# SOLARA SUNCARE - TIME TRAVELER SPF-30 UNSCENTED- 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.

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#### **SOLARA SUNCARE -TIME TRAVELER SPF-30 UNSCENTED (73054-105)**

#### **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**

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, Copper Tripeptide-1, Acetyl Heptapeptide-4, Ceramide Ng, 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, Caprylyl Glycol, Phenylpropanol, Sorbitan Olivate, Isostearic Acid, Lecithin, Cetyl Palmitate, Sorbitan Palmitate, Polyglyceryl-3 Polyricinoleate, Polyhydroxystearic Acid, Fructose

#### OTHER INFORMATION

Protect this product from excessive heat and direct sun.

#### QUESTIONS OR COMMENTS

• 1-855-859-1600 (9am - 5pm ET)



### SOLARA SUNCARE - TIME TRAVELER SPF-30 UNSCENTED

zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73054-105
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	20 g in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
C13-15 ALKANE (UNII: 114P5I43UJ)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SHEA BUTTER (UNII: K49155WL9Y)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
PROPANEDIOL (UNII: 5965N8W85T)	
COCONUT OIL (UNII: Q9L0073W7L)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
MAGNESIUM SULFATE ANHYDROUS (UNII: ML30MJ2U7I)	
PREZATIDE COPPER (UNII: 6BJQ43T1I9)	
ACETYL HEXAPEPTIDE-8 (UNII: L4EL31FWL)	
CERAMIDE NG (UNII: C04977SRJ5)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
SQUALANE (UNII: GW89575KF9)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
TOCOPHEROL (UNII: ROZB2556P8)	
WITHANIA SOMNIFERA ROOT (UNII: V038D626IF)	
PERILLA FRUTESCENS LEAF (UNII: T4L5881Y68)	
PUNICA GRANATUM FLOWER (UNII: D9B634V4GP)	
OAT (UNII: Z6J799EAJK)	
GARDENIA TAITENSIS FLOWER (UNII: TOOCU8201Y)	
RUBUS IDAEUS LEAF (UNII: 802V33JG64)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
SORBITAN MONOPALMITATE (UNII: 77K6Z421KU)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENYLPROPANOL (UNII: 0F897O3O4M)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	

ISOSTEARIC ACID (UNII: X33R8U0062)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
FRUCTOSE (UNII: 6YSS42VSEV)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73054-105- 11	1 in 1 BOX	07/06/2019	
1	NDC:73054-105- 01	50 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)

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