

**CY HYDRAFULL LABIAL HIDRATANTE FULL COLOR FPS 15 RED/RED-
octinoxate lipstick**
**CY HYDRAFULL LABIAL HIDRATANTE FULL COLOR FPS 15 APPLE/RED-
octinoxate lipstick**
**CY HYDRAFULL LABIAL HIDRATANTE FULL COLOR FPS 15 ROSE/RED-
octinoxate lipstick**
**CY HYDRAFULL LABIAL HIDRATANTE FULL COLOR FPS 15 FUCSIA/RED-
octinoxate lipstick**
**CY HYDRAFULL LABIAL HIDRATANTE FULL COLOR FPS 15 GRAPE/RED-
octinoxate lipstick**
**CY HYDRAFULL LABIAL HIDRATANTE FULL COLOR FPS 15 CHOCOLATE/BROWN-
octinoxate lipstick**
**CY HYDRAFULL LABIAL HIDRATANTE FULL COLOR FPS 15 MARSALA/RED-
octinoxate lipstick**
**CY HYDRAFULL LABIAL HIDRATANTE FULL COLOR FPS 15 ROSE NUDE/RED-
octinoxate lipstick**
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° HYDRAFULL LABIAL HIDRATANTE FULL COLOR FPS 15

Drug Facts

Active Ingredients

OCTINOXATE 7.5%

Purpose

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

RICINUS COMMUNIS (CASTOR) SEED OIL, OCTYLDODECANOL, POLYETHYLENE, BUTYROSPERMUM PARKII (SHEA) BUTTER, SYNTHETIC BEESWAX, COPERNICIA CERIFERA (CARNAUBA) WAX, DISTEARDIMONIUM HECTORITE, VITIS VINIFERA (GRAPE) SEED OIL, PROPYLENE CARBONATE, SILICA DIMETHYL SILYLATE, TOCOPHERYL ACETATE, PHENOXYETHANOL, FRAGRANCE, METHYLPROPANEDIOL, CAPRYLYL GLYCOL, SILANEDIOL SALICYLATE, CHLORPHENESIN, TROMETHAMINE, CERAMIDE 3, PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE, HEXYL CINNAMAL. **MAY CONTAIN:** TITANIUM DIOXIDE, RED 21 LAKE, RED 30 LAKE, IRON OXIDES, YELLOW 5 LAKE, RED 27 LAKE, RED 7 LAKE, TALC, BLUE 1 LAKE.

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

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - Red/Red

cy°

HYDRAFULL

Labial hidratante full color FPS 15

Net Wt. 0.14 oz. e (4 g)



PRINCIPAL DISPLAY PANEL - 4 g Tube Box - Apple/Red

cy°

HYDRAFULL

Labial hidratante full color FPS 15

Net Wt. 0.14 oz. e (4 g)



PRINCIPAL DISPLAY PANEL - 4 g Tube Box - Rose/Red

cy°

HYDRAFULL

Labial hidratante full color FPS 15

Net Wt. 0.14 oz. e (4 g)



PRINCIPAL DISPLAY PANEL - 4 g Tube Box - Fucsia/Red

cy°

HYDRAFULL

Labial hidratante full color FPS 15

Net Wt. 0.14 oz. e (4 g)



PRINCIPAL DISPLAY PANEL - 4 g Tube Box - Grape/Red

cy°

HYDRAFULL

Labial hidratante full color FPS 15

Net Wt. 0.14 oz. e (4 g)



PRINCIPAL DISPLAY PANEL - 4 g Tube Box - Chocolate/Brown

cy°

HYDRAFULL

Labial hidratante full color FPS 15

Net Wt. 0.14 oz. e (4 g)



PRINCIPAL DISPLAY PANEL - 4 g Tube Box - Marsala/Red

cy°

HYDRAFULL

Labial hidratante full color FPS 15

Net Wt. 0.14 oz. e (4 g)



PRINCIPAL DISPLAY PANEL - 4 g Tube Box - Rose Nude/Red

cy°

HYDRAFULL

Labial hidratante full color FPS 15

Net Wt. 0.14 oz. e (4 g)



CY HYDRAFULL LABIAL HIDRATANTE FULL COLOR FPS 15 RED/RED

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0064
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

