

**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**  
**BEL STAR S A**

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**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

**Other Information**

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

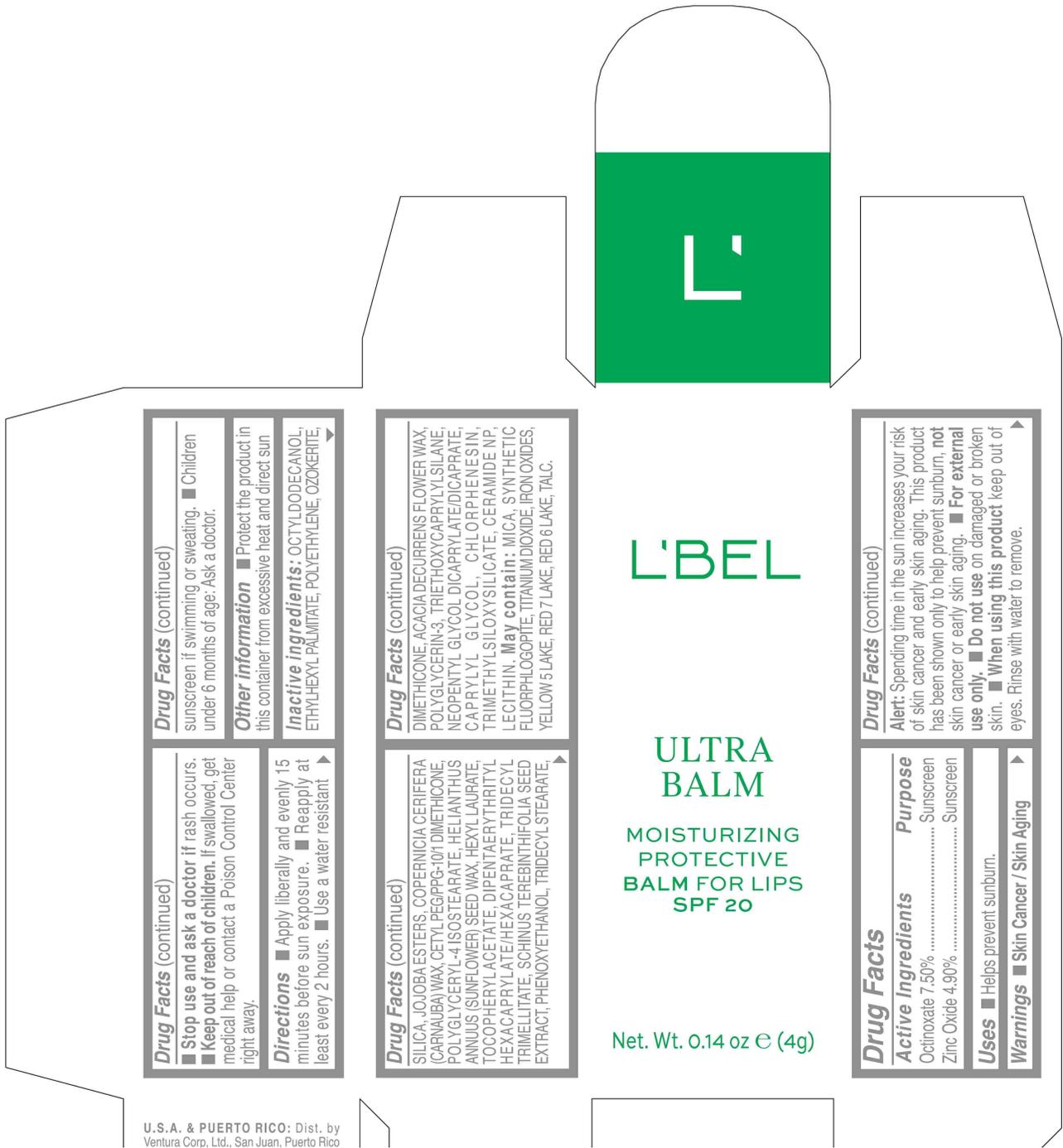
**Inactive ingredients:** octyldodecanol, ethylhexyl palmitate, polyethylene, ozokerite, silica, jojoba esters, copernicia cerifera (carnauba) wax, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, helianthus annuus (sunflower) seed wax, hexyl laurate, tocopheryl acetate, dipentaerythryl hexacaprylate/hexacaprate, 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.

