# ZOEY NATURALS BROAD SPECTRUM SPF 50PLUS FRAGRANCE FREE 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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# **ZOEY®** naturals BROAD SPECTRUM SPF 50+ Fragrance Free

## **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 docto**r 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, caprylhydroxamic acid, glyceryl caprylate, glycerin, sodium chloride.

## Questions?

Call us! 800-848-8498

WATER RESISTANT (80 MINUTES)

MINERAL (NON-NANO) SUNSCREEN, VEGAN, SHEER FINISH

made for babies loved by mamas®

gives UVA/UVB sun protection and is infused with nutrients to keep your little one's skin nourished while in the sun.

Remember to reapply every 2 hours or after excessive sweating or swimming.

- √ Reef Safe
- √ Sensitive Skin
- √ Hypoallergenic
- √ No Harsh Chemicals

Cruelty free

#### **MADE IN USA**

ZOEY naturals  $^{\otimes}$  is formulated for babies and loved by mamas all around the world. Our effective and gentle formulas are free of harsh chemicals and

#### safe on the environment.

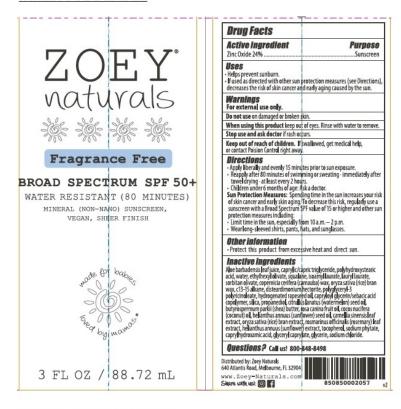
Distributed by: Zoey Naturals

640 Atlantis Road, Melbourne, FL 32904

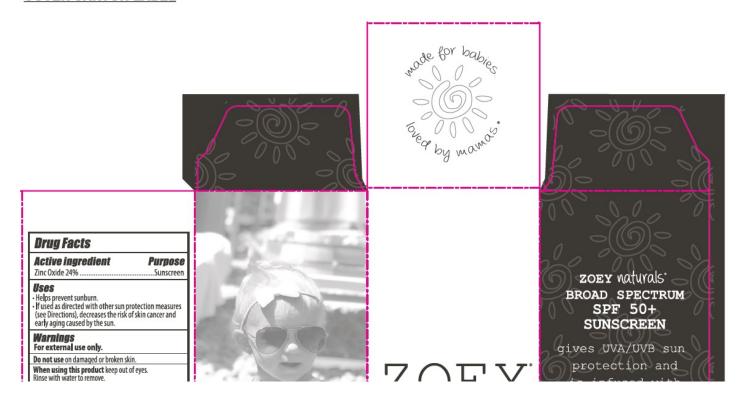
www. Zoey-Naturals.com

# **Packaging**

#### **INNER TUBE LABEL**



#### **OUTER CARTON LABEL**



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dlycerin/sebacic acid copolymer, slica, propanediol, citrullus
lanatus (watermelon) seed oil, butyrospermum parkii (shea)
butter, rosa canion i fruit oil, cocso nucifera (conqui) oil,
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www.Zoey-Naturals.com 800-848-8498 Share with us! 10 f



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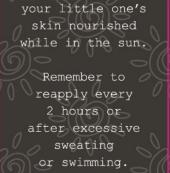
#### Fragrance Free

## BROAD SPECTRUM SPF 50+

WATER RESISTANT (80 MINUTES) MINERAL (NON-NANO) SUNSCREEN, VEGAN, SHEER FINISH



3 FL OZ / 88.72 mL



is infused with

nutrients to keep

- Reef Safe
- ☑ Sensitive Skin
- Hypoallergenic
- No Harsh Chemicals











# ZOEY NATURALS BROAD SPECTRUM SPF 50PLUS FRAGRANCE FREE SUNSCREEN

zinc oxide lotion

#### **Product Information**

**Product Type HUMAN OTC DRUG** NDC:70793-032 Item Code (Source)

**TOPICAL Route of Administration** 

# **Active Ingredient/Active Moiety**

**Ingredient Name Basis of Strength Strength** ZINC OXIDE ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) 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: 7Q00K5D0T4)	
HYDROGENATED RAPESEED OIL (UNII: K168T6Y0YU)	
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)	
SILICON DIOXIDE (UNII: ETJ7Z 6XBU4)	
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)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
GLYCERYL MONOCAPRYLATE (UNII: TM2TZ D4G4A)	
GLYCERIN (UNII: PDC6A3C00X)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:70793-032- 03	1 in 1 CARTON	05/18/2023			
1		88.72 mL in 1 TUBE; Type 0: Not a Combination Product				
2	NDC:70793-032- 10	10 mL in 1 PACKET; Type 0: Not a Combination Product	05/18/2023			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part352	05/18/2023			

# Labeler - Absolutely Natural (166425202)

Establishment						
Name	Address	ID/FEI	Business Operations			
Absolutely Natural		166425202	manufacture(70793-032)			

Revised: 5/2023 Absolutely Natural