ABSOLUTELY NATURAL BROAD SPECTRUM SPF 15 SUNSCREEN- zinc oxide lotion 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 15 Mineral Sunscreen

Drug Facts

Active ingredient

Zinc Oxide 12%

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 at least every 2 hours.
- Use a water-resistant sunscreen if swimming or sweating
- 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

Aloe barbadensis leaf juice, caprylic/capric triglyceride, polyhydroxystearic acid, water, ethylhexyl olivate, squalane, isoamyl laurate, lauryl laurate, sorbitan olivate, silica, copernicia cerifera (carnauba) wax, oryza sativa (rice) bran wax, c13-15 alkane, disteardimonium hectorite, polyglyceryl-3 polyricinoleate, hydrogenated rapeseed oil, capryloyl glycerin/sebacic acid copolymer, propanediol, citrullus lanatus (watermelon) seed oil, butyrospermum parkii (shea) butter, rosa canina fruit oil, cocos nucifera (coconut) oil, helianthus annuus (sunflower) seed oil, camellia sinensis leaf extract, oryza sativa (rice) bran extract, rosmarinus officinalis (rosemary) leaf extract, helianthus annuus (sunflower) extract, tocopherol, sodium phytate, phenoxyethanol, ethylhexylglycerin, sodium chloride, fragrance.

Questions?

Call us! 800-848-7623

Sheer Finish

Mineral Sunscreen

Vegan

REEF SAFE

Manufactured by: Absolutely Natural 640 Atlantis Road

Melbourne, FL 32904

absolutely-natural.com (800)-848-7623

cruelty**free**

MADE IN USA

Packaging



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











ABSOLUTELY NATURAL BROAD SPECTRUM SPF 15 SUNSCREEN

zinc oxide lotion

Product Information

HUMAN OTC DRUG NDC:70793-037 **Product Type** Item Code (Source)

TOPICAL Route of Administration

Active Ingredient/Active Moiety

Basis of Strength Ingredient Name Strength ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) ZINC OXIDE 12 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL OLEATE (UNII: R34927QY59)	
SQUALANE (UNII: GW89575KF9)	
ISOAMYL LAURATE (UNII: M1SLX00M3M)	
LAURYL LAURATE (UNII: GPW77G0937)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
RICE BRAN (UNII: R60QEP13IC)	
C13-15 ALKANE (UNII: 114P5I43UJ)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q00K5DOT4)	
HYDROGENATED RAPESEED OIL (UNII: K168T6Y0YU)	
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)	
PROPANEDIOL (UNII: 5965N8W85T)	
WATERMELON SEED OIL (UNII: L33J06UQTT)	
SHEA BUTTER (UNII: K49155WL9Y)	
ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ)	
COCONUT OIL (UNII: Q9L0O73W7L)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ROSEMARY (UNII: IJ67X351P9)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:70793-037- 03	88.72 mL in 1 TUBE; Type 0: Not a Combination Product	05/20/2023			
2	NDC:70793-037- 10	10 mL in 1 PACKET; Type 0: Not a Combination Product	05/20/2023			

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part352	05/20/2023				

Labeler - Absolutely Natural (166425202)

Establishment						
Na me	Address	ID/FEI	Business Operations			
Absolutely Natural		166425202	manufacture(70793-037)			

Revised: 5/2023 Absolutely Natural