SOLARA SUNCARE - FORTUNE TELLER SPF-30- zinc oxide lotion 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 - FORTUNE TELLER BRIGHTENING SUNSCREEN SERUM (73054-120)

ACTIVE INGREDIENTS

Zinc Oxide 22.4%

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

Water (Aqua), Caprylic/Capric Triglyceride, Glycerin, C13-14 Alkane, Polyglyceryl-4 Diisostearate/Polyhydroxystearate/Sebacate, Butyrospermum Parkii (Shea) Butter, Coco-Caprylate, Propanediol, Cocos Nucifera (Coconut) Oil, Hydrogenated Castor Oil, Magnesium Sulfate, Helianthus Annuus (Sunflower) Seed Wax, Squalane, Helianthus Annuus (Sunflower) Seed Oil, Tocopherol, Withania Somnifera (Ashwagandha) Root Extract, Perilla Frutescens (Mint) Leaf Extract, Punica Granatum Flower Extract, Avena Sativa (Oat) Kernel Extract, Gardenia Taitensis (Tahitian Gardenia) Flower Extract, Rubus Idaeus Leaf Extract, Potassium Sorbate, Terminalia Ferdinandiana Fruit Extract, Polyglyceryl-3 Polyricinoleate, Polyhydroxystearic Acid, Cetyl Palmitate, Sorbitan Palmitate, Caprylyl Glycol, Phenylpropanol, Sorbitan Olivate, Isostearic Acid, Lecithin, Fructose

OTHER INFORMATION

• Protect this product from excessive heat and direct sun.

QUESTIONS OR COMMENTS

• 1-855-859-1600 (9am – 5pm ET)

Drug Facts

Active ingredient Purpose Zinc Oxide 22.4%

. 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

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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.

- . shake before each use . apply generously and evenly to face and neck 15 minutes before sun exposure
- . 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 a.m. - 2 p.m. • wear long-sleeve shirts, pants, hats, and sunglasses . children under 6 months: Ask a doctor

Inactive ingredients

Albe Barbadensis Leaf Juice, Water (Agua), Caprylic/Capric Triglyceride, Glycerin, Coconut Alkanes, Cetearyl Alcohol, Coco-Glucoside, Hydrolyzed Jojoba Esters, Tetrahexyldecyl Ascorbate, Sodium Hyaluronate, Glycyrrhiza Glabra (Licorice Root Extract, Argania Spinosa Kernel Oil, Butyrospemium Parkii Nut Extract, Phyllanthus Emblica Fruit Extract, Rubus idaeus (Red Raspberry) Seed Oil, Pyrus Malus (Apple) Fruit Extract, Hydrolyzed Pea Protein, Butylene glycol, Caprylhydroxamic Acid, Glyceryl Caprylate, Cetearyl Giucoside, Caprylyl/Capryl Giucoside, Coco-Caprylate/Capryle, Polyhydroxystearic Acid, Polyglyceryl-3 Polyricinoleate, Isostearic Acid, Lecithin, Dipotassium Glycyrrhizinate, Xanthan Gura, Scierotium Gum, Glucose, Sodium Phytate, Sodium Chloride, Sodium Succinate, Tocopherol Magnesium Oxide, Octyldodecanol, Sorbitan Oleate, May Contain +/- Mica (Cl 77019). Titanium Dioxide Cl 77891, Cl 77492, Cl 77499 (Iron Oxides)

Other information

 Protect this product from excessive heat and direct sun.

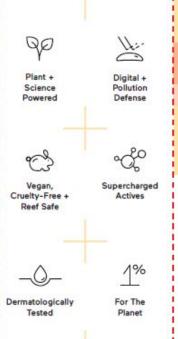
Questions or comments

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



Clean & upercharged"

We're fully dedicated to crafting luxurious, skin loving protective products that heal, nourish and support the skin's defense barrier. We're proud to formulate consciously for the love of our skin, health and planet.



SOLARA SUNCARE

Brighten + Balance

Fortune Teller

BRIGHTENING SUNSCREEN SERUM work SuperBright Complex

30

Zinc Oxide Broad Spectrum SPF 30 UVA / UVB / HEV / Pollution

50 mL / 1.7 fl oz

Vitamin C Hyaluronic Acid Adaptogens

Your future skin will thank you. This silky, protective gel-to-milk sunscreen serum hydrates and visibly brightens with each use. Infuses nourishing, skin-changing actives curated to help protect against inflammatory environmental elements and future damage such as hyperpigmentation and premature skin aging.

SuperBright Complex™

Adaptogenic Amla and Licorice Root blends with THA-C and antioxidant rich fruit extracts to help visibly brighten, protect and address inflammation

Nurture + Protect

Argan Oil, Hyaluronic Acid and Aloe help nurture, hydrate and strengthen the skin barrier

Mineral Magic

Light touch, responsibly sourced mica + iron oxides visibly brighten with each use

SOLARASUNCARE.COM

Manufactured in the US with globally sourced ingredients.

Dist by: Solara Suncare Morristown, NJ 07960 USA RP: Repertoire Compliance Dublin D07 P4AX, IE London WC2H 9JQ, UK









SOLARA SUNCARE - FORTUNE TELLER SPF-30

zinc oxide lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:73054-120

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 mL			

Ingredient Name	Strength
GLYCERYL CAPRYLATE (UNII: TM2TZ D4G4A)	
CAPRYLYL/CAPRYL OLIGOGLUCOSIDE (UNII: E00JL9G9K0)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPANEDIOL (UNII: 5965N8W85T)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
ENOXOLONE DIPOTASSIUM (UNII: ZJI2YIM6Z9)	
BETASIZOFIRAN (UNII: 2X51AD1X3T)	
COCONUT ALKANES (UNII: 1E5KJY107T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
COCO GLUCOSIDE (UNII: ICS790225B)	
POTASSIUM HYDROLYZED JOJOBA ESTERS (UNII: CH428W5O62)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
ARGAN OIL (UNII: 4V59G5UW9X)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
PEA PROTEIN (UNII: 7Q50F46595)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PHYLLANTHUS EMBLICA FRUIT (UNII: YLX4CW2576)	
SODIUM SUCCINATE HEXAHYDRATE (UNII: U16QOD6C4E)	
TOCOPHEROL (UNII: R0ZB2556P8)	
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q00K5D0T4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SHEANUT (UNII: 84H6HBP32L)	
APPLE (UNII: B423VGH5S9)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73054-120- 11	1 in 1 BOX	07/06/2019	
	NDC:73054-120- 01	90 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		
	part352	07/06/2019		

Labeler - SOLARA SUNCARE, INC. (040998319)

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