Inactive Ingredients	
Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
SHEA BUTTER (UNII: K49155WL9Y)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
TROMETHAMINE (UNII: 023C2WHX2V)	
CERAMIDE NP (UNII: 4370DF050B)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Product Characteristics			
Color	RED	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0064-2	1 in 1 BOX	08/24/2017	
1	NDC:43596-0064-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC MONOGRAPH FINAL	part352	08/24/2017	
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CY HYDRAFULL LABIAL HIDRATANTE FULL COLOR FPS 15 APPLE/RED

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0065
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

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
SHEA BUTTER (UNII: K49155WL9Y)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
TROMETHAMINE (UNII: 023C2WHX2V)	
CERAMIDE NP (UNII: 4370DF050B)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0065-2	1 in 1 BOX	08/24/2017	
1	NDC:43596-0065-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	08/24/2017	

CY HYDRAFULL LABIAL HIDRATANTE FULL COLOR FPS 15 ROSE/RED

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0066
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

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
SHEA BUTTER (UNII: K49155WL9Y)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	

CAPRYLYL GLYCOL (UNII: 00YIU5438U)
SILANEDIOL SALICYLATE (UNII: C054DF30K0)
CHLORPHENESIN (UNII: I670DAL4SZ)
TROMETHAMINE (UNII: 023C2WHX2V)
CERAMIDE NP (UNII: 4370DF050B)
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 30 (UNII: 2S42T2808B)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0066-2	1 in 1 BOX	08/24/2017	
1	NDC:43596-0066-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	08/24/2017	

CY HYDRAFULL LABIAL HIDRATANTE FULL COLOR FPS 15 FUCSIA/RED

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0067
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

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
SHEA BUTTER (UNII: K49155WL9Y)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
TROMETHAMINE (UNII: 023C2WHX2V)	
CERAMIDE NP (UNII: 4370DF050B)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
.ALPHA.-HEXYL CINNAMALDEHYDE (UNII: 7X6O37OK2I)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0067-2	1 in 1 BOX	08/24/2017	
1	NDC:43596-0067-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	08/24/2017	

CY HYDRAFULL LABIAL HIDRATANTE FULL COLOR FPS 15 GRAPE/RED

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0068
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

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
SHEA BUTTER (UNII: K49155WL9Y)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
TROMETHAMINE (UNII: 023C2WHX2V)	
CERAMIDE NP (UNII: 4370DF050B)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

D&C RED NO. 27 (UNII: 2LRS185U6K)

D&C RED NO. 7 (UNII: ECW0LZ41X8)

TALC (UNII: 7SEV7J4R1U)

FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0068-2	1 in 1 BOX	08/24/2017	
1	NDC:43596-0068-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	08/24/2017	

CY HYDRAFULL LABIAL HIDRATANTE FULL COLOR FPS 15 CHOCOLATE/BROWN

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0069
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

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
SHEA BUTTER (UNII: K49155WL9Y)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	

PROPYLENE CARBONATE (UNII: 8D08K3S51E)
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
METHYLPROPANEDIOL (UNII: N8F53B3R4R)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
SILANEDIOL SALICYLATE (UNII: C054DF30K0)
CHLORPHENESIN (UNII: I670DAL4SZ)
TROMETHAMINE (UNII: 023C2WHX2V)
CERAMIDE NP (UNII: 4370DF050B)
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 30 (UNII: 2S42T2808B)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Product Characteristics

Color	BROWN	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0069-2	1 in 1 BOX	08/24/2017	
1	NDC:43596-0069-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	08/24/2017	

CY HYDRAFULL LABIAL HIDRATANTE FULL COLOR FPS 15 MARSALA/RED

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0070
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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

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
SHEA BUTTER (UNII: K49155WL9Y)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
TROMETHAMINE (UNII: 023C2WHX2V)	
CERAMIDE NP (UNII: 4370DF050B)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0070-2	1 in 1 BOX	08/24/2017	
1	NDC:43596-0070-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	08/24/2017	

CY HYDRAFULL LABIAL HIDRATANTE FULL COLOR FPS 15 ROSE NUDE/RED

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0071
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

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
SHEA BUTTER (UNII: K49155WL9Y)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
TROMETHAMINE (UNII: 023C2WHX2V)	
CERAMIDE NP (UNII: 4370DF050B)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
.ALPHA.-HEXYL CINNAMALDEHYDE (UNII: 7X6O37OK2I)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0071-2	1 in 1 BOX	08/24/2017	
1	NDC:43596-0071-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	08/24/2017	

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(43596-0064, 43596-0065, 43596-0066, 43596-0067, 43596-0068, 43596-0069, 43596-0070, 43596-0071)