

PERFECT SUN KIDS SUNSCREEN PROTECTOR AGAINST SOLAR RAYS FOR CHILDREN, FACE AND BODY SPF 50 FM- ensulizole, octinoxate, octisalate, octocrylene, oxybenzone, and titanium dioxide lotion
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.

Perfect Sun Kids Sunscreen protector against solar rays for children, face and body SPF 50 FM
Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
Ensulizole (3.00 %)	Sunscreen
Octinoxate (7.50 %)	Sunscreen
Octisalate (5.00 %)	Sunscreen
Octocrylene (7.00 %)	Sunscreen
Oxybenzone (6.00 %)	Sunscreen
Titanium Dioxide (4.68 %)	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

WATER, DICAPRYLYL CARBONATE, VP/EICOSENE COPOLYMER, PHENETHYL BENZOATE, ARGININE, CYCLOHEXASILOXANE, CETEARYL ALCOHOL, SORBITAN STEARATE, DIMETHICONE, GLYCERYL STEARATE, POTASSIUM CETYL PHOSPHATE, TRIMETHYLSILOXYSILICATE, SILICA, DISODIUM LAURIMINODIPROPIONATE TOCOPHERYL PHOSPHATES, HYDROXYACETOPHENONE, METHYL METHACRYLATE CROSSPOLYMER, METHICONE, CETEARETH-20, 1,2 – HEXANEDIOL, CAPRYLYL GLYCOL, XANTHAN GUM, FRAGRANCE, CYCLOPENTASILOXANE.

PUERTO RICO: Dist. by Ventura Corp, Ltd., San Juan, Puerto Rico 00926.

PRINCIPAL DISPLAY PANEL - 80 ml Bottle Label

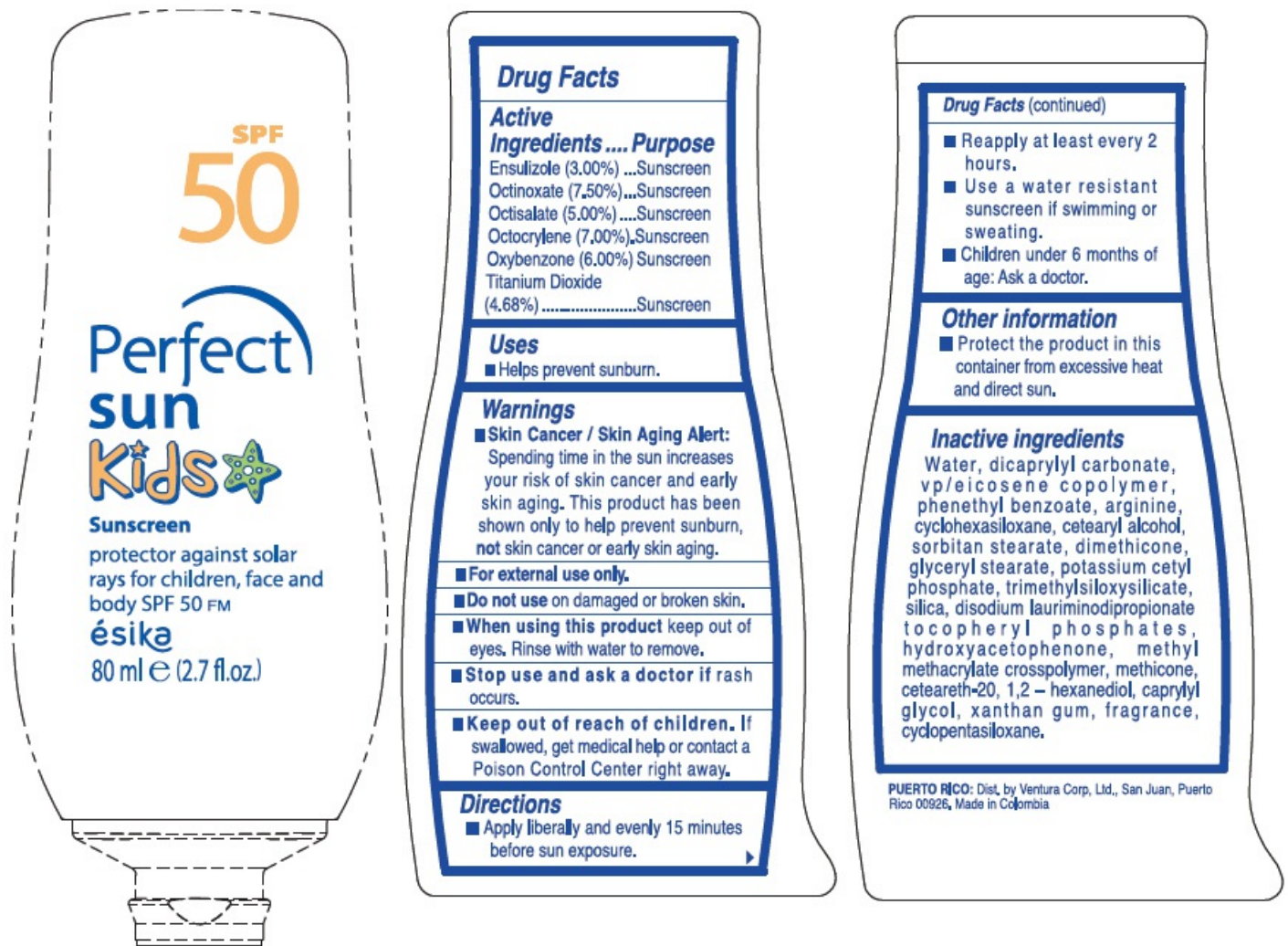
**SPF
50**

**Perfect
sun
Kids
Sunscreen**

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

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80 ml e (2.7 fl.oz.)



PERFECT SUN KIDS SUNSCREEN PROTECTOR AGAINST SOLAR RAYS FOR CHILDREN, FACE AND BODY SPF 50 FM

ensulizole, octinoxate, octisalate, octocrylene, oxybenzone, and titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-387
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Ensilizole (UNII: 9 YQ9 D11W42) (Ensilizole - UNII:9 YQ9 D11W42)	Ensilizole	0.03 g in 1 mL
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.075 g in 1 mL
Octisalate (UNII: 4X49 Y0596 W) (Octisalate - UNII:4X49 Y0596 W)	Octisalate	0.05 g in 1 mL
Octocrylene (UNII: 5A68 WGF6 WM) (Octocrylene - UNII:5A68 WGF6 WM)	Octocrylene	0.07 g in 1 mL
Oxybenzone (UNII: 95OOS7VE0 Y) (Oxybenzone - UNII:95OOS7VE0 Y)	Oxybenzone	0.06 g in 1 mL
Titanium Dioxide (UNII: 15FIX9 V2JP) (Titanium Dioxide - UNII:15FIX9 V2JP)	Titanium Dioxide	0.047 g in 1 mL

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)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DISODIUM LAURIMINODIPROPIONATE TOCOPHERYL PHOSPHATES (UNII: 0K5Y9U1P6M)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-387-02	1 in 1 BOX		
1	NDC:13537-387-01	80 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	10/22/2015	

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-387)

Revised: 10/2015

Ventura Corporation LTD