

TINTED REPLENISHING DAILY PROTECTION- zinc oxide cream  
MANTRA WELLNESS SPA

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DRUG FACTS

|                    |           |
|--------------------|-----------|
| ACTIVE INGREDIENT: | PURPOSE:  |
| Zinc Oxide 16%     | Sunscreen |

**USES:**  
Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early 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
- Use a water resistant product if swimming or sweating.
- Reapply 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 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

**INACTIVE INGREDIENTS:**  
Capric/Caprylic Triglyceride, Ceramide 3, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Hydrogen Dimethicone, Iron Oxide, PEG-10 Dimethicone, Polyhydroxystearic Acid, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer

**OTHER INFORMATION:**

- Protect this product from excessive heat and direct sun
- May stain some fabrics.

**MANUFACTURED FOR:**  
Mantra Wellness Spa  
Yauco, PR 00698



MANTRA  
WELLNESS SPA  
SKIN RITUAL

TINTED  
MANTRA

TINTED REPLENISHING  
DAILY PROTECTION

BROAD SPECTRUM SPF 40  
WITH CERAMIDES, ZINC OXIDE  
& ANTIOXIDANTS C & E

REEF FRIENDLY · CRUELTY FREE  
NON-COMEDOGENIC

NET WT. 1.75 OZ /50 G

TINTED REPLENISHING DAILY PROTECTION  
zinc oxide cream

Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:85377-208 |
| Route of Administration | TOPICAL        |                    |               |

Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength      |
|--|-------------------|---------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE        | 160 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

|  |  |
|--|--|
| <b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)                                    |  |
| <b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5) |  |
| <b>CI 77491</b> (UNII: 1K09F3G675)   |  |
| <b>CI 77492</b> (UNII: EX438O2MRT)   |  |
| <b>CERAMIDE 3</b> (UNII: 4370DF050B)   |  |
| <b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)   |  |
| <b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)                              |  |
| <b>CAPRYLIC/CAPRIC TRIGLYCERIDE</b> (UNII: C9H2L21V7U)                               |  |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)  |  |
| <b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)                                   |  |
| <b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)  |  |
| <b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                                   |  |
| <b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)                               |  |
| <b>VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER</b> (UNII: 9NH1UDD2RR)    |  |
| <b>CI 77499</b> (UNII: XM0M87F357)   |  |
| <b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)                                  |  |
| <b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)                          |  |

### Packaging

| # | Item Code        | Package Description                                       | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:85377-208-50 | 50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 03/31/2023           |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020                                     | 03/31/2023           |                    |

**Labeler** - MANTRA WELLNESS SPA (119470242)

### Establishment

| Name                         | Address | ID/FEI    | Business Operations    |
|------------------------------|---------|-----------|------------------------|
| Fragrance Manufacturing Inc. |         | 793406000 | manufacture(85377-208) |

### Establishment

| Name                 | Address | ID/FEI    | Business Operations |
|----------------------|---------|-----------|---------------------|
| Custom Analytics LLC |         | 144949372 | analysis(85377-208) |