

**LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - MOKA-
octinoxate and oxybenzone lipstick**
**LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - ROMANCE-
octinoxate and oxybenzone lipstick**
**LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - ROSE
NATURAL- octinoxate and oxybenzone lipstick**
**LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - ROSE
CLASIQUE- octinoxate and oxybenzone lipstick**
**LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - ROUGE
INTENSE- octinoxate and oxybenzone lipstick**
**LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - AMOUR-
octinoxate and oxybenzone lipstick**
**LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - CHOCOLAT-
octinoxate and oxybenzone lipstick**
**LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - ALMOND-
octinoxate and oxybenzone lipstick**
**LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - MALVE-
octinoxate and oxybenzone lipstick**
**LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - MARRON
GLACE- octinoxate and oxybenzone lipstick**
**LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - TULIP-
octinoxate and oxybenzone lipstick**
**LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - NUDE- octinoxate
and oxybenzone lipstick**
**LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - LILY BEIGE-
octinoxate and oxybenzone lipstick**
**LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - MANDARINE-
octinoxate and oxybenzone lipstick**
**LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - VIN- octinoxate
and oxybenzone lipstick**
Ventura International 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 HYDRATESS
long-lasting intense moisturizing SPF 20**

Drug Facts

Active Ingredients

OCTINOXATE: 7.1%; OXYBENZONE: 1.6%

Purpose

Sunscreen

Uses

- Helps prevent sunburn

Warnings

- Skin Cancer / Skin Aging Alert; Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.
- For external use only.
- Do not use on damage or broken skin.
- When using this product keep out of eyes. Rinse with water to remove.
- Stop use and ask a doctor if rash occurs.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Children under 6 months of age: Ask a doctor.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Apply lipstick following the curves of natural lip line. For added definition, use with a lip pencil.

Other information

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

Inactive ingredients

CAPRYLIC/CAPRIC TRIGLYCERIDE, DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL TRIMELLITATE, MICA, TRIDECYL STEARATE, POLYETHYLENE, COPERNICIA CERIFERA CERA (COPERNICIA CERIFERA (CARNAUBA) WAX), OZOKERITE, POLYMETHYL METHACRYLATE, NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE, DISTEARDIMONIUM HECTORITE, PROPYLENE CARBONATE, PHENOXYETHANOL, COCOS NUCIFERA OIL (COCOS NUCIFERA (COCONUT) OIL), TOCOPHERYL ACETATE, ALOE BARBADENSIS LEAF EXTRACT, SILICA, PARFUM (FRAGRANCE), BUTYROSPERMUM PARKII BUTTER (BUTYROSPERMUM PARKII (SHEA) BUTTER), Elaeis Guineensis (Palm) Oil, Gossypium Herbaceum (Cotton) Seed Oil, Bidens Pilosa Extract, DIMETHICONE, CAPRYLYL GLYCOL, Linum Usitatissimum (Linseed) Seed Oil, CHLORPHENESIN, BHT, CERAMIDE 3, CRAMBE MARITIMA EXTRACT, TRIMETHYLSILOXYSILICATE, PROPYLPARABEN, TOCOPHEROL

MAY CONTAIN:

RED 7 LAKE, TITANIUM DIOXIDE, IRON OXIDES, MICA, YELLOW 5 LAKE, RED 30 LAKE, TALC, BLUE 1 LAKE, RED 27 LAKE, CARMINE.

US: Dist by Ventura Int Ltd. DBA Belcorp USA, San Francisco, CA 94111.

PRINCIPAL DISPLAY PANEL - 4g Tube Box - MOKA

HYDRATESS

long-lasting intense moisturizing lipstick SPF 20

4 g e (.14 oz.)

L'BEL



PRINCIPAL DISPLAY PANEL - 4g Tube Box - ROMANCE

HYDRATESS

long-lasting intense moisturizing lipstick SPF 20

4 g e (.14 oz.)

