

LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (ROSE NATURAL) - BROWN- octinoxate and oxybenzone lipstick
 LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (ROJO VIF) - BROWN- octinoxate and oxybenzone lipstick
 LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (MOKA) - PINK- octinoxate and oxybenzone lipstick
 LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (MANDARINE) - PURPLE- octinoxate and oxybenzone lipstick
 LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (CAPUCCINO) - PURPLE- octinoxate and oxybenzone lipstick
 LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (VIN) - PURPLE- octinoxate and oxybenzone lipstick
 LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (FUCHSIA INTENSE) - PURPLE- octinoxate and oxybenzone lipstick
 LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (ROUGE BRILLANCE) - BROWN- octinoxate and oxybenzone lipstick
 LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (ROUGE INTENSE) - PURPLE- octinoxate and oxybenzone lipstick
 LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (FUCHSIA BRILLANCE) - RED- octinoxate and oxybenzone lipstick
 LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (ROSE BRILLANCE) - RED- octinoxate and oxybenzone lipstick
 LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (ROSE CLASSIQUE) - RED- octinoxate and oxybenzone 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 Couleur luxe rouge irrésistible maximum hydration lipstick SPF 17

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
Octinoxate (7.1%)	Sunscreen
Oxybenzone (1.6%)	Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.
- **For external use only.**
- **Do not use** on damaged or broken skin.
- **When using this product** keep out of eyes. Rinse with water to remove.

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor

Other information

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

Inactive ingredients

Ethylhexyl palmitate, dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, polyethylene, ozokerite, butyrospermum parkii (shea butter), tridecyl stearate, copernicia cerifera cera (carnauba) wax, polymethyl methacrylate, neopentyl glycol dicaprylate/dicaprate, disteardimonium hectorite, octyldodecanol, caprylic/capric triglyceride, phenoxyethanol, propylene carbonate, tocopheryl acetate, parfum (fragrance), microcrystalline wax, silica, methylparaben, petrolatum, phospholipids, bht, cholesterol, propylparaben, aloe barbadensis leaf extract, butylparaben, ethylparaben, crambe maritima extract, bha, euphorbia cerifera (candelilla) wax, beeswax, cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, isobutylparaben, glycosphingolipids.

May contain:

Mica , red 7 lake , iron oxides, titanium dioxide , red 30 lake, yellow 5 lake , red 21 lake , bismuth oxychloride, red 40 lake , talc, blue 1 lake , hydrogenated polyisobutene, carmine, palmitic acid.

PR: Distributed by Ventura Corporation, Ltd. San Juan, Puerto Rico 00926.

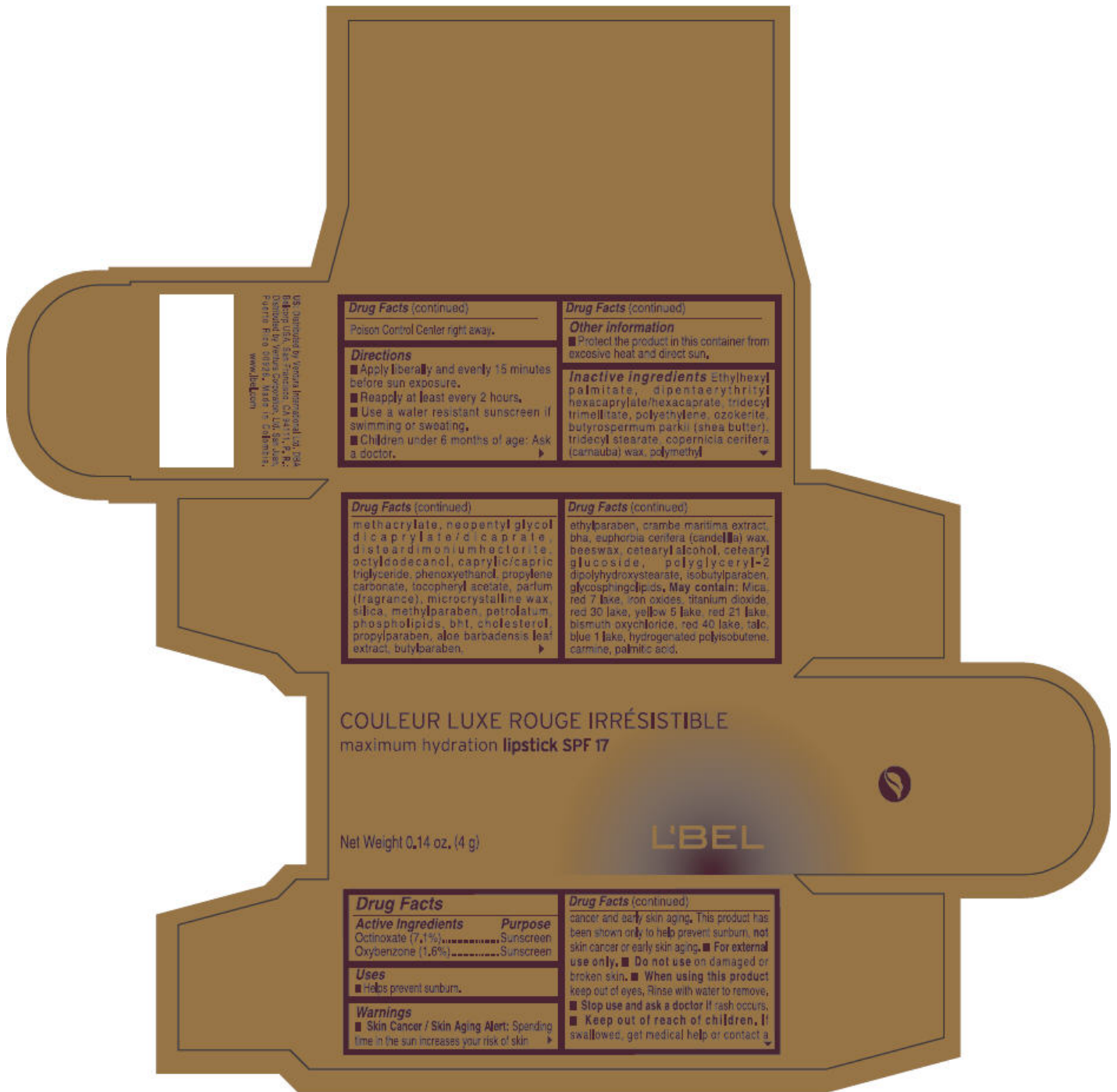
PRINCIPAL DISPLAY PANEL - 4 g Tube Box - ROSE NATURAL - BROWN

COULEUR LUXE ROUGE IRRÉSISTIBLE

maximum hydration **lips tick SPF 17**

Net Weight 0.14 oz. (4 g)

L'BEL



US: Manufactured by L'Oréal, licensed to L'Oréal
 L'Oréal USA, Inc., Stamford, CT 06407, U.S.A.
 Manufactured by L'Oréal, licensed to L'Oréal
 L'Oréal, S.A., Paris, France, Made in Colombia.
 www.lbel.com

Drug Facts (continued)
 Poison Control Center right away.

Directions
 ■ Apply liberally and evenly 15 minutes before sun exposure.
 ■ Reapply at least every 2 hours.
 ■ Use a water resistant sunscreen if swimming or sweating.
 ■ Children under 6 months of age: Ask a doctor. ▶

Drug Facts (continued)
Other information
 ■ Protect the product in this container from excessive heat and direct sun.

Inactive ingredients Ethylhexyl palmitate, dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, polyethylene, ozokerite, butyrospermum parkii (shea butter), tridecyl stearate, copernicia cerifera (carnauba) wax, polymethyl ▶

Drug Facts (continued)
 methacrylate, neopentyl glycol dicaprylate/dicaprate, disteardimonium hectorite, octyldecyl alcohol, caprylic/capric triglyceride, phenoxyethanol, propylene carbonate, tocopheryl acetate, parfum (fragrance), microcrystalline wax, silica, methylparaben, petrolatum, phospholipids, bht, cholesterol, propylparaben, aloe barbadensis leaf extract, butylparaben. ▶

Drug Facts (continued)
 ethylparaben, cramba maritima extract, bha, euphorbia cerifera (candelilla) wax, beeswax, cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, isobutylparaben, glycosphingolipids, May contain: Mica, red 7 lake, iron oxides, titanium dioxide, red 30 lake, yellow 5 lake, red 21 lake, bismuth oxychloride, red 40 lake, talc, blue 1 lake, hydrogenated polyisobutene, carmine, palmitic acid.

