

**ULTRA BALM MOISTURIZING PROTECTIVE LIPS SPF 20 NUDE TRANSLUCIDE-
octinoxate, zinc oxide stick**

**ULTRA BALM MOISTURIZING PROTECTIVE LIPS SPF 20 CORAL PETALE- octinoxate,
zinc oxide stick**

**ULTRA BALM MOISTURIZING PROTECTIVE LIPS SPF 20 ROSE PARADISE- octinoxate,
zinc oxide stick**

**ULTRA BALM MOISTURIZING PROTECTIVE LIPS SPF 20 ROSE COTTON- octinoxate,
zinc oxide stick**

**ULTRA BALM MOISTURIZING PROTECTIVE LIPS SPF 20 CERISE BRISE- octinoxate, zinc
oxide stick**

**ULTRA BALM MOISTURIZING PROTECTIVE LIPS SPF 20 NUDE CARAMEL- 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 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, 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 terebinthifolia seed extract, phenoxyethanol, dimethicone, acacia decurrens flower wax, polyglycerin-3, triethoxycaprylylsilane, caprylyl glycol, chlorphenesin, trimethylsiloxysilicate, ceramide np.

may contain:

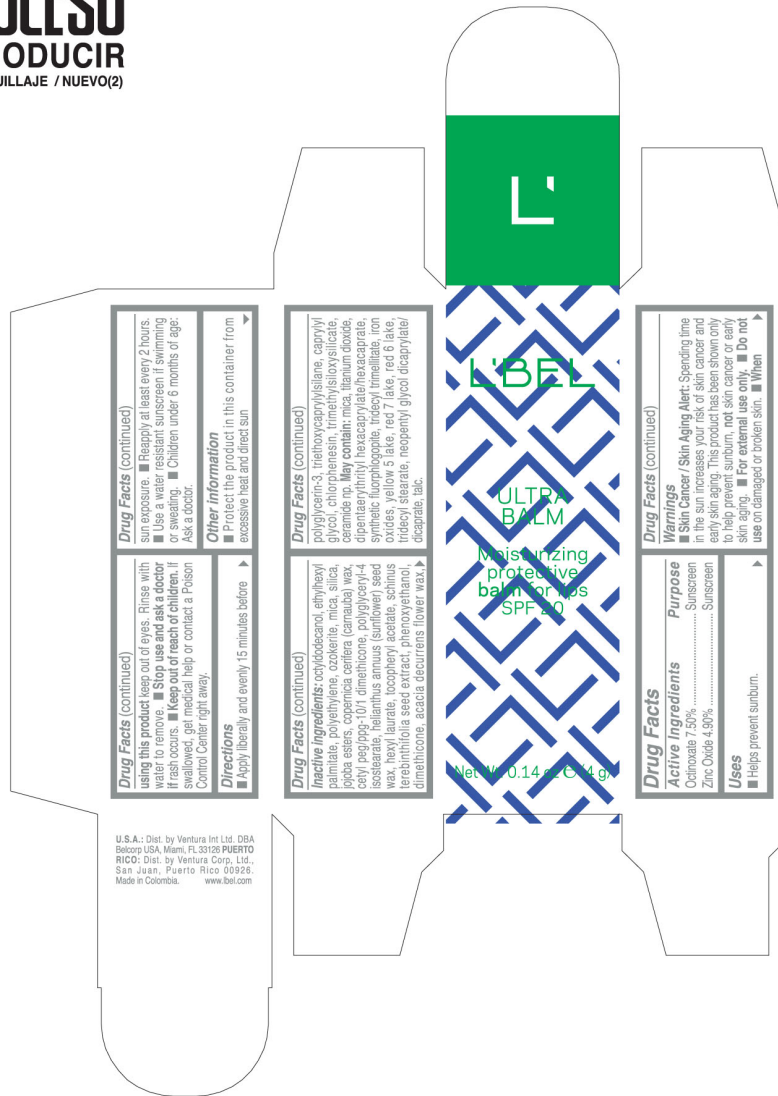
mica, titanium dioxide, dipentaerythryl hexacaprylate/hexacaprate, synthetic fluorphlogopite, tridecyl trimellitate, iron oxides, yellow 5 lake, red 7 lake, red 6 lake, tridecyl stearate, neopentyl glycol dicaprylate/dicaprate, talc.

