

ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 CORAL PETALE- octinoxate, zinc oxide stick
ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 ROSE PARADISE- octinoxate, zinc oxide stick
ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 ROSE COTTON- octinoxate, zinc oxide stick
ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 NUDE TRANSLUCIDE- octinoxate, zinc oxide stick
ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 CERISE BRISE- octinoxate, zinc oxide stick
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.

Ultra Balm Moisturizing Protective Balm for Lips SPF 20

Active Ingredients Purpose

Octinoxate 7.50%.....Sunscreen

Zinc oxide 4.90 %..... Sunscreen

Uses

- Helps prevent sunburn.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.
- **Stop use and ask a doctor if** rash occurs.

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.

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

Inactive ingredients: octyldodecanol, ethylhexyl palmitate, polyethylene, ozokerite, 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, dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, schinus terebinthifolia seed extract, phenoxyethanol, tridecyl stearate, dimethicone, acacia decurrens flower wax, polyglycerin-3, triethoxycaprylylsilane, neopentyl glycol

dicaprylate/dicaprate, caprylyl glycol, chlorphenesin, trimethylsiloxysilicate, ceramide np, lecithin.

may contain:

mica, titanium dioxide, synthetic fluorphlogopite, iron oxides, yellow 5 lake, red 7 lake, red 6 lake, talc.

