# ABSOLUTELY NATURAL BROAD SPECTRUM SPF 8 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.

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## ABSOLUTELY natural® Broad Spectrum SPF 8 Mineral Sunscreen

## **Drug Facts**

## Active ingredient

Zinc Oxide 8%

## **Purpose**

Sunscreen

#### Uses

Helps prevent sunburn.

## Warnings

**Skin Cancer/Skin Aging Alert**: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.

## 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.

#### 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

EST.1992

Sheer Finish

Mineral Sunscreen

Vegan

**REEF SAFE** 

Manufactured by: Absolutely Natural 640 Atlantis Road, Melbourne, FL 32904

absolutely-natural.com

cruelty**free** 

**MADE IN USA** 

**Packaging** 

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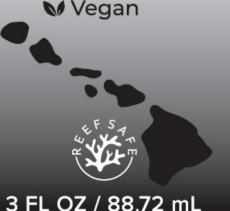
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Sheer Finish Mineral Sunscreen **Broad Spectrum SPF 8** 



## ABSOLUTELY NATURAL BROAD SPECTRUM SPF 8 SUNSCREEN

zinc oxide lotion

#### **Product Information**

**Product Type HUMAN OTC DRUG Item Code (Source)** NDC:70793-038

**Route of Administration TOPICAL** 

## **Active Ingredient/Active Moiety**

**Basis of Strength** Strength **Ingredient Name** 8 g in 100 mL ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) ZINC OXIDE

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: 7Q00K5D0T4)	
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)	

ı	Packaging						
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1	NDC:70793-038- 03	88.72 mL in 1 TUBE; Type 0: Not a Combination Product	05/17/2023			
	2	NDC:70793-038- 10	10 mL in 1 PACKET; Type 0: Not a Combination Product	05/17/2023			

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part352	05/17/2023				

# Labeler - Absolutely Natural (166425202)

Establishment						
Name	Address	ID/FEI	<b>Business Operations</b>			
Absolutely Natural		166425202	manufacture(70793-038)			

Revised: 5/2023 Absolutely Natural