

MINERAL LIP SUNSCREEN- titanium dioxide, zinc oxide stick  
Mantra Wellness Spa

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MANTRA MINERAL  
LIP SUNSCREEN

BROAD SPECTRUM SPF 45  
WATER RESISTANT (80 MINUTES)  
NET WT. .14 OZ /4.5 G



MANTRA  
WELLNESS SPA  
SKIN RITUAL

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**DRUG FACTS:**  
**ACTIVE INGREDIENTS:** Titanium Dioxide 4.0%, Sunscreen, Zinc Oxide 5.5%  
**PURPOSE:** 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 the reach of children.** 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, and at least every 2 hours • Children under 6 months: Ask a doctor

**MANUFACTURED FOR:** Mantra Wellness Spa | Yauco, PR 00698      NDC 385377212455





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| MINERAL LIP SUNSCREEN  |                |                    |               |
|--|----------------|--------------------|---------------|
| titanium dioxide, zinc oxide stick                                       |                |                    |               |
|  |                |                    |               |
| Product Information  |                |                    |               |
| Product Type   | HUMAN OTC DRUG | Item Code (Source) | NDC:85377-212 |
| 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  |

| Inactive Ingredients  |          |
|---|----------|
| Ingredient Name   | Strength |
| CETEARYL ISONONANOATE (UNII: P5O01U99NI)                        |          |
| CI 77492 (UNII: EX438O2MRT)                                     |          |
| PEG-8 (UNII: B697894SGQ)  |          |
| ALUMINA (UNII: LMI26O6933)                                      |          |
| PEG/PPG-15/15 DIMETHICONE (UNII: 184IZ28A2G)                    |          |
| CI 77499 (UNII: XM0M87F357)                                     |          |
| ASCORBYL PALMITATE (UNII: QN83US2B0N)                           |          |
| ASCORBIC ACID (UNII: PQ6CK8PD0R)                                |          |
| CI 77491 (UNII: 1K09F3G675)                                     |          |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)                 |          |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                     |          |
| CETYL DIMETHYLBUTYL ETHER (UNII: 7LAB1GXG9G)                    |          |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62)                            |          |
| CITRIC ACID (UNII: 2968PHW8QP)                                  |          |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)            |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                                   |          |
| CERESIN (UNII: Q1LS2UJO3A)                                      |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                         |          |
| HEXYLDECYL LAURATE (UNII: 0V595C1P6M)                           |          |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)                           |          |
| HEXYLDECANOL (UNII: 151Z7P1317)                                 |          |
| ZINGIBER OFFICINALE (GINGER) ROOT OIL (UNII: SAS9Z1SVUK)        |          |
| ALUMINUM STEARATE (UNII: U6XF9NP8HM)                            |          |
| HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX (UNII: 42DG15CHXV)       |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)                                 |          |
| DIPROPYLENE GLYCOL CAPRATE/CAPRYLATE DIESTER (UNII: R6G12EY23X) |          |
| C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)                        |          |

| Packaging |                  |  |                      |                    |
|-----------|------------------|--|----------------------|--------------------|
| #         | Item Code        | Package Description                                    | Marketing Start Date | Marketing End Date |
| 1         | NDC:85377-212-45 | 4.5 g in 1 CYLINDER; 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           |                    |

| Establishment                |         |           |                        |
|------------------------------|---------|-----------|------------------------|
| Name                         | Address | ID/FEI    | Business Operations    |
| Fragrance Manufacturing Inc. |         | 793406000 | manufacture(85377-212) |

| Establishment        |         |           |                     |
|----------------------|---------|-----------|---------------------|
| Name                 | Address | ID/FEI    | Business Operations |
| Custom Analytics LLC |         | 144949372 | analysis(85377-212) |

Revised: 4/2025

Mantra Wellness Spa