L'BEL



PRINCIPAL DISPLAY PANEL - 4g Tube Box - ROSE NATURAL

HYDRATESS

long-lasting intense moisturizing lipstick SPF 20

4 g e (.14 oz.)

L'BEL



ROSE
NATURAL

US: Dist by Ventura Int Ltd, DBA
Belcorp USA, San Francisco, CA
94111, P.A.: Dist by Ventura Corp,
Ltd., San Juan, Puerto Rico 00926.
Made in Colombia www.lbel.com

Drug Facts (continued)

■ When using this product keep out of eyes. Rinse with water to remove. • Stop use and ask a doctor if rash occurs. ■ Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

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

Other Information:

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

Drug Facts (continued)

Inactive Ingredients: caprylic/capric triglyceride, dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, mica, tridecyl stearate, polyethylene, copernicia cerifera cera (copernicia cerifera (carnauba) wax), ozokerite, polymethyl methacrylate, neopentyl glycol dicaprylate/dicaprate, disteardimonium hectorite, propylene carbonate, phenylethanol, cocos nucifera oil (cocos nucifera (coconut) oil), tocopheryl acetate, alca barbadensis leaf extract, silica, parfum (fragrance), butyrospermium parkii butter (butyrospermium parkii (shea) butter), elaeis guineensis (palm) oil, gossypium herbaceum (cotton) seed oil, bidens pilosa extract, dimethicone, caprylyl glycol, linum usitatissimum (linseed) seed oil, chlorophanesin, bht, caramide 3, crambe maritima extract, trimethylsilyloxysilicate, propylparaben, tocopherol. May contain: red 7 lake, titanium dioxide, iron oxides, mica, yellow 5 lake, red 30 lake, lake, blue 1 lake, red 27 lake, carmine.

HYDRATESS

lápiz labial de hidratación profunda y prolongada FPS 20
long-lasting intense moisturizing lipstick SPF 20

4g e (.14 oz.)

L'BEL

Active Ingredients **Purpose**

Ocinoxate: 7.1%; 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 damage or broken skin. ▶

PRINCIPAL DISPLAY PANEL - 4g Tube Box - ROSE CLASIQUE

HYDRATESS

long-lasting intense moisturizing lipstick SPF 20

4 g e (.14 oz.)

L'BEL



ROSE
CLASSIQUE

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Belcorp USA, San Francisco, CA
94111. P.A.: Dist by Ventura Corp,
Ltd., San Juan, Puerto Rico, 00926.
Made in Colombia www.lbel.com

Drug Facts (continued)
 ■ When using this product keep out of eyes. Rinse with water to remove. ■ Stop use and ask a doctor if rash occurs. ■ Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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

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

Drug Facts (continued)
Inactive Ingredients: caprylic/capric triglyceride, dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, mica, tridecyl stearate, polyethylene, copernicia cerifera cera (copernicia cerifera (carnauba) wax), ozokerite, polymethyl methacrylate, neopentyl glycol dicaprylate/dicaprate, disteardimonium Hectorite, propylene carbonate, phenoxethanol, cocos nucifera oil (cocos nucifera (coconut) oil), tocopheryl acetate, albe barbadensis leaf extract, silica, parfum (fragrance), butyrospermum parkii butter (butyrospermum parkii (shea) butter), elaeis guineensis (palm) oil, gossypium hirsutum (cotton) seed oil, bidens pilosa extract, dimethicone, caprylyl glycol, linum usitatissimum (linseed) seed oil, chlorphenesin, bht, caramide 3, crambe maritima extract, trimethylsilyloxysilicate, propylparaben, tocopherol. May contain: red 7 lake, titanium dioxide, iron oxides, mica, yellow 5 lake, red 30 lake, talc, blue 1 lake, red 27 lake, carmine.

HYDRATESS
 lápiz labial de hidratación profunda y prolongada FPS 20
 long-lasting intense moisturizing lipstick SPF 20

4 g e (.14 oz.)

L'BEL

Active Ingredients	Purpose
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Uses ■ Helps prevent sunburn.

