

CONSCIOUS SUNSCREEN, PROTECT-RESPECT, FACE SPF-40- zinc oxide, titanium dioxide stick
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 17%

TITANIUM DIOXIDE 3%

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.
- STOP USE AND CONTACT A DOCTOR IS RASH OCCURS.
- WHEN USING THIS PRODUCT KEEP OUT OF EYES. RINSE WITH WATER TO REMOVE.

- 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

CASTOR SEED OIL, BEESWAX, C12-15 ALKYL BENZOATE, CAPRYLIC CAPRIC TRIGLYCERIDES, DICAPRYLYL ETHER, CARNAUBA WAX, SHEA BUTTER, KAOLIN, VITAMIN E ACETATE, ALOE LEAF JUICE, GREEN TEA EXTRACT, SEA KELP EXTRACT



(01)0861072000417

DRUG FACTS

Active Ingredients

Micronized Zinc Oxide 17% }
Titanium Dioxide 3%

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.
- Stop use and contact 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.
- When using this product keep out of eyes. Rinse with water to remove.

Learn More About Our Trusted Ingredients At: SOLIDSUNLOGISTICS.COM

Inactive Ingredients: Castor Seed Oil, Beeswax, C12-C15 Alkyl Benzoate, Caprylic Capric Triglycerides, Dicaprylyl Ether, Carnauba Wax, Shea Butter, Kaolin, Vitamin E Acetate, Aloe Leaf Juice, Green Tea Extract, Sea Kelp Extract

Purpose

Sunscreen

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 this 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.

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

CONSCIOUS SUNSCREEN, PROTECT-RESPECT, FACE SPF-40

zinc oxide, titanium dioxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71524-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	17 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DICAPRYLYL ETHER (UNII: 77JZM5516Z)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SHEA BUTTER (UNII: K49155WL9Y)	
KAOLIN (UNII: 24H4NWX5CO)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71524-102-11	50 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(71524-102)

Revised: 1/2020

SOLID SKIN LLC