

CORAL SURE SUNSCREEN SPF 35- zinc oxide lotion
EPONINE LABS LLC

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.

EPO9 - CORAL SURE SUNSCREEN SPF35 (79811-101)

ACTIVE INGREDIENTS

Zinc Oxide 25.2%

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 skin aging caused by the sun.

WARNINGS

- for external use only
- do not use on damaged or broken skin
- stop use and ask a doctor if rash occurs
- when using this product, keep out of eyes. Rinse with water to remove

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

DIRECTIONS

- Apply liberally 15 minutes before sun exposure • Reapply: • After 40 minutes of swimming or sweating • Immediately after towel drying • At least every 2 hours • Children under 6 months: 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 the CDC recommends regular use of sunscreen with a broad spectrum SPF value of 15 or higher, with both UVA and UVB (broad spectrum) protection, 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.

INACTIVE INGREDIENT

Water, Caprylic/Capric Triglyceride, C13-15 Alkane, Polyhydroxystearic Acid, Isostearic Acid, Lecithin, Polyglyceryl-3 olycerinoleate, Capryloyl Glycerin/Sebacic Acid Copolymer, Ethylcellulose, Butyloctyl Salicylate, Sorbitol, Erythritol, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Glyceryl Behenate, Glyceryl Caprylate, Polyglyceryl-10 Mono/Dioleate, Pentylene Glycol, C13-C14 Alkane, C15-C23 Alkane, Glycerin, Decyl Glucoside, Vitis Vinifera (Grape) Seed Oil, Magnolia Officinalis Bark Extract, Fragrance, Oryza Sativa (Rice) Bran Extract, Helianthus Annuus (Sunflower) Extract, Tocopherol (Vitamin E), Rosmarinus Officinalis (Rosemary) Leaf Extract, Aloe Barbadensis (Aloe Vera) Leaf Juice, Sodium Hyaluronate, Bisabolol, Argania Spinosa Kernel Oil, Tocopheryl Acetate, Diisopropyl Sebacate, Lauryl Lactate, Isodecyl Neopentanoate, Diisopropyl Adipate

QUESTIONS? COMMENTS?

Contact us at: Eponine Corp., PO Box 642111, Los Angeles, CA 90064. • Manufactured for and distributed by Eponine Corporation.

• To learn more please visit us at: www.epo9coralsure.com.

OTHER INFORMATION

• protect this product from excessive heat and direct sun.

EPO9™

CORAL SURE SUNSCREEN

REEF SAFE

NON-NANO
NON-TOXIC
MINERAL
WATER RESISTANT
(40 minutes)
Broad Spectrum
UVA/UVB
Defense

SPF 35

5 fl oz/148ml

Moisturizing, non-nano, mineral sunscreen safe for children, animals, and face application. Sheer, no white cast. Free from Oxybenzone, Avobenzone, Octinoxate, and Parabens. 100% recyclable tube made from plants.

2x7mm eye mark

Drug Facts

Active Ingredient	Purpose
Zinc Oxide 25.2% (non-nano particle)	Sunscreen

Use: • helps prevent sunburn • if used as directed with other sun protection measures (see **Directions**) decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings: • for external use only • do not use on damaged or broken skin • stop use and ask a doctor if rash occurs • when using this product, keep out of eyes. Rinse with water to remove • keep out of the reach of children • if swallowed, get medical help or contact a Poison Control Center right away.

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Other information: • protect this product from excessive heat and direct sun.

Questions? Comments?

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Formulated in California, USA
www.epo9coralsure.com



CORAL SURE SUNSCREEN SPF 35

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79811-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	25.2 g in 100 mL

Inactive Ingredients		
Ingredient Name		Strength
HELIANTHUS ANNUUS WHOLE (UNII: 17S27ZT6KR)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
HYALURONATE SODIUM (UNII: YSE9PPT4TH)		
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)		
LAURYL LACTATE (UNII: G5SU0BFK7O)		
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)		
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)		
ARGAN OIL (UNII: 4V59G5UW9X)		
GLYCERIN (UNII: PDC6A3C0OX)		
GRAPE SEED OIL (UNII: 930MLC8XGG)		
MAGNOLIA OFFICINALIS BARK (UNII: 5M609NV974)		
RICE BRAN (UNII: R60QEP13IC)		
C15-23 ALKANE (UNII: J3N6X3YK96)		
.BETA.-TOCOPHEROL (UNII: 9U6A490501)		
ROSEMARY (UNII: IJ67X351P9)		
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)		
WATER (UNII: 059QF0KO0R)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
C13-15 ALKANE (UNII: 114P5I43UJ)		
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)		
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)		
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)		
ETHYLCELLULOSE (10 MPA.S) (UNII: 3DYK7UYZ62)		
ISOSTEARIC ACID (UNII: X33R8U0062)		
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)		
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)		
SORBITOL (UNII: 506T60A25R)		
ERYTHRITOL (UNII: RA96B954X6)		
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)		
GLYCERETH-2 COCOATE (UNII: JWM00VS7HC)		
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)		
POLYGLYCERYL-10 DIOLEATE (UNII: 598RES7AXX)		
PENTYLENE GLYCOL (UNII: 50C1307PZG)		
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79811-101-15	148 mL in 1 TUBE; Type 0: Not a Combination Product	03/28/2022	

2	NDC:79811-101-11	29 mL in 1 POUCH; Type 0: Not a Combination Product	03/28/2022	
3	NDC:79811-101-13	88 mL in 1 TUBE; Type 0: Not a Combination Product	03/28/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/28/2022	

Labeler - EPONINE LABS LLC (118722079)

Revised: 7/2022

EPONINE LABS LLC