

**TINTED MINERAL SUNSCREEN- titanium dioxide, zinc oxide cream**  
**HSC MIAMI, INC**

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**TINTED**  
**MINERAL SUNSCREEN**

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BROAD SPECTRUM SPF 40  
WATER RESISTANT (80 MINUTES)



MANUFACTURED FOR | Holistic Skin Care | Hialeah | FL | 33012

**TINTED MINERAL SUNSCREEN**

titanium dioxide, zinc oxide cream

**Product Information**

|                         |                |                    |                              |  |
|-------------------------|----------------|--------------------|------------------------------|--|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:85376-203(NDC:58892-203) |  |
| Route of Administration | TOPICAL        |                    |                              |  |

| Active Ingredient/Active Moiety                                          |  |                   |              |
|--------------------------------------------------------------------------|--|-------------------|--------------|
| Ingredient Name                                                          |  | Basis of Strength | Strength     |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)             |  | ZINC OXIDE        | 38 mg in 1 g |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) |  | TITANIUM DIOXIDE  | 80 mg in 1 g |

| Inactive Ingredients                                                          |          |
|-------------------------------------------------------------------------------|----------|
| Ingredient Name                                                               | Strength |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) |          |
| DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)                                    |          |
| HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)                              |          |
| CYCLOHEXASILOXANE (UNII: XHK3U310BA)                                          |          |
| DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)                                   |          |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)                                  |          |
| CI 77491 (UNII: 1K09F3G675)                                                   |          |
| CI 77492 (UNII: EX438O2MRT)                                                   |          |
| PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)                               |          |
| ALUMINA (UNII: LMI26O6933)                                                    |          |
| CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)                                         |          |
| DIMETHICONE (UNII: 92RU3N3Y1O)                                                |          |
| CI 77499 (UNII: XM0M87F357)                                                   |          |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                                   |          |
| LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)                             |          |

| Packaging |                  |                                                     |                      |                    |
|-----------|------------------|-----------------------------------------------------|----------------------|--------------------|
| #         | Item Code        | Package Description                                 | Marketing Start Date | Marketing End Date |
| 1         | NDC:85376-203-15 | 15 g in 1 PACKET; Type 0: Not a Combination Product | 01/27/2025           |                    |

| Marketing Information |                                          |                      |                    |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug    | M020                                     | 01/27/2025           |                    |

**Labeler** - HSC MIAMI, INC (123498175)

| Establishment        |         |           |                     |
|----------------------|---------|-----------|---------------------|
| Name                 | Address | ID/FEI    | Business Operations |
| Custom Analytics LLC |         | 144949372 | analysis(85376-203) |

| Establishment               |         |           |                        |
|-----------------------------|---------|-----------|------------------------|
| Name                        | Address | ID/FEI    | Business Operations    |
| Fragrance Manufacturing Inc |         | 793406000 | manufacture(85376-203) |

| Establishment               |         |           |                     |
|-----------------------------|---------|-----------|---------------------|
| Name                        | Address | ID/FEI    | Business Operations |
| Fallien Cosmeceuticals Ltd. |         | 958388357 | relabel(85376-203)  |

Revised: 12/2025

HSC MIAMI, INC