SOLAR SHIELD TINTED- zinc oxide cream DENISE BELL SKIN CARE

DRUG FACTS (cont)

• 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

5 Circle Skin Care | Austin, TX 78746 5circleskincare.com



5 Circle Skin Care



by Denise Bell

Solar Shield

Mineral Sunscreen Protection

broad spectrum spf 40 with ceramides, zinc oxide, antioxidants C & E

Net Wt 1.75 oz / 50 g

DRUG FACTS

ACTIVE INGREDIENTS: 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 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. If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

- Apply liberally 15 minutes before sun exposure.
- Use water resistant product if swimming or sweating.
- Reapply at least every 2 hours
- Children under 6 months: Ask a doctor

SOLAR SHIELD TINTED

zinc oxide cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:85890-208

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 |

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

| CERAMIDE 3 (UNII: 4370DF050B) | |
|---|--|
| CYCLOHEXASILOXANE (UNII: XHK3U310BA) | |
| CYCLOPENTASILOXANE (UNII: 0THT5PCI0R) | |
| DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6) | |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) | |
| DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y) | |
| HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N) | |
| PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0) | |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) | |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ) | |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR) | |
| CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U) | |
| CI 77491 (UNII: 1K09F3G675) | |
| CI 77492 (UNII: EX43802MRT) | |
| CI 77499 (UNII: XM0M87F357) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| | |

| ı | Packaging | | | | |
|---|-----------|----------------------|---|-------------------------|-----------------------|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | 1 | NDC:85890- 208-50 | 50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 03/01/2022 | |

| Marketing Information | | | |
|---|------|-------------------------|-----------------------|
| Marketing Application Number or Monograph Category Citation | | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M020 | 03/01/2022 | |
| | | | |

Labeler - DENISE BELL SKIN CARE (084486150)

| Establishment | | | | |
|-----------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Fragrance Manufacturing INC | | 793406000 | manufacture(85890-208) | |

| Establishment | | | | |
|----------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Custom Analytics LLC | | 144949372 | analysis (85890-208) | |

Revised: 7/2025 DENISE BELL SKIN CARE