

LBEL ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 NUDE TRANSLUCIDE - BEIGE- octinoxate and zinc oxide lipstick
LBEL ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 CORAL PETALE - PINK- octinoxate and zinc oxide lipstick
LBEL ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 ROSE PARADISE - PINK- octinoxate and zinc oxide lipstick
LBEL ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 ROSE COTTON - PINK- octinoxate and zinc oxide lipstick
LBEL ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 CERISE BRISE - PINK- octinoxate and zinc oxide lipstick
LBEL ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 NUDE CAMEL - BEIGE- octinoxate and zinc oxide 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.

L'BEL ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
OCTINOXATE: 7.95 %	Sunscreen
ZINC OXIDE 4.9%	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 damage 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.
- Children under 6 months of age: Ask a doctor.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Apply lipstick following the curves of natural lip line. For added definition, use with a lip pencil.

Other information

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

Inactive ingredients

OCTYLDODECANOL, ETHYLHEXYL PALMITATE, POLYETHYLENE, OZOKERITE, MICA, SILICA, JOJOBA ESTERS, COPERNICIA CERIFERA (CARNAUBA) WAX, CETYL PEG/PPG-10/1 DIMETHICONE, POLYGLYCERYL-4 ISOSTEARATE, HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX, HEXYL LAURATE, TOCOPHERYL ACETATE, SCHINUS TEREBINTHIFOLIUS SEED EXTRACT, PHENOXYETHANOL, DIMETHICONE, ACACIA DECURRENS FLOWER WAX, POLYGLYCERIN-3, TRIETHOXYCAPRYLYLSILANE, CAPRYLYL GLYCOL, CHLORPHENESIN, TRIMETHYLSILOXYSILICATE, CERAMIDE 3.

MAY CONTAIN :

MICA, TITANIUM DIOXIDE, DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL TRIMELLITATE, IRON OXIDES, YELLOW 5 LAKE, RED 7 LAKE, RED 6 LAKE, TRIDECYL STEARATE, NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE, TALC.

Dist. by Ventura Int Ltd.

