

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD PIMIENTA CALIENTE) - BROWN- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD VINO CAUTIVANTE) - BROWN- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROSA VIVA) - PINK- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD CORAL ENSUENO) - RED- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROJO GLAM) - RED- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD CAFE HABANO) - BROWN- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD FUCSIA VIBRANTE) - PINK- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD MELON INTENSE) - PINK- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROSADO CHIC) - PINK- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD CIRUELA GLAM) - RED- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD FRAMBUESA ENCANTO) - PURPLE- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD MAGENTA SWEET) - PURPLE- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD LAVA LIPS) - ORANGE- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD FRESA IMPERIAL) - RED- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD FUCSIA OPULENTO) - PINK- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD BERRY BALCANIC) - RED- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROSA OBSESSION) - PINK- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROJO EXHUBERANTE) - RED- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20- octinoxate
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.

ÉSIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20

Drug Facts

Active Ingredients

OCTINOXATE 6.80%

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

Inactive Ingredients

diisopropyl dimer dilinoleate, octyldodecanol, caprylic/capric triglyceride, polyethylene, tridecyl trimellitate, castor isostearate beeswax succinate, polyglyceryl-3 diisostearate, isopropyl lanolate, copernicia cerifera (carnauba) wax, mica, microcrystalline wax, diisostearyl malate, glyceryl isostearate, isostearyl alcohol, butyrospermum parkii (shea) butter, phenoxyethanol, beta-sitosterol, phenyl trimethicone, silica, silica silylate, euphorbia cerifera (candelilla) wax, fragrance, caprylyl glycol, dimethicone, chlorphenesin, ceramide 3, tocopheryl acetate, oleyl alcohol, trimethylsiloxysilicate, benzimidazole diamond amidoethyl urea carbamoyl propyl polymethylsiloxane, dioleoyl tocopheryl methylsilanol, alpha-isomethyl ionone, d-limonene, linalool, amyl cinnamal, citronellol. **May contain:** titanium dioxide, mica, iron oxides, red 30 lake, red 27 lake, red 7 lake, yellow 5 lake, red 21 lake, talc, calcium aluminum borosilicate, blue 1 lake, hydrogenated polyisobutene, carmine, palmitic acid, tin oxide

Dist by Ventura Corp, Ltd., San Juan, Puerto Rico 00926.

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD PIMIENTA CALIENTE) - BROWN

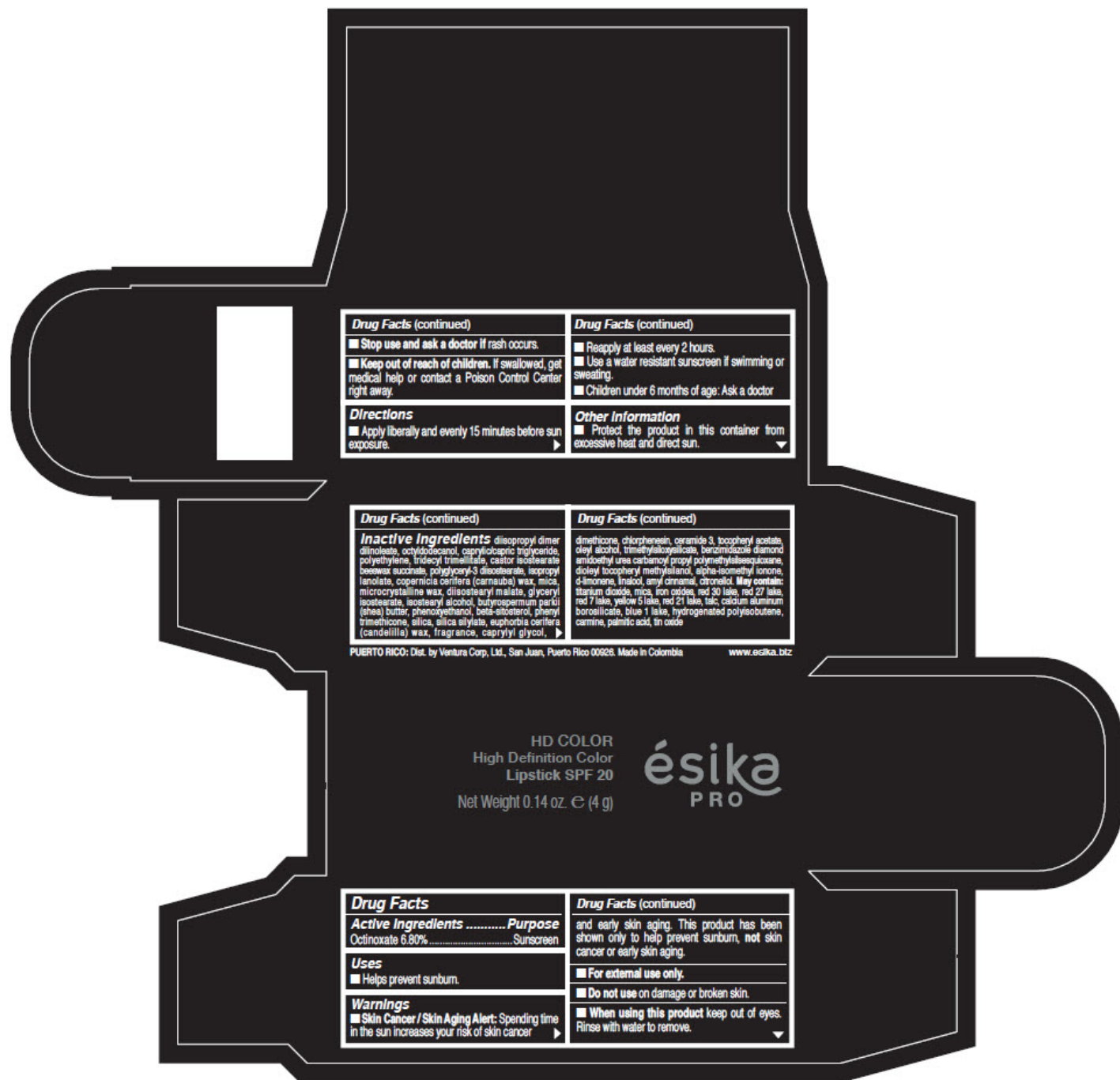
HD COLOR

High Definition Color

Lipstick SPF 20

Net Weight 0.14 oz. e (4 g)

ésika
PRO

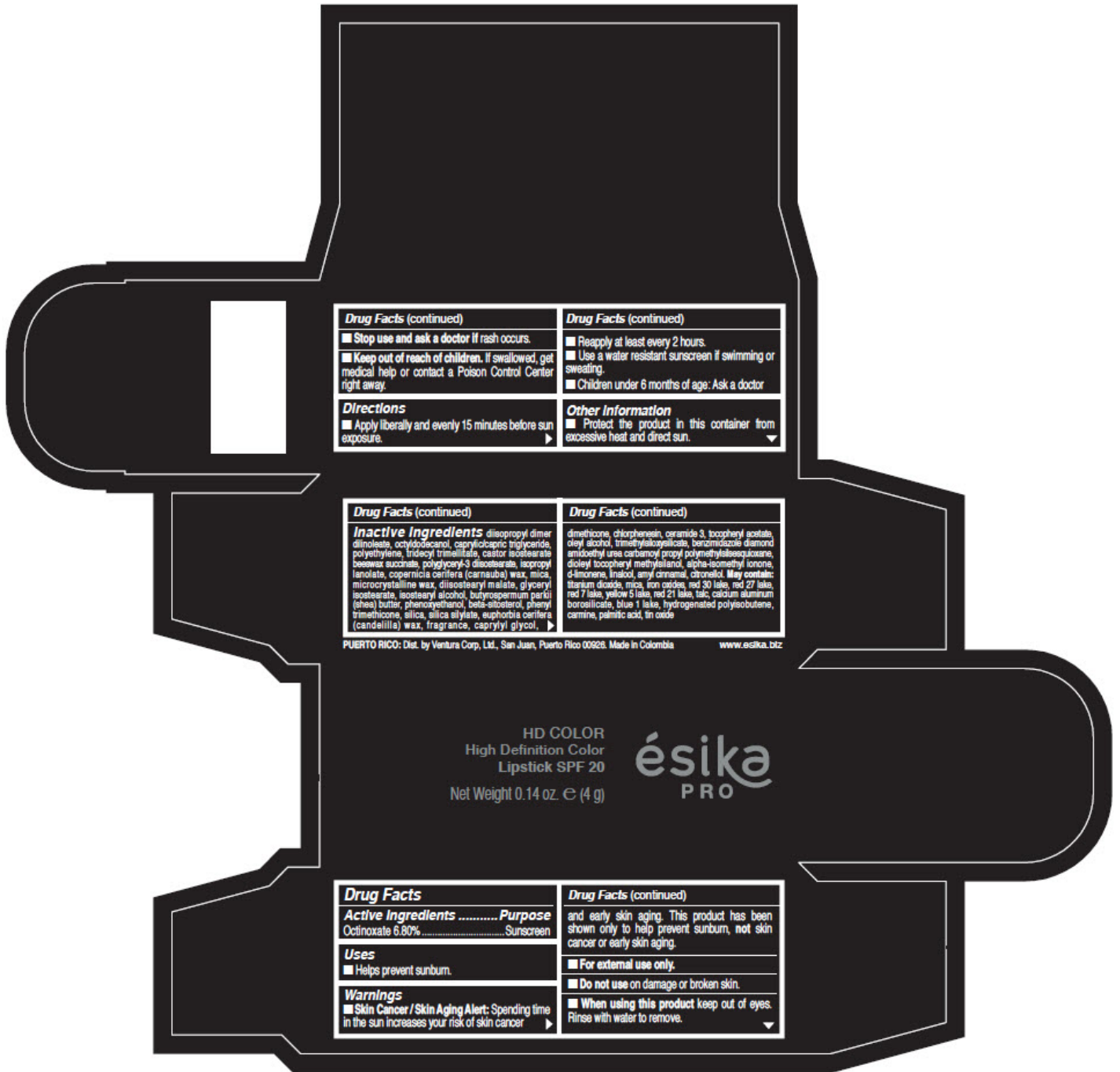


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD VINO CAUTIVANTE) - BROWN

HD COLOR
High Definition Color
Lipstick SPF 20

Net Weight 0.14 oz. e (4 g)

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Drug Facts (continued)

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure.

