

ESIKA SILK SKIN SPF 9 (TRANSLUCIDO) - BEIGE- octinoxate and titanium dioxide powder
ESIKA SILK SKIN SPF 9 (TERRACOTA) - BEIGE- octinoxate and titanium dioxide powder
Ventura Corporation LTD

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
Silk Skin Face Powder SPF 9

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
Octinoxate (2%)	Sunscreen
Titanium Dioxide (4.4%)	Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.
- **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.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor

Other information

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

Inactive ingredients

TALC, ZEA MAYS STARCH (ZEA MAYS (CORN) STARCH), CALCIUM CARBONATE, SILICA, ZINC STEARATE, PARAFFINUM LIQUIDUM (MINERAL OIL), MICA, HYDROGEN DIMETHICONE, OCTYLDODECANOL, ALUMINA, METHYLPARABEN, PROPYLPARABEN, CERA MICROCRISTALLINA (MICROCRYSTALLINE WAX), PETROLATUM, PHOSPHOLIPIDS,

POLYETHYLENE, CHOLESTÈROL, CANDELILLA CERA (EUPHORBIA CERIFERA (CANDELILLA) WAX), CERA ALBA (BEESWAX), CETEARYL ALCOHOL, CETEARYL GLUCOSIDE, COPERNICIA CERIFERA CERA (COPERNICIA CERIFERA (CARNAUBA) WAX), POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE, GLYCOSPHINGOLIPIDS.

MAY CONTAIN:

IRON OXIDES (CI 77492), IRON OXIDES (CI 77491), IRON OXIDES (CI 77499).

Distributed by Ventura Corporation, Ltd. San Juan, Puerto Rico 00926.

PRINCIPAL DISPLAY PANEL - 15 g Bottle Box (Translucido) - BEIGE

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Silk Skin

Face Powder SPF 9

Net Weight 0.53 oz. (15 g)



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**Silk Skin
Face Powder SPF 9**

Net Weight 0.53 oz. (15 g)

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

Drug Facts

Active Ingredients	Purpose
Octinoxate 2.0%	Sunscreen
Titanium dioxide 4.4%	Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.
- **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.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating. ▶

Drug Facts (continued)

- Children under 6 months of age:
Ask a doctor.

Other information

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

Inactive ingredients Talc, zeamays starch (zeamays (corn) starch), calcium carbonate, silica, zinc stearate, paraffinum liquidum (mineral oil), mica, hydrogen dimethicone, octyldodecanol, alumina, methylparaben, propylparaben, ceramicrocristallina (microcrystalline wax), petrolatum, phospholipids, polyethylene, cholesterol, candelilla cera (euphorbia cerifera (candelilla) wax), cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids. **May contain:** iron oxides (CI 77492), iron oxides (CI 77491), iron oxides (CI 77499).

PRINCIPAL DISPLAY PANEL - 15 g Bottle Box (Terracota) - BEIGE

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Silk Skin

Face Powder SPF 9

Net Weight 0.53 oz. (15 g)



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**Silk Skin
Face Powder SPF 9**

Net Weight 0.53 oz. (15 g)

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

Drug Facts

Active Ingredients	Purpose
Octinoxate 2.0%	Sunscreen
Titanium dioxide 4.4%	Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.
- **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.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating. ▶

Drug Facts (continued)

- Children under 6 months of age:
Ask a doctor.

Other information

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

Inactive ingredients Talc, zeamays starch (zeamays (corn) starch), calcium carbonate, silica, zinc stearate, paraffinum liquidum (mineral oil), mica, hydrogen dimethicone, octyldodecanol, alumina, methylparaben, propylparaben, ceramicrocristallina (microcrystalline wax), petrolatum, phospholipids, polyethylene, cholesterol, candelilla cera (euphorbia cerifera (candelilla) wax), cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids. **May contain:** iron oxides (CI 77492), iron oxides (CI 77491), iron oxides (CI 77499).

ESIKA SILK SKIN SPF 9 (TRANSLUCIDO) - BEIGE

octinoxate and titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-275
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)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-275-02	1 in 1 BOX		
1	NDC:13537-275-01	15 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/16/2013	

ESIKA SILK SKIN SPF 9 (TERRACOTA) - BEIGE

octinoxate and titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-276
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: A218C7H9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PETROLATUM (UNII: 4T6H12BN9U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-276-02	1 in 1 BOX		
1	NDC:13537-276-01	15 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/16/2013	

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-275, 13537-276)

Revised: 12/2013

Ventura Corporation LTD