

TRANSPARENT MINERAL SUNSCREEN FACESTICK BROAD SPECTRUM SPF 50- zinc oxide stick

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.

Transparent Mineral Sunscreen Faces tick SPF 50

Active Ingredients Purpose

Zinc Oxide 22.5% Sunscreen

Uses

- Helps Prevent Sunburn
- Higher SPF gives more sunburn protection
- 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.

Keep out of reach of children

If product is swallowed, get medical help or contact a poison Control Center right away

Warnings

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove

For external use only

Stop use and ask a doctor if

rash occurs or irritation develops and lasts.

Directions

- Apply liberally and generously 15 minutes before sun exposure and 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 your time in the sun, especially from 10 a.m. – 2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses
 - Reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours.

Inactive Ingredients: Butyloctyl Salicylate, Octyldodecyl Neopentanoate, Caprylic/Capric Triglyceride, Silica, Ozokerite, Nylon-12, Polyethylene, Dimethicone, Hydrogenated Olive Oil, Olea Europaea (Olive) Oil Unsaponifiables, Dimethicone/Vinyl Dimethicone Crosspolymer Hydrogenated Olive Oil Unsaponifiables, Polyhydroxystearic Acid, Tribehenin, Acrylates/Dimethicone Copolymer, Distearidimonium Hectorie, Polymethyl Methacrylate, Laureth-3, Laureth-25, Helianthus Annuus (Sunflower) Seed Wax, 1,2 Hexanediol, 1,2-Octanediol, Tocopheryl Acetate, Polymethylmethacrylate, Cerium Oxide, Bisabolol, Benzylidene Dimethoxydimethylindanone, Phenethyl Alcohol, Caprylyl Glycol, Aluminum Oxide, Zingiber Officinale (Ginger) Root Extract

Transparent Mineral Sunscreen Facestick

Safe for Sensitive Skin

Water Resistant 80 minutes

Broad Spectrum SPF 50

Net. Wt. 0.6 oz 16.8 g



No Artificial Colors • No Parabens
Reef Safe • Vegan • Cruelty Free


AMAVARA®
Protecting Your World

SPF 50
UVA / UVB

Transparent Mineral
Sunscreen Facestick
• EarthWell® Zinc Technology

Safe for Sensitive Skin

Water Resistant 80 Minutes

Broad Spectrum SPF 50

Net Wt. 0.6 OZ - 16.8 g



Why EarthWell® Zinc?

Advanced Zinc Protection.
No White, Pasty Residue.

Our hypoallergenic and non-comedogenic formula is water resistant, safe for sensitive skin, and uses 100% non-nano zinc oxide as the only active ingredient.

This means you won't come across secondary active ingredients some other brands use that can cause harm to our ocean ecosystems and cause coral reef bleaching.

Go ahead, be Overly Protective®.



Proudly Made in the USA
Distributed by: Amavara Skincare 4980 N.
Harbor Drive, Suite 204, San Diego, CA 92106
www.amavara.com

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 of activity in the water, sweating or perspiring
- Provides high protection against sunburn

Warnings:

- 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.
- For external use only.

Directions:

- Apply liberally 15 minutes before sun exposure and 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 your time in the sun, especially from 10 a.m. - 2 p.m.
 - Wear long-sleeved shirts, pants, hats, and sunglasses • Reapply after 80 minutes of swimming or sweating • Immediately after towel drying • at least every 2 hours

Other Information:

- Protect the product and this container from excessive heat and direct sun

Inactive Ingredients:

Butyloctyl Salicylate, Octyldodecyl Neopentanoate, Caprylic/Capric Triglyceride, Silica, Ozokerite, Nylon-12, Polyethylene, Dimethicone, Hydrogenated Olive Oil, Olea Europaea (Olive) Oil Unsaponifiables, Dimethicone/Vinyl Dimethicone Crosspolymer Hydrogenated Olive Oil Unsaponifiables, Polyhydroxystearic Acid, Tribehenin, Acrylates/Dimethicone Copolymer, Distearidimonium Hectorite, Polymethyl Methacrylate, Laureth-3, Laureth-25, Helianthus Annuus (Sunflower) Seed Wax, 1,2 Hexanediol, 1,2-Octanediol, Tocopheryl Acetate, Polymethylmethacrylates, Cerium Oxide, Bisabolol, Benzylidene Dimethoxydimethylindanone, Phenethyl Alcohol, Caprylyl Glycol, Aluminum Oxide, Zingiber Officinale (Ginger) Root Extract



AMAVARA®

Protecting Your World

SPF 50

UVA / UVB

**Transparent Mineral
Sunscreen Facestick**

+ EarthWell® Zinc Technology

Water Resistant 80 Minutes



Broad Spectrum SPF 50

Net Wt. 0.6 OZ - 16.8 g

Active Ingredients **Purpose**
 Zinc Oxide 22.5%.....Sunscreen

Directions:

- Apply liberally 15 minutes before sun exposure and at least every 2 hours
- Children under 6 months of age: ask a doctor.

Dermatologist Recommended



Pediatrician Recommended



Non-comedogenic



EarthWell® Zinc Technology • Reef Safe • Vegan
 Cruelty Free • No Parabens • No Artificial Colors

Proudly Made in the USA

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TRANSPARENT MINERAL SUNSCREEN FACESTICK BROAD SPECTRUM SPF 50

zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71942-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	22.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
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DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
CERIC OXIDE (UNII: 619G5K328Y)
LEVOMENOL (UNII: 24WE03BX2T)
BENZYLIDENE DIMETHOXYDIMETHYLINDANONE (UNII: 75HIF3C97L)
ALUMINUM OXIDE (UNII: LM26O6933)
TRIBEHENIN (UNII: 8OC9U7TQZ0)
LAURETH-3 (UNII: F32E4CB0UJ)
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
CERESIN (UNII: Q1LS2UJO3A)
NYLON-12 (UNII: 446U8J075B)
LOW DENSITY POLYETHYLENE (UNII: J245LN42A)
DIMETHICONE (UNII: 92RU3N3Y1O)
HYDROGENATED OLIVE OIL (UNII: 53839415GI)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)
GINGER (UNII: C5529G5JPQ)
OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT)
HYDROGENATED OLIVE OIL UNSAPONIFIABLES (UNII: B8MIX97W95)
LAURETH-25 (UNII: RPD53041LR)
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71942-103-01	16.8 g in 1 BOX; Type 0: Not a Combination Product	02/12/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/12/2018	

Labeler - Amavara, Inc (079636282)

Establishment

Name	Address	ID/FEI	Business Operations
Northwest Cosmetic Laboratories LLC		929572014	manufacture(71942-103)