ABSOLUTELY NATURAL BROAD SPECTRUM SPF 50 SUNSCREEN- zinc oxide stick Absolutely Natural

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.

ABSOLUTELY *natural*[®] Broad Spectrum SPF 50 Mineral Sunscreen

Drug Facts

Active ingredient

Zinc Oxide 19%

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 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 doctor if rash occurs.

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

Directions

• Apply liberally and evenly 15 minutes prior to sun exposure.

Reapply after 80 minutes of swimming or sweating
immediately after towel drying
at least every 2 hours.

• Children under 6 months of age: Ask a doctor.

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 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-sleeved shirts, pants, hats, and sunglasses.

Other information

• Protect this product from excessive heat and direct sun.

Inactive ingredients

Cocos nucifera (coconut) oil, euphorbia cerifera (candelilla) wax, helianthus annuus (sunflower) seed wax, olea europaea (olive) oil unsaponifiables, rhus verniciflua peel wax, shorea robusta resin, lauryl laurate, polyhydroxystearic acid, theobroma cacao (cocoa) seed butter, caprylic/capric triglyceride, copernicia cerifera (carnauba) wax, calcium silicate, argania spinosa kernel oil, tocopheryl acetate, bisabolol, butyrospermum parkii (shea) butter, glyceryl caprylate, glyceryl undecylenate, citrus aurantium dulcis peel wax, oryza sativa (rice) bran extract, rosmarinus officinalis (rosemary) leaf extract, helianthus annuus (sunflower) extract, tocopherol.

Questions?

Call us! 800-848-7623

EST. 1992

Mineral Sunscreen

Water Resistant (80 Minutes)

Vegan

MINERAL FACE & BODY STICK helps prevent sunburn and is infused with nutrients to help keep your skin nourished while in the sun.

 $\sqrt{\text{Reef Safe}}$

√ Sensitive Skin

√ Fragrance Free

 \checkmark Biodegradable

 \checkmark No Harsh Chemicals

Cruelty**free**

MADE IN USA

Manufactured by: Absolutely Natural 640 Atlantis Road, Melbourne, FL 32904 www. Absolutely-Natural.com

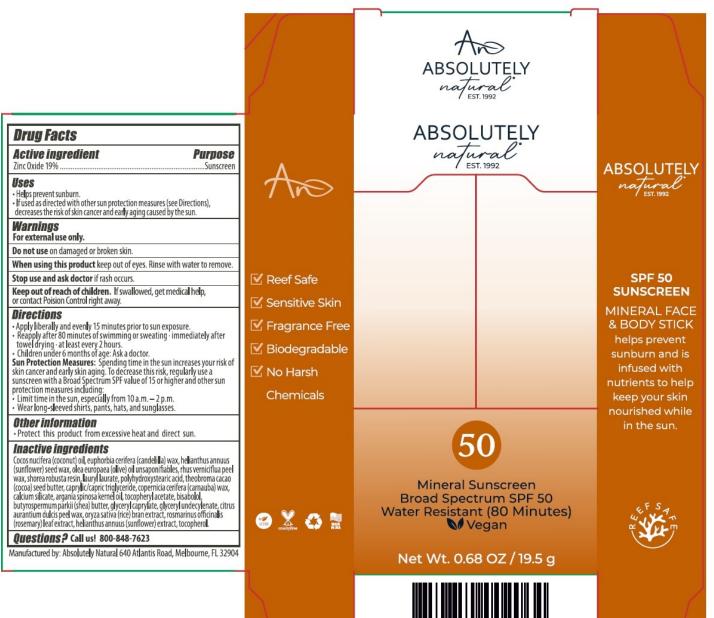
Packaging

INNER PACKAGE LABEL





OUTER PACKAGE LABEL







14

ABSOLUTELY NATURAL BROAD SPECTRUM SPF 50 SUNSCREEN zinc oxide stick **Product Information** HUMAN OTC DRUG **Product Type** Item Code (Source) NDC:70793-035 TOPICAL **Route of Administration Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength **ZINC OXIDE** (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) ZINC OXIDE 19 g in 100 g **Inactive Ingredients Ingredient Name** Strength COCONUT OIL (UNII: Q9L0073W7L) CANDELILLA WAX (UNII: WL0328HX19) HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV) OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT) TOXICODENDRON VERNICIFLUUM FRUIT RIND WAX (UNII: 6RG2461FCH) SHOREA ROBUSTA RESIN (UNII: XUK1106UBO) LAURYL LAURATE (UNII: GPW77G0937) POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) COCOA BUTTER (UNII: 5120YT1CRR) MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) CARNAUBA WAX (UNII: R12CBM0EIZ) CALCIUM SILICATE (UNII: S4255P4G5M) ARGAN OIL (UNII: 4V59G5UW9X) .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) LEVOMENOL (UNII: 24WE03BX2T) SHEA BUTTER (UNII: K49155WL9Y) **GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)** GLYCERYL 1-UNDECYLENATE (UNII: B68LIT9544) ORANGE PEEL WAX (UNII: 0U715N387C) RICE BRAN (UNII: R60QEP13IC) **ROSEMARY** (UNII: I|67X351P9) HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP) TOCOPHEROL (UNII: R0ZB2556P8) Packaging **Marketing Start Marketing End Item Code Package Description** Date Date

Marketing Category	Application Number or Monograph Citation	Date	Date		
U		Marketing Start	Marketing End		
Marketing Information					
	19.5 g in 1 CONTAINER; Type 0: Not a Combination Product				
035-68	1 in 1 CARTON	05/22/2023			

Labeler - Absolutely Natural (166425202)

Establishment					
Name	Address	ID/FEI	Business Operations		
Absolutely Natural		166425202	manufacture(70793-035)		

Revised: 5/2023

Absolutely Natural