L'Bel

Ultra Balm

Moisturizing Protective Balm for Lips SPF 20 Nude Translucide

Net Wt. 0.14 oz (4g)

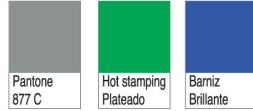


Arte - Caja		
Arte N°: CJ-56720-A	Nombre del Producto: ULTRA BALM Bálsamo Hidratante 4g	
Plano: DS3150B	Fecha: 13/01/19	Destino: Puerto Rico; USA
<p>Metodo de Impresión 1: OFFSET</p> <p>Metodo de Impresión 2: HOT STAMPING</p> <p>Color de Fondo 1: COLOR DEL MATERIAL</p> <p>Color Impresión 1: PANTONE 877 C: TEXTOS POSTERIORES + LATERALES + RECUADROS</p> <p>Color Impresión de Retira 1: NO LLEVA</p> <p>Color Hot Stamping: PLATA STANDARD: TAPA (EL ISOTIPO L' VA CALADO AL MATERIAL)</p> <p>Repujado: NO LLEVA</p> <p>Acabado 1: BARNIZ MATE</p>		

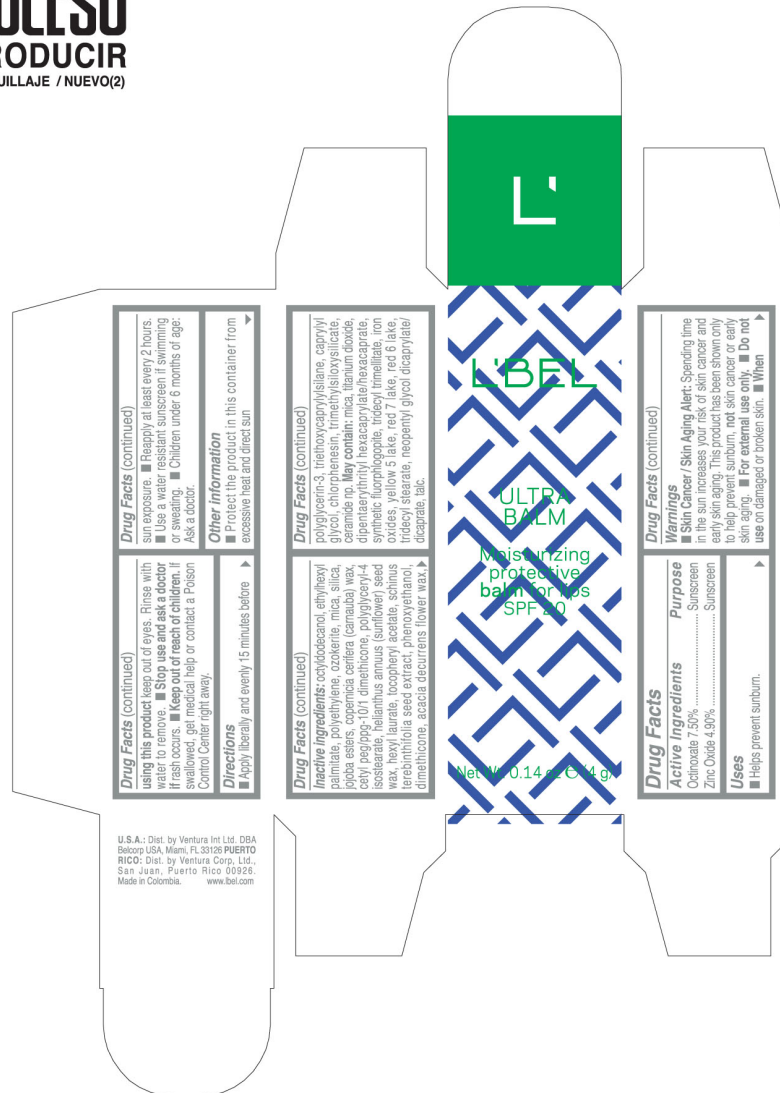
Acabado 2: SECTORIZADO BRILLANTE: TRAMA DE L				
Control de Calidad: DE ACUERDO A PATRON MAXIMO Y MINIMO DE CARTA DE COLOR APROBADA				
Observaciones:				
PATTY SOUSA DISEÑADORA GRAFICA	CRISTINA MALLA ARTE FINALISTA	MITSUKO IREI JEFE DE ARTE FINAL	NATALIA NARVAEZ SOLICITANTE	FIRMA LEGAL

