

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



NON-TINTED
MINERAL SUNSCREEN

BROAD SPECTRUM SPF 40
WATER RESISTANT (80 MINUTES)



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

NON-TINTED MINERAL SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:85376-202(NDC:58892-202) |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:85376-202-15 | 15 g in 1 PACKET; Type 0: Not a Combination Product | 01/06/2025 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020 | 01/06/2025 | |

Labeler - HSC MIAMI, INC (123498175)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|---------------------|
| Custom Analytics LLC | | 144949372 | analysis(85376-202) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

| | | | |
|-----------------------------|--|-----------|------------------------|
| Fragrance Manufacturing Inc | | 793406000 | manufacture(85376-202) |
|-----------------------------|--|-----------|------------------------|

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|---------------------|
| Fallien Cosmeceuticals Ltd. | | 958388357 | relabel(85376-202) |

Revised: 12/2025

HSC MIAMI, INC