Drug Facts (continued)

- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor

Other Information

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

Drug Facts (continued)

Inactive Ingredients diisopropyl dimer dilinolate, octyldodecanol, caprylic/capric triglyceride, polyethylene, triethyl trimellitate, castor isosteerate beeswax succinate, polyglyceryl-3 distearate, isopropyl lanolate, copernicia cerifera (carnauba) wax, mica, microcrystalline wax, diisostearyl sebacate, glyceryl isostearate, isostearyl alcohol, butyrospermum parkii (shea) butter, phenoxyethanol, beta-sitosterol, phenyl trimethicone, silica, silica silylate, euphorbia cerifera (candelilla) wax, fragrance, caprylyl glycol.

Drug Facts (continued)

dimethicone, chlorphenesin, ceramide 3, tocopheryl acetate, dleyl alcohol, trimethylsilylate, benzimidazole diamond amidoethyl urea carbamoyl propyl polymethylsilsesquioxane, dioleyl tocopheryl methylsilanol, alpha-isomethyl ionone, d-limonene, linoleol, amyl cinnamyl, citronellol. May contain: titanium dioxide, mica, iron oxides, red 30 lake, red 27 lake, red 7 lake, yellow 5 lake, red 21 lake, talc, calcium aluminum borosilicate, blue 1 lake, hydrogenated polyisobutene, carmine, palmitic acid, tin oxide

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HD COLOR
High Definition Color
Lipstick SPF 20
Net Weight 0.14 oz. e (4 g)

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Drug Facts

Active Ingredients **Purpose**
Octinoxate 6.80% Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer

Drug Facts (continued)

and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.

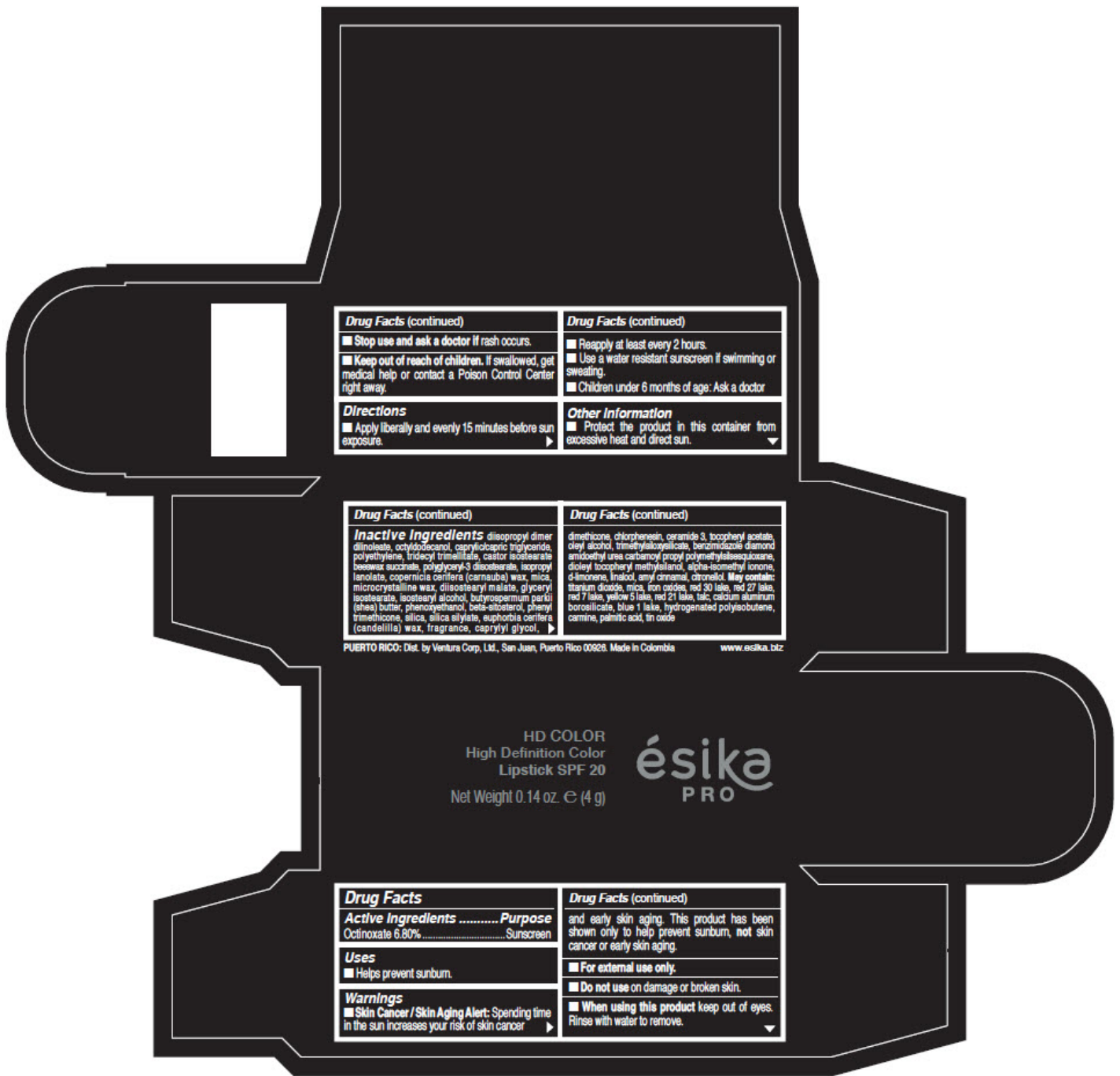
- For external use only.
- Do not use on damage or broken skin.
- When using this product keep out of eyes. Rinse with water to remove.

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD ROSA VIVA) - PINK

**HD COLOR
High Definition Color
Lipstick SPF 20**

Net Weight 0.14 oz. e (4 g)

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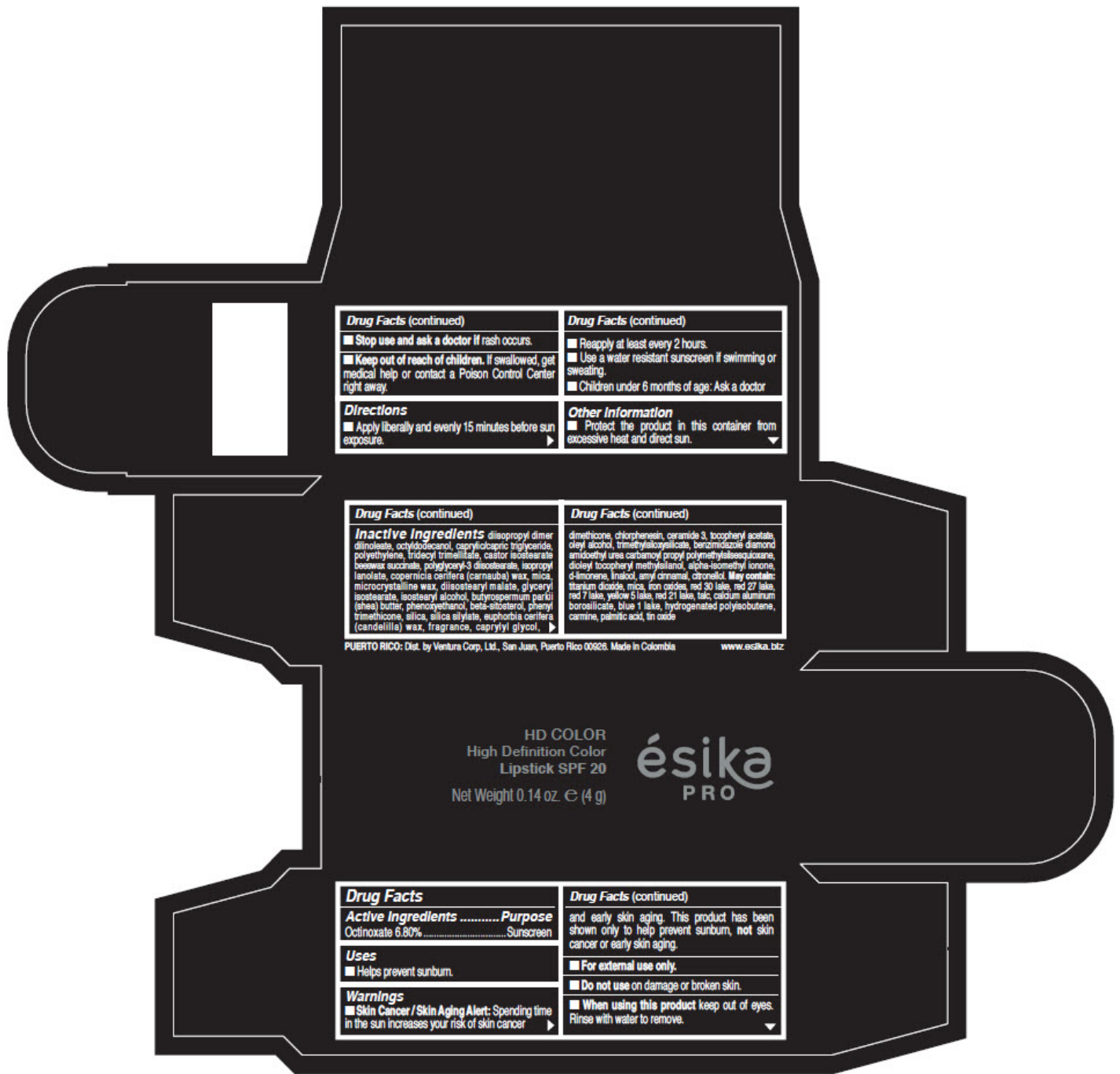


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD CORAL ENSUENO) - RED

**HD COLOR
High Definition Color
Lipstick SPF 20**

Net Weight 0.14 oz. e (4 g)