CÓDIGO: FM.IN.02.23.02.07 (06/15 – V2)

COLORES:



L'Bel
Ultra Balm
Moisturizing Protective Balm for Lips SPF 20 Coral Petal
Net Wt. 0.14 oz (4g)



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

Arte - Caja		
Arte N°: CJ-56720-A	Nombre del Producto: ULTRA BALM Bálsamo Hidratante 4g	
Plano: DS3150B	Fecha: 13/01/19	Destino: Puerto Rico; USA
Metodo de Impresión 1: OFFSET		
Metodo de Impresión 2: HOT STAMPING		

Metodo de impresion 2: HOT STAMPING

Color de Fondo 1: COLOR DEL MATERIAL

Color Impresión 1: PANTONE 877 C: TEXTOS POSTERIORES + LATERALES + RECUADROS

Color Impresión de Retira 1: NO LLEVA

Color Hot Stamping: PLATA STANDARD: TAPA (EL ISOTIPO L' VA CALADO AL MATERIAL)

Repujado: NO LLEVA

Acabado 1: BARNIZ MATE

Acabado 2: SECTORIZADO BRILLANTE: TRAMA DE L

Control de Calidad: DE ACUERDO A PATRON MAXIMO Y MINIMO DE CARTA DE COLOR APROBADA

Observaciones:

PATTY SOUSA DISEÑADORA GRAFICA	CRISTINA MALLA ARTE FINALISTA	MITSUKO IREI JEFE DE ARTE FINAL	NATALIA NARVAEZ SOLICITANTE	FIRMA LEGAL
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CÓDIGO: FM.IN.02.23.02.07 (06/15 – V2)

COLORES:

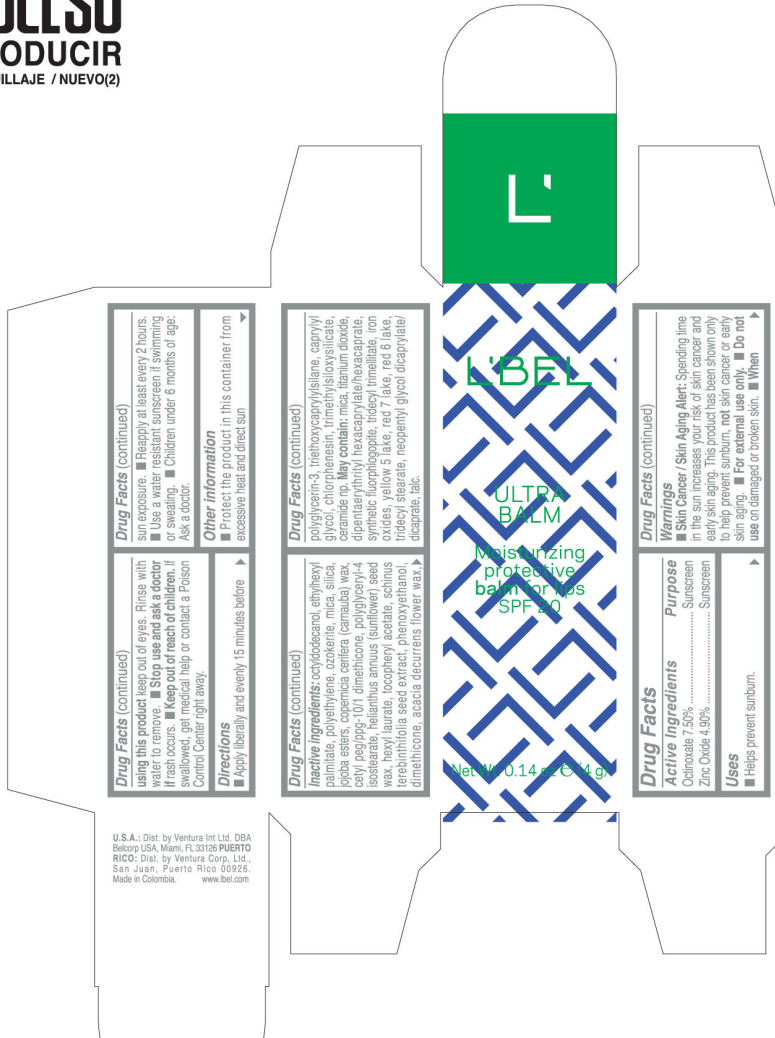


L'Bel

Ultra Balm

Moisturizing Protective Balm for Lips SPF 20 Rose Paradise

Net Wt. 0.14 oz (4g)



