

SOLARA SUNCARE - POUT PROTECTOR SPF-15- zinc oxide cream
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 - POUT PROTECTOR SPF-15 (73054-104)

ACTIVE INGREDIENTS

Non-Nano, Non-Coated 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 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

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

DIRECTIONS

- shake or knead before each use
- apply generously and evenly 15 minutes before sun exposure
- reapply:
 - after 40 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


Aqua (Water), Bisabolol, Bis-Diglyceryl Polyacyladipate-2, Butyrospermum Parkii (Shea) Butter, Caprylic/Capric Triglyceride, Cetearyl Ethylhexanoate, Cetearyl Nonanoate, Cocos Nucifera (Coconut) Oil, Ethylhexyl Palmitate, Fructose, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Helianthus, Annuus (Sunflower) Seed Wax, Isostearic Acid, Lecithin, Mentha Spicata (Spearmint) Oil, Palmitoyl Tripeptide-1, Palmitoyl Tripeptide-38, Polyglyceryl-3 Polyricinoleate, Polyhydroxystearic Acid, Portulaca Pilosa Extract (Purslane), Rubus Laciniatus (Blackberry) extract, Sorbitan Isostearate, Sorbitol/ Sebacic Acid Copolymer Behenate, Stearic Acid, Sucrose Cocoate (Stevia), Tiare Flower Extract, Tocopherol, Tribehenin , Withania Somnifera (Ashwaganda) Root Extract

OTHER INFORMATION

- Protect this product from excessive heat and direct sun.

QUESTIONS OR COMMENTS

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

<p>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 • Keep out of reach of children. If product is swallowed, get medical help or contact Poison Control Center right away</p>	<p>Drug Facts</p> <p>Active ingredient (Purpose): Non-Nano, Uncoated Zinc Oxide 11% (Sunscreen) <i>Uses:</i> • 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</p> <p>Always, 100% Transparent • Responsibly Sourced Never, Over 1,500 Ingredients We Feel Compromise Health of The Earth <i>(buh-bye fake fragrance, petroleum/PCGs, silicones and more)</i></p>	<p><i>Clean & Supercharged™</i></p> <p>Peptides + Antioxidants + Vitamins</p> <p>Plant + Science Powered</p> <p>Amped Up Actives</p> <p>Vegan + Cruelty Free + Reef Friendly</p> <p>Digital + Environmental Defense</p> <p>SOLARASUNCARE.COM Made in Sunny California, USA</p> <p>Dist. by: Solara Suncare Morristown, NJ 07960 USA</p>	<p>SOLARA SUNCARE®</p> <p>Hydrate + Plump</p> <p><i>Post Protector</i></p> <p>MOISTURIZING LIP SERUM</p> <p></p> <p>15</p> <p>Broad Spectrum SPF 15 10 mL / .35 fl oz</p>	<p>Other Information: Protect this product from excessive heat or cold and direct sun. Questions or Comments: 1-855-859-1600 (9am - 5pm ET)</p>	<p>Directions: Shake or knead before each use. In excessive cold, natural oils may freeze, warm tube in hands. Apply generously and evenly 15 minutes before sun exposure and again after 40 minutes of swimming or sweating. Reapply at least every 2 hours.</p> <p>Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the 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 p.m. and wear long-sleeve shirts, pants, hats, and sunglasses. Children under 6 months: Ask a doctor.</p> <p>Inactive Ingredients: Aqua (Water), Bisabolol, Bis-Diglyceryl Polyacyladipate-2, Butyrospermum Parkii (Shea) Butter, Caprylic/Capric Triglyceride, Cetearyl Ethylhexanoate, Cetearyl Nonanoate, Cocos Nucifera (Coconut) Oil, Ethylhexyl Palmitate, Fructose, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Helianthus, Annuus (Sunflower) Seed Wax, Isostearic Acid, Lecithin, Mentha Spicata (Spearmint) Oil, Palmitoyl Tripeptide-1, Palmitoyl Tripeptide-38, Polyglyceryl-3 Polyricinoleate, Polyhydroxystearic Acid, Portulaca Pilosa Extract (Purslane), Rubus Laciniatus (Blackberry) extract, Sorbitan Isostearate, Sorbitol/ Sebacic Acid Copolymer Behenate, Stearic Acid, Sucrose Cocoate (Stevia), Tiare Flower Extract, Tocopherol, Tribehenin , Withania Somnifera (Ashwaganda) Root Extract</p>
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zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73054-104
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	11 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ISOSTEARIC ACID (UNII: X33R8U0062)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
SPEARMINT OIL (UNII: C3M81465G5)	
PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M)	
PALMITOYL LYSYLDIOXYMETHIONYLLYSINE (UNII: T7A529FB80)	
WATER (UNII: 059QF0KO0R)	
.ALPHA.-BISABOLOL, (+/-)- (UNII: 36HQN158VC)	
BIS-DIGLYCERYL POLYACYLADIPATE-2 (UNII: 6L246LAM9T)	
SHEA BUTTER (UNII: K49155WL9Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETEARYL ETHYLHEXANOATE (UNII: 9M64UO4C25)	
CETEARYL NONANOATE (UNII: F6ZWW2F361)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
FRUCTOSE (UNII: 6YSS42VSEV)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
PORTULACA PILOSA WHOLE (UNII: II29C6E5R3)	
RUBUS LACINIATUS WHOLE (UNII: HYX7YK7LE7)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
SORBITOL (UNII: 506T60A25R)	
SEBACIC ACID (UNII: 97AN39ICTC)	
BEHENIC ACID (UNII: H390488X0A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE COCOATE (UNII: 3H18P0UK73)	
GARDENIA TAITENSIS FLOWER (UNII: T0OCU8201Y)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
WITHANIA SOMNIFERA ROOT (UNII: V038D626IF)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73054-104-11	1 in 1 BOX	07/06/2019	
1	NDC:73054-104-01	10 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/06/2019	

Labeler - SOLARA SUNCARE, INC. (040998319)

Revised: 3/2023

SOLARA SUNCARE, INC.