

CYZONE SUN BY ME SUNBLOCK SPF 50- octinoxate, octocrylene, oxybenzone, octisalate, titanium dioxide, and ensulizole cream

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.

Cyzone SUN BY ME Sunblock SPF 50

Drug Facts

Active Ingredients	Purpose
Octinoxate 7.5%	Sunscreen
Octocrylene 7.0%	Sunscreen
Oxybenzone 6.0%	Sunscreen
Octisalate 5.0%	Sunscreen
Titanium Dioxide 4.68%	Sunscreen
Ensulizole 3.0%	Sunscreen

Uses

- Helps prevent sunburn.
- Provides high protection against sunburn.
- Retains SPF after 40 minutes of activity in the water.

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:
 - 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

Other information

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

Inactive ingredients

water, dicaprylyl carbonate, phenethyl benzoate, stearyl dimethicone, dimethicone, arginine, cyclopentasiloxane, cetearyl alcohol, methyl methacrylate crosspolymer, trimethylsiloxysilicate, sorbitan stearate, potassium cetyl phosphate, tocopheryl acetate, phenoxyethanol, silica, methicone, methylparaben, acrylates copolymer, cetareth-20, propylparaben, xanthan gum, fragrance, butylene glycol, butylparaben, ethylparaben, isobutylparaben, litchi chinensis pericarp extract.

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

PRINCIPAL DISPLAY PANEL - 60 g Bottle Label**50 FPS**

faceblock

60 g e (2.1 oz.)

sun

by me

cy°zone



Drug Facts

Active Ingredients	Purpose
Octinoxate 7.5%, Octocrylene 7.0%, Oxybenzone 6.0%, Octisalate 5.0%, Titanium Dioxide 4.68%, Ensulizole 3.0%	Sunscreen

Uses

- Helps prevent sunburn.
- Provides high protection against sunburn.
- Retains SPF after 40 minutes of activity in the water.

Warnings
For external use only.
When using this product keep out of eyes. Rinse with water to remove. ▶

Drug Facts (continued)

Stop use and ask a doctor if rash or 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 liberally before sun exposure and as needed.

Other Information

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

Drug Facts (continued)

Inactive Ingredients
Aqua (water), dicaprylyl carbonate, phenethyl benzoate, stearyl dimethicone, dimethicone, arginine, cyclopentasiloxane, cetearyl alcohol, methyl methacrylate crosspolymer, trimethylsiloxysilicate, sorbitan stearate, potassium cetyl phosphate, tocopheryl acetate, phenoxyethanol, silica, methicone, methylparaben, acrylates copolymer, ceteareth-20, propylparaben, xanthan gum, parfum (fragrance), butylene glycol, butylparaben, ethylparaben, isobutylparaben, litchi chinensis pericarp extract.

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-155
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.07 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.06 g in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.05 g in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.0468 g in 1 g
ENSULIZOLE (UNII: 9YQ9D11W42) (ENSULIZOLE - UNII:9YQ9D11W42)	ENSULIZOLE	0.03 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
PHENETHYL BENZOATE (UNII: 0C143929GK)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ARGININE (UNII: 94ZLA3W45F)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
PROPYL PARABEN (UNII: Z8IX2SC10H)	
XANTHAN GUM (UNII: TTV12P4NEE)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
BUTYL PARABEN (UNII: 3QPIIU3FV8)	
ETHYL PARABEN (UNII: 14255EXE39)	
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)	
LITCHI FRUIT (UNII: Y5P61KP51E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-155-01	60 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	01/24/2012	

Labeler - Ventura Corporation Ltd (602751344)

Establishment

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

Revised: 1/2012

Ventura Corporation Ltd