U.S.A.: Dist. by Ventura Int Ltd. DBA
 Seizeco USA, Miami, FL 33126 PUERTO
 RICO: Dist. by Ventura Corp. Ltd.
 San Juan, Puerto Rico 00928.
 Made in Colombia. www.bel.com

Arte - Caja				
Arte N°: CJ-56720-A	Nombre del Producto: ULTRA BALM Bálsamo Hidratante 4g			
Plano: DS3150B	Fecha: 13/01/19	Destino: Puerto Rico; USA		
Metodo de Impresión 1: OFFSET Metodo de Impresión 2: HOT STAMPING Color de Fondo 1: COLOR DEL MATERIAL Color Impresión 1: PANTONE 877 C: TEXTOS POSTERIORES + LATERALES + RECUADROS Color Impresión de Retira 1: NO LLEVA Color Hot Stamping: PLATA STANDARD: TAPA (EL ISOTIPO L´ VA CALADO AL MATERIAL) Repujado: NO LLEVA Acabado 1: BARNIZ MATE Acabado 2: SECTORIZADO BRILLANTE: TRAMA DE L				
Control de Calidad: DE ACUERDO A PATRON MAXIMO Y MINIMO DE CARTA DE COLOR APROBADA				
Observaciones:				
PATTY SOUSA DISEÑADORA GRAFICA	CRISTINA MALLA ARTE FINALISTA	MITSUKO IREI JEFE DE ARTE FINAL	NATALIA NARVAEZ SOLICITANTE	FIRMA LEGAL

CÓDIGO: FM.IN.02.23.02.07 (06/15 – V2)

COLORES:

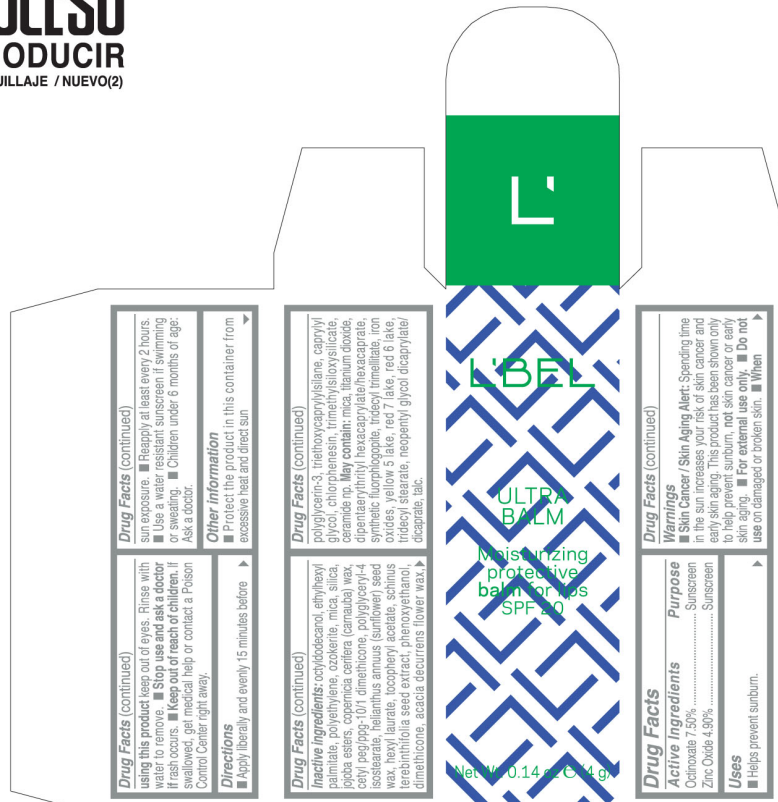


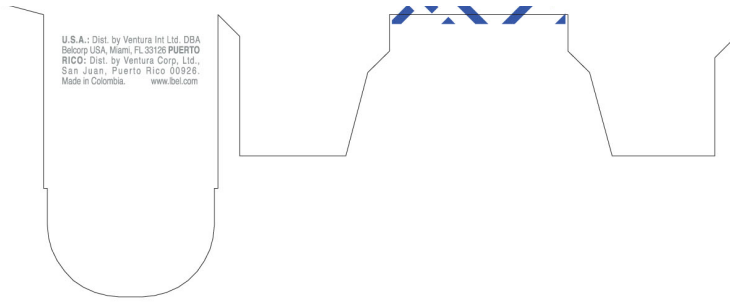
L'Bel

Ultra Balm

Moisturizing Protective Balm for Lips SPF 20 Rose Cotton

Net Wt. 0.14 oz (4g)