**Ultra Balm SPF 20 Nude Translucide**



**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)**

■ **Stop use** 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, ▶

**Drug Facts (continued)**

SILICA, JOJOBA ESTERS, COPERNICIA CERIFERA (CARNAUBA) WAX, CETYL PEG/PPG-101 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, ▶

**Drug Facts (continued)**

DIMETHICONE, ACACIA DECURRENS FLOWER WAX, POLYGLYCERIN-3, TRIETHOXYCAPRYLYLSILANE, NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE, CAPRYLYL GLYCOL, CHLORPHENESIN, TRIMETHYLSILOXYLICATE, CERAMIDE NP, LECITHIN. **May contain:** MICA, SYNTHETIC FLUORPHLOGOPITE, TITANIUM DIOXIDE, IRON OXIDES, YELLOW 5 LAKE, RED 7 LAKE, RED 6 LAKE, TALC.



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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**

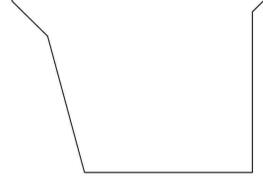
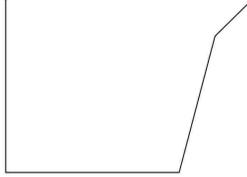
Active Ingredients	Purpose
Octinoxate 7.50%	Sunscreen
Zinc Oxide 4.90%	Sunscreen

**Uses** ■ Helps prevent sunburn.

**Warnings** ■ Skin Cancer / Skin Aging ▶

00926. Made in Colombia.  
www.lbel.com

**tone: NUDE TRANSLUCIDE**



## Ultra Balm SPF 20 Coral Petal

**Drug Facts (continued)**

**Warning:** Stop use if rash occurs, or if irritation develops. If swallowed, get medical attention. Call Poison Control Center at 1-800-235-7631.

**Directions:** Apply liberally and evenly 15 minutes before sun exposure. Reapply at least every 2 hours, or after a water resistant activity.

**Other Information:** Protect the product in this container from excessive heat and direct sun.

**Inactive ingredients:** OCTYLDODECANOL, ETHYLHEXYL PALMITATE, POLYETHYLENE, OZOKERITE, PARAFFIN.

**L'BEL**

**ULTRA BALS**

**MOISTURIZING PROTECTIVE BALM FOR LIPS**

**Drug Facts (continued)**

**Warning:** 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.

**Purpose:** Sunscreen

**Directions:** Sunscreen

**Warnings:** Sunburn

**Other Information:** For Skin Aging

**Drug Facts (continued)**

**Warning:** Stop use if rash occurs, or if irritation develops. If swallowed, get medical attention. Call Poison Control Center at 1-800-235-7631.

**Directions:** Apply liberally and evenly 15 minutes before sun exposure. Reapply at least every 2 hours, or after a water resistant activity.

**Other Information:** Protect the product in this container from excessive heat and direct sun.

**Inactive ingredients:** OCTYLDODECANOL, ETHYLHEXYL PALMITATE, POLYETHYLENE, OZOKERITE, PARAFFIN.

**Drug Facts (continued)**

**Warning:** Stop use if rash occurs, or if irritation develops. If swallowed, get medical attention. Call Poison Control Center at 1-800-235-7631.

**Directions:** Apply liberally and evenly 15 minutes before sun exposure. Reapply at least every 2 hours, or after a water resistant activity.

