

AMAVARA TRANSPARENT MINERAL SUNSCREEN SPF50 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 SPF50
EARTHWELL® ZINC TECHNOLOGY, REEF SAFE**

Drug Facts

Active Ingredients

Zinc Oxide 22.5%

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, Styrene/Acrylates Copolymer, Polyglyceryl-3 Sorbityl Linseedate, Dimethicone, Caprylic/Capric Triglyceride, Mica, Cetyl Dimethicone, Silica, Polyhydroxystearic Acid, Phenyl Caprylic/Capric Triglyceride, Silica, Phenyl Trimethicone, Sodium Chloride, Hydroxyacetophenone, Iron Oxides, CI 77492, Distearidimonium Hectorite, 1,2 Hexanediol, Caprylyl Glycol, Polymethylmethacrylate, Tocopheryl Acetate, Iron Oxides (CI 77499, CI 77491, CI 77492), Glycerin, Bisabolol, Triethyl Citrate, Acrylates/Dimethicone Copolymer, Benzylidene Dimethoxydimethylindanone, Iron Oxides, Cerium Oxide, Aluminum Oxide, Zingiber Officinale (Ginger) Root Extract

PRINCIPAL DISPLAY PANEL - 49 mL Tube Label

AMAVARA®

REEF SAFE

SPF 50

+ EarthWell® Zinc Technology
Tinted Mineral Sunscreen

Safe for Sensitive Skin

Broad Spectrum SPF 50

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. 

 Reef Safe
 Cruelty Free
 Child Friendly
 Dry Grip

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AMAVARA TRANSPARENT MINERAL SUNSCREEN SPF50 EARTHWELL ZINC TECHNOLOGY, REEF SAFE			
zinc oxide lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71942-102
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	225 mg in 1 mL
Inactive Ingredients			

Ingredient Name	Strength
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
ALUMINUM OXIDE (UNII: LM26O6933)	
GINGER (UNII: C5529G5JPQ)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
MICA (UNII: V8A1AW0880)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
GLYCERIN (UNII: PDC6A3C0OX)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
WATER (UNII: 059QF0KO0R)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CERIC OXIDE (UNII: 619G5K328Y)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BENZYLIDENE DIMETHOXYDIMETHYLINDANONE (UNII: 75HIF3C97L)	
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
LEVOMENOL (UNII: 24WE03BX2T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71942-102-01	70 mL in 1 BOX; Type 0: Not a Combination Product	02/10/2018	
2	NDC:71942-102-04	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	02/10/2018	

Labeler - Amavara, Inc (079636282)

Establishment

Name	Address	ID/FEI	Business Operations
Northwest Cosmetic Laboratories LLC		929572014	manufacture(71942-102)