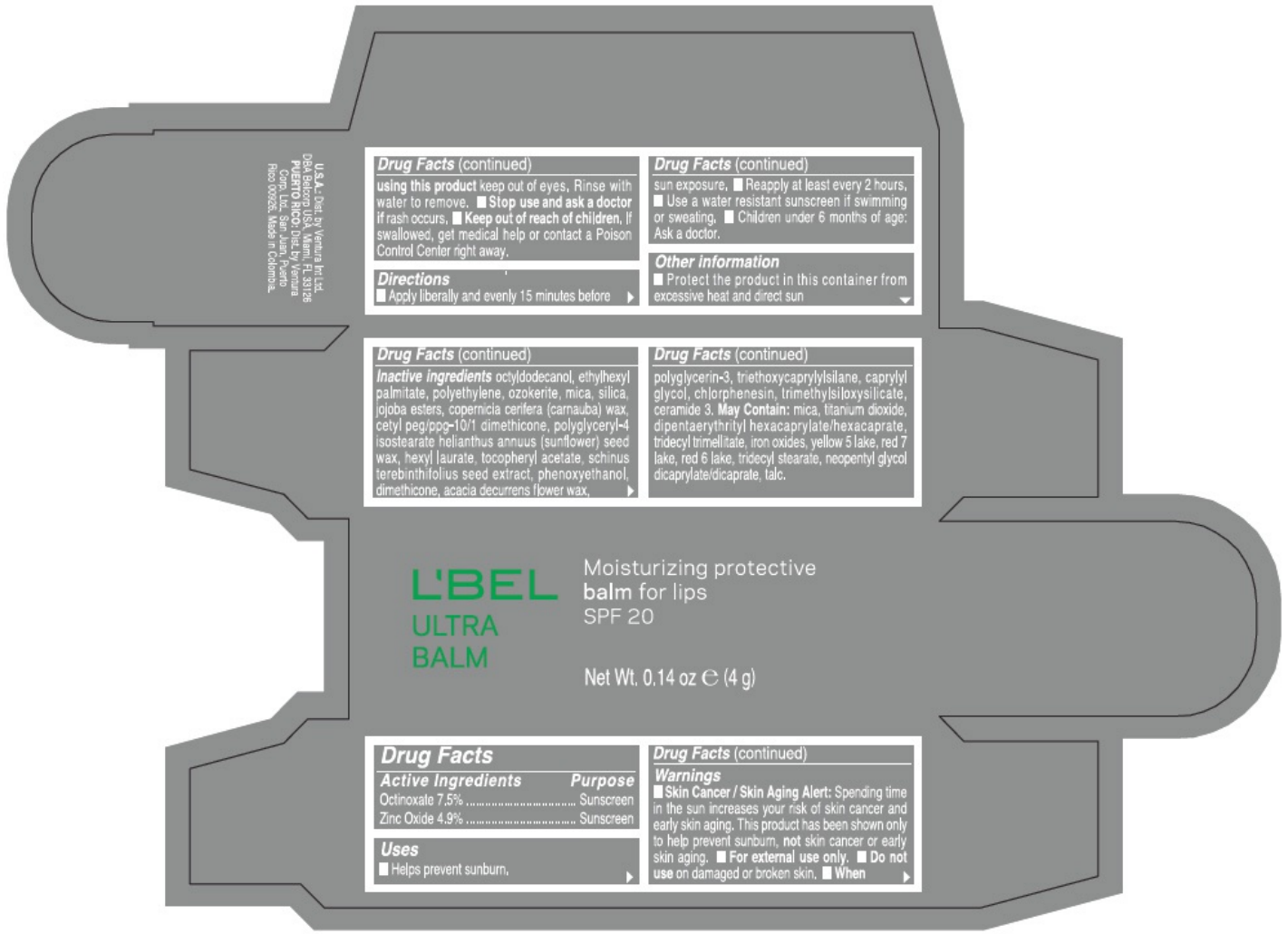
DBA Belcorp USA, Miami, FL 33126

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - NUDE TRANSLUCIDE - BEIGE

**L'BEL
ULTRA
BALM**

Moisturizing protective
balm for lips
SPF 20

Net Wt. 0.14 oz e (4 g)

