

# **SOLAR SHIELD FACE AND BODY SPF 40- zinc oxide cream**

## **BRIGHT SKINCARE, LLC**

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### **Active Ingredient:**

Zinc Oxide 20%

### **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 broken or damaged 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.

### **Warning:**

Keep out of reach of children

### **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 a.m. - 2 p.m. Wear long-sleeved shirts, pants, hats and sunglasses.

### **Inactive Ingredients:**

C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogen Dimethicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate,

Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

Other Information:

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

DRUG FACTS

ACTIVE INGREDIENTS:  
Zinc Oxide 20%

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 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
  - Reapply:
    - After 40 minutes of swimming or sweating
    - Immediately after towel drying
    - 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 sleeve shirts and hats and sunglasses

INACTIVE INGREDIENTS:  
C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG 10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogren Dimethicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

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

Bright Skincare, LLC Greenville, SC 29617  
www.thebrightskincare.com



reef friendly · cruelty free · non-comedogenic  
suitable for all skin types



SOLAR SHIELD  
FACE & BODY  
SPF 40

SPF 40 Broad Spectrum Sunscreen  
Water Resistant (40 minutes)

net wt. 4 oz | 113 g

SOLAR SHIELD FACE AND BODY SPF 40

zinc oxide cream

| Product Information                                          |                |                    |                              |
|--------------------------------------------------------------|----------------|--------------------|------------------------------|
| Product Type                                                 | HUMAN OTC DRUG | Item Code (Source) | NDC:85944-205(NDC:58892-205) |
| Route of Administration                                      | TOPICAL        |                    |                              |
| Active Ingredient/Active Moiety                              |                |                    |                              |
| Ingredient Name                                              |                | Basis of Strength  | Strength                     |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) |                | ZINC OXIDE         | 200 mg in 1 g                |
| Inactive Ingredients                                         |                |                    |                              |

| Ingredient Name                                                               | Strength |
|-------------------------------------------------------------------------------|----------|
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) |          |
| HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)                              |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                                            |          |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)                                    |          |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)                                  |          |
| POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)                                 |          |
| PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)                               |          |
| DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)                                    |          |
| CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)                                         |          |
| MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)                                       |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                                            |          |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)                                 |          |
| STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)                     |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                                   |          |
| POLYSORBATE 20 (UNII: 7T1F30V5YH)                                             |          |
| PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)                               |          |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)                          |          |
| TRIETHANOLAMINE (UNII: 9O3K93S3TK)                                            |          |
| CYCLOHEXASILOXANE (UNII: XHK3U310BA)                                          |          |
| DIMETHICONE (UNII: 92RU3N3Y1O)                                                |          |
| CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)                                      |          |
| DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)                                   |          |
| WATER (UNII: 059QF0KO0R)                                                      |          |
| C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)                                      |          |
| CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)                     |          |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                                   |          |

Packaging

| # | Item Code        | Package Description                                        | Marketing Start Date | Marketing End Date |
|---|------------------|------------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:85944-205-04 | 113 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 10/27/2023           |                    |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| OTC Monograph Drug | M020                                     | 10/27/2023           |                    |

Labeler - BRIGHT SKINCARE, LLC (030046454)

Establishment

| Name                 | Address | ID/FEI    | Business Operations |
|----------------------|---------|-----------|---------------------|
| Custom Analytics LLC |         | 144949372 | analysis(85944-205) |

| Establishment                |         |           |                        |
|------------------------------|---------|-----------|------------------------|
| Name                         | Address | ID/FEI    | Business Operations    |
| Fragrance Manufacturing Inc. |         | 793406000 | manufacture(85944-205) |

| Establishment               |         |           |                     |
|-----------------------------|---------|-----------|---------------------|
| Name                        | Address | ID/FEI    | Business Operations |
| Fallien Cosmeceuticals Ltd. |         | 958388357 | relabel(85944-205)  |

Revised: 12/2025

BRIGHT SKINCARE, LLC