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

PRINCIPAL DISPLAY PANEL - 4g Tube Box - ROUGE INTENSE

HYDRATESS

long-lasting intense moisturizing lipstick SPF 20

4 g e (.14 oz.)

L'BEL



PRINCIPAL DISPLAY PANEL - 4g Tube Box - AMOUR

HYDRATESS

long-lasting intense moisturizing lipstick SPF 20

4 g e (.14 oz.)

L'BEL



AMOUR

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Ltd. San Juan, Puerto Rico 00926.
Made in Colombia www.bel.com

Drug Facts (continued)

■ When using this product keep out of eyes. Rinse with water to remove. ■ Stop use and ask a doctor if rash occurs. ■ Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

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

Other information:

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

Drug Facts (continued)

Inactive Ingredients: caprylic/capric triglyceride, dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, mica, didecyl stearate, polyethylene, copernicia cerifera cera (copernicia cerifera (carnauba) wax), ozokerite, polymethyl methacrylate, neopentyl glycol dicaprylate/dicaprate, disteardimonium hectorite, propylene carbonate, phenylethanol, cocos nucifera oil (cocos nucifera (coconut) oil), tocopheryl acetate, alce barbaricis leaf extract, silica, parfum (fragrance), butyrospermum parkii butter (butyrospermum parkii (shea) butter), elaeis guineensis (palm) oil, gossypium hirsutum (cotton) seed oil, bidens pilosa extract, dimethicone, caprylyl glycol, linum usitatissimum (linseed) seed oil, chlorphenesin, bht, caramide 3, crambe maritima extract, trimethylsiloxysilicate, propylparaben, tocopherol. May contain: red 7 lake, titanium dioxide, iron oxides, mica, yellow 5 lake, red 30 lake, lake, blue 1 lake, red 27 lake, carmine.

HYDRATESS

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long-lasting intense moisturizing lipstick SPF 20

4g e (.14 oz.)

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Active Ingredients	Purpose
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Uses ■ Helps prevent sunburn.

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PRINCIPAL DISPLAY PANEL - 4g Tube Box - CHOCOLAT

HYDRATESS

long-lasting intense moisturizing lipstick SPF 20

4 g e (.14 oz.)

L'BEL



PRINCIPAL DISPLAY PANEL - 4g Tube Box - ALMOND

HYDRATESS

long-lasting intense moisturizing lipstick SPF 20

4 g e (.14 oz.)

L'BEL



PRINCIPAL DISPLAY PANEL - 4g Tube Box - MALVE

HYDRATESS

long-lasting intense moisturizing lipstick SPF 20

4 g e (.14 oz.)

L'BEL



PRINCIPAL DISPLAY PANEL - 4g Tube Box - MARRON GLACÉ

HYDRATESS

long-lasting intense moisturizing lipstick SPF 20

4 g e (.14 oz.)

L'BEL



PRINCIPAL DISPLAY PANEL - 4g Tube Box - TULIP

HYDRATESS

long-lasting intense moisturizing lipstick SPF 20

4 g e (.14 oz.)

L'BEL



PRINCIPAL DISPLAY PANEL - 4g Tube Box - NUDE

HYDRATESS

long-lasting intense moisturizing lipstick SPF 20

4 g e (.14 oz.)

L'BEL



NUDE

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Drug Facts (continued)

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

Drug Facts (continued)

Inactive Ingredients: caprylic/capric triglyceride, dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, mica, triethyl stearate, polyethylene, copernicia cerifera cera (copernicia cerifera (carnauba) wax), ozokerite, polymethyl methacrylate, neopentyl glycol dicaprylate/dicaprate, disteardimonium hectorite, propylene carbonate, phenylethanol, cocos nucifera oil (cocos nucifera (coconut) oil), tocopheryl acetate, alba barbadensis leaf extract, silica, parfum (fragrance), butyrospermum parkii butter (butyrospermum parkii (shea) butter), elaeis guineensis (palm) oil, gossypium hirsutum (cotton) seed oil, bidens pilosa extract, dimethicone, caprylyl glycol, linum usitatissimum (linseed) seed oil, chlorphenesin, bht, caramide 3, crambe maritima extract, trimethylsiloxysilicate, propylparaben, tocopherol. May contain: red 7 lake, titanium dioxide, iron oxides, mica, yellow 5 lake, red 30 lake, talc, blue 1 lake, red 27 lake, carmine.