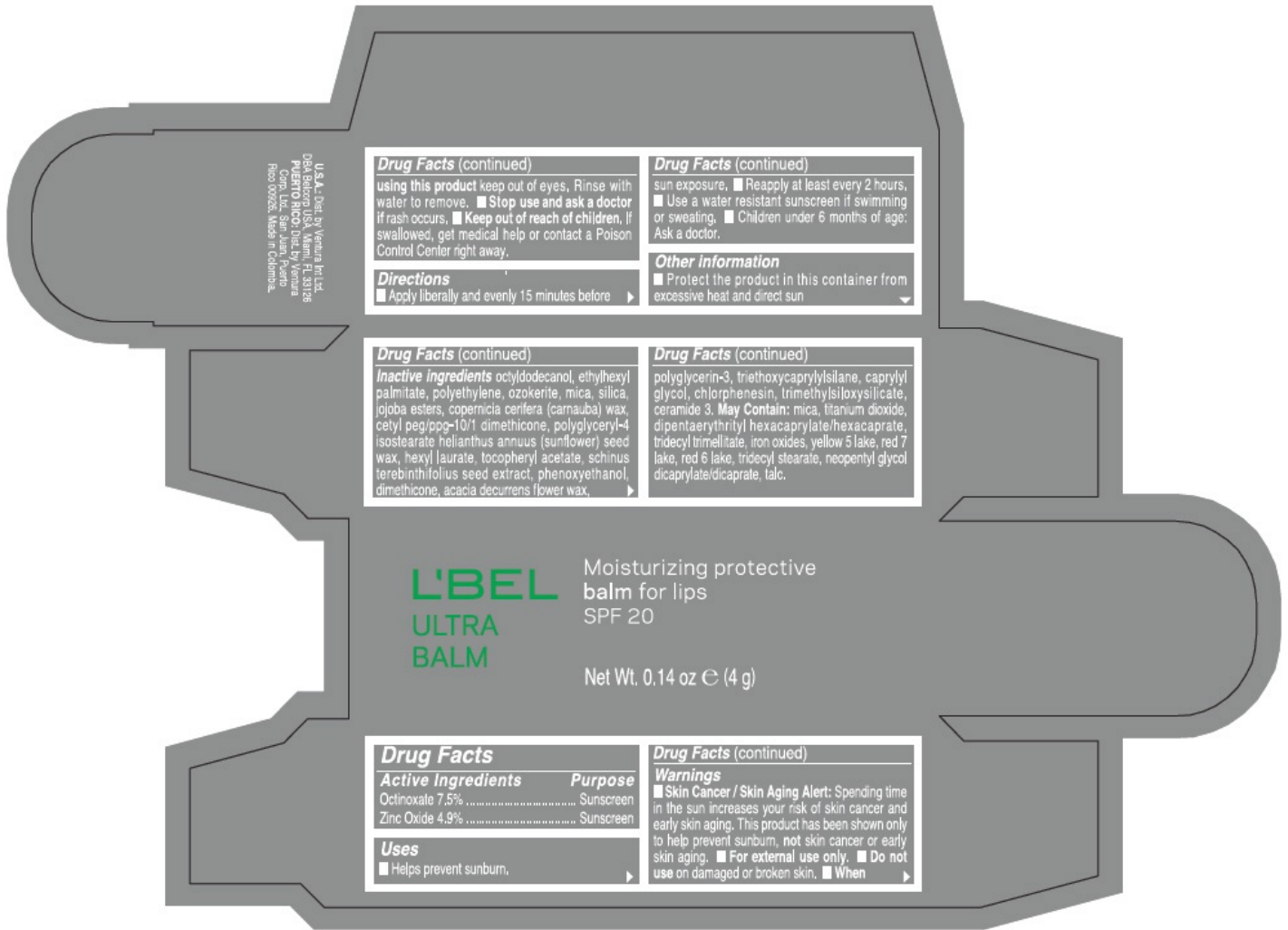


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - CORAL PETALE - PINK

**L'BEL
 ULTRA
 BALM**

Moisturizing protective
balm for lips
 SPF 20

Net Wt. 0.14 oz e (4 g)



U.S.A. & Can. Dist. by Ventura Int'l, Inc.
 1781 Belcorra USA, Miami, FL 33178
 U.S. & Can. Dist. by Ventura
 Paso Verde, Miami, FL 33178

Drug Facts (continued)

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 ▶

Drug Facts (continued)

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 ▶

Drug Facts (continued)

Inactive ingredients octyldodecanol, ethylhexyl palmitate, polyethylene, ozokerite, mica, silica, jojoba esters, copernicia cerifera (carnauba) wax, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate helianthus annuus (sunflower) seed wax, hexyl laurate, tocopheryl acetate, schinus terebinthifolius seed extract, phenoxyethanol, dimethicone, acacia decurrens flower wax, ▶

Drug Facts (continued)

polyglycerin-3, triethoxycaprylylsilane, caprylyl glycol, chlorphenesin, trimethylsiloxy silicate, ceramide 3. **May Contain:** mica, titanium dioxide, dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, iron oxides, yellow 5 lake, red 7 lake, red 6 lake, tridecyl stearate, neopentyl glycol dicaprylate/dicaprate, talc. ▶

**L'BEL
ULTRA
BALM**

Moisturizing protective
balm for lips
SPF 20

Net Wt. 0.14 oz e (4 g)

Drug Facts

Active Ingredients	Purpose
Octinoxate 7.5%	Sunscreen
Zinc Oxide 4.9%	Sunscreen

Uses

■ Helps prevent sunburn. ▶

Drug Facts (continued)