**Other Information:** Protect the product in this container from excessive heat and direct sun.

**Inactive ingredients:** OCTYLDODECANOL, ETHYLHEXYL PALMITATE, POLYETHYLENE, OZOKERITE, PARAFFIN.



**Drug Facts**  
 sunscreen if sw  
 under 6 months

**Other inform**  
 this container fr

**Inactive ing**  
 ETHYLHEXYL PA

**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**  
 DIMETHICONE, A  
 POLYGLYCERIN  
 NEOPENTYL GL  
 CAPRYLYL C  
 TRIMETHYLSII  
 LECITHIN, Ma  
 FLUORPHLOGOP  
 YELLOW 5 LAKE, I

**Drug Facts (continued)**  
 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, ▶

**ULTRA  
 BALM**

**MOISTURIZING  
 PROTECTIVE  
 BALM FOR LIPS  
 SPF 20**

Net. Wt. 0.14 oz e (4g)

**Drug Facts**  
 Alert: Spending  
 of skin cancer &  
 has been show  
 skin cancer or &  
 use only. ■ Di  
 skin. ■ When  
 eyes. Rinse with

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

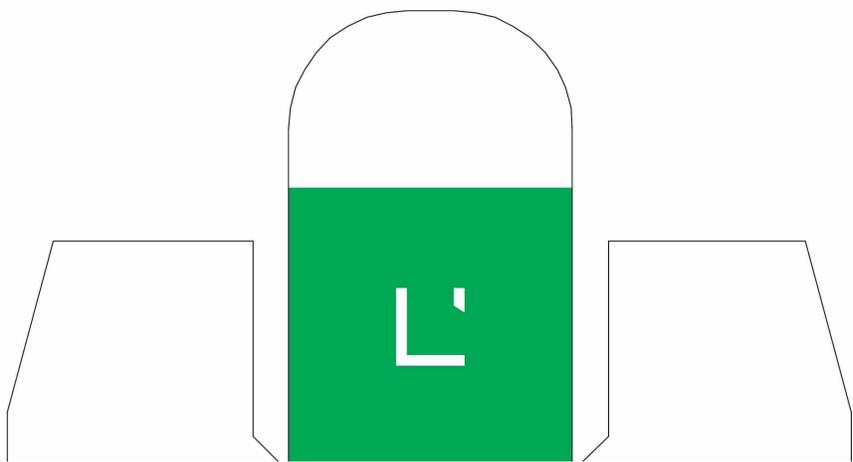
**Uses** ■ Helps prevent sunburn.

**Warnings** ■ Skin Cancer / Skin Aging ▶

U.S.A. & PUERTO RICO: Dist. by  
 Ventura Corp, Ltd., San Juan, Puerto Rico  
 00926. Made in Colombia.  
 www.lbel.com

**TONE: ROSE PARADISE**

**Ultra Balm SPF 20 Rose Cotton**



**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, ▶

**Drug Facts (continued)**  
 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, ▶

**Drug Facts (continued)**  
 DIMETHICONE, ACACIADECURENS FLOWER WAX, POLYGLYCERIN-3, TRIETHOXYCAPRYLSILANE, NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE, CAPRYLYL GLYCOL, CHLORPHENESIN, TRIMETHYLSILOXYMETHYL METHACRYLATE, LECITHIN. **May contain:** MICA, SYNTHETIC FLUOROPHLOGOPITE, TITANIUM DIOXIDE, IRON OXIDES, YELLOW 5 LAKE, RED 7 LAKE, RED 6 LAKE, TALC.

L'BEL

**ULTRA BLM**

**MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20**

Net. Wt. 0.14 oz e (4g)

**Drug Facts**  
**Active Ingredients**  
 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. ▶

U.S.A. & PUERTO RICO: Dist. by Ventura Corp, Ltd., San Juan, Puerto Rico 00926. Made in Colombia.  
 www.lbel.com

TONE: ROSE COTTON

**Ultra Balm SPF 20 Cerise Brise**

U.S.A. & PUERTO RICO: Dist. by  
Ventura Corp, Ltd., San Juan, Puerto Rico  
00926. Made in Colombia.  
[www.lbel.com](http://www.lbel.com)

TONE: CERISE BRISE

**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, ▶

**Drug Facts (continued)**

SILICA, JOBA 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, ▶

**Drug Facts (continued)**

DIMETHICONE, ACACIADECURRENS FLOWER WAX,  
POLYGLYCERIN-3, TRIETHOXYCAPRYLYLSILANE,  
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE,  
CAPRYLYL GLYCOL, CHLORPHENESIN,  
TRIMETHYLSILOXYLICATE, CERAMIDE NP,  
LECITHIN. **May contain:** MICA, SYNTHETIC  
FLUORPHLOGOPITE, TITANIUM DIOXIDE, IRON OXIDES,  
YELLOW 5 LAKE, RED 7 LAKE, RED 6 LAKE, TALC.