HYDRATESS

lápiz labial de hidratación profunda y prolongada FPS 20
long-lasting intense moisturizing lipstick SPF 20

4g e (.14 oz.)

L'BEL

Active Ingredients	Purpose
Oclinoxate: 7.1%; 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 damage or broken skin. ▶

PRINCIPAL DISPLAY PANEL - 4g Tube Box - LILY BEIGE

HYDRATESS

long-lasting intense moisturizing lipstick SPF 20

4 g e (.14 oz.)

L'BEL



LILY BEIGE

US: Dist by Ventura Int'l Ltd. DBA
Belcorp USA, San Francisco, CA
94111. P.R.: Dist by Ventura Corp.
Ltc., San Juan, Puerto Rico 00926.
Made in Colombia. www.lbel.com

Drug Facts (continued)

■ When using this product keep out of eyes. Rinse with water to remove. • Stop use and ask a doctor if rash occurs. ■ Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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

Other information: ■ Protect the product in this container from excessive heat and direct sun

Drug Facts (continued)

Inactive Ingredients: caprylic/capric triglyceride, dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, mica, tridecyl stearate, polyethylene, copernicia cerifera ceta (copernicia cerifera (carnauba) wax), ozokerite, polymethyl methacrylate, neopentyl glycol dicaprylate/dicaprate, disteardimonium hectorite, propylene carbonate, phenoxethanol, cocos nucifera oil (cocos nucifera (coconut) oil), tocopheryl acetate, aloe barbadensis leaf extract, silica, parfum (fragrance), butyrospermum parkii butter (butyrospermum parkii (shea) butter), elaeis guineensis (palm) oil, gossypium herbaceum (cotton) seed oil, bidens pilosa extract, dimethicone, caprylyl glycol, linum usitatissimum (linseed) seed oil, chlorphenesin, bht, caramide 3, crambe maritima extract, trimethylsiloxysilicate, propylparaben, tocopherol. May contain: red 7 lake, titanium dioxide, iron oxides, mica, yellow 5 lake, red 30 lake, lake, blue 1 lake, red 27 lake, carmine.

HYDRATESS

lápiz labial de hidratación profunda y prolongada FPS 20
long-lasting intense moisturizing lipstick SPF 20

4 g e (.14 oz.)

L'BEL

Active Ingredients	Purpose
Octinoxate: 7.1%; 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 damage or broken skin ▶

PRINCIPAL DISPLAY PANEL - 4g Tube Box - MANDARINE

HYDRATESS

long-lasting intense moisturizing lipstick SPF 20

4 g e (.14 oz.)

L'BEL



PRINCIPAL DISPLAY PANEL - 4g Tube Box - VIN

HYDRATESS

long-lasting intense moisturizing lipstick SPF 20

4 g e (.14 oz.)

L'BEL



LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - MOKA

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-095
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
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MICA (UNII: V8A1AW0880)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SHEA BUTTER (UNII: K49155WL9Y)	
Palm Oil (UNII: 5QUO05548Z)	
Levant Cottonseed Oil (UNII: N5CFT140R8)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
Linseed Oil (UNII: 84XB4DV00W)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CERAMIDE 3 (UNII: 4370DF050B)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TOCOPHEROL (UNII: R0ZB2556P8)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

Product Characteristics

Color	BROWN (Pink brown)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-095-02	1 in 1 BOX		
1	NDC:14783-095-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/27/2013	

LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - ROMANCE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-096
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
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MICA (UNII: V8A1AW0880)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SHEA BUTTER (UNII: K49155WL9Y)	
Palm Oil (UNII: 5QUO05548Z)	
Levant Cottonseed Oil (UNII: N5CFT140R8)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
Linseed Oil (UNII: 84XB4DV00W)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CERAMIDE 3 (UNII: 4370DF050B)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