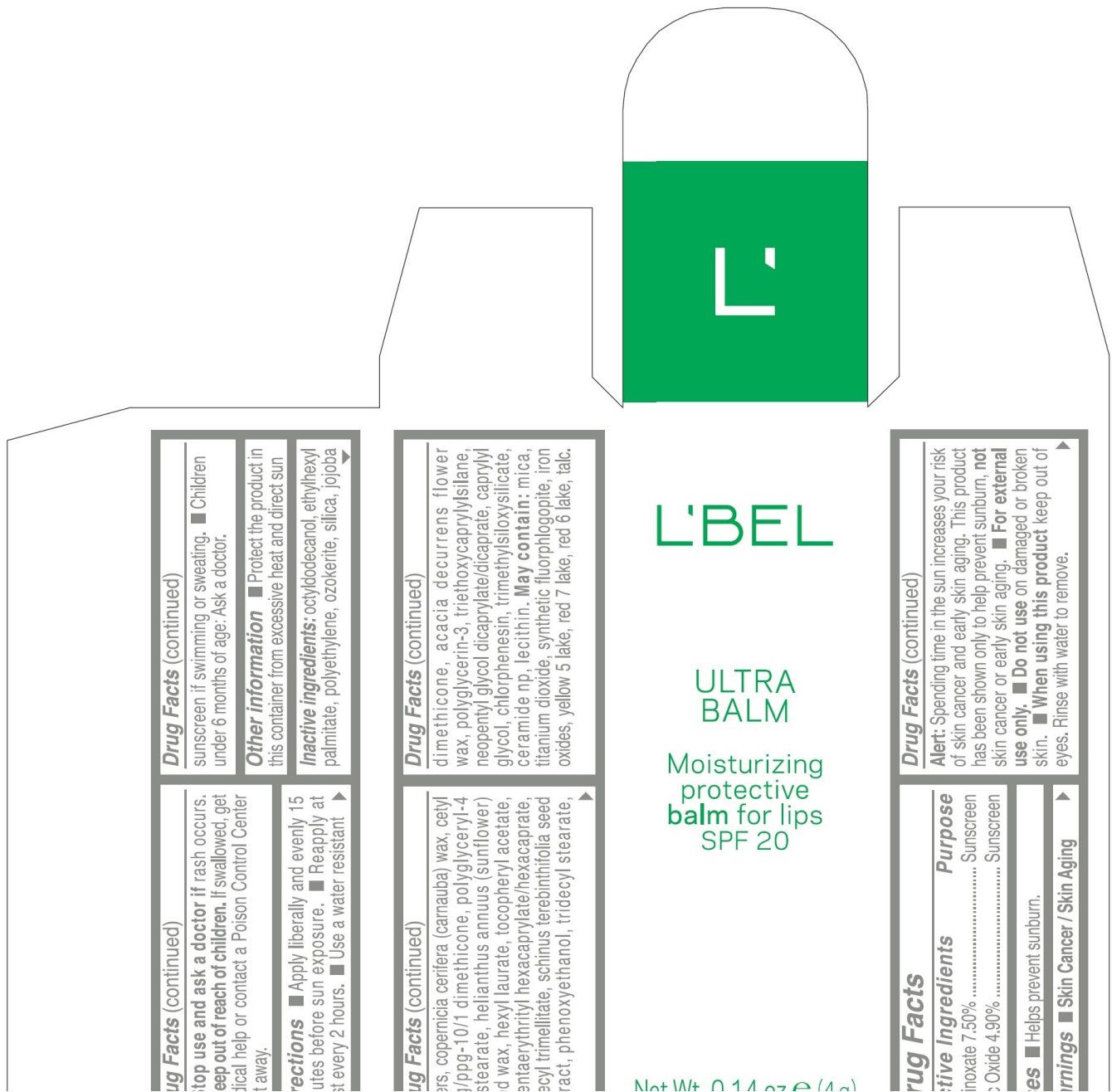
Other information

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

Ultra Balm SPF 20 Nude Translucide

L'BEL ULTRA BALM Moisturizing Protective Balm for lips SPF 20 Nude Translucide

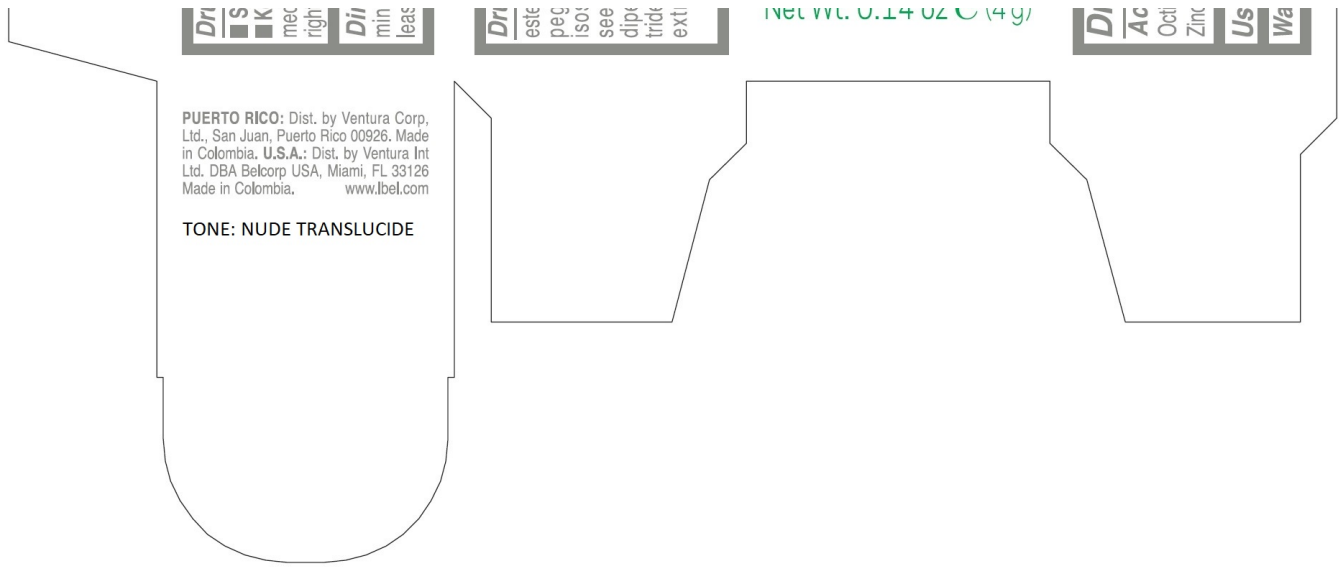
Net. Wt. 0.14 oz (4 g)



Drug Facts (continued)
Use and Warnings: ■ Apply liberally and evenly 15 minutes before sun exposure. ■ Reapply at least every 2 hours. ■ Use a water resistant lip balm.
Other information: ■ Protect the product in this container from excessive heat and direct sun.
Warnings: ■ Children under 6 months of age: Ask a doctor.
Directions: ■ 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.

