

FOUNDATION SUNSCREEN FACE STICK BROAD SPECTRUM SPF 35 COOLY BEIGE-titanium dioxide stick

Eai-Jr286, 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.

Foundation Sunscreen Face Stick Broad Spectrum SPF 35 Cooly Beige

Active Ingredients Purpose

Titanium Dioxide 23% 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
- Higher SPF gives more sunburn protection
- 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.

Stop use and ask a doctor if rash or irritation develops and lasts

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

Directions

- apply liberally and evenly 15 minutes before sun exposure
- apply to all skin exposed to sun
- use a water resistant sunscreen if swimming or sweating
- reapply: after 80 minutes of swimming or sweating
- immediately after towel drying
- at least 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 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. - 2 p.m.
 - wear long-sleeve shirts, pants, hats, and sunglasses
 - children under 6 months of age: ask a doctor

Hexyldecyl Isostearate, Aluminum Hydroxide, Mica, Iron oxides, Stearic Acid, Paraffin, Ozokerite, Synthetic Wax, Ethylene/Propylene Copolymer, Polyglyceryl-2 Oleate, Tocopherol, Stearyl Glycyrrhetinate, Fragrance

Vertra Premium Suncare

Foundation
Sunscreen Face Stick

Broad Spectrum SPF 35
Water Resistant (80 minutes)

Color: Cooly Beige

11g NET WT. .39 OZ.

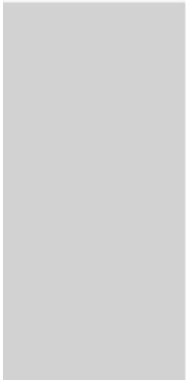
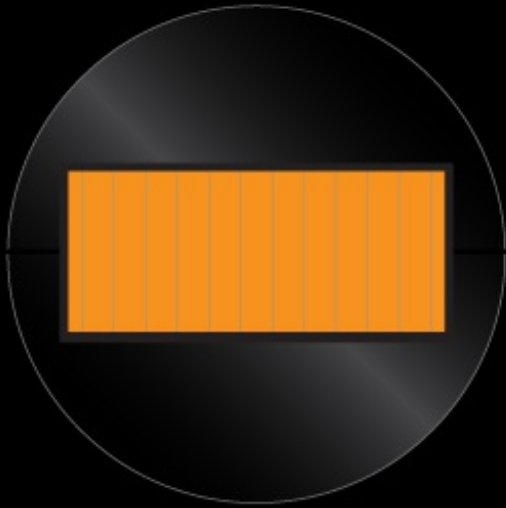


Vertra
ELEMENTAL RESISTANCE

Mick Fanning
MICK FANNING

SPF35

SUNSCREEN FACE STICK
BROAD SPECTRUM SPF 35
WATER RESISTANT (80 MINUTES)
11g NET WT. 0.39 OZ.



Active Ingredients

TITANIUM DIOXIDE 23%

Purpose: SUNSCREEN

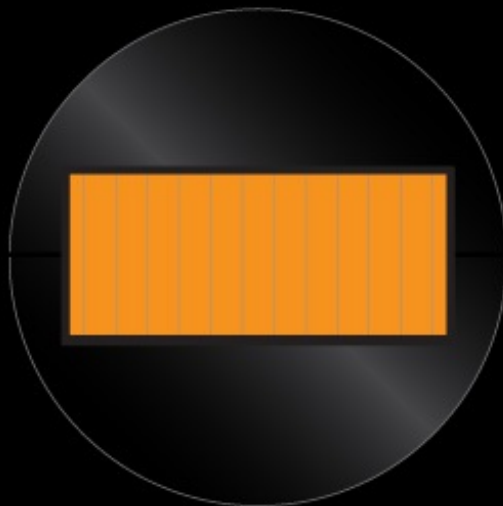
Warnings

For external use only • Do not use on damaged or broken skin • When using this product keep out of eyes • Keep out of reach of children

Directions

• Apply liberally 15 minutes before sun exposure • Reapply every 80 minutes of swimming or sweating • Do not use on children under 6 months of age

Vertra, EAI-JR286, Inc.
Torrance, CA 90502
Made in Japan



BEIGE

titanium dioxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:710 14-021
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	23 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
HEXYLDECYL ISOSTEARATE (UNII: 3V20TC06U5)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
MICA (UNII: V8A1AW0880)	
CERESIN (UNII: Q1LS2UJO3A)	
PARAFFIN (UNII: I9O0E3H2ZE)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SYNTHETIC WAX (1200 MW) (UNII: Q3Z4BCH099)	
TOCOPHEROL (UNII: R0ZB2556P8)	
STEARYL GLYCYRRHETINATE (UNII: 3YYE6VJS0P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:710 14-021-02	1 in 1 BOX	10/07/2016	
1	NDC:710 14-021-01	11 g in 1 CYLINDER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/07/2016	

Labeler - Eai-Jr286, Inc. (827896718)

Establishment

Name	Address	ID/FEI	Business Operations
Toshiki Pigment Co., Ltd.		716 140 285	manufacture(710 14-021)

