

**MINERAL DEFENSE SPORT CERAMIDE SPF-30- zinc oxide stick
SOLARA SUNCARE, INC.**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

**SOLARA SUNCARE - GO! MINERAL DEFENSE SPORT CERAMIDE SUNSCREEN
STICK (73054-108)**

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 skin aging caused by the sun

Keep out of reach of children. If product is swallowed, get medical help or contact Poison Control Center right away.

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

DIRECTIONS

- keep out of direct heat or sunlight
- apply generously and evenly 15 minutes before sun exposure
- reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use asunscreen 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-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

INACTIVE INGREDIENTS

Coco-Caprylate, Beeswax/Cera Alba, Jojoba Esters, Simmondsia Chinensis (Jojoba) Seed Oil, Helianthus Annus (Sunflower) Seed Oil, Euphorbia Cerifera (Candelilla) Wax, Lauryl Laurate, Caprylic/Capric Triglyceride, Methyl Dihydroabietate, Stearyl/Octyldodecyl Citrate Crosspolymer, Isostearic Acid, Lecithin, Polyglyceryl-3 Polyricinoleate, Mangifera Indica (Mango) Seed Butter, Ceramide NG, Ceramide NP, Theobroma Cacao (Cocoa) Seed Butter, Glycine Soja (Soybean) Seed Extract, Silica, Glyceryl Caprylate, Glyceryl Undecylenate, Tocopherol

OTHER INFORMATION

- Protect this product from excessive heat and direct sun.

QUESTIONS OR COMMENTS

- 1-855-859-1600 (9am - 5pm ET)

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Dermatologist Approved.</p> <p>NET WT. 1 oz / 28g</p> | <p>Blocking The Negative Is So Zen.</p> <p>A touch of calming on-the-go protection for sensitive skin, this ceramide infused sheer mineral sunscreen stick soothes, nourishes and protects from environmental aggressors.</p> <p>We believe in Conscious and Sustainable Sourcing For Our:</p> <p>Health Skin Planet</p> <p>SOLARASUNCARE.COM Made in the USA Dist by: Solara Suncare Morristown, NJ 07960 USA RP: Repertoire Compliance Dublin D07 P4AX, IE London WC2H 9JQ, UK</p> |
|--|------------|--|-------------------|---------|----------------|-----------|------|--|---|--|----------|--|-----------------------|--|--------------------------------------|--|---|--|--|--|---|--|------------|--|--|--|--|--|---|------------------------|--|----------------------|--|---|--|-------------------|--|--|--|-----------------------|--|---------------------------------|--|--|---|
| Drug Facts | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Active ingredient | Purpose | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Zinc Oxide 20% | Sunscreen | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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MINERAL DEFENSE SPORT CERAMIDE SPF-30

zinc oxide stick

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:73054-108 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION | 20 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| LECITHIN, SUNFLOWER (UNII: 834K0WOS5G) | |
| POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4) | |
| MANGIFERA INDICA SEED BUTTER (UNII: 4OXD9M35X2) | |
| CERAMIDE NG (UNII: C04977SRJ5) | |
| CERAMIDE NP (UNII: 4370DF050B) | |
| COCOA BUTTER (UNII: 512OYT1CRR) | |
| SOYBEAN (UNII: L7HT8F1ZOD) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A) | |
| GLYCERYL 1-UNDECYLENATE (UNII: B68LJT9544) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| COCO-CAPRYLATE (UNII: 4828G836N6) | |
| WHITE WAX (UNII: 7G1J5DA97F) | |
| JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL) | |
| SIMMONDSIA CHINENSIS SEED (UNII: D24K2Q1F6H) | |
| HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV) | |
| CANDELILLA WAX (UNII: VL0328HX19) | |
| LAURYL LAURATE (UNII: GPW77G0937) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F) | |
| OCTYLDODECYL CITRATE CROSSPOLYMER (UNII: X323T6QO4M) | |
| ISOSTEARIC ACID (UNII: X33R8U0062) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:73054-108-11 | 1 in 1 BOX | 10/17/2021 | |
| 1 | | 28 g in 1 APPLICATOR; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | M020 | 10/17/2021 | |

Revised: 2/2023

SOLARA SUNCARE, INC.