Drug Facts (continued)
Warnings: ■ Children under 6 months of age: Ask a doctor.
Directions: ■ 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.

Drug Facts (continued)
Warnings: ■ Children under 6 months of age: Ask a doctor.
Directions: ■ 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.



Ultra Balm SPF 20 Coral Petal

L'BEL ULTRA BALM Moisturizing Protective Balm for lips SPF 20 Coral Petale

Net. Wt. 0.14 oz (4 g)



Drug Facts (continued)
 sunscreens 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: octyldodecanol, ethylhexyl palmitate, polyethylene, ozokerite, silica, jojoba

Drug Facts (continued)
 dimethicone, acacia decurrens flower wax, polyglycerin-3, triethoxycaprylylsilane, neopentyl glycol dicaprylate/dicaprate, caprylyl glycol, chlorphenesin, trimethylsiloxysilicate, ceramide np, lecithin. **May contain:** mica, titanium dioxide, synthetic fluorophlogopite, iron oxides, yellow 5 lake, red 7 lake, red 6 lake, talc.

Drug Facts (continued)
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.

L'BEL

ULTRA BALM

Moisturizing protective balm for lips SPF 20

Drug Facts (continued)
 ■ **Stop use and ask a doctor if ra**
 ■ **Keep out of reach of children. If swc**
 medical help or contact a Poison Con
 right away.

Directions ■ Apply liberally and
 minutes before sun exposure. ■ F
 least every 2 hours. ■ Use a water tr

Drug Facts (continued)
 esters, copernicia cerifera (carnauba)
 peg/ppg-10/1 dimethicone, poly
 isostearate, helianthus annuus (s
 seed wax, hexyl laurate, tocophery
 dipentaerythryl hexacaprylate/hex
 tridecyl trimellitate, schinus terebinth
 extract, phenoxyethanol, tridecyl

Drug Facts
Active Ingredients
 Octinoxate 7.50%
 Zinc Oxide 4.90%

Uses ■ Helps prevent sunburn.
Warnings ■ Skin Cancer / Skin A

Net Wt. 0.14 oz e (4g)

PUERTO RICO: Dist. by Ventura Corp,
 Ltd., San Juan, Puerto Rico 00926. Made
 in Colombia. U.S.A.: Dist. by Ventura Int
 Ltd. DBA Belcorp USA, Miami, FL 33126
 Made in Colombia. www.lbel.com

TONE: CORAL PETALE

Ultra Balm SPF 20 Rose Paradise

L'BEL ULTRA BALM Moisturizing Protective Balm for lips SPF 20 Rose Paradise

Net. Wt. 0.14 oz (4 g)

ntinued)
 ning or sweating. ■ Children
 ige. Ask a doctor.

