

ESIKA PERFECT SUN KIDS- ensulizole, octinoxate, octisalate, octocrylene, oxybenzone, and titanium dioxide cream

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.

ē s i k a
Perfect
sun
kids

Drug Facts

Active Ingredients

Ensulizole (3%), Octinoxate (7.5%), Octisalate (5%), Octocrylene (7%), Oxybenzone (6%), Titanium Dioxide (4.68%)

Purpose

Sunscreen

Uses

- helps prevent sunburn
- higher SPF gives more sunburn protection

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.
- **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.
- Children under 6 months of age: ask a doctor.

Other information

- High sun protection product.
- 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

Aqua (water), dicaprylyl carbonate, vp/eicosene copolymer, phenethyl benzoate, arginine, cyclohexasiloxane, cetearyl alcohol, sorbitan stearate, dimethicone, glyceryl stearate, potassium cetyl phosphate, phenoxyethanol, trimethylsiloxysilicate, silica, disodium lauriminodipropionate tocopheryl phosphates, methyl methacrylate crosspolymer, methicone, methylparaben, cetareth-20, propylparaben, xanthan gum, parfum (fragrance), cyclopentasiloxane, butylparaben, ethylparaben, isobutylparaben.

PRINCIPAL DISPLAY PANEL - 82 g Bottle Label

UVB SPF

50

High Protection

UVA

Perfect

sun

kids

protector against solar
rays for children, face and
body SPF 50

ēsika

80 g e (2.8 oz.)

UVB SPF

50

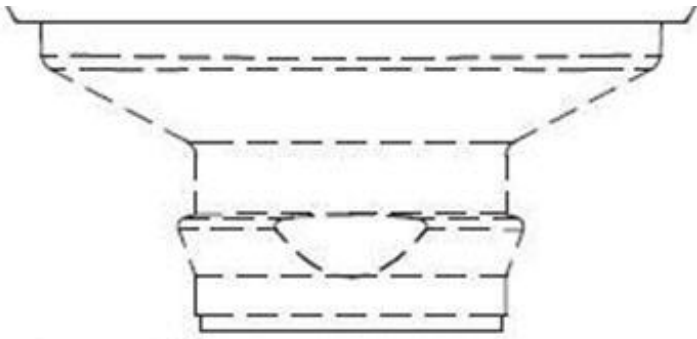
High Protection
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cyclopentasiloxane,
butylparaben, ethylparaben,
isobutylparaben.

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

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-363
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ENSULIZOLE (UNII: 9YQ9D11W42) (ENSULIZOLE - UNII:9YQ9D11W42)	ENSULIZOLE	0.03 g in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.05 g in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.07 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.6 g in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.0468 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
PHENETHYL BENZOATE (UNII: 0C143929GK)	
ARGININE (UNII: 94ZLA3W45F)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DISODIUM LAURIMINODIPROPIONATE TOCOPHERYL PHOSPHATES (UNII: 0K5Y9U1P6M)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

XANTHAN GUM (UNII: TTV12P4NEE)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
BUTYLPARABEN (UNII: 3QP1U3FV8)	
ETHYLPARABEN (UNII: 14255EXE39)	
ISOBUTYLPARABEN (UNII: 0QJ25X58G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-363-01	80 g in 1 BOTTLE		
2	NDC:13537-363-02	1 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/30/2011	

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)