**ésika
PRO**

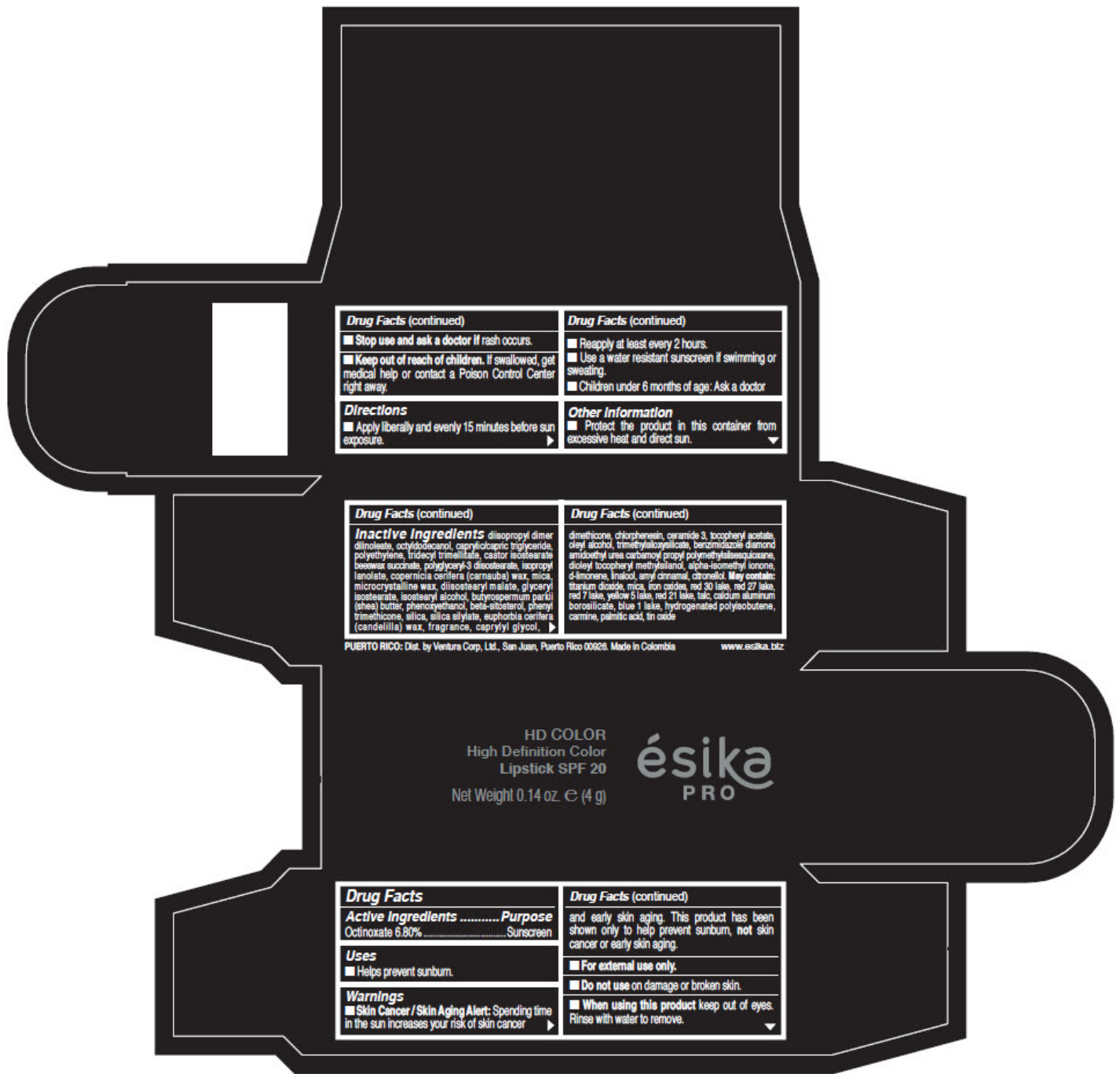


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD ROJO GLAM) - RED

**HD COLOR
High Definition Color
Lipstick SPF 20**

Net Weight 0.14 oz. e (4 g)

**ésika
PRO**

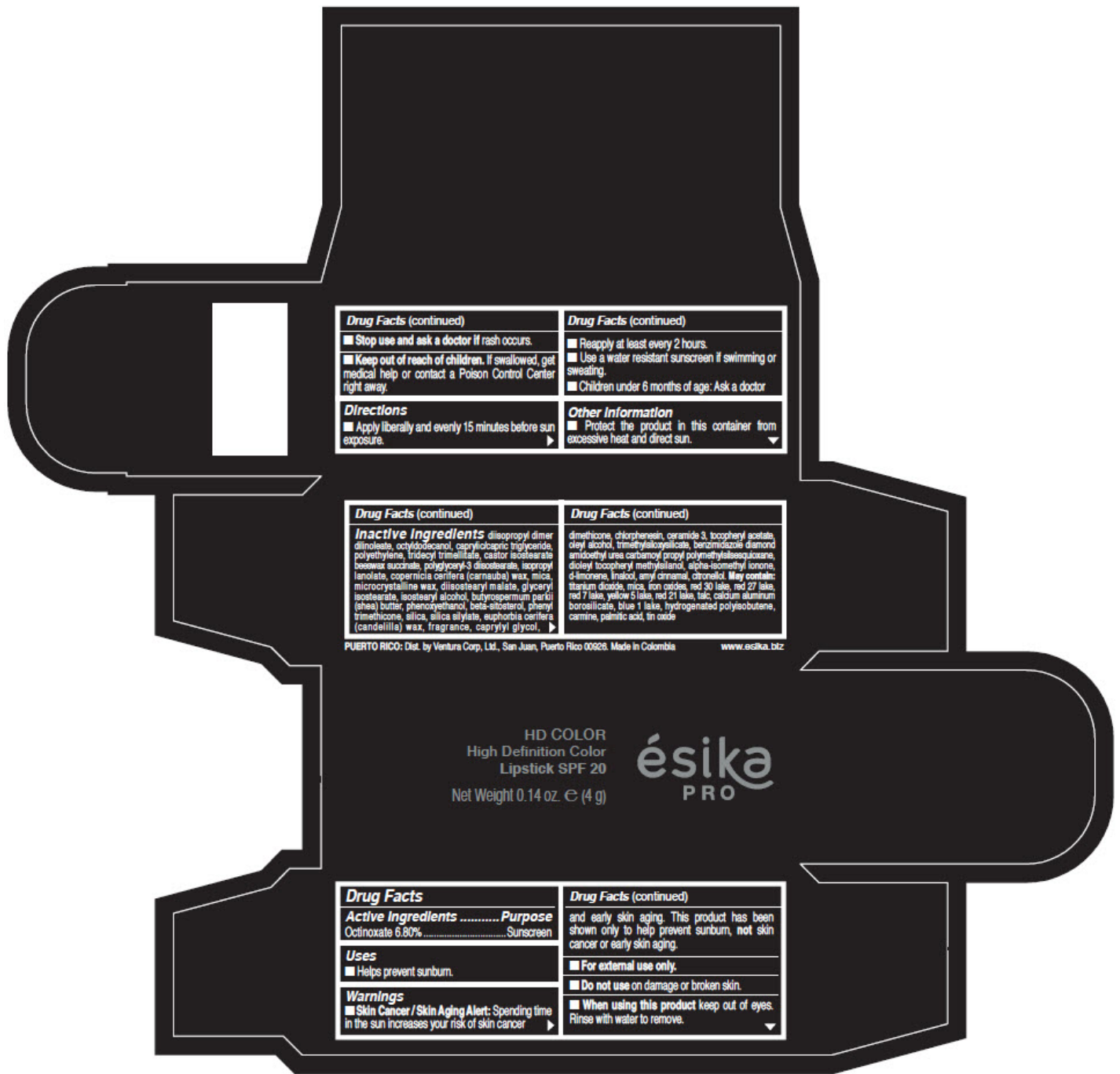


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD CAFE HABANO) - BROWN

**HD COLOR
High Definition Color
Lipstick SPF 20**

Net Weight 0.14 oz. e (4 g)

**ésika
PRO**

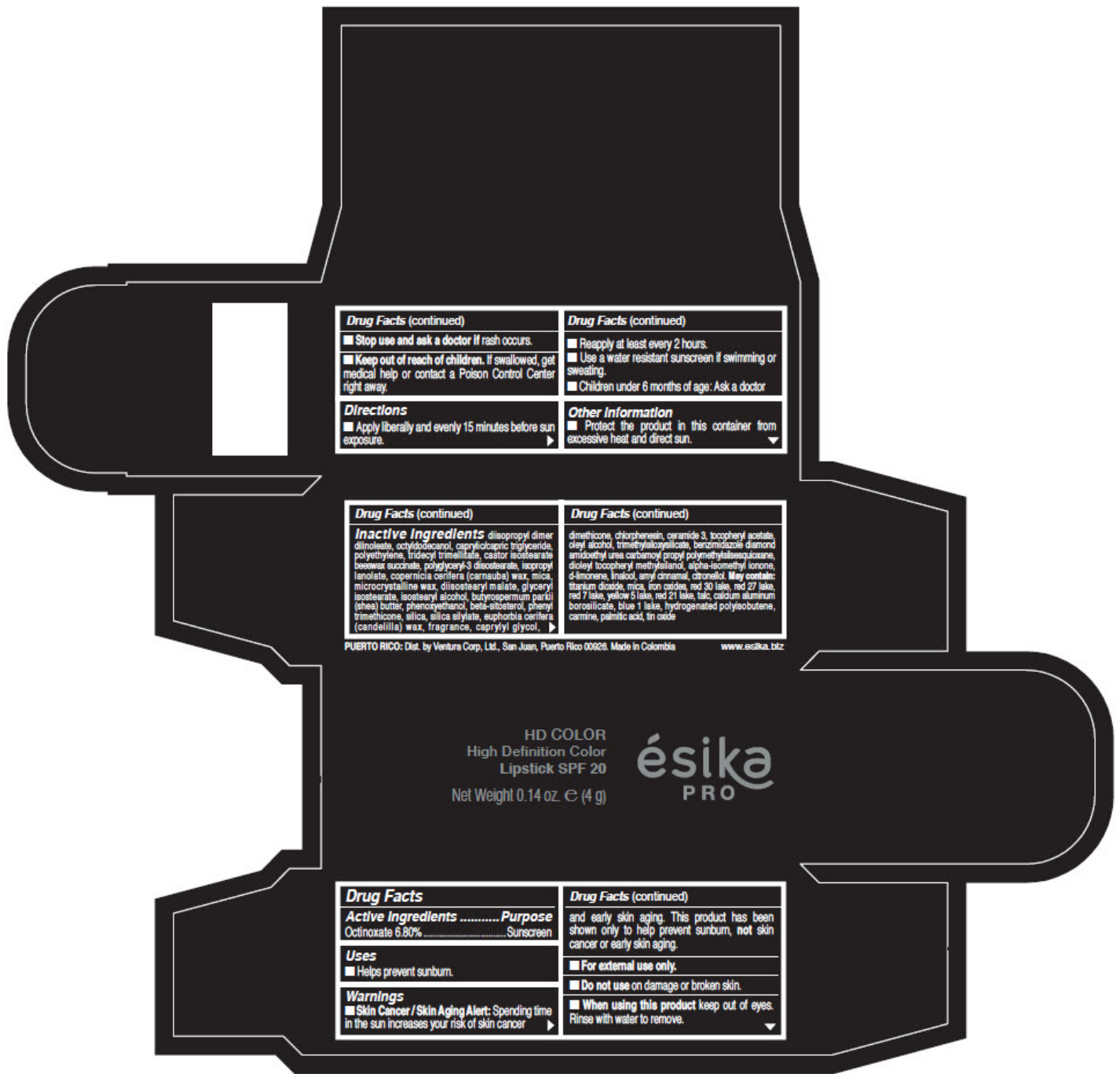


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD FUCSIA VIBRANTE) - PINK

**HD COLOR
High Definition Color
Lipstick SPF 20**

Net Weight 0.14 oz. e (4 g)

