

ESIKA PERFECT SUN- avobenzone, octisalate, octocrylene, and oxybenzone liquid
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 Perfect sun

Drug Facts

Active Ingredients	Purpose
AVOBENZONE (3.0%)	Sunscreen
OCTISALATE (5.0%)	Sunscreen
OCTOCRYLENE (10.0%)	Sunscreen
OXYBENZONE:6.0%	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.

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.
- **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:
 - after 40 minutes of swimming or sweating
 - immediately after towel drying
 - 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 time in the sun, especially from 10 a.m.–2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses.

Other information

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

Inactive ingredients

ALCOHOL DENAT., CYCLOPENTASILOXANE, ACRYLATES/OCTYLACRYLAMIDE COPOLYMER, C12-15 ALKYL BENZOATE, DIMETHICONE, FRAGRANCE, TOCOPHERYL ACETATE, ALOE BARBADENSIS LEAF JUICE.

P.R.: Dist. by Ventura Corporation, Ltd., San Juan, Puerto Rico 00926. Made in Colombia.

PRINCIPAL DISPLAY PANEL - 150 ml Bottle

**SPF
30
BROAD
SPECTRUM**

**Perfect
sun**

sunscreen body spray SPF 30
WATER RESISTANT
(40 MINUTES)

ērika

150 ml e (5 fl.oz.)



Drug Facts

Active Ingredients Purpose

Avobenzone 3.0%,
Octisalate 5.0%,
Octocrylene 10.0%,
Oxybenzone 6.0%.....Sunscreen

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Drug Facts (continued)

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Drug Facts (continued)

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Other information

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

Inactive ingredients

alcohol denat., cyclopentasiloxane, acrylates / octylacrylamide copolymer, c12-15 alkyl benzoate, dimethicone, parfum (fragrance), tocopheryl acetate, aloe barbadensis leaf juice.

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avobenzone, octisalate, octocrylene, and oxybenzone liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-153
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	0.03 g in 1 mL
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.05 g in 1 mL
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	0.1 g in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.06 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
cyclomethicone 5 (UNII: 0THT5PCI0R)	
alkyl (c12-15) benzoate (UNII: A9EJ3J61HQ)	
dimethicone (UNII: 92RU3N3Y1O)	
alpha-tocopherol acetate (UNII: 9E8X80D2L0)	
aloe vera leaf (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-153-01	150 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/24/2012	

Labeler - Ventura Corporation, Ltd. (602751344)

Establishment

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