

AMAVARA TRANSPARENT MINERAL SUNSCREEN SPF30 EARTHWELL ZINC TECHNOLOGY, REEF SAFE- zinc oxide lotion

Amavara, Inc

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.

**AMAVARA® TRANSPARENT MINERAL SUNSCREEN LOTION SPF30
EARTHWELL® ZINC TECHNOLOGY, REEF SAFE**

Drug Facts

Active Ingredients

Zinc Oxide 19%

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. Retains SPF after 80 minutes activity in the water, sweating or perspiring. Provides high protection against sunburn.

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 a doctor if

- rash occurs or irritation develops and lasts.

Keep out of reach of children

- If Product is swallowed get medical help or contact a Poison Control Center right away.

Directions

Apply liberally and generously 15 minutes before sun exposure and at least every 2 hours

- Children under 6 months of age, ask doctor
- Reapply :
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least after every 2 hours
- 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 your time in the sun, especially from 10 a.m.-2 p.m.

- Wear long sleeved shirts, pants, hats, and sunglasses.

Other Information

Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients

Water, Butyloctyl Salicylate, Polyglyceryl-3 Sorbityl Linseedate, Styrene/Acrylates Copolymer, Dimethicone, Cetyl Dimethicone, Caprylic/Capric Triglyceride, Silica, Phenyl Trimethicone, Polyhydroxystearic Acid, Sodium Chloride, Caramel, Hydroxyacetophenone, Distearidimonium, Hectorite, 1,2-Hexanediol, Caprylyl Glycol, Polymethylmethacrylate, Tocopheryl Acetate, Triethyl Citrate, Glycerin, Bisabolol, Acrylates/Dimethicone Copolymer, Benzylidene Dimethoxydimethylindanone, Cerium Oxide, Aluminum Oxide, Zingiber Officinale (Ginger) Root Extract

PRINCIPAL DISPLAY PANEL - 49 mL Tube Label

AMAVARA®

REEF SAFE

SPF 30

+ EarthWell® Zinc Technology
Transparent Mineral Sunscreen

Safe for Sensitive Skin

Broad Spectrum SPF 30

Water Resistant (80 Minutes)

1.65 FL. OZ. / 49 mL

Reef Safe

Cruelty Free

Child Friendly

Dry Grip



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PROTECT WHAT YOU LOVE™

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Amavara® Skincare 4980 N. Harbor Drive, Suite 204 San Diego, CA 92106	
This packaging is made from post consumer recycled plastic. 	

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Proudly Made in the U.S.A.

AMAVARA TRANSPARENT MINERAL SUNSCREEN SPF30 EARTHWELL ZINC TECHNOLOGY, REEF SAFE

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71942-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	190 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ALUMINUM OXIDE (UNII: LM26O6933)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
GLYCERIN (UNII: PDC6A3C0OX)	
GINGER (UNII: C5529G5JPQ)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
BENZYLIDENE DIMETHOXYDIMETHYLINDANONE (UNII: 75HIF3C97L)	
CERIC OXIDE (UNII: 619G5K328Y)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
CARAMEL (UNII: T9D99G2B1R)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
LEVOMENOL (UNII: 24WE03BX2T)	
WATER (UNII: 059QF0K00R)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71942-101-01	88.7 mL in 1 BOX; Type 0: Not a Combination Product	02/09/2018	
2	NDC:71942-101-03	49 mL in 1 TUBE; Type 0: Not a Combination Product	04/09/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/09/2018	

Labeler - Amavara, Inc (079636282)

Establishment

Name	Address	ID/FEI	Business Operations
Northwest Cosmetic Laboratories LLC		929572014	manufacture(71942-101)