

**CONSCIOUS SUNSCREEN, PROTECT-RESPECT SPF-50- zinc oxide, titanium dioxide cream
SOLID SKIN LLC**

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.

ACTIVE INGREDIENTS

MICRONIZED ZINC OXIDE 7%

TITANIUM DIOXIDE 5%

PURPOSE

SUNSCREEN

USES

HELPS PREVENT SUNBURN. IF USED AS DIRECTED WITH OTHER SUN PROTECTION MEASURES (SEE DIRECTIONS), DECREASES THE RISK OF SKIN CANCER, EARLY SKIN AGING BY THE SUN.

WARNING

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 CONTACT A DOCTOR IS RASH OCCURS.

KEEP OUT OF REACH OF CHILDREN. IF PRODUCT IS SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

APPLY LIBERALLY 15 MINUTES BEFORE SUN EXPOSURE.

REAPPLY:

- AFTER 80 MINUTES OF SWIMMING OR SWEATING
- AT LEAST EVERY 2 HOURS OR IMMEDIATELY AFTER TOWEL DRYING.

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 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, PANTS, HATS AND SUNGLASSES
- CHILDREN UNDER 6 MONTHS, ASK A DOCTOR

INACTIVE INGREDIENTS

WATER, CAPRYLIC/CAPRIC TRIGLYCERIDES, C12-15 ALKYL BENZOATE, GLYCERIN, PROPANEDIOL, DICAPRYLYL ETHER, POLYHYDROXYSTEARIC ACID, ISOSTEARIC ACID, OCTYLDODECYL STEARYL CITRATE CROSSPOLYMER, PHENOXYETHANOL, BENZOIC ACID, ETHYLHEXYLGLYCERIN, GLYCERETH-2 COCOATE, CETYL PEG/PPG-10/1

DIMETHICONE, SODIUM CHLORIDE, SEA KELP (LACTOBACILLUS/KELP FERMENT FILTRATE), MACROCYSTIS PYRIFERA (SEA KELP) EXTRACT (AND) SPIRULINA MAXIMA (BLUE ALGAE) EXTRACT, CAMELLIA SINENSIS (GREEN TEA) LEAF EXTRACT, TOCOPHEROL, TRIETHOXYCAPRYLYLSILANE, SODIUM HYALURONATE ACID POWDER, ALLANTOIN

Drug Facts

Active Ingredients: Micronized Zinc Oxide 7% Titanium Dioxide 5%	Purpose: Sunscreen
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STEP 1 (Protect + Respect): Sun exposure is synonymous with skin damage. Minimize this by using Solid Step 1 every time you get out there.

Uses: Helps prevent sunburn. If used as directed with other sun protection measures (see directions), decreases the risk of skin cancer, early skin aging 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 contact a doctor if rash occurs. Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions: Apply liberally 15 minutes before sun exposure. Reapply:

- After 80 minutes of swimming or sweating
- At least every 2 hours or immediately after towel drying

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 of 15 or higher and other sun protection measures including:


- Limit time in the sun, especially from 10am - 2pm
- Wear long-sleeve shirts, pants, hats and sunglasses
- Children under 6 months, ask a doctor

Inactive Ingredients: Water, Caprylic/Capric Triglycerides, C12-C15 Alkyl Benzoate, Glycerin, Propanediol, Dicaprylyl ether, Polyhydroxystearic Acid, Isostearic Acid, Octyldodecyl Stearyl Citrate Crosspolymer, Phenoxyethanol, Benzoic Acid, Ethylhexylglycerin, Glycereth-2 Cocoate, Cetyl PEG/PPG-10/1 Dimethicone, Sodium Chloride, Sea Kelp (Lactobacillus/kelp ferment filtrate), Macrocyctis Pyrifera (Sea Kelp) Extract (and) Spirulina Maxima (Blue Algae) Extract, Camellia sinensis (Green Tea) Leaf Extract, Tocopherol, Triethoxycaprylylsilane, Sodium Hyaluronate Acid Powder, Allantoin

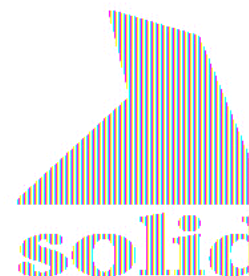
Learn More About Our Trusted Ingredients At:
SOLIDSUNLOGISTICS.COM
5% of online sales go directly to ocean based non-profit initiatives
Learn More: SolidSunLogistics.com/BeSolid

PLEASE RECYCLE

Manufactured for Solid Sun Logistics, LLC.
Costa Mesa, CA 92627



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STEP 1 **5**

CONSCIOUS
SUNSCREEN
protect • re

broad spectrum spf 50 • water re

150 ML

CONSCIOUS SUNSCREEN, PROTECT-RESPECT SPF-50

zinc oxide, titanium dioxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:71524-101

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	7 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPANEDIOL (UNII: 5965N8W85T)	
DICAPRYLYL ETHER (UNII: 77JZM5516Z)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
OCTYLDODECYL STEAROYL STEARATE (UNII: 3D47Q6D93C)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERETH-2 COCOATE (UNII: JWM00VS7HC)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
LACTOBACILLIC ACID (UNII: SVS08S87RL)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	
SPIRULINA MAXIMA (UNII: 9K7IG15M0Q)	
CAMELLIA SINENSIS WHOLE (UNII: C5M4585ZBZ)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
ALLANTOIN (UNII: 344S277G0Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71524-10-11	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/25/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/25/2017	

Labeler - SOLID SKIN LLC (080721409)

Establishment

Name	Address	ID/FEI	Business Operations
HealthSpecialty		794053863	manufacture(71524-101)

Revised: 1/2020

SOLID SKIN LLC