TOCOPHEROL (UNII: R0ZB2556P8)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

Product Characteristics

Color	PINK (Dark magenta)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-096-02	1 in 1 BOX		
1	NDC:14783-096-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/27/2013	

LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - ROSE NATURAL

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-097
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
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
MICA (UNII: V8A1AW0880)
TRIDECYL STEARATE (UNII: A8OE252M6L)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
CARNAUBA WAX (UNII: R12CBM0EIZ)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SHEA BUTTER (UNII: K49155WL9Y)
Palm Oil (UNII: 5QUO05548Z)
Levant Cottonseed Oil (UNII: N5CFT140R8)
DIMETHICONE (UNII: 92RU3N3Y1O)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
Linseed Oil (UNII: 84XB4DV00W)
CHLORPHENESIN (UNII: I670DAL4SZ)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
CERAMIDE 3 (UNII: 4370DF050B)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
TOCOPHEROL (UNII: R0ZB2556P8)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 30 (UNII: 2S42T2808B)
TALC (UNII: 7SEV7J4RIU)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
D&C RED NO. 27 (UNII: 2LRS185U6K)

Product Characteristics

Color	PINK (Intense yellowish pink)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-097-02	1 in 1 BOX		
1	NDC:14783-097-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/27/2013	

LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - ROSE CLASIQUE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-098
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
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MICA (UNII: V8A1AW0880)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SHEA BUTTER (UNII: K49155WL9Y)	
Palm Oil (UNII: 5QUO05548Z)	
Levant Cottonseed Oil (UNII: N5CFT140R8)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
Linseed Oil (UNII: 84XB4DV00W)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CERAMIDE 3 (UNII: 4370DF050B)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TOCOPHEROL (UNII: R0ZB2556P8)	

D&C RED NO. 7 (UNII: ECW0LZ41X8)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

Product Characteristics

Color	PINK (Intense bluish pink)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-098-02	1 in 1 BOX		
1	NDC:14783-098-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/27/2013	

LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - ROUGE INTENSE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-099
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
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
MICA (UNII: V8A1AW0880)
TRIDECYL STEARATE (UNII: A8OE252M6L)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
CARNAUBA WAX (UNII: R12CBM0EIZ)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SHEA BUTTER (UNII: K49155WL9Y)
Palm Oil (UNII: 5QUO05548Z)
Levant Cottonseed Oil (UNII: N5CFT140R8)
DIMETHICONE (UNII: 92RU3N3Y1O)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
Linseed Oil (UNII: 84XB4DV00W)
CHLORPHENESIN (UNII: I670DAL4SZ)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
CERAMIDE 3 (UNII: 4370DF050B)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
TOCOPHEROL (UNII: R0ZB2556P8)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 30 (UNII: 2S42T2808B)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
D&C RED NO. 27 (UNII: 2LRS185U6K)

Product Characteristics			
Color	RED (Bluish red)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-099-02	1 in 1 BOX		
1	NDC:14783-099-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/27/2013	

LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - AMOUR

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-100
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
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MICA (UNII: V8A1AW0880)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SHEA BUTTER (UNII: K49155WL9Y)	
Palm Oil (UNII: 5QUO05548Z)	
Levant Cottonseed Oil (UNII: N5CFT140R8)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
Linseed Oil (UNII: 84XB4DV00W)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CERAMIDE 3 (UNII: 4370DF050B)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TOCOPHEROL (UNII: R0ZB2556P8)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	

ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

Product Characteristics

Color	BROWN (Red brown)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-100-02	1 in 1 BOX		
1	NDC:14783-100-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/27/2013	

LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - CHOCOLAT

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-101
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
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	