tion ■ Protect the product in
 excessive heat and direct sun

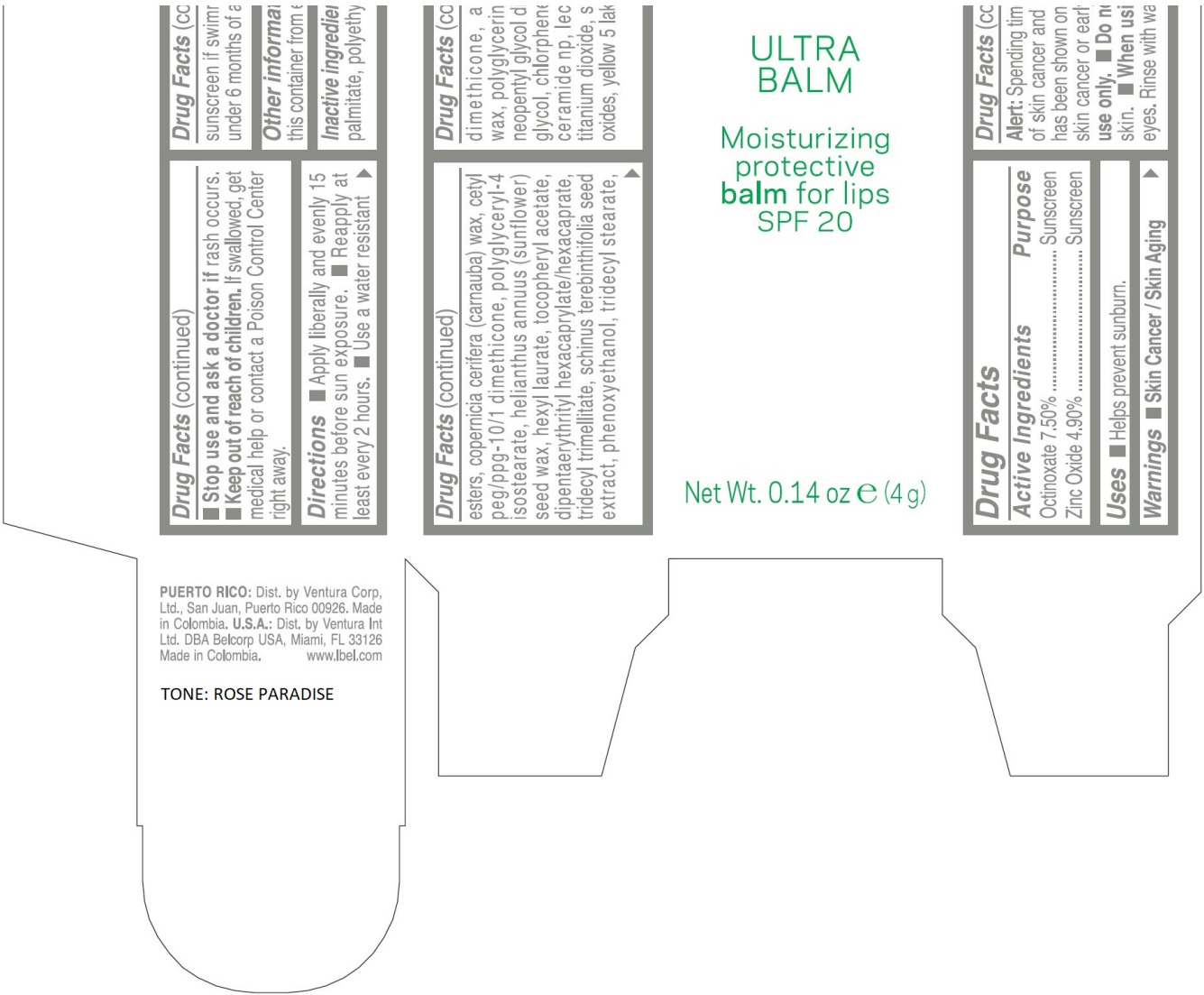
nts: octyldodecanol, ethylhexyl
 /lene, ozokerite, silica, jojoba

ntinued)
 cacia decurrens flower
 -3, triethoxycaprylylsilane,
 icaprylate/dicaprylate, caprylyl
 esin, trimethylsilyloxydiclate,
 :ithin. **May contain:** mica,
 ynthetic fluorophlogopite, iron
 (e, red 7 lake, red 6 lake, talc,

L'BEL

ntinued)
 e in the sun increases your risk
 early skin aging. This product
 ly to help prevent sunburn, **not**
 y skin aging. ■ **For external**
ot use on damaged or broken
ing this product keep out of
 iter to remove.