**ésika
PRO**

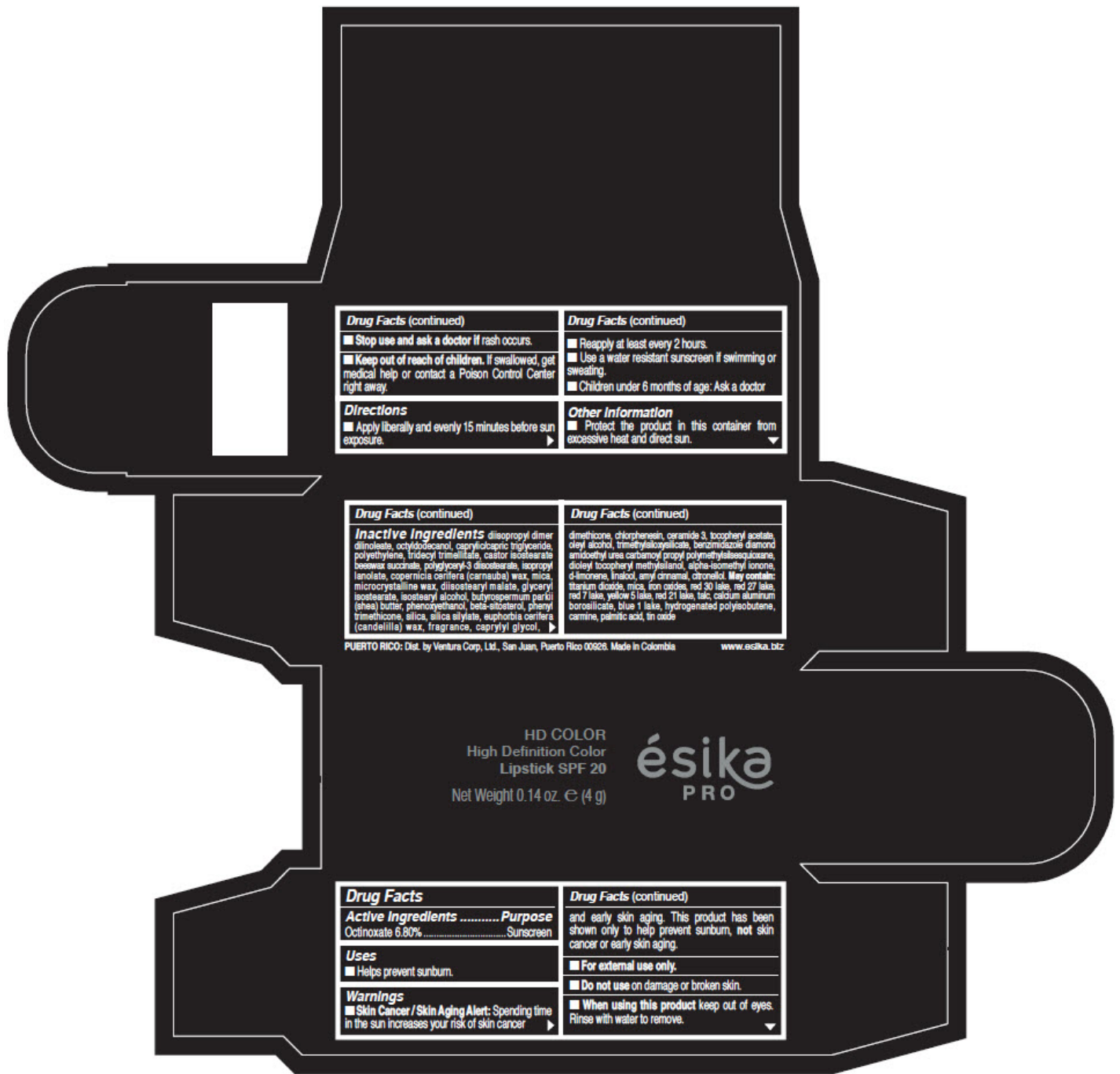


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD MELON INTENSE) - PINK

**HD COLOR
High Definition Color
Lipstick SPF 20**

Net Weight 0.14 oz. e (4 g)

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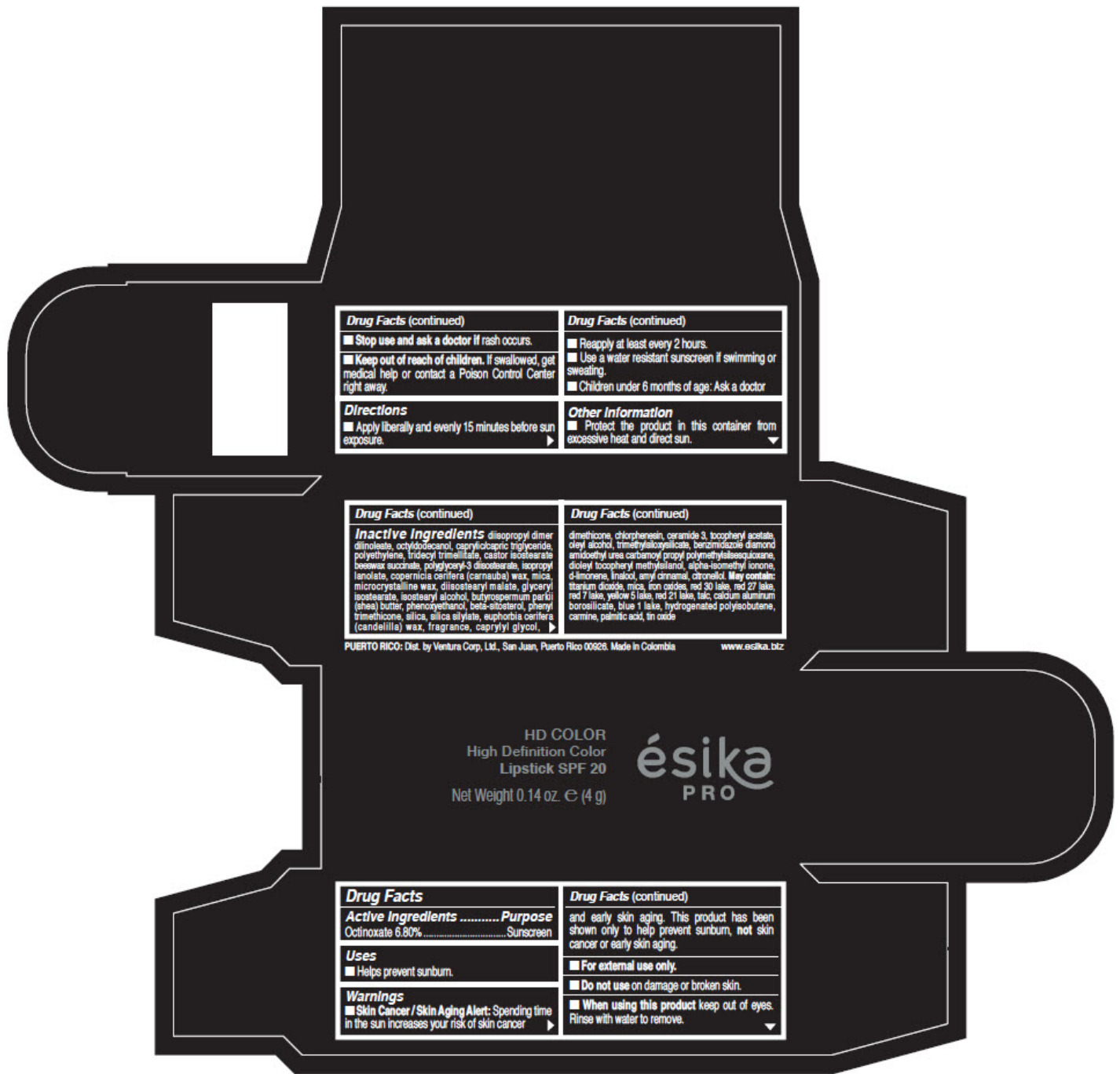


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD ROSADO CHIC) - PINK

**HD COLOR
High Definition Color
Lipstick SPF 20**

Net Weight 0.14 oz. e (4 g)