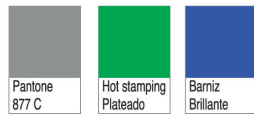


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Belcorp USA, Miami, FL 33126 PUERTO
RICO; Dist. by Ventura Corp. Ltd.,
San Juan, Puerto Rico 00926.
Made in Colombia. www.bel.com

Arte - Caja				
Arte N°: CJ-56720-A	Nombre del Producto: ULTRA BALM Bálsamo Hidratante 4g			
Plano: DS3150B	Fecha: 13/01/19	Destino: Puerto Rico; USA		
Metodo de Impresión 1: OFFSET Metodo de Impresión 2: HOT STAMPING Color de Fondo 1: COLOR DEL MATERIAL Color Impresión 1: PANTONE 877 C: TEXTOS POSTERIORES + LATERALES + RECUADROS Color Impresión de Retira 1: NO LLEVA Color Hot Stamping: PLATA STANDARD: TAPA (EL ISOTIPO L' VA CALADO AL MATERIAL) Repujado: NO LLEVA Acabado 1: BARNIZ MATE Acabado 2: SECTORIZADO BRILLANTE: TRAMA DE L				
Control de Calidad: DE ACUERDO A PATRON MAXIMO Y MINIMO DE CARTA DE COLOR APROBADA				
Observaciones:				
PATTY SOUSA DISEÑADORA GRAFICA	CRISTINA MALLA ARTE FINALISTA	MITSUKO IREI JEFE DE ARTE FINAL	NATALIA NARVAEZ SOLICITANTE	FIRMA LEGAL

CÓDIGO: FM.IN.02.23.02.07 (06/15 - V2)

COLORES:



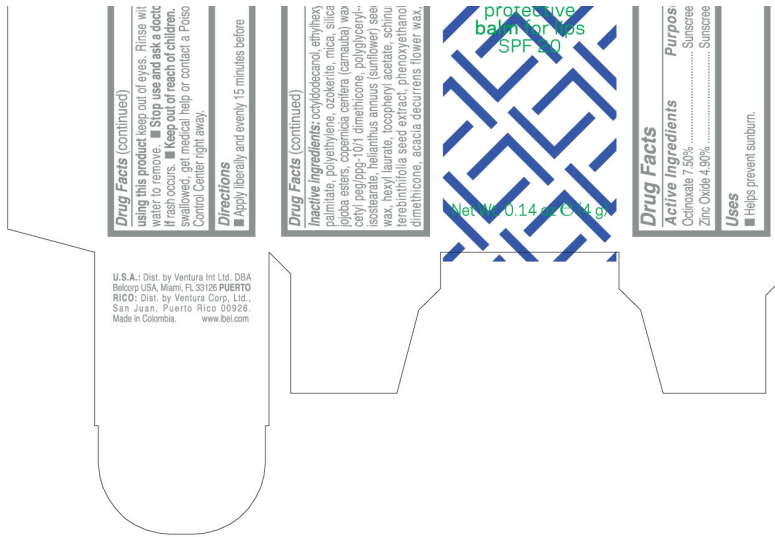
L'Bel

Ultra Balm

Moisturizing Protective Balm for Lips SPF 20 Cerise Brise

Net Wt. 0.14 oz (4g)