COULEUR LUXE ROUGE IRRÉSISTIBLE
 maximum hydration lipstick SPF 17

Net Weight 0.14 oz. (4 g)

L'BEL

Drug Facts

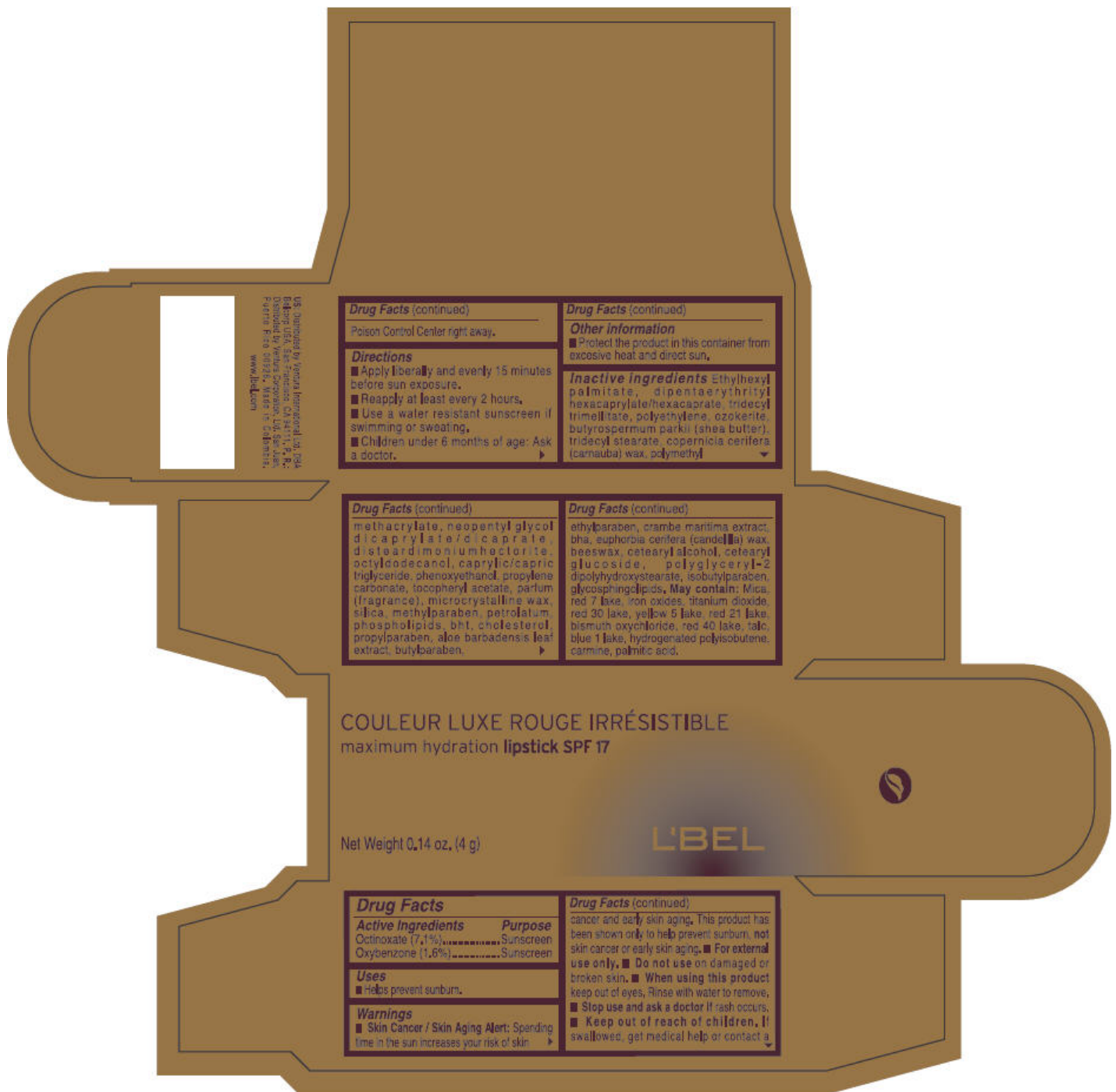
Active Ingredients	Purpose
Octinoxate (7.1%)	Sunscreen
Oxybenzone (1.6%)	Sunscreen

Uses
 ■ Helps prevent sunburn.

Warnings
 ■ Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin ▶

Drug Facts (continued)
 cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging. ■ For external use only. ■ Do not use on damaged or broken skin. ■ When using this product keep out of eyes. Rinse with water to remove. ■ Stop use and ask a doctor if rash occurs. ■ Keep out of reach of children. If swallowed, get medical help or contact a ▶

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - ROJO VIF - BROWN
 COULEUR LUXE ROUGE IRRÉSISTIBLE
 maximum hydration lipstick SPF 17
 Net Weight 0.14 oz. (4 g)
 L'BEL



PRINCIPAL DISPLAY PANEL - 4 g Tube Box - MOKA - PINK

COULEUR LUXE ROUGE IRRÉSISTIBLE
 maximum hydration **lipstick SPF 17**

Net Weight 0.14 oz. (4 g)

L'BEL

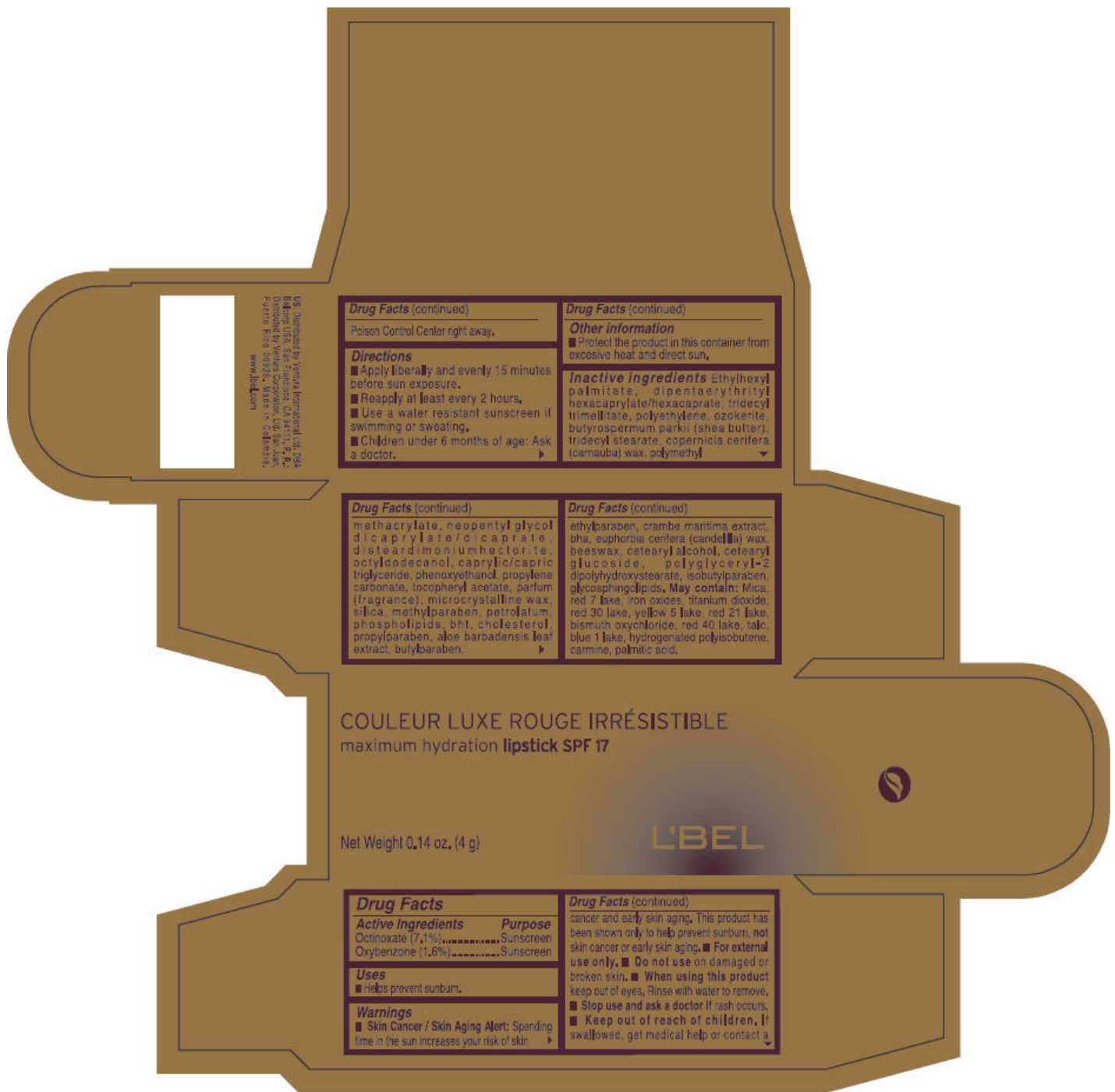


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - CAPUCCINO - PURPLE

COULEUR LUXE ROUGE IRRÉSISTIBLE
maximum hydration **lipstick** SPF 17

Net Weight 0.14 oz. (4 g)

L'BEL



US: Manufactured by Lorena International, Inc.
 10000 Wilshire Blvd., Suite 2000, Culver City, CA 90230, U.S.A.
 Manufactured by Veneta Cosmetics, S.A. de C.V.
 P.O. Box 1000, Mexico City, Mexico
 www.lbel.com

Drug Facts (continued)
 Poison Control Center right away.

Directions
 ■ Apply liberally and evenly 15 minutes before sun exposure.
 ■ Reapply at least every 2 hours.
 ■ Use a water resistant sunscreen if swimming or sweating.
 ■ Children under 6 months of age: Ask a doctor. ▶

Drug Facts (continued)
Other information
 ■ Protect the product in this container from excessive heat and direct sun.

Inactive ingredients Ethylhexyl palmitate, dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, polyethylene, ozokerite, butyrospermum parkii (shea butter), tridecyl stearate, copernicia cerifera (carnauba) wax, polymethyl ▶

Drug Facts (continued)
 methacrylate, neopentyl glycol dicaprylate/dicaprate, disteardimonium hectorite, octyldecyl alcohol, caprylic/capric triglyceride, phenoxyethanol, propylene carbonate, tocopheryl acetate, parfum (fragrance), microcrystalline wax, silica, methylparaben, petrolatum, phospholipids, bht, cholesterol, propylparaben, aloe barbadensis leaf extract, butylparaben. ▶

Drug Facts (continued)
 ethylparaben, cramba maritima extract, bha, euphorbia cerifera (candelilla) wax, beeswax, cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, isobutylparaben, glycosphingolipids, May contain: Mica, red 7 lake, iron oxides, titanium dioxide, red 30 lake, yellow 5 lake, red 21 lake, bismuth oxychloride, red 40 lake, talc, blue 1 lake, hydrogenated polyisobutene, carmine, palmitic acid.

