

**CYZONE SUN BY ME- octinoxate, oxybenzone, octisalate, and titanium dioxide lotion**  
**Ventura Corporation Limited**

*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.*

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**sun**  
**by me**  
**cy°zone**

**Drug Facts**

<b>Active Ingredients</b>	<b>Purpose</b>
Octinoxate 7.5 %	sunscreen
Octisalate 5.0 %	sunscreen
Oxybenzone 5.0%	sunscreen
Titanium dioxide 0.948%	sunscreen

**Uses**

- Helps prevent sunburn.
- Higher SPF gives more sunburn protection.
- Provides moderate 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.

**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 20 minutes 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.

**Inactive ingredients**

Aqua (water), dicaprylyl carbonate, c12-15 alkyl benzoate, dimethicone, cetearyl alcohol, vp/eicosene copolymer, potassium cetyl phosphate, trimethylsiloxysilicate, titanium dioxide, phenoxyethanol, isopropyl myristate glyceryl stearate, panthenol, peg-100 stearate, methylparaben, cetareth-20, xanthan gum, parfum (fragrance), propylparaben, propylene glycol, polysorbate 40, ci77019(mica), silica, triethanolamine, methicone, acrylates/c10-30 alkyl acrylate crosspolymer, tetrasodium edta, daucus carota sativa root extract(daucus carota sativa (carrot) root extract), aloe barbadensis leaf juice,

butylparaben, ethylparaben, isobutylparaben, ci 77491(iron oxides), ci 19140 (yellow5), ci 14700 (red4), cocos nucifera (coconut) oil, gardenia tahitensis flower, gardenia tahitensis flower extract ci42090 (blue 1).

**PRINCIPAL DISPLAY PANEL - 120 ml Bottle Label**

**15**

**FPS**

golden bronze

120 ml e (4 fl oz.)

**sun**

**by me**

**cy°zone**



## Drug Facts

### Active Ingredients

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Oxybenzone 5.00%

Titanium dioxide 0.948%.....Sunscreen

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## CYZONE SUN BY ME

octinoxate, oxybenzone, octisalate, and titanium dioxide lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-110
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 mL

<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.05 g in 1 mL
<b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.05 g in 1 mL
<b>Titanium dioxide</b> (UNII: 15FIX9V2JP) (Titanium dioxide - UNII:15FIX9V2JP)	Titanium dioxide	0.00948 g in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>water</b> (UNII: 059QF0KO0R)	
<b>dicaprylyl carbonate</b> (UNII: 609A3V1SUA)	
<b>c12-15 alkyl benzoate</b> (UNII: A9EJ3J61HQ)	
<b>dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>isopropyl myristate</b> (UNII: 0RE8K4LNJS)	
<b>glyceryl monostearate</b> (UNII: 230OU9XXE4)	
<b>panthenol</b> (UNII: WV9CM0O67Z)	
<b>polyoxyl 100 stearate</b> (UNII: YD01N1999R)	
<b>methylparaben</b> (UNII: A2I8C7HI9T)	
<b>polyoxyl 20 cetostearyl ether</b> (UNII: YRC528SWUY)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	
<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>propylene glycol</b> (UNII: 6DC9Q167V3)	
<b>polysorbate 40</b> (UNII: STI11B5A2X)	
<b>mica</b> (UNII: V8A1AW0880)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>trolamine</b> (UNII: 9O3K93S3TK)	
<b>carbomer interpolymmer type a (55000 cps)</b> (UNII: 59TL3WG5CO)	
<b>edetate sodium</b> (UNII: MP1J8420LU)	
<b>carrot</b> (UNII: L56Z1JK48B)	
<b>aloe vera leaf</b> (UNII: ZY81Z83H0X)	
<b>butylparaben</b> (UNII: 3QPI1U3FV8)	
<b>ethylparaben</b> (UNII: 14255EXE39)	
<b>isobutylparaben</b> (UNII: 0QQJ25X58G)	
<b>ferric oxide red</b> (UNII: 1K09F3G675)	
<b>FD&amp;C yellow no. 5</b> (UNII: I753WB2F1M)	
<b>FD&amp;C red no. 4</b> (UNII: X3W0AM1JLX)	
<b>coconut oil</b> (UNII: Q9L0O73W7L)	
<b>FD&amp;C blue no. 1</b> (UNII: H3R47K3TBD)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-110-13	1 in 1 CARTON		
1	NDC:13537-110-12	120 mL in 1 BOTTLE		
2	NDC:13537-110-06	1 in 1 CARTON		
2	NDC:13537-110-05	5 mL in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	04/22/2011	

**Labeler** - Ventura Corporation Limited (602751344)

**Establishment**

Name	Address	ID/FEI	Business Operations
BelStar, S.A.		880160197	MANUFACTURE

Revised: 11/2010

Ventura Corporation Limited