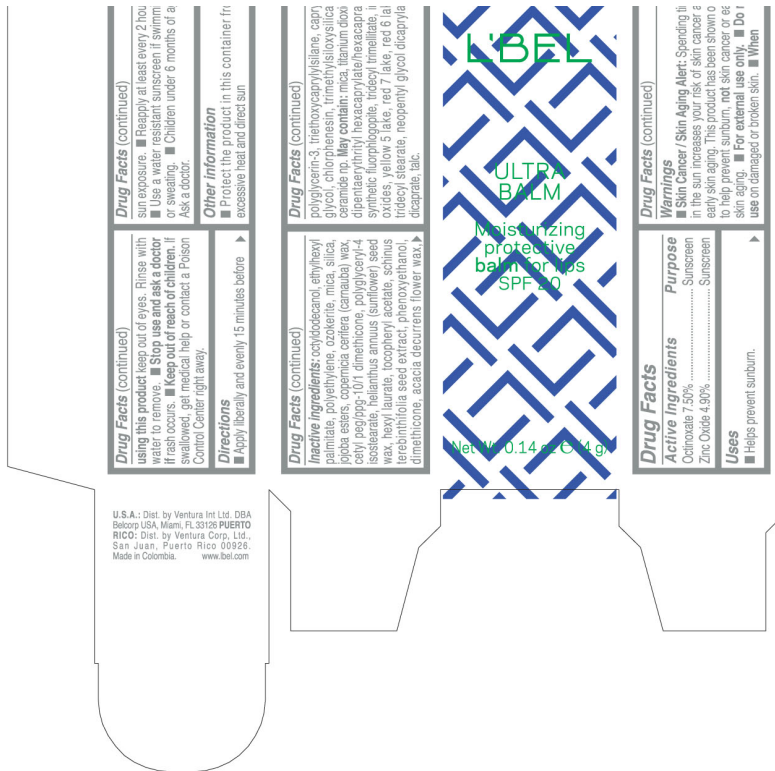
Arte - Caja				
Arte N°: CJ-56720-A	Nombre del Producto: ULTRA BALM Bálsamo Hidratante 4g			
Plano: DS3150B	Fecha: 13/01/19	Destino: Puerto Rico; USA		
<p>Metodo de Impresión 1: OFFSET</p> <p>Metodo de Impresión 2: HOT STAMPING</p> <p>Color de Fondo 1: COLOR DEL MATERIAL</p> <p>Color Impresión 1: PANTONE 877 C: TEXTOS POSTERIORES + LATERALES + RECUADROS</p> <p>Color Impresión de Retira 1: NO LLEVA</p> <p>Color Hot Stamping: PLATA STANDARD: TAPA (EL ISOTIPO L' VA CALADO AL MATERIAL)</p> <p>Repujado: NO LLEVA</p> <p>Acabado 1: BARNIZ MATE</p> <p>Acabado 2: SECTORIZADO BRILLANTE: TRAMA DE L</p>				
Control de Calidad: DE ACUERDO A PATRON MAXIMO Y MINIMO DE CARTA DE COLOR APROBADA				
Observaciones:				
PATTY SOUSA DISEÑADORA GRAFICA	CRISTINA MALLA ARTE FINALISTA	MITSUKO IREI JEFE DE ARTE FINAL	NATALIA NARVAEZ SOLICITANTE	FIRMA LEGAL

CÓDIGO: FM.IN.02.23.02.07 (06/15 – V2)



L'Bel
 Ultra Balm
 Moisturizing Protective Balm for Lips SPF 20 Nude Caramel
 Net Wt. 0.14 oz (4g)





Arte - Caja				
Arte N°: CJ-56720-A	Nombre del Producto: ULTRA BALM Bálsamo Hidratante 4g			
Plano: DS3150B	Fecha: 13/01/19	Destino: Puerto Rico; USA		
Metodo de Impresión 1: OFFSET Metodo de Impresión 2: HOT STAMPING Color de Fondo 1: COLOR DEL MATERIAL Color Impresión 1: PANTONE 877 C: TEXTOS POSTERIORES + LATERALES + RECUADROS Color Impresión de Retira 1: NO LLEVA Color Hot Stamping: PLATA STANDARD: TAPA (EL ISOTIPO L´ VA CALADO AL MATERIAL) Repujado: NO LLEVA Acabado 1: BARNIZ MATE Acabado 2: SECTORIZADO BRILLANTE: TRAMA DE L				
Control de Calidad: DE ACUERDO A PATRON MAXIMO Y MINIMO DE CARTA DE COLOR APROBADA				
Observaciones:				
PATTY SOUSA DISEÑADORA GRAFICA	CRISTINA MALLA ARTE FINALISTA	MITSUKO IREI JEFE DE ARTE FINAL	NATALIA NARVAEZ SOLICITANTE	FIRMA LEGAL