**ésika
PRO**

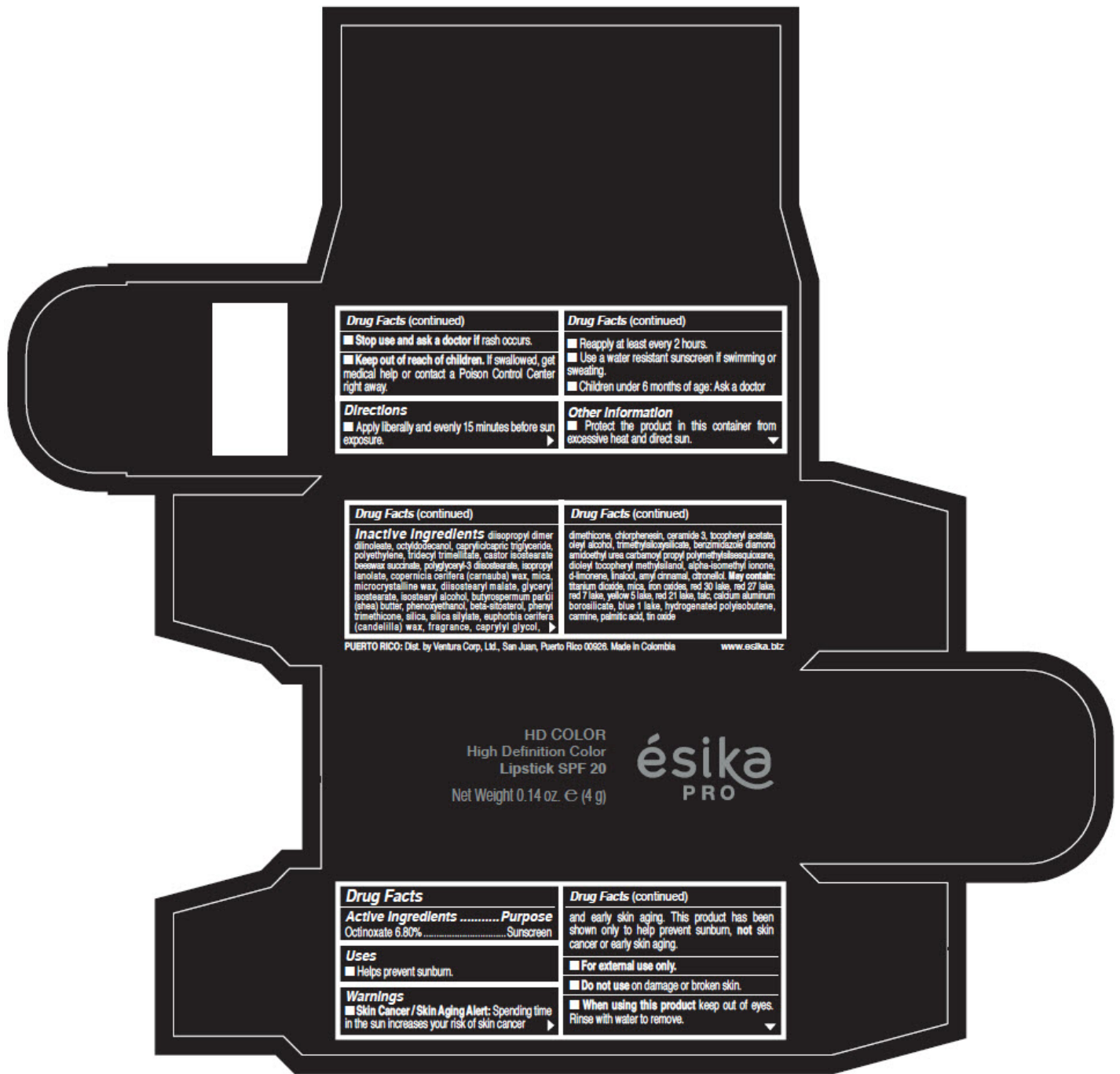


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD CIRUELA GLAM) - RED

**HD COLOR
High Definition Color
Lipstick SPF 20**

Net Weight 0.14 oz. e (4 g)

**ésika
PRO**

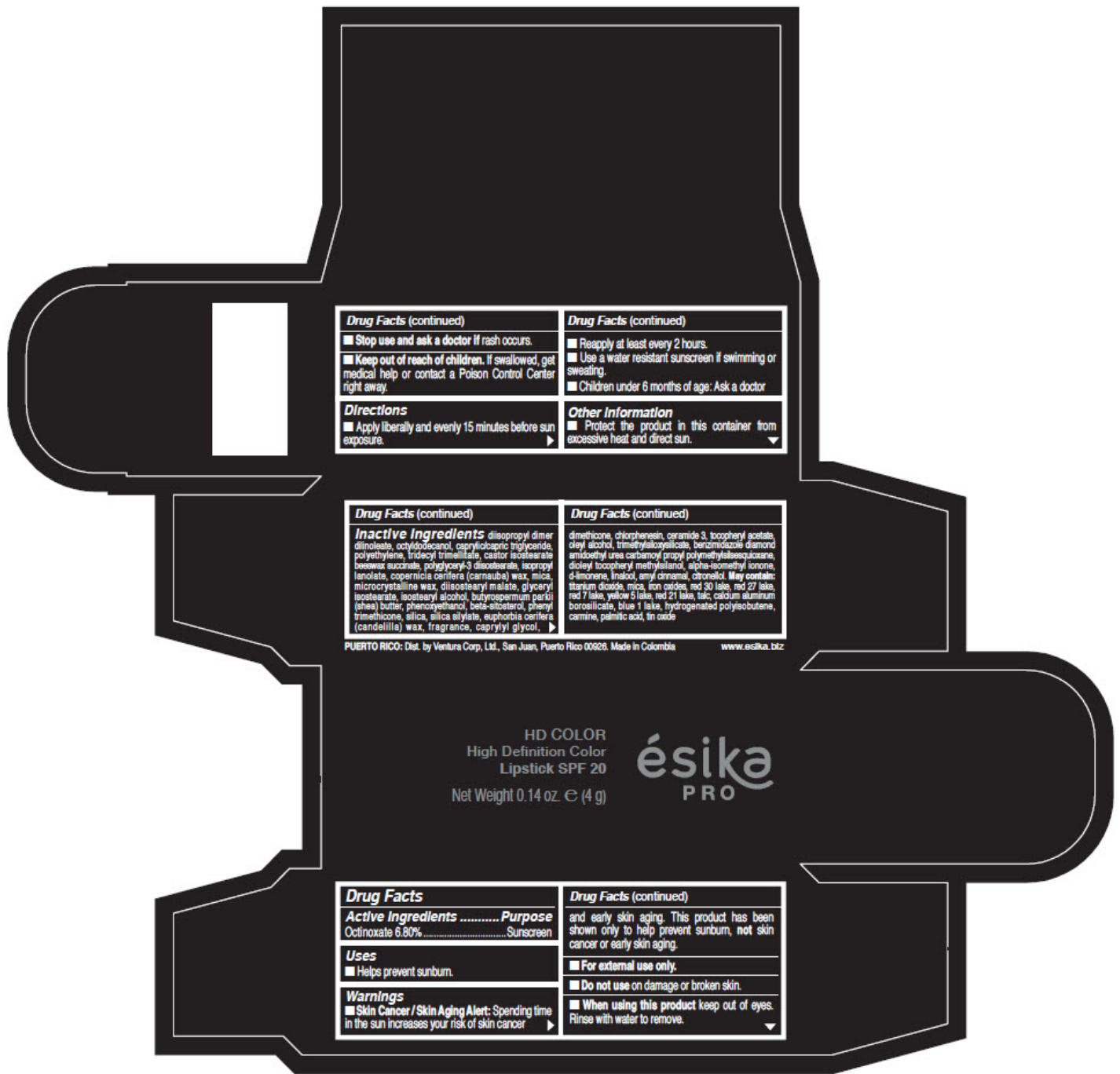


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD FRAMBUESA ENCANTO) - PURPLE

**HD COLOR
High Definition Color
Lipstick SPF 20**

Net Weight 0.14 oz. e (4 g)

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PRO**

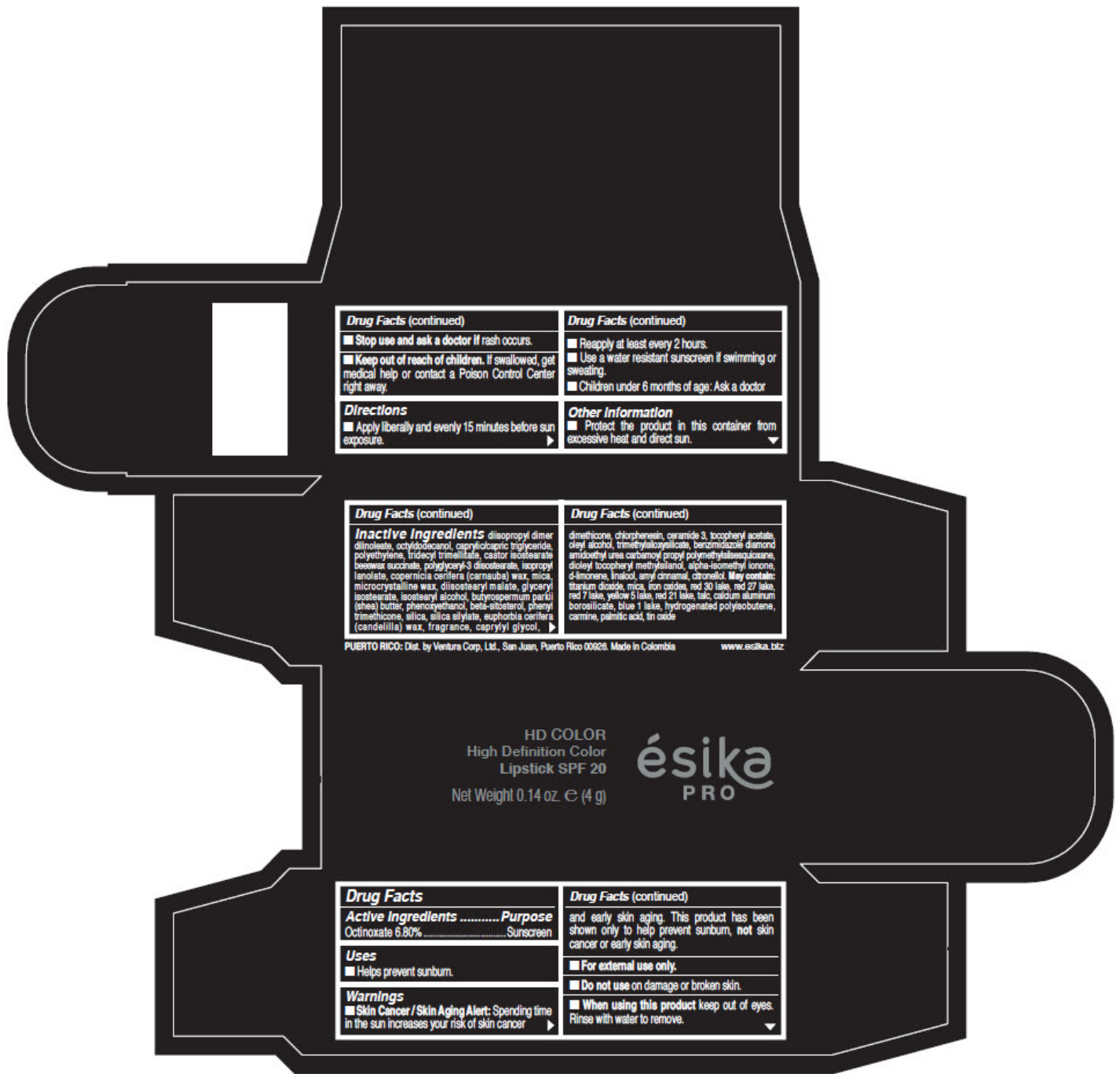


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD MAGENTA SWEET) - PURPLE

**HD COLOR
High Definition Color
Lipstick SPF 20**

Net Weight 0.14 oz. e (4 g)