Warnings

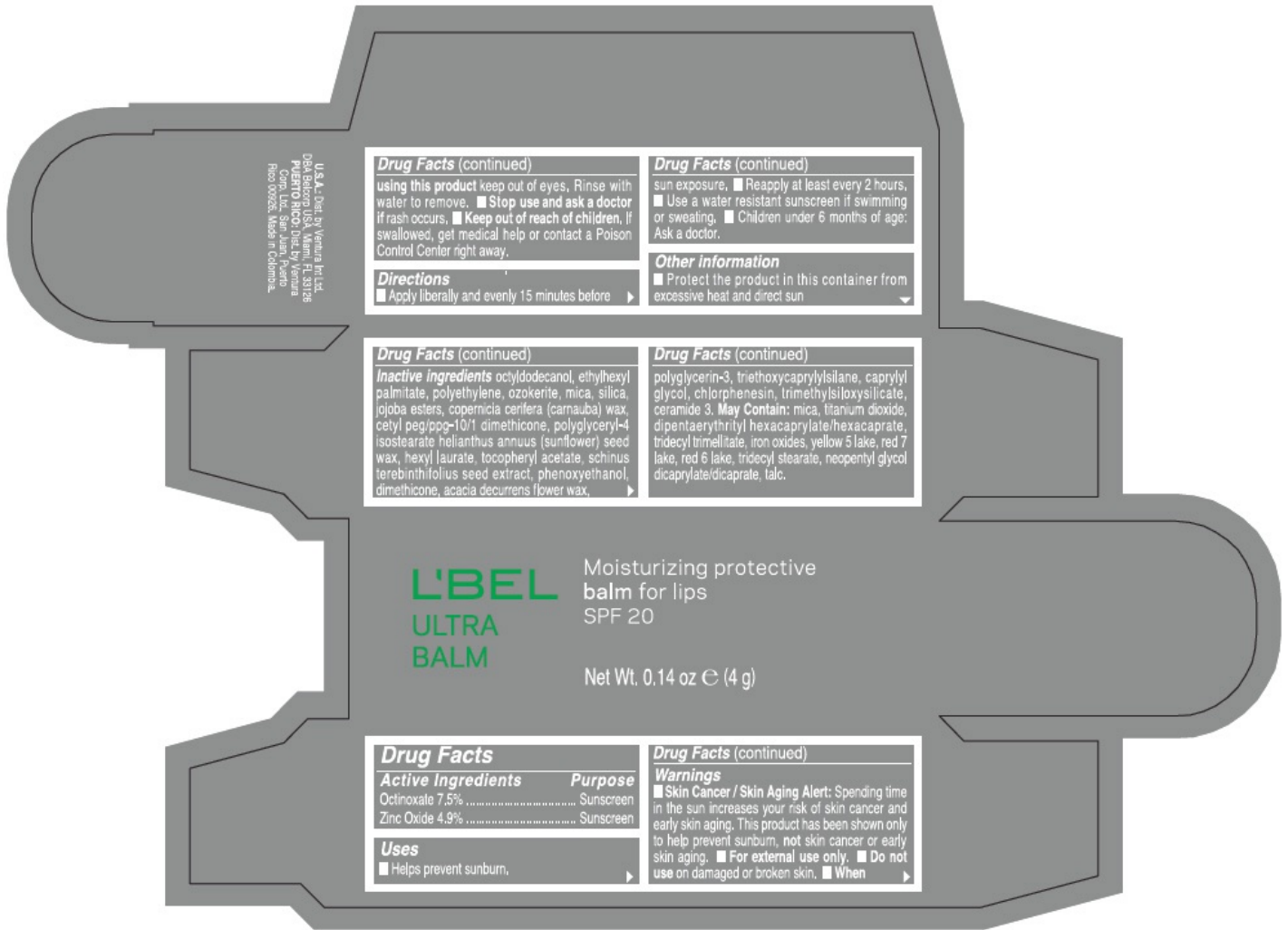
■ **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging. ■ **For external use only.** ■ **Do not use on damaged or broken skin.** ■ **When** ▶

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - ROSE PARADISE - PINK

**L'BEL
ULTRA
BALM**

Moisturizing protective
balm for lips
SPF 20

Net Wt. 0.14 oz e (4 g)



PRINCIPAL DISPLAY PANEL - 4 g Tube Box - ROSE COTTON - PINK

**L'BEL
 ULTRA
 BALM**

Moisturizing protective
balm for lips
 SPF 20

Net Wt. 0.14 oz e (4 g)

USA: Act. Dist. by Ventura Int'l, Inc.
 DBI-Belcora USA, Miami, FL 33178
 Canada: Act. Dist. by Ventura
 Paso Verde, Missis. in Columbia.

