

CYZONE CY- octinoxate and octocrylene ointment
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.

humectante para labios
con aroma FPS 15
cy°zone
cy°bulkyz

Active Ingredients

Octinoxate: 6.0%, Octocrylene: 4,0%.

Purpose

Sunscreen.

Uses

Helps prevent sunburn.

Warnings

Stop use if skin rash occurs.

Ingredients

Diisopropyl dimer dilinoleate, petrolatum, polybutene, butyrospermum parkii (butyrospermum parkii (shea butter)), cera alba (beeswax), silica, cera microcristallina (microcrystalline wax), parfum (fragrance), silica dimethyl silylate, bht, caprylic/capric triglyceride, diethylhexyl syringylidene malonate, glycerin, methylparaben, ozokerite, propylparaben, sodium saccharin, theobroma cacao seed butter (theobroma cacao (cocoa) seed butter), tocopheryl acetate. **May contain:** CI 77019 (mica), CI 45380 (red 21 lake), CI 77891 (titanium dioxide), CI 15850 (red 7 lake), CI 19140 (yellow 5 lake), CI 42090 (blue 1 lake), CI 45410 (red 27 lake).

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

PRINCIPAL DISPLAY PANEL - 14 g CherryLemon Container

humectante para labios con aroma FPS 15
14 g e (.49 oz.)

cy°bulkyz



PRINCIPAL DISPLAY PANEL - 14 g PassionBerry Container

humectante para labios con aroma FPS 15
14 g e (.49 oz.)

cy°bulkyz



PRINCIPAL DISPLAY PANEL - 14 g MintGrape Container

humectante para labios con aroma FPS 15
14 g e (.49 oz.)

cy°bulkyz



PRINCIPAL DISPLAY PANEL - 14 g CocoPine Container

humectante para labios con aroma FPS 15
14 g e (.49 oz.)

cy°bulkyz



CYZONE CY

octinoxate and octocrylene ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-012
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
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	0.04 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
SHEA BUTTER (UNII: K49155WL9Y)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
CERESIN (UNII: Q1LS2UJO3A)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
CHOCOLATE (UNII: D9108TZ9KG)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
Aluminum Oxide (UNII: LMI26O6933)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY, LEMON	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-012-15	1 in 1 CARTON		
1	NDC:13537-012-14	14 g in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	01/21/2011	

CYZONE CY

octinoxate and octocrylene ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-013
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
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	0.04 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
SHEA BUTTER (UNII: K49155WL9Y)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CERESIN (UNII: Q1LS2UJO3A)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
CHOCOLATE (UNII: D9108TZ9KG)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
Aluminum Oxide (UNII: LMI26O6933)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY (PassionBerry)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-013-15	1 in 1 CARTON		
1	NDC:13537-013-14	14 g in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	01/21/2011	

CYZONE CY

octinoxate and octocrylene ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-014
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
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.04 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
SHEA BUTTER (UNII: K49155WL9Y)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CERESIN (UNII: Q1LS2UJO3A)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
CHOCOLATE (UNII: D9108TZ9KG)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

Aluminum Oxide (UNII: LMI26O6933)

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT, GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-014-15	1 in 1 CARTON		
1	NDC:13537-014-14	14 g in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	01/21/2011	

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-015
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
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SHEA BUTTER (UNII: K49155WL9Y)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CERESIN (UNII: Q1LS2UJO3A)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
CHOCOLATE (UNII: D9108TZ9KG)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
Aluminum Oxide (UNII: LMI26O6933)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	COCONUT (CocoPine)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-015-15	1 in 1 CARTON		
1	NDC:13537-015-14	14 g in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	01/21/2011	

Labeler - Ventura Corporation Limited (602751344)

Establishment

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

Revised: 11/2010

Ventura Corporation Limited