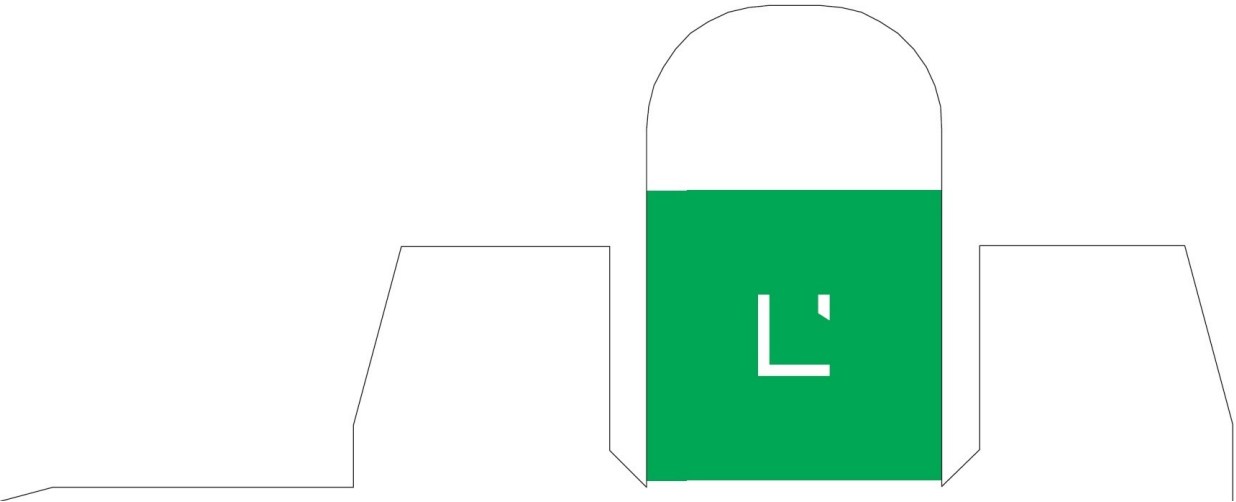
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TONE: ROSE PARADISE

Ultra Balm SPF 20 Rose Cotton

L'BEL ULTRA BALM Moisturizing Protective Balm for lips SPF 20 Rose Cotton

Net. Wt. 0.14 oz (4 g)



Drug Facts (continued)
 ■ **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

Drug Facts (continued)
 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: octyldecanol, ethylhexyl palmitate, polyethylene, ozokerite, silica, jojoba

Drug Facts (continued)
 esters, copernicia cerifera (carnauba) wax, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, helianthus annuus (sunflower) seed wax, hexyl laurate, tocopheryl acetate, dipentaerythrityl hexacaprylate/hexacaprare, tridecyl trimellitate, schinus terebinthifolia seed extract, phenoxylethanol, tridecyl stearate,

Drug Facts (continued)
 dimethicone, acacia decurrens flower wax, polyglycerin-3, triethoxycaprylsilane, neopentyl glycol dicaprylate/dicaprate, caprylyl glycol, chlorphenesin, trimethylsilyloxyisilicate, ceramide np, lecithin. **May contain:** mica, titanium dioxide, synthetic fluorophlogopite, iron oxides, yellow 5 lake, red 7 lake, red 6 lake, talc.

L'BEL

ULTRA BALM

Moisturizing protective balm for lips SPF 20

Net Wt. 0.14 oz e (4g)

Drug Facts (continued)
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.

Drug Facts
Active Ingredients **Purpose**
 Octinoxate 7.50% Sunscreen
 Zinc Oxide 4.90% Sunscreen

Uses ■ Helps prevent sunburn.
Warnings ■ Skin Cancer / Skin Aging

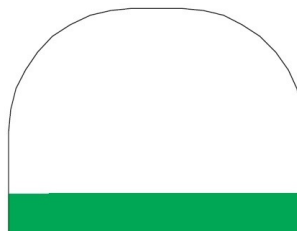
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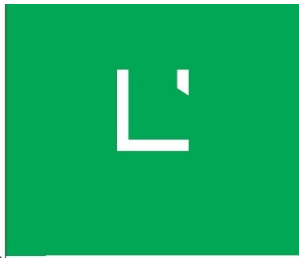
TONE: ROSE COTTON

Ultra Balm SPF 20 Cerise Brise

L'BEL ULTRA BALM Moisturizing Protective Balm for lips SPF 20 Cerise Brise

Net. Wt. 0.14 oz (4 g)





L'BEL

ULTRA BALM

Moisturizing protective balm for lips SPF 20

Net Wt. 0.14 oz e (4g)

Drug Facts (continued)

■ **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 ▶

Drug Facts (continued)

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: octyldodecanol, ethylhexyl palmitate, polyethylene, ozokerite, silica, jojoba ▶