Net. Wt. 0.14 oz e (4g)

MOISTURIZING  
PROTECTIVE  
BALM FOR LIPS  
SPF 20

ULTRA  
BALM

L'BEL

**Drug Facts**

**Active Ingredients**

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. ▶



**ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20  
CORAL PETALE**

octinoxate, zinc oxide stick

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:14141-453
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>BRAZILIAN PEPPER</b> (UNII: SUG822G7CD)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: VLV429K27K)	
<b>OCTYLDODECANOL</b> (UNII: 461N1O614Y)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5)</b> (UNII: V2W71V8T0X)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>HELIANTHUS ANNUUS SEED WAX</b> (UNII: 42DG15CHXV)	
<b>HEXYL LAURATE</b> (UNII: 4CG9F9W01Q)	
<b>ACACIA DECURRENS FLOWER WAX</b> (UNII: AU6XZ E9IY9)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE</b> (UNII: 554N82UWWV)	
<b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)	
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)	
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>POLYGLYCERIN-3</b> (UNII: 4A0NCJ6RD6)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8)</b> (UNII: 5041RX63GN)	
<b>CERAMIDE NP</b> (UNII: 4370DF050B)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE</b> (UNII: YK3DC63Y5M)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14141-453-01	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 Drug	M020	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:14141-455
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)	

<b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)
<b>POLYGLYCERIN-3</b> (UNII: 4A0NCJ6RD6)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8)</b> (UNII: 5041RX63GN)
<b>CERAMIDE NP</b> (UNII: 4370DF050B)
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)
<b>MICA</b> (UNII: V8A1AW0880)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE</b> (UNII: YK3DC63Y5M)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>TALC</b> (UNII: 7SEV7J4R1U)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14141-455-01	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 Drug	M020	06/15/2021	

## ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 ROSE COTTON

octinoxate, zinc oxide stick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:14141-454
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14141-454-01	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 Drug	M020	06/15/2021	

**ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20**

# NUDE TRANSLUCIDE

octinoxate, zinc oxide stick

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:14141-452
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>BRAZILIAN PEPPER</b> (UNII: SUG822G7CD)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: VLV429K27K)	
<b>OCTYLDODECANOL</b> (UNII: 461N1O614Y)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5)</b> (UNII: V2W71V8T0X)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>HELIANTHUS ANNUUS SEED WAX</b> (UNII: 42DG15CHXV)	
<b>HEXYL LAURATE</b> (UNII: 4CG9F9W01Q)	
<b>ACACIA DECURRENS FLOWER WAX</b> (UNII: AU6XZE9IY9)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE</b> (UNII: 554N82UWWW)	
<b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)	
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)	
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>POLYGLYCERIN-3</b> (UNII: 4A0NCJ6RD6)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8)</b> (UNII: 5041RX63GN)	
<b>CERAMIDE NP</b> (UNII: 4370DF050B)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE</b> (UNII: YK3DC63Y5M)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	

TALC (UNII: 7SEV7J4R1U)

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14141-452-01	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 Drug	M020	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:14141-456
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: 554N82UWWW)	

<b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)
<b>CERESIN</b> (UNII: Q1LS2UJ03A)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)
<b>POLYGLYCERIN-3</b> (UNII: 4A0NCJ6RD6)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8)</b> (UNII: 5041RX63GN)
<b>CERAMIDE NP</b> (UNII: 4370DF050B)
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)
<b>MICA</b> (UNII: V8A1AW0880)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE</b> (UNII: YK3DC63Y5M)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>TALC</b> (UNII: 7SEV7J4R1U)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14141-456-01	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 Drug	M020	06/15/2021	

**Labeler -** BEL STAR S A (880160197)

### Establishment

Name	Address	ID/FEI	Business Operations
BEL STAR S A		880160197	manufacture(14141-452, 14141-453, 14141-454, 14141-455, 14141-456)