COULEUR LUXE ROUGE IRRÉSISTIBLE
 maximum hydration lipstick SPF 17

Net Weight 0.14 oz. (4 g)

L'BEL

Drug Facts

Active Ingredients	Purpose
Octinoxate (7.1%)	Sunscreen
Oxybenzone (1.6%)	Sunscreen

Uses
 ■ Helps prevent sunburn.

Warnings
 ■ Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin ▶

Drug Facts (continued)
 cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging. ■ For external use only. ■ Do not use on damaged or broken skin. ■ When using this product keep out of eyes. Rinse with water to remove. ■ Stop use and ask a doctor if rash occurs. ■ Keep out of reach of children. If swallowed, get medical help or contact a ▶

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - VIN - PURPLE

COULEUR LUXE ROUGE IRRÉSISTIBLE
 maximum hydration lipstick SPF 17

Net Weight 0.14 oz. (4 g)

L'BEL



US: Manufactured by Loreal, International, Inc.
 400 North Zeeb Road, Suite 200, San Francisco, CA 94117, U.S.A.
 Manufactured by Loreal, International, Inc.
 P.O. Box 10000, Fort Worth, TX 76181, U.S.A.
 www.lbel.com

Drug Facts (continued)
 Poison Control Center right away.

Directions
 ■ Apply liberally and evenly 15 minutes before sun exposure.
 ■ Reapply at least every 2 hours.
 ■ Use a water resistant sunscreen if swimming or sweating.
 ■ Children under 6 months of age: Ask a doctor. ▶

Drug Facts (continued)
Other information
 ■ Protect the product in this container from excessive heat and direct sun.

Inactive ingredients Ethylhexyl palmitate, dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, polyethylene, ozokerite, butyrospermum parkii (shea butter), tridecyl stearate, copernicia cerifera (carnauba) wax, polymethyl ▶

Drug Facts (continued)
 methacrylate, neopentyl glycol dicaprylate/dicaprate, disteardimonium hectorite, octyldecyl alcohol, caprylic/capric triglyceride, phenoxyethanol, propylene carbonate, tocopheryl acetate, parfum (fragrance), microcrystalline wax, silica, methylparaben, petrolatum, phospholipids, bht, cholesterol, propylparaben, aloe barbadensis leaf extract, butylparaben. ▶

Drug Facts (continued)
 ethylparaben, cramba maritima extract, bha, euphorbia cerifera (candelilla) wax, beeswax, cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, isobutylparaben, glycosphingolipids, May contain: Mica, red 7 lake, iron oxides, titanium dioxide, red 30 lake, yellow 5 lake, red 21 lake, bismuth oxychloride, red 40 lake, talc, blue 1 lake, hydrogenated polyisobutene, carmine, palmitic acid.

COULEUR LUXE ROUGE IRRÉSISTIBLE
 maximum hydration lipstick SPF 17

Net Weight 0.14 oz. (4 g)

L'BEL

Drug Facts

Active Ingredients	Purpose
Octinoxate (7.1%)	Sunscreen
Oxybenzone (1.6%)	Sunscreen

Uses
 ■ Helps prevent sunburn.

Warnings
 ■ Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin ▶

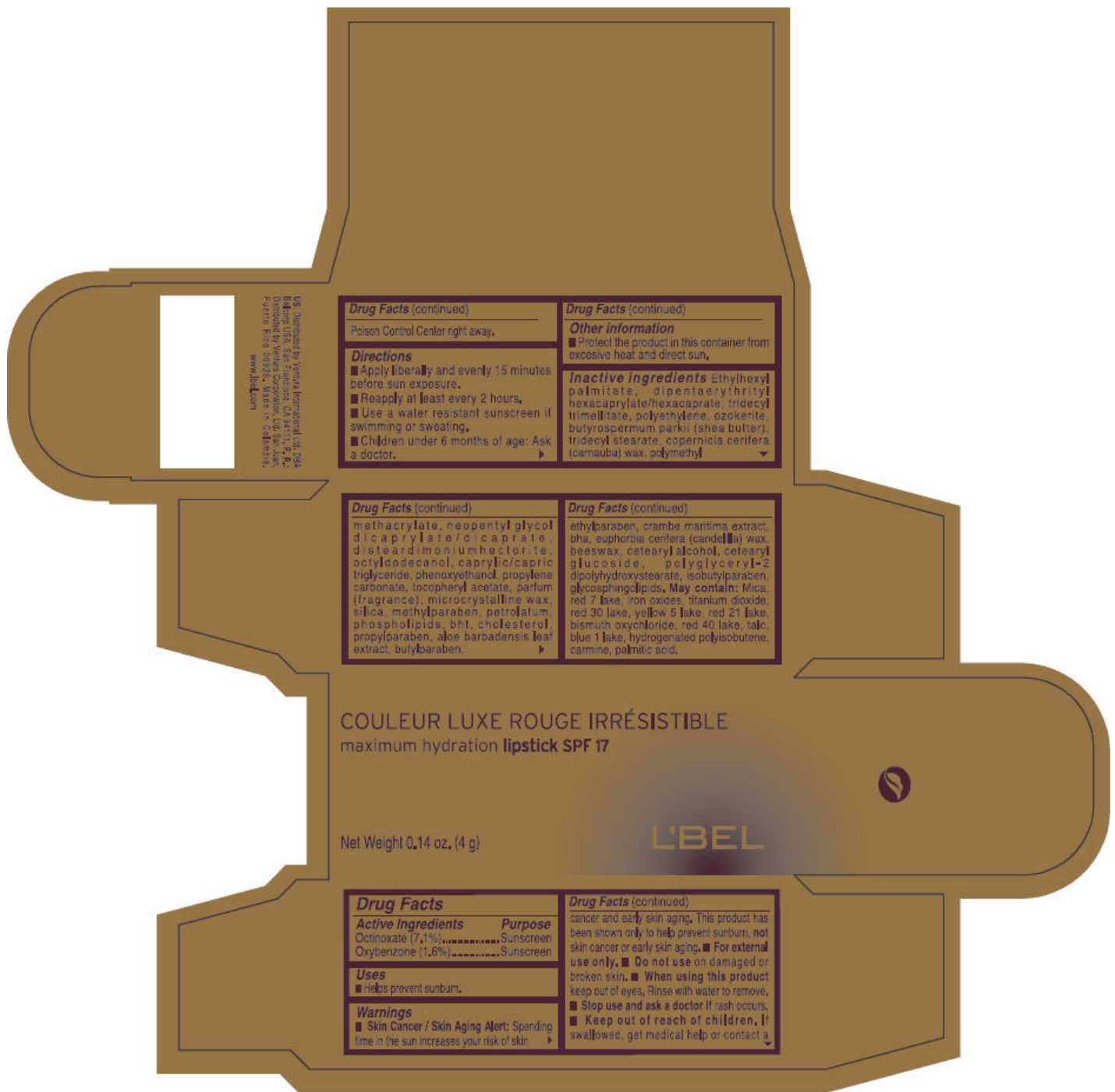
Drug Facts (continued)
 cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging. ■ For external use only. ■ Do not use on damaged or broken skin. ■ When using this product keep out of eyes. Rinse with water to remove. ■ Stop use and ask a doctor if rash occurs. ■ Keep out of reach of children. If swallowed, get medical help or contact a ▶

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - FUCHSIA INTENSE - PURPLE

COULEUR LUXE ROUGE IRRÉSISTIBLE
 maximum hydration lipstick SPF 17

Net Weight 0.14 oz. (4 g)