CÓDIGO: FM.IN.02.23.02.07 (06/15 – V2)

COLORES:



ULTRA BALM MOISTURIZING PROTECTIVE LIPS SPF 20 NUDE TRANSLUCIDE

octinoxate, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0745
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
TRIDECYL STEARATE (UNII: A8OE252M6L)	
BRAZILIAN PEPPER (UNII: SUG822G7CD)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZE9IY9)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
CERAMIDE NP (UNII: 4370DF050B)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TALC (UNII: 7SEV7J4R1U)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MICA (UNII: V8A1AW0880)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0745-1	4 g in 1 CARTON; Type 0: Not a Combination Product	02/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/28/2020	

ULTRA BALM MOISTURIZING PROTECTIVE LIPS SPF 20 CORAL PETALE

octinoxate, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0746
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
TRIDECYL STEARATE (UNII: A8OE252M6L)	
BRAZILIAN PEPPER (UNII: SUG822G7CD)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZE9IY9)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
CERAMIDE NP (UNII: 4370DF050B)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TALC (UNII: 7SEV7J4R1U)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MICA (UNII: V8A1AW0880)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0746-1	4 g in 1 CARTON; Type 0: Not a Combination Product	02/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/28/2020	

ULTRA BALM MOISTURIZING PROTECTIVE LIPS SPF 20 ROSE PARADISE

octinoxate, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0747
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
TRIDECYL STEARATE (UNII: A8OE252M6L)	
BRAZILIAN PEPPER (UNII: SUG822G7CD)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZE9IY9)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
CERAMIDE NP (UNII: 4370DF050B)	
POLYGLYCERYL-4 ISO STEARATE (UNII: 820DPX33S7)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TALC (UNII: 7SEV7J4R1U)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MICA (UNII: V8A1AW0880)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0747-1	4 g in 1 CARTON; Type 0: Not a Combination Product	02/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/28/2020	

ULTRA BALM MOISTURIZING PROTECTIVE LIPS SPF 20 ROSE COTTON

octinoxate, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0748
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
TRIDECYL STEARATE (UNII: A8OE252M6L)	
BRAZILIAN PEPPER (UNII: SUG822G7CD)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZE9IY9)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	

CHLORPHENESIN (UNII: I670DAL4SZ)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)
CERAMIDE NP (UNII: 4370DF050B)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
TALC (UNII: 7SEV7J4R1U)
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
CARNAUBA WAX (UNII: R12CBM0EIZ)
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)
OCTYLDODECANOL (UNII: 461N1O614Y)
MICA (UNII: V8A1AW0880)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
ETHYLHEXYL PALMITATE (UNII: 2865993309)
CERESIN (UNII: Q1LS2UJO3A)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0748-1	4 g in 1 CARTON; Type 0: Not a Combination Product	02/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/28/2020	

ULTRA BALM MOISTURIZING PROTECTIVE LIPS SPF 20 CERISE BRISE

octinoxate, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0749
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
TRIDECYL STEARATE (UNII: A8OE252M6L)	
BRAZILIAN PEPPER (UNII: SUG822G7CD)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZE9IY9)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
CERAMIDE NP (UNII: 4370DF050B)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TALC (UNII: 7SEV7J4R1U)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MICA (UNII: V8A1AW0880)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0749-1	4 g in 1 CARTON; Type 0: Not a Combination Product	02/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/28/2020	

ULTRA BALM MOISTURIZING PROTECTIVE LIPS SPF 20 NUDE CARAMEL

octinoxate, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0750
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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	7.5 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4.9 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
TRIDECYL STEARATE (UNII: A8OE252M6L)	
BRAZILIAN PEPPER (UNII: SUG822G7CD)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZE9IY9)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
CERAMIDE NP (UNII: 4370DF050B)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TALC (UNII: 7SEV7J4R1U)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MICA (UNII: V8A1AW0880)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0750-1	4 g in 1 CARTON; Type 0: Not a Combination Product	02/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/28/2020	

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
BEL STAR S A		880160197	manufacture(43596-0745, 43596-0746, 43596-0747, 43596-0748, 43596-0749, 43596-0750)

Revised: 2/2020

Ventura Corporation LTD