**ésika
PRO**

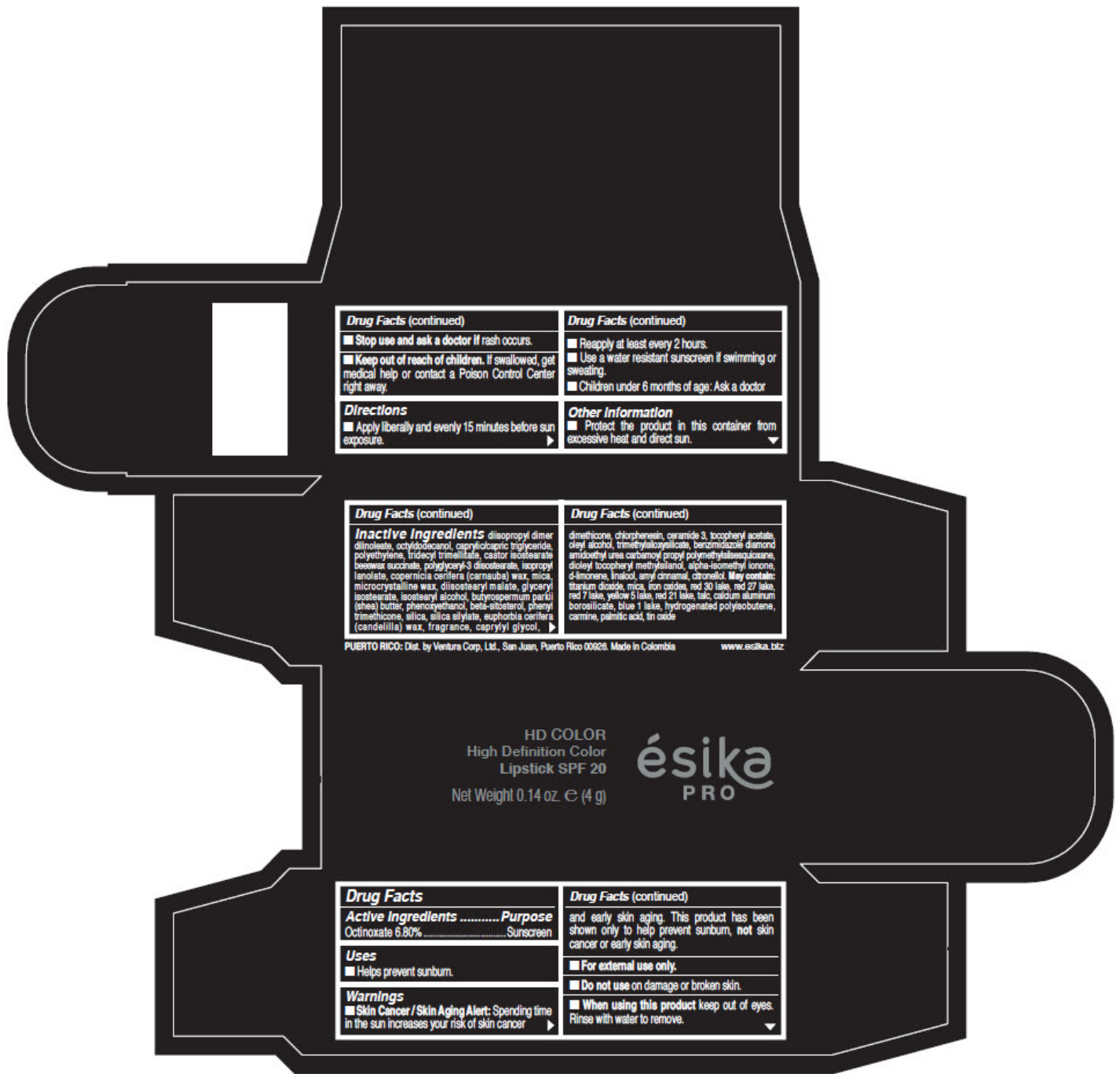


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD LAVA LIPS) - ORANGE

**HD COLOR
High Definition Color
Lipstick SPF 20**

Net Weight 0.14 oz. e (4 g)

**ésika
PRO**

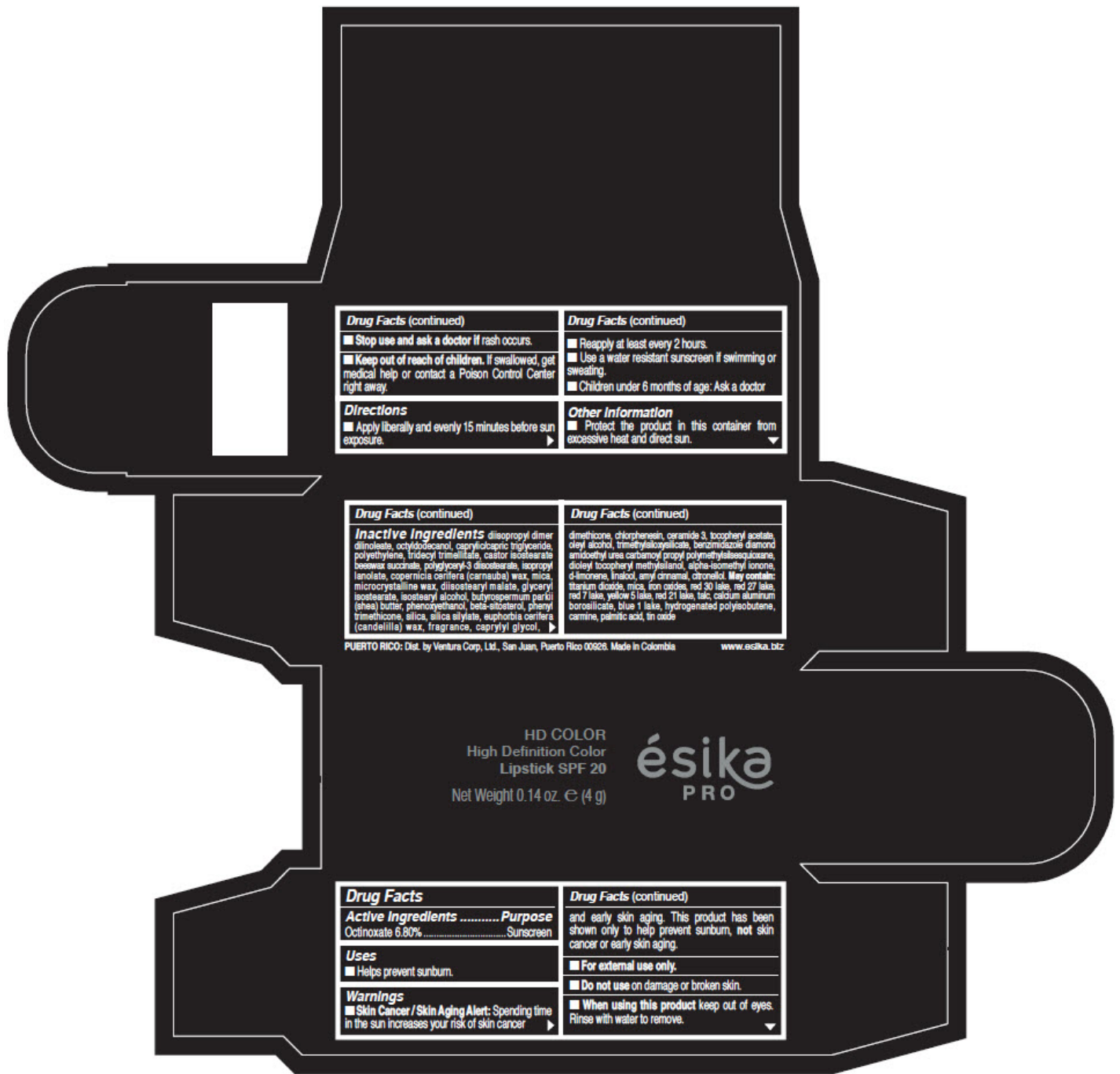


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD FRESA IMPERIAL) - RED

**HD COLOR
High Definition Color
Lipstick SPF 20**

Net Weight 0.14 oz. e (4 g)

**ésika
PRO**

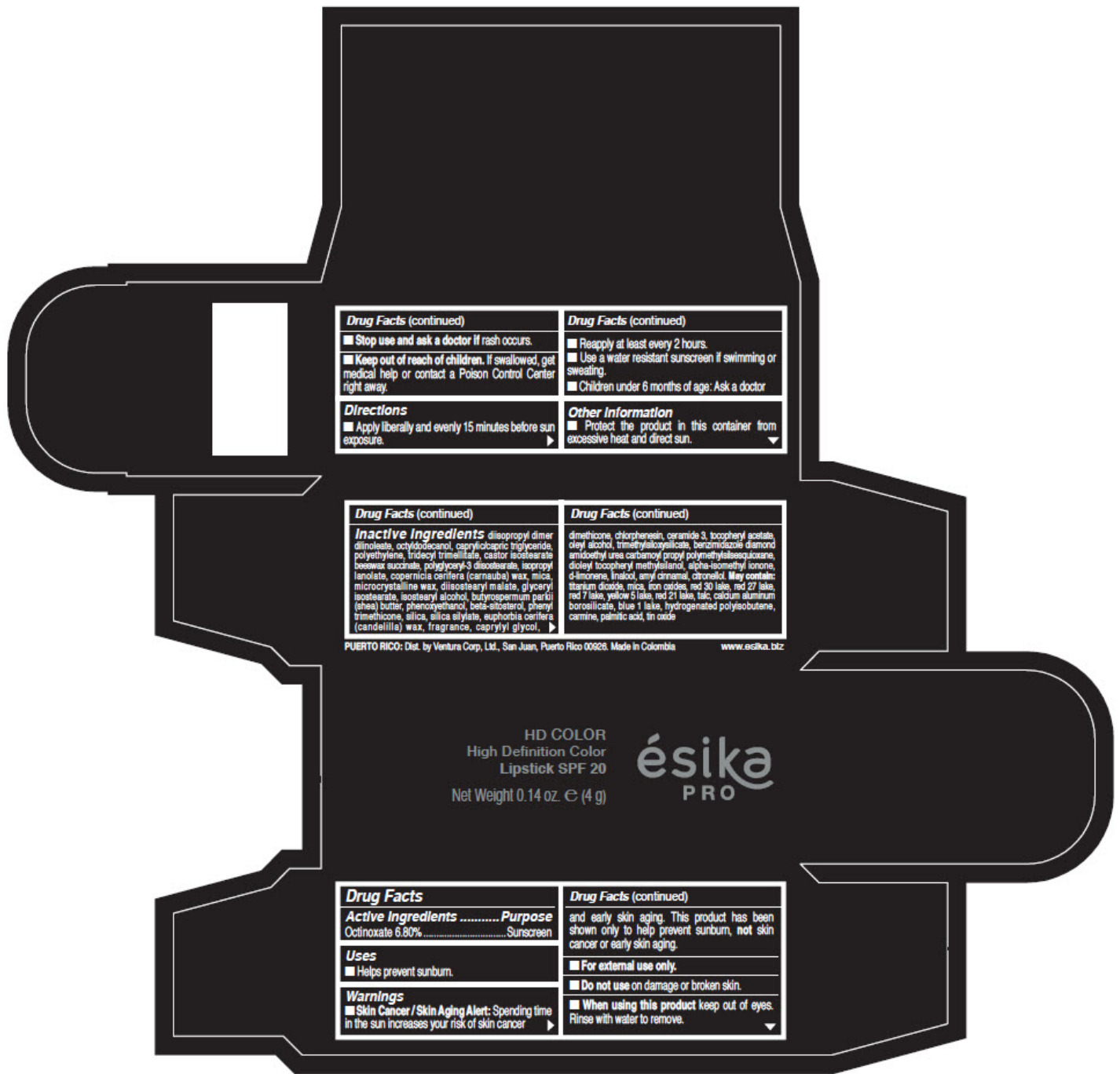


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD FUCSIA OPULENTO) - PINK

**HD COLOR
High Definition Color
Lipstick SPF 20**

Net Weight 0.14 oz. e (4 g)