L'BEL

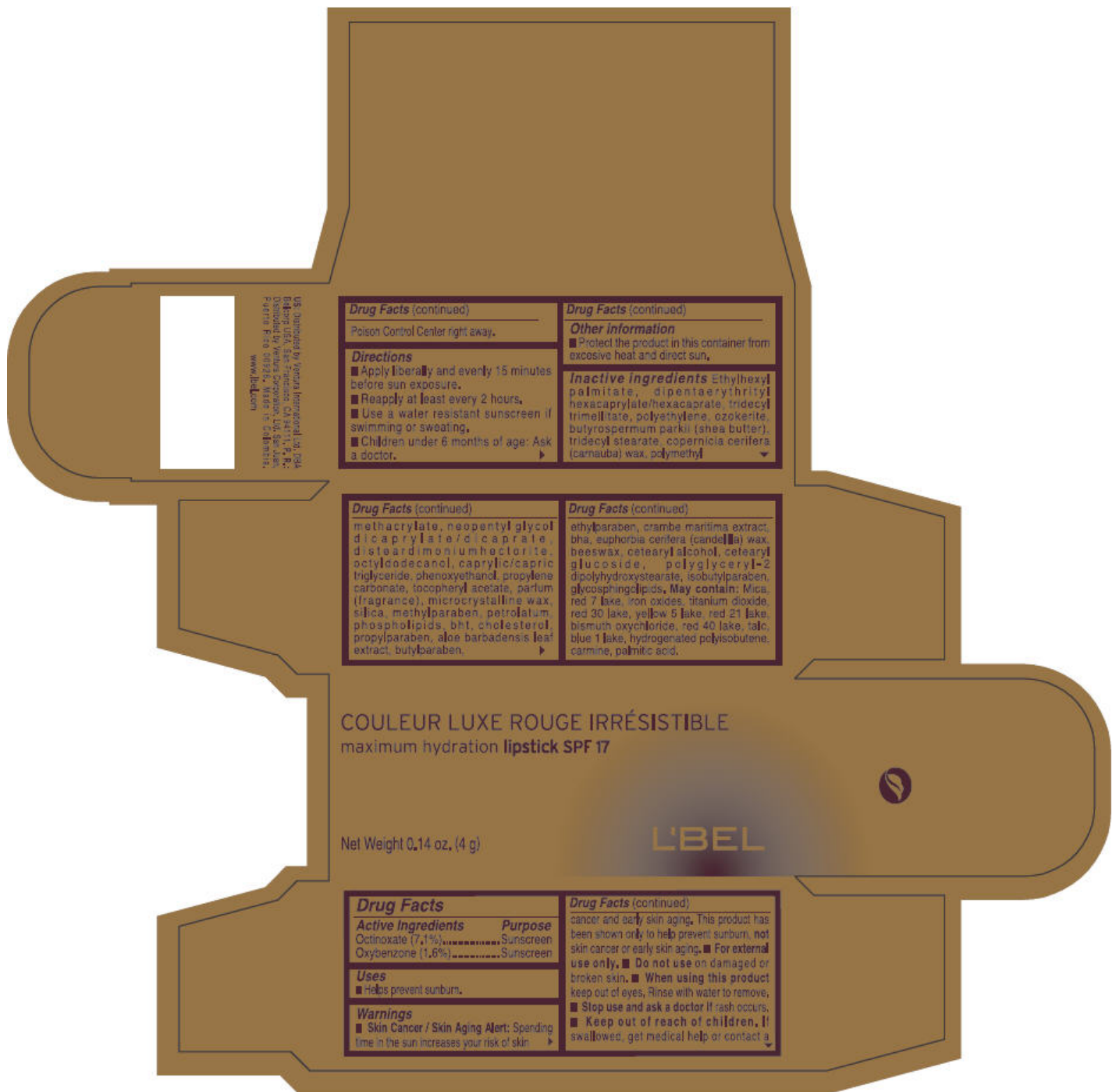


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - ROUGE BRILLANCE - BROWN

COULEUR LUXE ROUGE IRRÉSISTIBLE
 maximum hydration **lipstick SPF 17**

Net Weight 0.14 oz. (4 g)

L'BEL

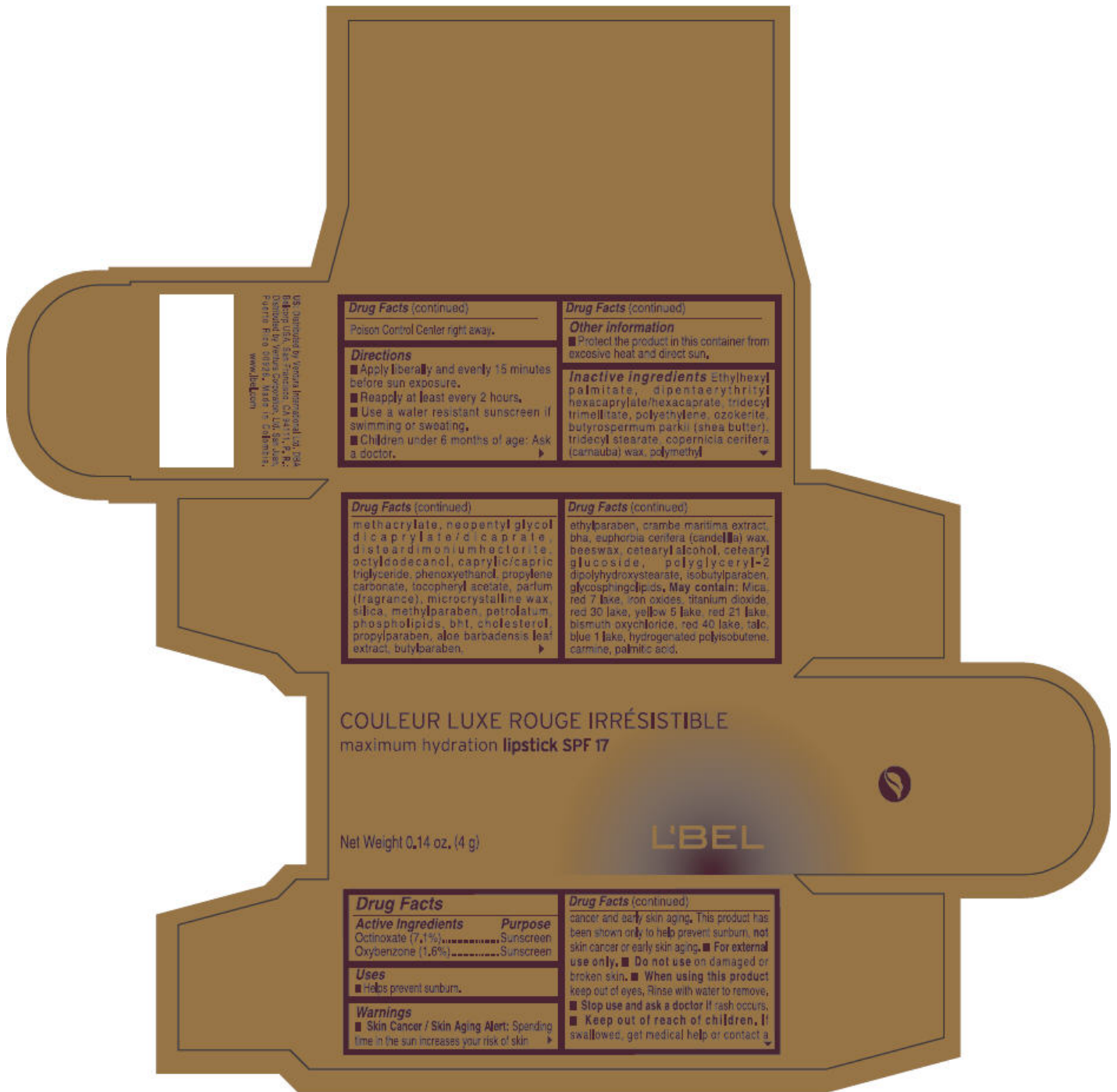


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - ROUGE INTENSE - PURPLE

COULEUR LUXE ROUGE IRRÉSISTIBLE
 maximum hydration **lipstick** SPF 17

Net Weight 0.14 oz. (4 g)

L'BEL



PRINCIPAL DISPLAY PANEL - 4 g Tube Box - FUCHSIA BRILLANCE - RED

COULEUR LUXE ROUGE IRRÉSISTIBLE
maximum hydration **lipstick** SPF 17

Net Weight 0.14 oz. (4 g)

L'BEL



PRINCIPAL DISPLAY PANEL - 4 g Tube Box - ROSE BRILLANCE - RED

COULEUR LUXE ROUGE IRRÉSISTIBLE
maximum hydration **lipstick** SPF 17

Net Weight 0.14 oz. (4 g)

L'BEL

Drug Facts (continued)

Poison Control Center right away.

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor. ▶

Drug Facts (continued)

Other information

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

Inactive ingredients

Ethylhexyl palmitate, dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, polyethylene, ozokerite, butyrospermum parkii (shea butter), tridecyl stearate, copernicia cerifera (carnauba) wax, polymethyl

Drug Facts (continued)

methacrylate, neopentyl glycol dicaprylate/dicaprate, disteardimonium hexoctrile, octyldecyl alcohol, caprylic/capric triglyceride, phenoxyethanol, propylene carbonate, tocopheryl acetate, parfum (fragrance), microcrystalline wax, silica, methylparaben, petrolatum, phospholipids, bht, cholesterol, propylparaben, aloe barbadensis leaf extract, butylparaben. ▶

Drug Facts (continued)

ethylparaben, cramba maritima extract, bha, euphorbia cerifera (candelilla) wax, beeswax, cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, isobutylparaben, glycosphingolipids, May contain: Mica, red 7 lake, iron oxides, titanium dioxide, red 30 lake, yellow 5 lake, red 21 lake, bismuth oxychloride, red 40 lake, talc, blue 1 lake, hydrogenated polyisobutene, carmine, palmitic acid.

COULEUR LUXE ROUGE IRRÉSISTIBLE
maximum hydration **lipstick** SPF 17

Net Weight 0.14 oz. (4 g)

L'BEL

Drug Facts

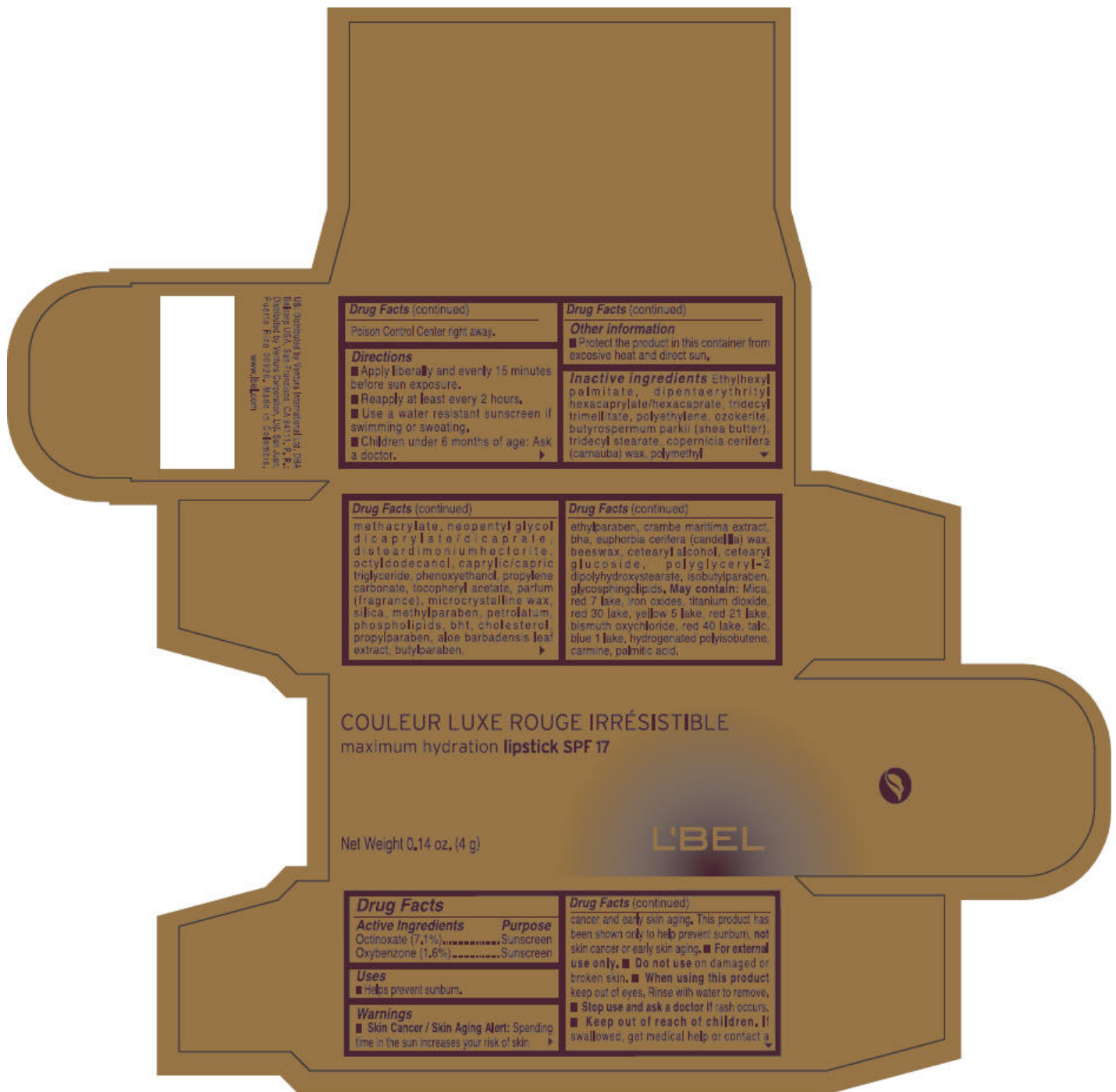
Active Ingredients	Purpose
Octinoxate (7.1%)	Sunscreen
Oxybenzone (1.6%)	Sunscreen