MICA (UNII: V8A1AW0880)
TRIDECYL STEARATE (UNII: A8OE252M6L)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
CARNAUBA WAX (UNII: R12CBM0EIZ)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SHEA BUTTER (UNII: K49155WL9Y)
Palm Oil (UNII: 5QUO05548Z)
Levant Cottonseed Oil (UNII: N5CFT140R8)
DIMETHICONE (UNII: 92RU3N3Y1O)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
Linseed Oil (UNII: 84XB4DV00W)
CHLORPHENESIN (UNII: I670DAL4SZ)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
CERAMIDE 3 (UNII: 4370DF050B)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
TOCOPHEROL (UNII: R0ZB2556P8)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 30 (UNII: 2S42T2808B)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
D&C RED NO. 27 (UNII: 2LRS185U6K)

Product Characteristics

Color	BROWN (Yellowish brown)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-101-02	1 in 1 BOX		
1	NDC:14783-101-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - ALMOND

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-102
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
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MICA (UNII: V8A1AW0880)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SHEA BUTTER (UNII: K49155WL9Y)	
Palm Oil (UNII: 5QUO05548Z)	
Levant Cottonseed Oil (UNII: N5CFT140R8)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
Linseed Oil (UNII: 84XB4DV00W)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CERAMIDE 3 (UNII: 4370DF050B)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TOCOPHEROL (UNII: R0ZB2556P8)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
ALUMINUM OXIDE (UNII: LM26O6933)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

Product Characteristics

Color	BROWN (Reddish brown)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-102-02	1 in 1 BOX		
1	NDC:14783-102-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/27/2013	

LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - MALVE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-103
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
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MICA (UNII: V8A1AW0880)	

TRIDECYL STEARATE (UNII: A8OE252M6L)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
CARNAUBA WAX (UNII: R12CBM0EIZ)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
PHENOXYETHANOL (UNII: HE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SHEA BUTTER (UNII: K49155WL9Y)
Palm Oil (UNII: 5QUO05548Z)
Levant Cottonseed Oil (UNII: N5CFT140R8)
DIMETHICONE (UNII: 92RU3N3Y1O)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
Linseed Oil (UNII: 84XB4DV00W)
CHLORPHENESIN (UNII: I670DAL4SZ)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
CERAMIDE 3 (UNII: 4370DF050B)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
TOCOPHEROL (UNII: R0ZB2556P8)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 30 (UNII: 2S42T2808B)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)
D&C RED NO. 27 (UNII: 2LRS185U6K)

Product Characteristics

Color	RED (Yellowish red)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-103-02	1 in 1 BOX		
1	NDC:14783-103-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/27/2013	

LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - MARRON GLACE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-104
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
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MICA (UNII: V8A1AW0880)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SHEA BUTTER (UNII: K49155WL9Y)	
Palm Oil (UNII: 5QUO05548Z)	
Levant Cottonseed Oil (UNII: N5CFT140R8)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
Linseed Oil (UNII: 84XB4DV00W)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CERAMIDE 3 (UNII: 4370DF050B)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TOCOPHEROL (UNII: R0ZB2556P8)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

D&C RED NO. 30 (UNII: 2S42T2808B)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

Product Characteristics

Color	BROWN (Purplish brown)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-104-02	1 in 1 BOX		
1	NDC:14783-104-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/27/2013	

LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - TULIP

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-105
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
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MICA (UNII: V8A1AW0880)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	

HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
CARNAUBA WAX (UNII: R12CBM0EIZ)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SHEA BUTTER (UNII: K49155WL9Y)
Palm Oil (UNII: 5QUO05548Z)
Levant Cottonseed Oil (UNII: N5CFT140R8)
DIMETHICONE (UNII: 92RU3N3Y1O)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
Linseed Oil (UNII: 84XB4DV00W)
CHLORPHENESIN (UNII: I670DAL4SZ)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
CERAMIDE 3 (UNII: 4370DF050B)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
TOCOPHEROL (UNII: R0ZB2556P8)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 30 (UNII: 2S42T2808B)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
D&C RED NO. 27 (UNII: 2LRS185U6K)