Drug Facts (continued)

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 ▶

Drug Facts (continued)

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 ▶

Drug Facts (continued)

Inactive ingredients octyldodecanol, ethylhexyl palmitate, polyethylene, ozokerite, mica, silica, jojoba esters, copernicia cerifera (carnauba) wax, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate helianthus annuus (sunflower) seed wax, hexyl laurate, tocopheryl acetate, schinus terebinthifolius seed extract, phenoxyethanol, dimethicone, acacia decurrens flower wax, ▶

Drug Facts (continued)

polyglycerin-3, triethoxycaprylylsilane, caprylyl glycol, chlorphenesin, trimethylsiloxy silicate, ceramide 3. **May Contain:** mica, titanium dioxide, dipentaerythryl hexacrylate/hexacaprinate, tridecyl trimellitate, iron oxides, yellow 5 lake, red 7 lake, red 6 lake, tridecyl stearate, neopentyl glycol dicaprylate/dicaprate, talc. ▶

**L'BEL
 ULTRA
 BALM**

Moisturizing protective
balm for lips
 SPF 20

Net Wt. 0.14 oz e (4 g)

Drug Facts

Active Ingredients	Purpose
Octinoxate 7.5%	Sunscreen
Zinc Oxide 4.9%	Sunscreen

Uses

■ Helps prevent sunburn. ▶

Drug Facts (continued)

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** ▶

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - CERISE BRISE - PINK

**L'BEL
 ULTRA
 BALM**

Moisturizing protective
balm for lips
 SPF 20

Net Wt. 0.14 oz e (4 g)

USA: Act. Dist. by Ventura Int'l, Inc.
 DBL Belcorp USA, Miami, FL 33178
 Canada: Act. Dist. by Ventura
 Paso Verde, Miami, FL 33178

Drug Facts (continued)

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 ▶

Drug Facts (continued)

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 ▶

Drug Facts (continued)

Inactive ingredients octyldodecanol, ethylhexyl palmitate, polyethylene, ozokerite, mica, silica, jojoba esters, copernicia cerifera (carnauba) wax, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate helianthus annuus (sunflower) seed wax, hexyl laurate, tocopheryl acetate, schinus terebinthifolius seed extract, phenoxyethanol, dimethicone, acacia decurrens flower wax, ▶

Drug Facts (continued)

polyglycerin-3, triethoxycaprylylsilane, caprylyl glycol, chlorphenesin, trimethylsiloxy silicate, ceramide 3. **May Contain:** mica, titanium dioxide, dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, iron oxides, yellow 5 lake, red 7 lake, red 6 lake, tridecyl stearate, neopentyl glycol dicaprylate/dicaprate, talc. ▶

L'BEL
ULTRA
BALM

Moisturizing protective
balm for lips
 SPF 20

Net Wt. 0.14 oz e (4 g)

Drug Facts

Active Ingredients	Purpose
Octinoxate 7.5%	Sunscreen
Zinc Oxide 4.9%	Sunscreen

Uses

■ Helps prevent sunburn. ▶

Drug Facts (continued)

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** ▶

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - NUDE CARAMEL - BEIGE

L'BEL
ULTRA
BALM

Moisturizing protective
balm for lips
 SPF 20

Net Wt. 0.14 oz e (4 g)

USA: Act. Dist. by Ventura Int'l, Inc.
 Del. Belco, USA, Miami, FL 33178
 Canada: Dist. by Ventura Int'l, Inc.
 P.O. Box 1000, Mississauga, Ontario
 L4V 1A1, Canada
 P.O. Box 1000, Mississauga, Ontario
 L4V 1A1, Canada

Drug Facts (continued)

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

Drug Facts (continued)

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

Drug Facts (continued)

Inactive ingredients octyldodecanol, ethylhexyl palmitate, polyethylene, ozokerite, mica, silica, jojoba esters, copernicia cerifera (carnauba) wax, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate helianthus annuus (sunflower) seed wax, hexyl laurate, tocopheryl acetate, schinus terebinthifolius seed extract, phenoxyethanol, dimethicone, acacia decurrens flower wax,

Drug Facts (continued)

polyglycerin-3, triethoxycaprylylsilane, caprylyl glycol, chlorphenesin, trimethylsiloxysilicate, ceramide 3. **May Contain:** mica, titanium dioxide, dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, iron oxides, yellow 5 lake, red 7 lake, red 6 lake, tridecyl stearate, neopentyl glycol dicaprylate/dicaprate, talc.