Uses
■ Helps prevent sunburn.

Warnings
■ Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin

Drug Facts (continued)

cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging. ■ For external use only. ■ Do not use on damaged or broken skin. ■ When using this product keep out of eyes. Rinse with water to remove. ■ Stop use and ask a doctor if rash occurs. ■ Keep out of reach of children. If swallowed, get medical help or contact a

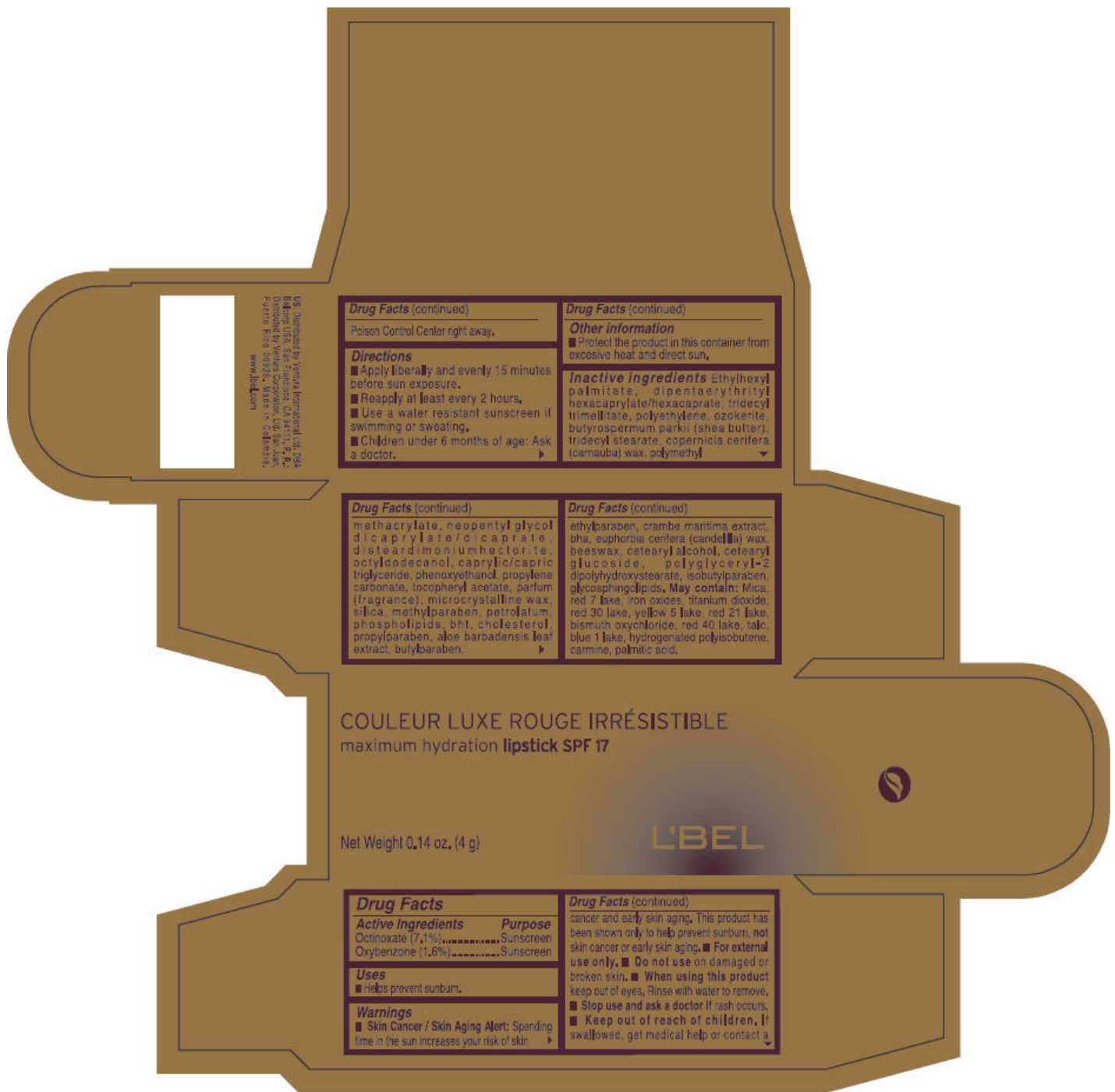


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - ROSE CLASSIQUE - RED

COULEUR LUXE ROUGE IRRÉSISTIBLE
maximum hydration **lipstick** SPF 17

Net Weight 0.14 oz. (4 g)

L'BEL



LBEL COULEUR LUXE ROUGE IRRÉSISTIBLE MAXIMUM HYDRATION SPF 17 (ROSE NATURAL) - BROWN

octinoxate and oxybenzone lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-100
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	

Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.071 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.016 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ethylhexyl palmitate (UNII: 2865993309)	
dipentaerythrityl hexacaprylate/hexacaprate (UNII: 554N82UWVW)	
tridecyl trimellitate (UNII: FY36J270ES)	
high density polyethylene (UNII: UG00KM4WR7)	
shea butter (UNII: K49155WL9Y)	
tridecyl stearate (UNII: A8OE252M6L)	
carnauba wax (UNII: R12CBM0EIZ)	
neopentyl glycol dicaprylate/dicaprate (UNII: VLW429K27K)	
disteardimonium hectorite (UNII: X687XDK09L)	
octyldodecanol (UNII: 461N1O614Y)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
phenoxyethanol (UNII: HIE492ZZ3T)	
propylene carbonate (UNII: 8D08K3S51E)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
microcrystalline wax (UNII: XOF597Q3KY)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
methylparaben (UNII: A2I8C7HI9T)	
petrolatum (UNII: 4T6H12BN9U)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
cholesterol (UNII: 97C5T2UQ7J)	
propylparaben (UNII: Z8IX2SC1OH)	
aloe vera leaf (UNII: ZY81Z83H0X)	
butylparaben (UNII: 3QPII1U3FV8)	
ethylparaben (UNII: 14255EXE39)	
butylated hydroxyanisole (UNII: REK4960K2U)	
candelilla wax (UNII: WL0328HX19)	
yellow wax (UNII: 2ZA36H0S2V)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetearyl glucoside (UNII: 09FUA47KNA)	
polyglyceryl-2 dipolyhydroxystearate (UNII: 9229XJ4V12)	
isobutylparaben (UNII: 0QQJ25X58G)	
mica (UNII: V8A1AW0880)	
d&c red no. 7 (UNII: ECW0LZ41X8)	
aluminum oxide (UNII: LM26O6933)	
ferric oxide red (UNII: 1K09F3G675)	
titanium dioxide (UNII: 15FIX9V2JP)	
d&c red no. 30 (UNII: 2S42T2808B)	
fd&c yellow no. 5 (UNII: I753WB2F1M)	
d&c red no. 21 (UNII: 08744Z6JNY)	
bismuth oxychloride (UNII: 4ZR792I587)	
fd&c red no. 40 (UNII: WZB9127XOA)	
talc (UNII: 7SEV7J4R1U)	
fd&c blue no. 1 (UNII: H3R47K3TBD)	
palmitic acid (UNII: 2V16EO95H1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-100-02	1 in 1 BOX		
1	NDC:13537-100-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/31/2014	

LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (ROJO VIF) - BROWN

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.071 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.016 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ethylhexyl palmitate (UNII: 2865993309)	
dipentaerythrityl hexacaprylate/hexacaprate (UNII: 554N82UWVW)	
tridecyl trimellitate (UNII: FY36J270ES)	
high density polyethylene (UNII: UG00KM4WR7)	
shea butter (UNII: K49155WL9Y)	
tridecyl stearate (UNII: A8OE252M6L)	
carnauba wax (UNII: R12CBM0EIZ)	
neopentyl glycol dicaprylate/dicaprate (UNII: VLW429K27K)	
disteardimonium hectorite (UNII: X687XDK09L)	
octyldodecanol (UNII: 461N1O614Y)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
phenoxyethanol (UNII: HIE492ZZ3T)	
propylene carbonate (UNII: 8D08K3S51E)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
microcrystalline wax (UNII: XOF597Q3KY)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
methylparaben (UNII: A218C7HI9T)	

petrolatum (UNII: 4T6H12BN9U)
butylated hydroxytoluene (UNII: 1P9D0Z171K)
cholesterol (UNII: 97C5T2UQ7J)
propylparaben (UNII: Z8IX2SC1OH)
aloe vera leaf (UNII: ZY81Z83H0X)
butylparaben (UNII: 3QPIU3FV8)
ethylparaben (UNII: 14255EXE39)
butylated hydroxyanisole (UNII: REK4960K2U)
candelilla wax (UNII: WL0328HX19)
yellow wax (UNII: 2ZA36H0S2V)
cetostearyl alcohol (UNII: 2DMT128M1S)
cetearyl glucoside (UNII: 09FUA47KNA)
polyglyceryl-2 dipolyhydroxystearate (UNII: 9229XJ4V12)
isobutylparaben (UNII: 0QQJ25X58G)
mica (UNII: V8A1AW0880)
d&c red no. 7 (UNII: ECW0LZ41X8)
aluminum oxide (UNII: LM26O6933)
ferric oxide red (UNII: 1K09F3G675)
titanium dioxide (UNII: 15FIX9V2JP)
d&c red no. 30 (UNII: 2S42T2808B)
fd&c yellow no. 5 (UNII: I753WB2F1M)
d&c red no. 21 (UNII: 08744Z6JNY)
bismuth oxychloride (UNII: 4ZR792I587)
fd&c red no. 40 (UNII: WZB9127XOA)
talc (UNII: 7SEV7J4R1U)
fd&c blue no. 1 (UNII: HBR47K3TBD)
palmitic acid (UNII: 2V16EO95H1)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-10 1-04	1 in 1 BOX		
1	NDC:13537-10 1-03	4 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/31/20 14	

LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (MOKA) - PINK
 octinoxate and oxybenzone lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-443
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.071 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.016 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ethylhexyl palmitate (UNII: 2865993309)	
dipentaerythrityl hexacaprylate/hexacaprate (UNII: 554N82UWVW)	
tridecyl trimellitate (UNII: FY36J270ES)	
high density polyethylene (UNII: UG00KM4WR7)	
shea butter (UNII: K49155WL9Y)	
tridecyl stearate (UNII: A8OE252M6L)	
carnauba wax (UNII: R12CBM0EIZ)	
neopentyl glycol dicaprylate/dicaprate (UNII: VLW429K27K)	
disteardimonium hectorite (UNII: X687XDK09L)	
octyldodecanol (UNII: 461N1O614Y)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
phenoxyethanol (UNII: HIE492ZZ3T)	
propylene carbonate (UNII: 8D08K3S51E)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
microcrystalline wax (UNII: XOF597Q3KY)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
methylparaben (UNII: A2I8C7HI9T)	
petrolatum (UNII: 4T6H12BN9U)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
cholesterol (UNII: 97C5T2UQ7J)	
propylparaben (UNII: Z8IX2SC1OH)	
aloe vera leaf (UNII: ZY81Z83H0X)	
butylparaben (UNII: 3QPIU3FV8)	
ethylparaben (UNII: 14255EXE39)	
butylated hydroxyanisole (UNII: REK4960K2U)	
candelilla wax (UNII: WL0328HX19)	
yellow wax (UNII: 2ZA36H0S2V)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetearyl glucoside (UNII: 09FUA47KNA)	
polyglyceryl-2 dipolyhydroxystearate (UNII: 9229XJ4V12)	
isobutylparaben (UNII: 0QQJ25X58G)	
mica (UNII: V8A1AW0880)	
d&c red no. 7 (UNII: ECW0LZ41X8)	
aluminum oxide (UNII: LMI26O6933)	
ferric oxide red (UNII: 1K09F3G675)	
titanium dioxide (UNII: 15FIX9V2JP)	
d&c red no. 30 (UNII: 2S42T2808B)	
fd&c yellow no. 5 (UNII: I753WB2F1M)	
d&c red no. 21 (UNII: 08744Z6JNY)	
bismuth oxychloride (UNII: 4ZR792I587)	

fd&c red no. 40 (UNII: WZB9127XOA)	
talc (UNII: 7SEV7J4RIU)	
fd&c blue no. 1 (UNII: H3R47K3TBD)	
palmitic acid (UNII: 2V16EO95H1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-443-06	1 in 1 BOX		
1	NDC:13537-443-05	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/31/2014	

LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (MANDARINE) - PURPLE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.071 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.016 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ethylhexyl palmitate (UNII: 2865993309)	
dipentaerythrityl hexacaprylate/hexacaprate (UNII: 554N82UWVW)	
tridecyl trimellitate (UNII: FY36J270ES)	
high density polyethylene (UNII: UG00KM4WR7)	
shea butter (UNII: K49155WL9Y)	
tridecyl stearate (UNII: A8OE252M6L)	
carnauba wax (UNII: R12CBM0EIZ)	
neopentyl glycol dicaprylate/dicaprate (UNII: VLW429K27K)	
disteardimonium hectorite (UNII: X687XDK09L)	
octyldodecanol (UNII: 461N1O614Y)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
phenoxyethanol (UNII: HIE492ZZ3T)	
propylene carbonate (UNII: 8D08K3S51E)	

.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)
microcrystalline wax (UNII: XOF597Q3KY)
silicon dioxide (UNII: ETJ7Z6XBU4)
methylparaben (UNII: A2I8C7HI9T)
petrolatum (UNII: 4T6HI2BN9U)
butylated hydroxytoluene (UNII: 1P9D0Z171K)
cholesterol (UNII: 97C5T2UQ7J)
propylparaben (UNII: Z8IX2SC1OH)
aloe vera leaf (UNII: ZY8IZ83H0X)
butylparaben (UNII: 3QPIU3FV8)
ethylparaben (UNII: 14255EXE39)
butylated hydroxyanisole (UNII: REK4960K2U)
candelilla wax (UNII: WL0328HX19)
yellow wax (UNII: 2ZA36H0S2V)
cetostearyl alcohol (UNII: 2DMT128M1S)
cetearyl glucoside (UNII: 09FUA47KNA)
polyglyceryl-2 dipolyhydroxystearate (UNII: 9229XJ4V12)
isobutylparaben (UNII: 0QQJ25X58G)
mica (UNII: V8A1AW0880)
d&c red no. 7 (UNII: ECW0LZ41X8)
aluminum oxide (UNII: LM26O6933)
ferric oxide red (UNII: 1K09F3G675)
titanium dioxide (UNII: 15FIX9V2JP)
d&c red no. 30 (UNII: 2S42T2808B)
fd&c yellow no. 5 (UNII: I753WB2F1M)
d&c red no. 21 (UNII: 08744Z6JNY)
bismuth oxychloride (UNII: 4ZR792I587)
fd&c red no. 40 (UNII: WZB9127XOA)
talc (UNII: 7SEV7J4R1U)
fd&c blue no. 1 (UNII: HBR47K3TBD)
palmitic acid (UNII: 2V16EO95HI)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-102-08	1 in 1 BOX		
1	NDC:13537-102-07	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/31/2014	

LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (CAPUCCINO) - PURPLE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.071 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.016 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ethylhexyl palmitate (UNII: 2865993309)	
dipentaerythrityl hexacaprylate/hexacaprate (UNII: 554N82UWVW)	
tridecyl trimellitate (UNII: FY36J270ES)	
high density polyethylene (UNII: UG00KM4WR7)	
shea butter (UNII: K49155WL9Y)	
tridecyl stearate (UNII: A8OE252M6L)	
carnauba wax (UNII: R12CBM0EIZ)	
neopentyl glycol dicaprylate/dicaprate (UNII: VLW429K27K)	
disteardimonium hectorite (UNII: X687XDK09L)	
octyldodecanol (UNII: 461N1O614Y)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
phenoxyethanol (UNII: HIE492ZZ3T)	
propylene carbonate (UNII: 8D08K3S51E)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
microcrystalline wax (UNII: XOF597Q3KY)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
methylparaben (UNII: A2I8C7HI9T)	
petrolatum (UNII: 4T6H12BN9U)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
cholesterol (UNII: 97C5T2UQ7J)	
propylparaben (UNII: Z8IX2SC1OH)	
aloe vera leaf (UNII: ZY81Z83H0X)	
butylparaben (UNII: 3QPIU3FV8)	
ethylparaben (UNII: 14255EXE39)	
butylated hydroxyanisole (UNII: REK4960K2U)	
candelilla wax (UNII: WL0328HX19)	
yellow wax (UNII: 2ZA36H0S2V)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetearyl glucoside (UNII: 09FUA47KNA)	
polyglyceryl-2 dipolyhydroxystearate (UNII: 9229XJ4V12)	
isobutylparaben (UNII: 0QQJ25X58G)	
mica (UNII: V8A1AW0880)	
d&c red no. 7 (UNII: ECW0LZ41X8)	
aluminum oxide (UNII: LMI26O6933)	
ferric oxide red (UNII: 1K09F3G675)	
titanium dioxide (UNII: 15FIX9V2JP)	

d&c red no. 30 (UNII: 2S42T2808B)	
fd&c yellow no. 5 (UNII: I753WB2F1M)	
d&c red no. 21 (UNII: 08744Z6JNY)	
bismuth oxychloride (UNII: 4ZR792I587)	
fd&c red no. 40 (UNII: WZB9127XOA)	
talc (UNII: 7SEV7J4RIU)	
fd&c blue no. 1 (UNII: H3R47K3TBD)	
palmitic acid (UNII: 2V16EO95HI)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-103-10	1 in 1 BOX		
1	NDC:13537-103-09	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/31/2014	

LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (VIN) - PURPLE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-104
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.071 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.016 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ethylhexyl palmitate (UNII: 2865993309)	
dipentaerythrityl hexacaprylate/hexacaprate (UNII: 554N82UWVW)	
tridecyl trimellitate (UNII: FY36J270ES)	
high density polyethylene (UNII: UG00KM4WR7)	
shea butter (UNII: K49155WL9Y)	
tridecyl stearate (UNII: A8OE252M6L)	
carnauba wax (UNII: R12CBM0EIZ)	
neopentyl glycol dicaprylate/dicaprate (UNII: VLW429K27K)	
disteardimonium hectorite (UNII: X687XDK09L)	

octyldodecanol (UNII: 461N1O614Y)
medium-chain triglycerides (UNII: C9H2L21V7U)
phenoxyethanol (UNII: HIE492ZZ3T)
propylene carbonate (UNII: 8D08K3S51E)
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)
microcrystalline wax (UNII: XOF597Q3KY)
silicon dioxide (UNII: ETJ7Z6XBU4)
methylparaben (UNII: A218C7H9T)
petrolatum (UNII: 4T6H12BN9U)
butylated hydroxytoluene (UNII: 1P9D0Z171K)
cholesterol (UNII: 97C5T2UQ7J)
propylparaben (UNII: Z8IX2SC1OH)
aloe vera leaf (UNII: ZY81Z83H0X)
butylparaben (UNII: 3QPHU3FV8)
ethylparaben (UNII: 14255EXE39)
butylated hydroxyanisole (UNII: REK4960K2U)
candelilla wax (UNII: WL0328HX19)
yellow wax (UNII: 2ZA36H0S2V)
cetostearyl alcohol (UNII: 2DMT128M1S)
cetearyl glucoside (UNII: 09FUA47KNA)
polyglyceryl-2 dipolyhydroxystearate (UNII: 9229XJ4V12)
isobutylparaben (UNII: 0QQJ25X58G)
mica (UNII: V8A1AW0880)
d&c red no. 7 (UNII: ECW0LZ41X8)
aluminum oxide (UNII: LMI26O6933)
ferric oxide red (UNII: 1K09F3G675)
titanium dioxide (UNII: 15FIX9V2JP)
d&c red no. 30 (UNII: 2S42T2808B)
fd&c yellow no. 5 (UNII: I753WB2F1M)
d&c red no. 21 (UNII: 08744Z6JNY)
bismuth oxychloride (UNII: 4ZR792I587)
fd&c red no. 40 (UNII: WZB9127XOA)
talc (UNII: 7SEV7J4RIU)
fd&c blue no. 1 (UNII: H3R47K3TBD)
palmitic acid (UNII: 2V16EO95H1)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-104-12	1 in 1 BOX		
1	NDC:13537-104-11	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/31/2014	

LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (FUCHSIA INTENSE) - PURPLE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-105
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.071 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.016 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ethylhexyl palmitate (UNII: 2865993309)	
dipentaerythrityl hexacaprylate/hexacaprate (UNII: 554N82UWVW)	
tridecyl trimellitate (UNII: FY36J270ES)	
high density polyethylene (UNII: UG00KM4WR7)	
shea butter (UNII: K49155WL9Y)	
tridecyl stearate (UNII: A8OE252M6L)	
carnauba wax (UNII: R12CBM0EIZ)	
neopentyl glycol dicaprylate/dicaprate (UNII: VLW429K27K)	
disteardimonium hectorite (UNII: X687XDK09L)	
octyldodecanol (UNII: 461N1O614Y)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
phenoxyethanol (UNII: HIE492ZZ3T)	
propylene carbonate (UNII: 8D08K3S51E)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
microcrystalline wax (UNII: XOF597Q3KY)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
methylparaben (UNII: A2I8C7HI9T)	
petrolatum (UNII: 4T6H12BN9U)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
cholesterol (UNII: 97C5T2UQ7J)	
propylparaben (UNII: Z8IX2SC1OH)	
aloe vera leaf (UNII: ZY81Z83H0X)	
butylparaben (UNII: 3QP1U3FV8)	
ethylparaben (UNII: 14255EXE39)	
butylated hydroxyanisole (UNII: REK4960K2U)	
candelilla wax (UNII: WL0328HX19)	
yellow wax (UNII: 2ZA36H0S2V)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetearyl glucoside (UNII: 09FUA47KNA)	
polyglyceryl-2 dipolyhydroxystearate (UNII: 9229XJ4V12)	
isobutylparaben (UNII: 0QQJ25X58G)	

mica (UNII: V8A1AW0880)
d&c red no. 7 (UNII: ECW0LZ41X8)
aluminum oxide (UNII: LM26O6933)
ferric oxide red (UNII: 1K09F3G675)
titanium dioxide (UNII: 15FIX9V2JP)
d&c red no. 30 (UNII: 2S42T2808B)
fd&c yellow no. 5 (UNII: I753WB2F1M)
d&c red no. 21 (UNII: 08744Z6JNY)
bismuth oxychloride (UNII: 4ZR792I587)
fd&c red no. 40 (UNII: WZB9127XOA)
talc (UNII: 7SEV7J4R1U)
fd&c blue no. 1 (UNII: H3R47K3TBD)
palmitic acid (UNII: 2V16EO95H1)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-105-14	1 in 1 BOX		
1	NDC:13537-105-13	4 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/31/2014	

LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (ROUGE BRILLANCE) - BROWN
 octinoxate and oxybenzone lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-106
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.071 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.016 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
ethylhexyl palmitate (UNII: 2865993309)	
dipentaerythrityl hexacaprylate/hexacaprate (UNII: 554N82UWVW)	
tridecyl trimellitate (UNII: FY36J270ES)	
high density polyethylene (UNII: UG00KM4WR7)	

shea butter (UNII: K49155WL9Y)
tridecyl stearate (UNII: A8OE252M6L)
carnauba wax (UNII: R12CBM0EIZ)
neopentyl glycol dicaprylate/dicaprate (UNII: VLW429K27K)
disteardimonium hectorite (UNII: X687XDK09L)
octyldodecanol (UNII: 461N1O614Y)
medium-chain triglycerides (UNII: C9H2L21V7U)
phenoxyethanol (UNII: HIE492ZZ3T)
propylene carbonate (UNII: 8D08K3S51E)
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)
microcrystalline wax (UNII: XOF597Q3KY)
silicon dioxide (UNII: ETJ7Z6XBU4)
methylparaben (UNII: A218C7H19T)
petrolatum (UNII: 4T6H12BN9U)
butylated hydroxytoluene (UNII: 1P9D0Z171K)
cholesterol (UNII: 97C5T2UQ7J)
propylparaben (UNII: Z8IX2SC10H)
aloe vera leaf (UNII: ZY81Z83H0X)
butylparaben (UNII: 3QPHU3FV8)
ethylparaben (UNII: 14255EXE39)
butylated hydroxyanisole (UNII: REK4960K2U)
candelilla wax (UNII: WL0328HX19)
yellow wax (UNII: 2ZA36H0S2V)
cetostearyl alcohol (UNII: 2DMT128M1S)
cetearyl glucoside (UNII: 09FUA47KNA)
polyglyceryl-2 dipolyhydroxystearate (UNII: 9229XJ4V12)
isobutylparaben (UNII: 0QQJ25X58G)
mica (UNII: V8A1AW0880)
d&c red no. 7 (UNII: ECW0LZ41X8)
aluminum oxide (UNII: LMI26O6933)
ferric oxide red (UNII: 1K09F3G675)
titanium dioxide (UNII: 15FIX9V2JP)
d&c red no. 30 (UNII: 2S42T2808B)
fd&c yellow no. 5 (UNII: I753WB2F1M)
d&c red no. 21 (UNII: 08744Z6JNY)
bismuth oxychloride (UNII: 4ZR792I587)
fd&c red no. 40 (UNII: WZB9127XOA)
talc (UNII: 7SEV7J4R1U)
fd&c blue no. 1 (UNII: H3R47K3TBD)
palmitic acid (UNII: 2V16EO95H1)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-106-16	1 in 1 BOX		
1	NDC:13537-106-15	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/31/2014	

LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (ROUGE INTENSE) - PURPLE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-107
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.071 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.016 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ethylhexyl palmitate (UNII: 2865993309)	
dipentaerythrityl hexacaprylate/hexacaprate (UNII: 554N82UWVW)	
tridecyl trimellitate (UNII: FY36J270ES)	
high density polyethylene (UNII: UG00KM4WR7)	
shea butter (UNII: K49155WL9Y)	
tridecyl stearate (UNII: A8OE252M6L)	
carnauba wax (UNII: R12CBM0EIZ)	
neopentyl glycol dicaprylate/dicaprate (UNII: VLW429K27K)	
disteardimonium hectorite (UNII: X687XDK09L)	
octyldodecanol (UNII: 461N10614Y)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
phenoxyethanol (UNII: HIE492ZZ3T)	
propylene carbonate (UNII: 8D08K3S51E)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
microcrystalline wax (UNII: XOF597Q3KY)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
methylparaben (UNII: A2I8C7HI9T)	
petrolatum (UNII: 4T6H12BN9U)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
cholesterol (UNII: 97C5T2UQ7J)	
propylparaben (UNII: Z8IX2SC1OH)	
aloe vera leaf (UNII: ZY81Z83H0X)	
butylparaben (UNII: 3QPII1U3FV8)	
ethylparaben (UNII: 14255EXE39)	
butylated hydroxyanisole (UNII: REK4960K2U)	
candelilla wax (UNII: WL0328HX19)	
yellow wax (UNII: 2ZA36H0S2V)	

cetostearyl alcohol (UNII: 2DMT128M1S)
cetearyl glucoside (UNII: 09FUA47KNA)
polyglyceryl-2 dipolyhydroxystearate (UNII: 9229XJ4V12)
isobutylparaben (UNII: 0QQJ25X58G)
mica (UNII: V8A1AW0880)
d&c red no. 7 (UNII: ECW0LZ41X8)
aluminum oxide (UNII: LM26O6933)
ferric oxide red (UNII: 1K09F3G675)
titanium dioxide (UNII: 15FIX9V2JP)
d&c red no. 30 (UNII: 2S42T2808B)
fd&c yellow no. 5 (UNII: I753WB2F1M)
d&c red no. 21 (UNII: 08744Z6JNY)
bismuth oxychloride (UNII: 4ZR792I587)
fd&c red no. 40 (UNII: WZB9127XOA)
talc (UNII: 7SEV7J4RIU)
fd&c blue no. 1 (UNII: H3R47K3TBD)
palmitic acid (UNII: 2V16EO95H1)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-107-18	1 in 1 BOX		
1	NDC:13537-107-17	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/31/2014	

LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (FUCHSIA BRILLANCE) - RED

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-108
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.071 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.016 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
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ethylhexyl palmitate (UNII: 2865993309)
dipentaerythryl hexacaprylate/hexacaprate (UNII: 554N82UWVW)
tridecyl trimellitate (UNII: FY36J270ES)
high density polyethylene (UNII: UG00KM4WR7)
shea butter (UNII: K49155WL9Y)
tridecyl stearate (UNII: A8OE252M6L)
carnauba wax (UNII: R12CBM0EIZ)
neopentyl glycol dicaprylate/dicaprate (UNII: VLW429K27K)
disteardimonium hectorite (UNII: X687XDK09L)
octyldodecanol (UNII: 461N1O614Y)
medium-chain triglycerides (UNII: C9H2L21V7U)
phenoxyethanol (UNII: HIE492ZZ3T)
propylene carbonate (UNII: 8D08K3S51E)
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)
microcrystalline wax (UNII: XOF597Q3KY)
silicon dioxide (UNII: ETJ7Z6XBU4)
methylparaben (UNII: A218C7HI9T)
petrolatum (UNII: 4T6H12BN9U)
butylated hydroxytoluene (UNII: 1P9D0Z171K)
cholesterol (UNII: 97C5T2UQ7J)
propylparaben (UNII: Z8IX2SC10H)
aloe vera leaf (UNII: ZY81Z83H0X)
butylparaben (UNII: 3QPHU3FV8)
ethylparaben (UNII: 14255EXE39)
butylated hydroxyanisole (UNII: REK4960K2U)
candelilla wax (UNII: WL0328HX19)
yellow wax (UNII: 2ZA36H0S2V)
cetostearyl alcohol (UNII: 2DMT128M1S)
cetearyl glucoside (UNII: 09FUA47KNA)
polyglyceryl-2 dipolyhydroxystearate (UNII: 9229XJ4V12)
isobutylparaben (UNII: 0QQJ25X58G)
mica (UNII: V8A1AW0880)
d&c red no. 7 (UNII: ECW0LZ41X8)
aluminum oxide (UNII: LMI26O6933)
ferric oxide red (UNII: 1K09F3G675)
titanium dioxide (UNII: 15FIX9V2JP)
d&c red no. 30 (UNII: 2S42T2808B)
fd&c yellow no. 5 (UNII: I753WB2F1M)
d&c red no. 21 (UNII: 08744Z6JNY)
bismuth oxychloride (UNII: 4ZR792I587)
fd&c red no. 40 (UNII: WZB9127XOA)
talc (UNII: 7SEV7J4RIU)
fd&c blue no. 1 (UNII: H3R47K3TBD)
palmitic acid (UNII: 2V16EO95H1)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-108-20	1 in 1 BOX		

1	NDC:13537-108-19	4 g in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part352	01/31/2014		

LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (ROSE BRILLANCE) - RED

octinoxate and oxybenzone lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-109
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.071 g in 1 g
	Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.016 g in 1 g
Inactive Ingredients			
	Ingredient Name	Strength	
	ethylhexyl palmitate (UNII: 2865993309)		
	dipentaerythrityl hexacaprylate/hexacaprate (UNII: 554N82UWVW)		
	tridecyl trimellitate (UNII: FY36J270ES)		
	high density polyethylene (UNII: UG00KM4WR7)		
	shea butter (UNII: K49155WL9Y)		
	tridecyl stearate (UNII: A8OE252M6L)		
	carnauba wax (UNII: R12CBM0EIZ)		
	neopentyl glycol dicaprylate/dicaprate (UNII: VLW429K27K)		
	disteardimonium hectorite (UNII: X687XDK09L)		
	octyldodecanol (UNII: 461N1O614Y)		
	medium-chain triglycerides (UNII: C9H2L21V7U)		
	phenoxyethanol (UNII: HIE492ZZ3T)		
	propylene carbonate (UNII: 8D08K3S51E)		
	.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)		
	microcrystalline wax (UNII: XOF597Q3KY)		
	silicon dioxide (UNII: ETJ7Z6XBU4)		
	methylparaben (UNII: A2I8C7HI9T)		
	petrolatum (UNII: 4T6H12BN9U)		
	butylated hydroxytoluene (UNII: 1P9D0Z171K)		
	cholesterol (UNII: 97C5T2UQ7J)		
	propylparaben (UNII: Z8IX2SC1OH)		
	aloe vera leaf (UNII: ZY81Z83HOX)		

butylparaben (UNII: 3QP1U3FV8)
ethylparaben (UNII: 14255EXE39)
butylated hydroxyanisole (UNII: REK4960K2U)
candelilla wax (UNII: WL0328HX19)
yellow wax (UNII: 2ZA36H0S2V)
cetostearyl alcohol (UNII: 2DMT128M1S)
cetearyl glucoside (UNII: 09FUA47KNA)
polyglyceryl-2 dipolyhydroxystearate (UNII: 9229XJ4V12)
isobutylparaben (UNII: 0QQJ25X58G)
mica (UNII: V8A1AW0880)
d&c red no. 7 (UNII: ECW0LZ41X8)
aluminum oxide (UNII: LM26O6933)
ferric oxide red (UNII: 1K09F3G675)
titanium dioxide (UNII: 15FIX9V2JP)
d&c red no. 30 (UNII: 2S42T2808B)
fd&c yellow no. 5 (UNII: I753WB2F1M)
d&c red no. 21 (UNII: 08744Z6JNY)
bismuth oxychloride (UNII: 4ZR792I587)
fd&c red no. 40 (UNII: WZB9127XOA)
talc (UNII: 7SEV7J4RIU)
fd&c blue no. 1 (UNII: H3R47K3TBD)
palmitic acid (UNII: 2V16EO95H1)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-109-22	1 in 1 BOX		
1	NDC:13537-109-21	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/31/2014	

LBEL COULEUR LUXE ROUGE IRRESISTIBLE MAXIMUM HYDRATION SPF 17 (ROSE CLASSIQUE) - RED

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.071 g in 1 g

Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)

Oxybenzone

0.016 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ethylhexyl palmitate (UNII: 2865993309)	
dipentaerythrityl hexacaprylate/hexacaprate (UNII: 554N82UWVW)	
tridecyl trimellitate (UNII: FY36J270ES)	
high density polyethylene (UNII: UG00KM4WR7)	
shea butter (UNII: K49155WL9Y)	
tridecyl stearate (UNII: A8OE252M6L)	
carnauba wax (UNII: R12CBM0EIZ)	
neopentyl glycol dicaprylate/dicaprate (UNII: VLW429K27K)	
disteardimonium hectorite (UNII: X687XDK09L)	
octyldodecanol (UNII: 461N1O614Y)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
phenoxyethanol (UNII: HIE492ZZ3T)	
propylene carbonate (UNII: 8D08K3S51E)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
microcrystalline wax (UNII: XOF597Q3KY)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
methylparaben (UNII: A218C7H19T)	
petrolatum (UNII: 4T6H12BN9U)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
cholesterol (UNII: 97C5T2UQ7J)	
propylparaben (UNII: Z8IX2SC10H)	
aloe vera leaf (UNII: ZY81Z83H0X)	
butylparaben (UNII: 3QPHU3FV8)	
ethylparaben (UNII: 14255EXE39)	
butylated hydroxyanisole (UNII: REK4960K2U)	
candelilla wax (UNII: WL0328HX19)	
yellow wax (UNII: 2ZA36H0S2V)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetearyl glucoside (UNII: 09FUA47KNA)	
polyglyceryl-2 dipolyhydroxystearate (UNII: 9229XJ4V12)	
isobutylparaben (UNII: 0QQJ25X58G)	
mica (UNII: V8A1AW0880)	
d&c red no. 7 (UNII: ECW0LZ41X8)	
aluminum oxide (UNII: LMI26O6933)	
ferric oxide red (UNII: 1K09F3G675)	
titanium dioxide (UNII: 15FIX9V2JP)	
d&c red no. 30 (UNII: 2S42T2808B)	
fd&c yellow no. 5 (UNII: I753WB2F1M)	
d&c red no. 21 (UNII: 08744Z6JNY)	
bismuth oxychloride (UNII: 4ZR792I587)	
fd&c red no. 40 (UNII: WZB9127XOA)	
talc (UNII: 7SEV7J4RIU)	
fd&c blue no. 1 (UNII: H3R47K3TBD)	
palmitic acid (UNII: 2V16EO95H1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-111-24	1 in 1 BOX		
1	NDC:13537-111-23	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/31/2014	

Labeler - Ventura Corporation LTD (602751344)**Establishment**

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-100, 13537-101, 13537-443, 13537-102, 13537-103, 13537-104, 13537-105, 13537-106, 13537-107, 13537-108, 13537-109, 13537-111)

Revised: 2/2014

Ventura Corporation LTD