | | | |
| CRANBERRY (UNII: 0MVO31Q | | | | | | |
| SILICON DIOXIDE (UNII: ETJ7 | 207804) | | | | | |
| | | | | | | |
| Other Ingredients | | | | | | |
| Ingredient Kind | Ing | Ingredient Name | | C | Quantity | |
| May contain | | ERRIC OXIDE YELLOW (UNII: EX43802MRT) | | | | |
| May contain | FERRIC OXIDE RED (UNII: 1K09F3G675) | | | | | |
| May contain | FERROSOFERRIC OXIDE (U | JNII: XM0M87F35 | 7) | | | |
| | | | | | | |
| Packaging | | | | | | |
| | | | rketing Start | Market | | |

| # | item Code | Раскаде резсприон | Date | Date | | | |
|-----------------------|-----------------------|---|-------------------------|-----------------------|--|--|--|
| 1 | NDC:49358-570- 01 | 1 in 1 CARTON | 07/01/2023 | | | | |
| 1 | | 50 mL in 1 TUBE; Type 0: Not a Combination Product | | | | | |
| 2 | NDC:49358-570- 02 | 1 in 1 CARTON | 07/01/2023 | | | | |
| 2 | | 100 mL in 1 TUBE; Type 0: Not a Combination Product | | | | | |
| | | | | | | | |
| Marketing Information | | | | | | | |
| | Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | | |
| - | rc monograph Nal | part352 | 07/01/2023 | | | | |
| | | | | | | | |

Labeler - MDSolarSciences (013647301)

Revised: 9/2023

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