**L'BEL
 ULTRA
 BALM**

Moisturizing protective
 balm for lips
 SPF 20

Net Wt. 0.14 oz e (4 g)

Drug Facts

Active Ingredients	Purpose
Octinoxate 7.5%	Sunscreen
Zinc Oxide 4.9%	Sunscreen

Uses

■ Helps prevent sunburn,

Drug Facts (continued)

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**

LBEL ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 NUDE TRANSLUCIDE - BEIGE

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-755
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
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
OCTYLDODECANOL (UNII: 461N1O614Y)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

CERESIN (UNII: Q1LS2UJO3A)
MICA (UNII: V8A1AW0880)
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)
CARNAUBA WAX (UNII: R12CBM0EIZ)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
BRAZILIAN PEPPER (UNII: SUG822G7CD)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
DIMETHICONE (UNII: 92RU3N3Y1O)
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZE9IY9)
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
TITANIUM DIO XIDE (UNII: 15FIX9V2JP)
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 6 (UNII: 481744AI4O)
TRIDECYL STEARATE (UNII: A8OE252M6L)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
TALC (UNII: 7SEV7J4R1U)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-755-02	1 in 1 BOX	10/26/2016	
1	NDC:13537-755-01	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	10/26/2016	

LBEL ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 CORAL PETALE - PINK

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-756
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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
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
OCTYLDODECANOL (UNII: 461N1O614Y)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CERESIN (UNII: Q1LS2UJO3A)	
MICA (UNII: V8A1AW0880)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BRAZILIAN PEPPER (UNII: SUG822G7CD)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZE9IY9)	
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 6 (UNII: 481744A14O)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
TALC (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-756-02	1 in 1 BOX	10/26/2016	
1	NDC:13537-756-01	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	10/26/2016	

LBEL ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 ROSE PARADISE - PINK

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-508
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
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
OCTYLDODECANOL (UNII: 461N1O614Y)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CERESIN (UNII: Q1LS2UJO3A)	
MICA (UNII: V8A1AW0880)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BRAZILIAN PEPPER (UNII: SUG822G7CD)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZE9IY9)	
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 6 (UNII: 481744A4O)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
TALC (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-508-02	1 in 1 BOX	10/26/2016	
1	NDC:13537-508-01	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	10/26/2016	

LBEL ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 ROSE COTTON - PINK

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-509
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
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
OCTYLDODECANOL (UNII: 461N1O614Y)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CERESIN (UNII: Q1LS2UJO3A)	
MICA (UNII: V8A1AW0880)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
BRAZILIAN PEPPER (UNII: SUG822G7CD)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
DIMETHICONE (UNII: 92RU3N3Y1O)
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZE9IY9)
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 6 (UNII: 481744AI4O)
TRIDECYL STEARATE (UNII: A8OE252M6L)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
TALC (UNII: 7SEV7J4R1U)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-509-02	1 in 1 BOX	10/26/2016	
1	NDC:13537-509-01	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	10/26/2016	

LBEL ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 CERISE BRISE - PINK

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-510
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
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
OCTYLDODECANOL (UNII: 461N1O614Y)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CERESIN (UNII: Q1LS2UJO3A)	
MICA (UNII: V8A1AW0880)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BRAZILIAN PEPPER (UNII: SUG822G7CD)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZE9IY9)	
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 6 (UNII: 481744AI4O)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
TALC (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-510-02	1 in 1 BOX	10/26/2016	
1	NDC:13537-510-01	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	10/26/2016	

LBEL ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 NUDE CARAMEL - BEIGE

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-569
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
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
OCTYLDODECANOL (UNII: 461N1O614Y)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CERESIN (UNII: Q1LS2UJO3A)	
MICA (UNII: V8A1AW0880)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BRAZILIAN PEPPER (UNII: SUG822G7CD)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZE9IY9)	
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 6 (UNII: 481744A14O)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
TALC (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-569-02	1 in 1 BOX	10/26/2016	
1	NDC:13537-569-01	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	10/26/2016	

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-755, 13537-756, 13537-508, 13537-509, 13537-510, 13537-569)

Revised: 10/2016

Ventura Corporation LTD