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PRO**

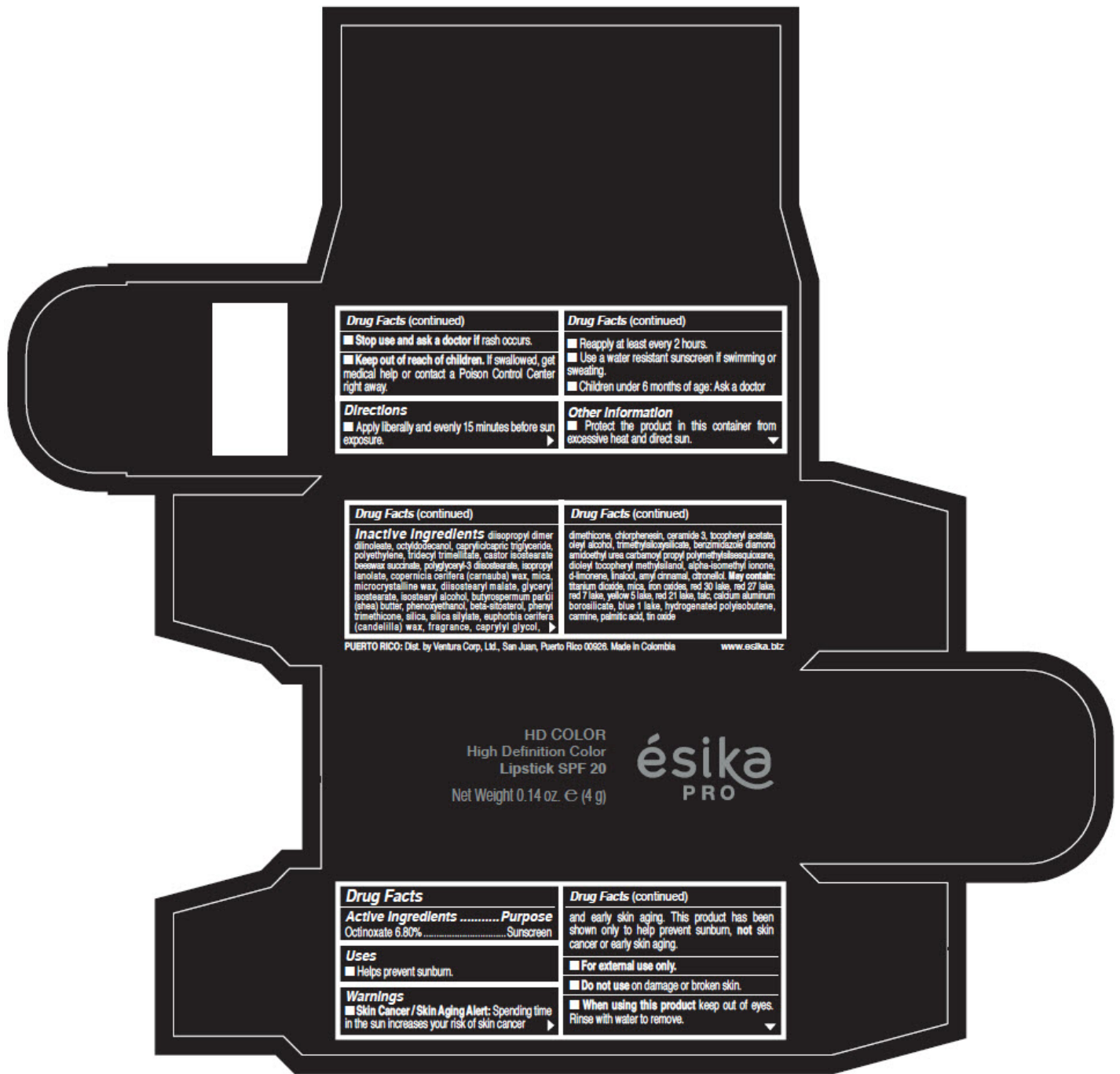


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD BERRY BALCANIC) - RED

**HD COLOR
High Definition Color
Lipstick SPF 20**

Net Weight 0.14 oz. e (4 g)

**ésika
PRO**

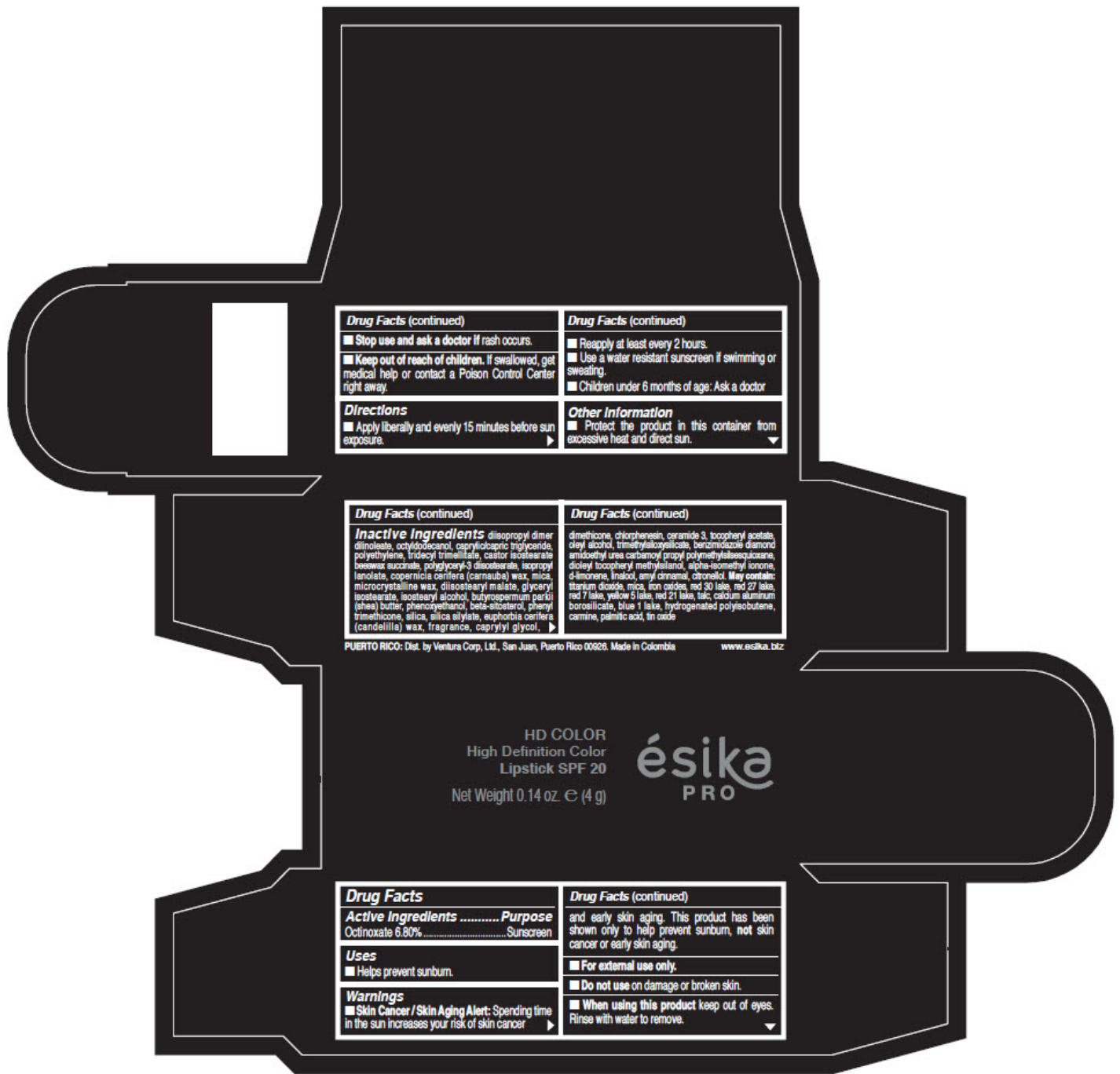


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD ROSA OBSESSION) - PINK

**HD COLOR
High Definition Color
Lipstick SPF 20**

Net Weight 0.14 oz. e (4 g)

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PRO**



Drug Facts (continued)

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure. ▶

Drug Facts (continued)

- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor

Other Information

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

Drug Facts (continued)

Inactive Ingredients diisopropyl dimer dilinolate, octyldodecanol, caprylic/capric triglyceride, polyethylene, tridecyl trimellitate, castor isosteate beeswax succinate, polyglyceryl-3 distearate, isopropyl lanolate, copernicia cerifera (carnauba) wax, mica, microcrystalline wax, diisosteryl melate, glyceryl isostearate, isostearyl alcohol, butyrospermum parkii (shea) butter, phenoxyethanol, beta-sitosterol, phenyl trimethicone, silica, silica silylate, euphorbia cerifera (candelilla) wax, fragrance, caprylyl glycol, ▶

Drug Facts (continued)

dimethicone, chlorphenesin, ceramide 3, tocopheryl acetate, dleyl alcohol, trimethylsilylate, benzimidazole diamond amidoethyl urea carbamoyl propyl polymethylsiloxane, dioleyl tocopheryl methylsilanol, alpha-isomethyl ionone, d-limonene, linoleol, amyli cinnamyl, citronellol. May contain titanium dioxide, mica, iron oxides, red 30 lake, red 27 lake, red 7 lake, yellow 5 lake, red 21 lake, talc, calcium aluminum borosilicate, blue 1 lake, hydrogenated polyisobutene, carmine, palmitic acid, tin oxide

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HD COLOR
High Definition Color
Lipstick SPF 20
Net Weight 0.14 oz. e (4 g)

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Drug Facts

Active Ingredients **Purpose**

Octinoxate 6.80% Sunscreen

Uses

- Helps prevent sunburn.

Warnings

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

Drug Facts (continued)

and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.

