

CYZONE CY COVER MAT- octinoxate and titanium dioxide 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.

cy°zone
cover mat

Drug Facts

Active Ingredients

OCTINOXATE 6.0 %, TITANIUM DIOXIDE 0.8 %

Purpose

sunscreen

Uses

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

Warnings

For external 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 the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- * Apply generously and evenly before sun exposure and as needed

Inactive ingredients

WATER, CYCLOPENTASILOXANE, SILICA, CYCLOHEXASILOXANE, CETYL PEG/PPG-10/1 DIMETHICONE, POLYGLYCERYL-4 ISOSTEARATE, HEXYL LAURATE, TRIMETHYLSILOXYSILICATE, GLYCERIN, SODIUM CHLORIDE, DISTEARDIMONIUM HECTORITE, BAMBUSA ARUNDINACEA STEM POWDER, PEG/PPG-19/19 DIMETHICONE, DIAZOLIDINYL UREA, METHYL PARABEN, PROPYLENE CARBONATE, PROPYL PARABEN, SILICA DIMETHYL SILYLATE, LYCOPODIUM CLAVATUM EXINE, TOCOPHERYL ACETATE, ALUMINA, TRIETHOXYCAPRYLYLSILANE, BHA, BHT, IMPERATA CYLINDRICA ROOT EXTRACT, DIMETHICONE. **MAY CONTAIN:** CI 77492 (IRON OXIDES), CI 77491 (IRON OXIDES), CI 77499 (IRON OXIDES))

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

PRINCIPAL DISPLAY PANEL - 27 g Tube Label

cover mat

cy°

cy°zone

27 g e (.95 oz.)

cover mat
base de maquillaje
para rostro ligera
antibrillo FPS 11

cy°

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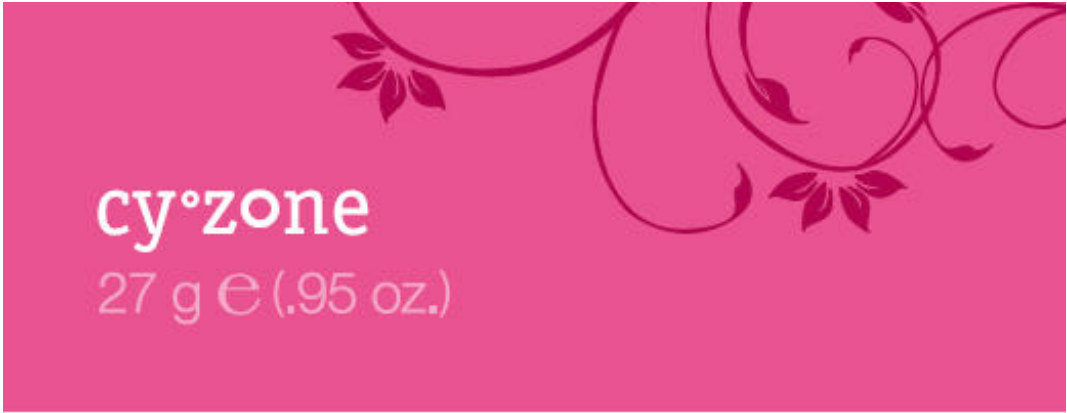
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Inactive ingredients

Aqua (water), cyclopentasiloxane, silica, cyclohexasiloxane, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, hexyl laurate, trimethylsiloxyethylacetate, glycerin, sodium chloride, disteardimonium hectorite, bambusa arundinacea stem powder, peg/ppg-19/19 dimethicone, diazolidinyl urea, methylparaben, propylene carbonate, propylparaben, silica dimethyl silylate, lycopodium clavatum extract, tocopheryl acetate, alumina, triethoxycaprylylsilane, bht, imperata cylindrica root extract, methicone. **May Contain:** C1 77891 (titanium dioxide), C1 77492 (iron oxides), C1 77491 (iron oxides), C1 77499 (iron oxides)



