

ABSOLUTELY NATURAL BROAD SPECTRUM SPF 50PLUS 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 50+ Mineral Sunscreen

Drug Facts

Active ingredient

Zinc Oxide 24%

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

Aloe barbadensis leaf juice, caprylic/capric triglyceride, polyhydroxystearic acid, water, ethylhexyl olivate, squalane, isoamyl laurate, lauryl laurate, sorbitan olivate, 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, silica, 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

EST.1992

Sheer Finish

Mineral Sunscreen

Water Resistant (80 Minutes)

Vegan

REEF SAFE

Manufactured by: Absolutely Natural

640 Atlantis Road

Melbourne, FL 32904

absolutely-natural.com

cruelty**free**

MADE IN USA

Packaging

Ao
ABSOLUTELY
natural
 EST. 1992

50+

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 Mineral Sunscreen
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3 FL OZ / 88.72 mL

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Manufactured by: Absolutely Natural absolutely-natural.com
 640 Atlantis Road (800) 848-7623



ABSOLUTELY NATURAL BROAD SPECTRUM SPF 50PLUS SUNSCREEN

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70793-034
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	24 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)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
RICE BRAN (UNII: R60QEP13IC)	
C13-15 ALKANE (UNII: 114P5I43UJ)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	
HYDROGENATED RAPESEED OIL (UNII: K168T6Y0YU)	
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
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:70793-034-03	88.72 mL in 1 TUBE; Type 0: Not a Combination Product	05/22/2023	
2	NDC:70793-034-10	10 mL in 1 PACKET; Type 0: Not a Combination Product	05/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/22/2023	

Labeler - Absolutely Natural (166425202)

Establishment

Name	Address	ID/FEI	Business Operations
Absolutely Natural		166425202	manufacture(70793-034)

Revised: 5/2023

Absolutely Natural