

ESIKA SILK SKIN TRANSLUCIDO- octinoxate and titanium dioxide powder

ESIKA SILK SKIN TERRACOTA- octinoxate and titanium dioxide powder

Ventura Corporation (San Juan, P.R)

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.

ēsika

Drug Facts

Active Ingredients

Octinoxate (2%), Titanium Dioxide (4.43%)

Purpose

Sunscreen

Uses

- Helps prevent sunburn.
- Higher SPF gives more sunburn protection.
- Provides minimum protection against sunburn

Warnings

- **For external use only**
- When using this product keep out of eyes. Rinse with water to remove.
- Stop use and ask a doctor if rash and irritation develops and lasts.
- Children under 6 months of age: ask a doctor.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply smoothly every morning before sun exposure and as needed.
- Sun protection product.

Other information

- Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risk of skin aging, skin cancer, and other harmful effects of the sun.

Inactive ingredients

Talc, zeamays starch(zeamays (corn) starch), calcium carbonate, silica, zinc stearate, paraffinum liquidum (mineral oil), CI 77019 (mica), dimethicone/methicone copolymer, octyldodecanol, alumina, methylparaben, propylparaben, microcristallina cera (microcrystalline wax), petrolatum, phospholipids, polyethylene, cholesterol, polyglyceryl-2 dipolyhydroxystearate, copernicia cerifera cera (copernicia

cerifera (carnauba) wax), candelilla cera (euphorbia cerifera (candelilla) wax), cera alba (beeswax), cetearyl glucoside, cetearyl alcohol, glycosphingolipids. **May contain:** CI 77491 (iron oxides), CI 77492 (iron oxides), CI 77499 (iron oxides).

PRINCIPAL DISPLAY PANEL - 15 g Carton (Translucido)

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Silk Skin

Face Powder SPF 9

15 g e (.53 oz.)



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Silk Skin
Face Powder SPF 9
15 g e (.53 oz.)

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Drug Facts (continued)

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PUERTO RICO: Distributed by Ventura Corporation, Ltd, San Juan, Puerto Rico 00926. Made in Colombia.

PRINCIPAL DISPLAY PANEL - 15 g Carton (Terracota)

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Silk Skin

Face Powder SPF 9

15 g e (.53 oz.)



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Silk Skin
Face Powder SPF 9
15 g e (.53 oz.)

Drug Facts

Active Ingredients

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Drug Facts (continued)

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ESIKA SILK SKIN TRANSLUCIDO

octinoxate and titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-354
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.02 g in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.044 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
TALC (UNII: 7SEV7J4R1U)	
STARCH, CORN (UNII: O8232NY3SJ)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ZINC STEARATE (UNII: H92E6QA4FV)	
MINERAL OIL (UNII: T5L8T28FGP)	
MICA (UNII: V8A1AW0880)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
ALUMINUM OXIDE (UNII: LM26O6933)	
METHYL PARABEN (UNII: A2I8C7H9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PETROLATUM (UNII: 4T6H12BN9U)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-354-02	1 in 1 BOX		
1	NDC:13537-354-01	15 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	07/24/2011	

ESIKA SILK SKIN TERRACOTA

octinoxate and titanium dioxide powder

Product Information

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Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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ZINC STEARATE (UNII: H92E6QA4FV)	
MINERAL OIL (UNII: T5L8T28FGP)	
MICA (UNII: V8A1AW0880)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
ALUMINUM OXIDE (UNII: LM26O6933)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
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OTC MONOGRAPH NOT FINAL	part352	07/24/2011	

Labeler - Ventura Corporation (San Juan, P.R) (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE

Revised: 5/2011

Ventura Corporation (San Juan, P.R)