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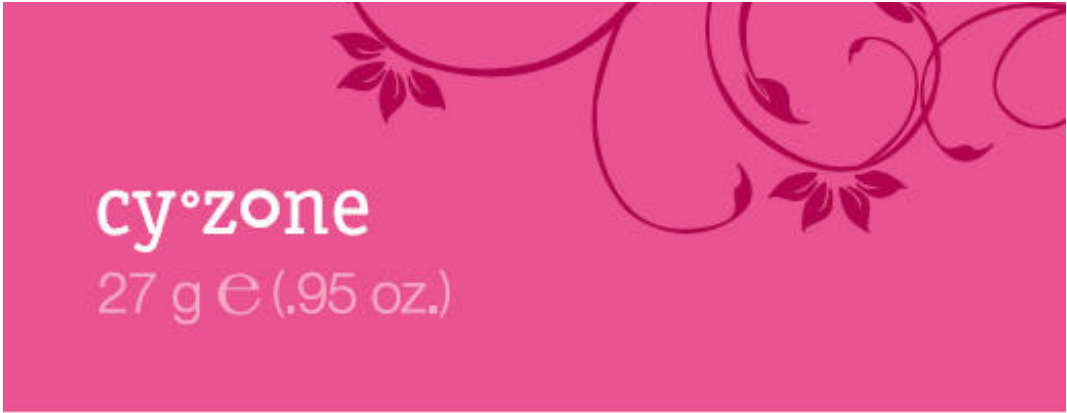
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Inactive ingredients

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silica, cyclohexasiloxane, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4-
isostearate, hexyl laurate, trimethylsiloxyethylacetate, glycerin, sodium chloride,
disteardimonium hectorite, bambusa arundinacea stem powder,
peg/ppg-19/19 dimethicone, diazolidinyl urea, methylparaben, propylene
carbonate, propylparaben, silica dimethyl silylate, lycopodium clavatum
extract, tocopheryl acetate, alumina, triethoxycaprylylsilane, bht, imperata
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cy°zone

27 g e (.95 oz.)

CYZONE CY COVER MAT

octinoxate and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-123
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.06 g in 1 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.008 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BAMBUSA ARUNDINACEA STEM (UNII: NRA4497HC5)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
IMPERATA CYLINDRICA ROOT (UNII: VYT2JA85NH)	

FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Product Characteristics

Color	BROWN (Sun Beige - Beige)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-123-01	1 in 1 BAG		
1		27 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/13/2011	

CYZONE CY COVER MAT

octinoxate and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-124
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.06 g in 1 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.008 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
POLYGLYCERYL-4 ISO STEARATE (UNII: 820DPX33S7)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

BAMBUSA ARUNDINACEA STEM (UNII: NRA4497HC5)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
METHYL PARABEN (UNII: A2I8C7HI9T)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
ALUMINUM OXIDE (UNII: LM26O6933)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
IMPERATA CYLINDRICA ROOT (UNII: VYT2JA85NH)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)

Product Characteristics

Color	BROWN (Over Sand - Beige)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-124-01	1 in 1 BAG		
1		27 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/13/2011	

CYZONE CY COVER MAT

octinoxate and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-125
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.06 g in 1 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.008 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BAMBUSA ARUNDINACEA STEM (UNII: NRA4497HC5)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
IMPERATA CYLINDRICA ROOT (UNII: VYT2JA85NH)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Product Characteristics

Color	BROWN (Midd Confidential - Beige)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-125-01	1 in 1 BAG		
1		27 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/13/2011	

octinoxate and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-126
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.06 g in 1 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.008 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BAMBUSA ARUNDINACEA STEM (UNII: NRA4497HC5)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSPOG0W)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
IMPERATA CYLINDRICA ROOT (UNII: VYT2JA85NH)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Product Characteristics

Color	BROWN (Secret Light - Beige)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-126-01	1 in 1 BAG		
1		27 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/13/2011	

Labeler - Ventura Corporation Ltd. (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star, S. A.(Colombia)		880160197	MANUFACTURE(13537-123, 13537-124, 13537-125, 13537-126)

Establishment

Name	Address	ID/FEI	Business Operations
Yobel Supply Chain Management (Peru)		934116930	MANUFACTURE(13537-123, 13537-124, 13537-125, 13537-126)

Revised: 11/2011

Ventura Corporation Ltd.