Product Characteristics

Color	PINK (Yellowish pink)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-105-02	1 in 1 BOX		
1	NDC:14783-105-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/27/2013	

LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - NUDE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-106
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
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MICA (UNII: V8A1AW0880)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SHEA BUTTER (UNII: K49155WL9Y)	
Palm Oil (UNII: 5QUO05548Z)	
Levant Cottonseed Oil (UNII: N5CFT140R8)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
Linseed Oil (UNII: 84XB4DV00W)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CERAMIDE 3 (UNII: 4370DF050B)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TOCOPHEROL (UNII: R0ZB2556P8)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

TALC (UNII: 7SEV7J4R1U)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
D&C RED NO. 27 (UNII: 2LRS185U6K)				
Product Characteristics				
Color	PINK (Light Yellowish pink)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-106-02	1 in 1 BOX		
1	NDC:14783-106-01	4 g in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part352	05/27/2013		

LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - LILY BEIGE

octinoxate and oxybenzone lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-107
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		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)			
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)			
MICA (UNII: V8A1AW0880)			
TRIDECYL STEARATE (UNII: A8OE252M6L)			
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)			
CARNAUBA WAX (UNII: R12CBM0EIZ)			

NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SHEA BUTTER (UNII: K49155WL9Y)
Palm Oil (UNII: 5QUO05548Z)
Levant Cottonseed Oil (UNII: N5CFT140R8)
DIMETHICONE (UNII: 92RU3N3Y1O)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
Linseed Oil (UNII: 84XB4DV00W)
CHLORPHENESIN (UNII: I670DAL4SZ)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
CERAMIDE 3 (UNII: 4370DF050B)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
TOCOPHEROL (UNII: R0ZB2556P8)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 30 (UNII: 2S42T2808B)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
D&C RED NO. 27 (UNII: 2LRS185U6K)

Product Characteristics

Color	BROWN (Light pinkish brown)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-107-02	1 in 1 BOX		
1	NDC:14783-107-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/27/2013	

LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 -

MANDARINE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-108
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
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MICA (UNII: V8A1AW0880)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SHEA BUTTER (UNII: K49155WL9Y)	
Palm Oil (UNII: 5QUO05548Z)	
Levant Cottonseed Oil (UNII: N5CFT140R8)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
Linseed Oil (UNII: 84XB4DV00W)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CERAMIDE 3 (UNII: 4370DF050B)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TOCOPHEROL (UNII: R0ZB2556P8)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
TALC (UNII: 7SEV7J4R1U)	

FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

Product Characteristics

Color	ORANGE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-108-02	1 in 1 BOX		
1	NDC:14783-108-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/27/2013	

LBEL HYDRATESS LONG-LASTING INTENSE MOISTURIZING SPF 20 - VIN

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-109
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
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MICA (UNII: V8A1AW0880)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	

PROPYLENE CARBONATE (UNII: 8D08K3S51E)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SHEA BUTTER (UNII: K49155WL9Y)
Palm Oil (UNII: 5QUO05548Z)
Levant Cottonseed Oil (UNII: N5CFT140R8)
DIMETHICONE (UNII: 92RU3N3Y1O)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
Linseed Oil (UNII: 84XB4DV00W)
CHLORPHENESIN (UNII: I670DAL4SZ)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
CERAMIDE 3 (UNII: 4370DF050B)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
TOCOPHEROL (UNII: R0ZB2556P8)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 30 (UNII: 2S42T2808B)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
D&C RED NO. 27 (UNII: 2LRS185U6K)

Product Characteristics

Color	PURPLE (Brownish purple)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-109-02	1 in 1 BOX		
1	NDC:14783-109-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/27/2013	

Labeler - Ventura International LTD. (603192787)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(14783-095, 14783-096, 14783-097, 14783-098, 14783-099, 14783-100, 14783-101, 14783-102, 14783-103, 14783-104, 14783-105, 14783-106, 14783-107, 14783-108, 14783-109)

Revised: 6/2013

Ventura International LTD.