Drug Facts (continued)

esters, copernicia cerifera (carnauba) wax, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, helianthus annuus (sunflower) seed wax, hexyl laurate, tocopheryl acetate, dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, schinus terebinthifolia seed extract, phenoxyethanol, tridecyl stearate, ▶

Drug Facts (continued)

dimethicone, acacia decurrens flower wax, polyglycerin-3, triethoxycaprylsilane, neopentyl glycol dicaprylate/dicaprate, caprylyl glycol, chlorphenesin, trimethylsiloxyisilicate, ceramide np, lecithin. **May contain:** mica, titanium dioxide, synthetic fluorophlogopite, iron oxides, yellow 5 lake, red 7 lake, red 6 lake, talc.

Drug Facts

Active Ingredients Purpose
 Octinoxate 7.50% Sunscreen
 Zinc Oxide 4.90% Sunscreen

Uses ■ Helps prevent sunburn.

Warnings ■ Skin Cancer / Skin Aging ▶

Drug Facts (continued)

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. ▶

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STONE: CERISE BRISE

ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 CORAL PETALE

octinoxate, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0886
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4.9 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BRAZILIAN PEPPER (UNII: SUG822G7CD)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZE9IY9)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
CERESIN (UNII: Q1LS2UJO3A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
CERAMIDE NP (UNII: 4370DF050B)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TALC (UNII: 7SEV7J4R1U)	

Packaging

		Marketing Start	Marketing End
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0886-1	4 g in 1 CARTON; Type 0: Not a Combination Product	06/15/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/15/2021	

ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 ROSE PARADISE

octinoxate, zinc oxide stick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0888
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4.9 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
BRAZILIAN PEPPER (UNII: SUG822G7CD)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZE9IY9)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
CERESIN (UNII: Q1LS2UJO3A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
TRIDECYL STEARATE (UNII: A8OE252M6L)
DIMETHICONE (UNII: 92RU3N3Y1O)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)
CERAMIDE NP (UNII: 4370DF050B)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TALC (UNII: 7SEV7J4R1U)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0888-1	4 g in 1 CARTON; Type 0: Not a Combination Product	06/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/15/2021	

ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 ROSE COTTON

octinoxate, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0887
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4.9 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

FERROSFERRIC OXIDE (UNII: XM0M87F357)
BRAZILIAN PEPPER (UNII: SUG822G7CD)
CHLORPHENESIN (UNII: I670DAL4SZ)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
OCTYLDODECANOL (UNII: 461N1O614Y)
CARNAUBA WAX (UNII: R12CBM0EIZ)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZ E9IY9)
ETHYLHEXYL PALMITATE (UNII: 2865993309)
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWW)
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
CERESIN (UNII: Q1LS2UJO3A)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
TRIDECYL STEARATE (UNII: A8OE252M6L)
DIMETHICONE (UNII: 92RU3N3Y1O)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)
CERAMIDE NP (UNII: 4370DF050B)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TALC (UNII: 7SEV7J4R1U)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0887-1	4 g in 1 CARTON; Type 0: Not a Combination Product	06/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/15/2021	

ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 NUDE TRANSLUCIDE

octinoxate, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0885
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4.9 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
BRAZILIAN PEPPER (UNII: SUG822G7CD)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZ E9IY9)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
CERESIN (UNII: Q1LS2UJO3A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
CERAMIDE NP (UNII: 4370DF050B)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TALC (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0885-1	4 g in 1 CARTON; Type 0: Not a Combination Product	06/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/15/2021	

ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 CERISE BRISE

octinoxate, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0889
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4.9 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
BRAZILIAN PEPPER (UNII: SUG822G7CD)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZE9IY9)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWV)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	

CERESIN (UNII: Q1LS2UJO3A)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)
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Labeler - Ventura Corporation LTD (602751344)

Registrant - BEL STAR S A (880160197)

Establishment

Name	Address	ID/FEI	Business Operations
BEL STAR S A		880160197	manufacture(43596-0885, 43596-0886, 43596-0887, 43596-0888, 43596-0889)