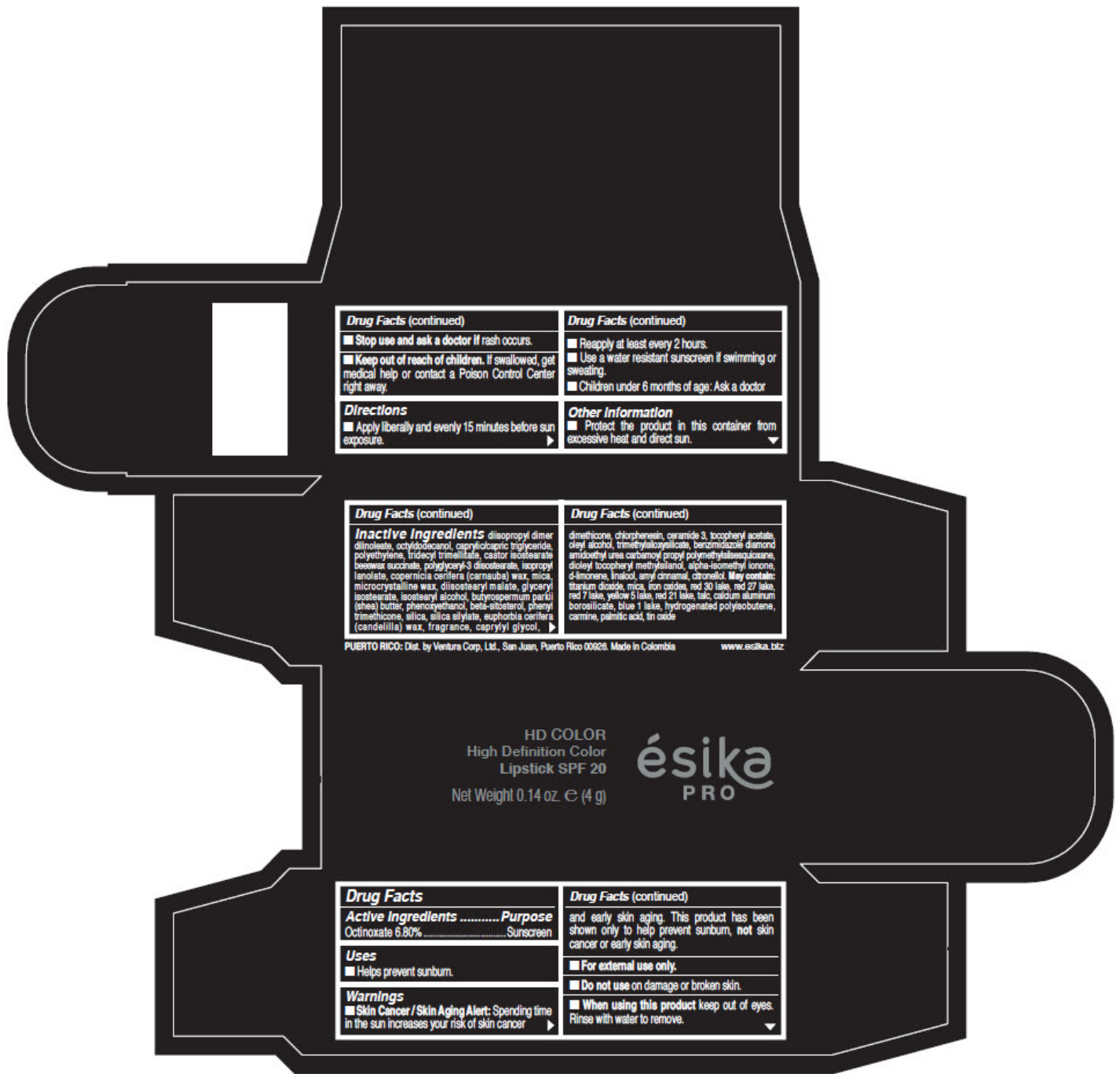
- For external use only.
- Do not use on damage or broken skin.
- When using this product keep out of eyes. Rinse with water to remove. ▼

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD ROJO EXHUBERANTE) - RED

HD COLOR
High Definition Color
Lipstick SPF 20

Net Weight 0.14 oz. e (4 g)

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Drug Facts (continued)

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure. ▶

Drug Facts (continued)

- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor

Other Information

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

Drug Facts (continued)

Inactive Ingredients diisopropyl dimer dilinolate, octyldodecanol, caprylic/capric triglyceride, polyethylene, tridecyl trimellitate, castor isocostearate beeswax succinate, polyglyceryl-3 distearate, isopropyl lanolate, copernicia cerifera (carnauba) wax, mica, microcrystalline wax, diisostearyl melate, glyceryl isostearate, isostearyl alcohol, butyrospermum parkii (shea) butter, phenoxyethanol, beta-sitosterol, phenyl trimethicone, silica, silica silylate, euphorbia cerifera (candelilla) wax, fragrance, caprylyl glycol, ▶

Drug Facts (continued)

dimethicone, chlorphenesin, ceramide 3, tocophenyl acetate, dleyl alcohol, trimethylsilyl silicate, benzimidazole diamond amidoethyl urea carbamoyl propyl polymethylsilsesquioxane, dioleyl tocophenyl methylsilanol, alpha-isomethyl ionone, d-limonene, linoleol, amyl cinnemal, citronellol. May contain titanium dioxide, mica, iron oxides, red 30 lake, red 27 lake, red 7 lake, yellow 5 lake, red 21 lake, talc, calcium aluminum borosilicate, blue 1 lake, hydrogenated polyisobutene, carmine, palmitic acid, tin oxide

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HD COLOR
High Definition Color
Lipstick SPF 20
Net Weight 0.14 oz. e (4 g)



Drug Facts

Active Ingredients **Purpose**
Octinoxate 6.80% Sunscreen

Uses
■ Helps prevent sunburn.

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

Drug Facts (continued)

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. ▼

PRINCIPAL DISPLAY PANEL - Kit Carton

**HD COLOR
HIGH DEFINITION COLOR LIPSTICK
SPF 20**

**ésika
PRO**

Net Weight
0.275 oz. e (7.8 g)



www.esika.biz

P.R.: Dist by Ventura Corp, Ltd, San Juan, Puerto Rico 00926. Made in Colombia.

Inactive Ingredients DIISOPROPYL DIMER DILINOLEATE, OCTYLDODECANOL, CAPRYLIC/CAPRIC TRIGLYCERIDE, POLYETHYLENE, TRIDECYL TRIMELLITATE, CASTOR, ISOSTEARATE BEESWAX SUCCINATE, CERIFERA (CARNAUBA) WAX, MICA, MICROCRYSTALLINE WAX, DIISOSTEARYL MALATE, GLYCERYL ISOSTEARATE, ISOSTEARYL ALCOHOL, BUTYROSPERMUM PARKII (SHEA) BUTTER, PHENOXYETHANOL, BETA-SITOSTEROL, PHENYL TRIMETHICONE, SILICA, SILICA SILYATE, ACETATE, OLEYL ALCOHOL, TRIMETHYLSILOXYLICATE, BENZIMIDAZOLE DIAMOND AMIDOETHYL UREA CARBAMOYL PROPYL POLYMETHYLSILSESQUOXANE, DIOLEYL TOCOPHERYL METHYLSILANOL, **May Contain:** TITANIUM DIOXIDE, MICA, IRON OXIDES, RED 30 LAKE, RED 7 LAKE, YELLOW 5 LAKE, RED 27 LAKE, TALC, CALCIUM ALUMINUM BOROSILICATE, CARBAMINE, TIN OXIDE

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

Drug Facts (continued)
■ Reapply at least every 2 hours.
■ Children under 6 months of age: Ask a doctor.

Directions
■ Apply liberally and evenly 15 minutes before sun exposure.
■ Use a water resistant sunscreen if swimming or sweating.

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.

Uses
■ Helps prevent sunburn.

Drug Facts
Active Ingredients
OCTINOXATE 6.80%
Sunscreen

HD COLOR
HIGH DEFINITION COLOR LIPSTICK
SPF 20

ésika
PRO

Net Weight
0.275 oz. e (7.8 g)

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD PIMIENTA CALIENTE) - BROWN

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-729
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
MICA (UNII: V8A1AW0880)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)
SHEA BUTTER (UNII: K49155WL9Y)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
.BETA.-SITOSTEROL (UNII: S347WMO6M4)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
CANDELILLA WAX (UNII: WL0328HX19)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
DIMETHICONE (UNII: 92RU3N3Y1O)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)
PALMITIC ACID (UNII: 2V16EO95H1)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-729-02	1 in 1 BOX	02/29/2016	
1	NDC:13537-729-01	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	02/29/2016	

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD VINO CAUTIVANTE) - BROWN

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-730
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISO STEARATE (UNII: HYE7O27HAO)	
ISO STEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
PALMITIC ACID (UNII: 2V16EO95HI)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-730-04	1 in 1 BOX	02/29/2016	
1	NDC:13537-730-03	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	02/29/2016	

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROSA VIVA) - PINK

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-731
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	

POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
MICA (UNII: V8A1AW0880)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)
SHEA BUTTER (UNII: K49155WL9Y)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
.BETA.-SITOSTEROL (UNII: S347WMO6M4)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
CANDELILLA WAX (UNII: WL0328HX19)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
DIMETHICONE (UNII: 92RU3N3Y1O)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
PALMITIC ACID (UNII: 2V16EO95H1)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-731-06	1 in 1 BOX	02/29/2016	
1	NDC:13537-731-05	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	02/29/2016	

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD CORAL ENSUENO) - RED

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-732
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
PALMITIC ACID (UNII: 2V16EO95HI)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-732-08	1 in 1 BOX	02/29/2016	
1	NDC:13537-732-07	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	02/29/2016	

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROJO GLAM) - RED

octinoxate lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-733
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISO STEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

MICA (UNII: V8A1AW0880)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)
SHEA BUTTER (UNII: K49155WL9Y)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
.BETA.-SITOSTEROL (UNII: S347WMO6M4)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
CANDELILLA WAX (UNII: WL0328HX19)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
DIMETHICONE (UNII: 92RU3N3Y1O)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
PALMITIC ACID (UNII: 2V16EO95HI)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-733-10	1 in 1 BOX	02/29/2016	
1	NDC:13537-733-09	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	02/29/2016	

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD CAFE HABANO) - BROWN

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-734
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
PALMITIC ACID (UNII: 2V16EO95H1)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-734-12	1 in 1 BOX	02/29/2016	
1	NDC:13537-734-11	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	02/29/2016	

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD FUCSIA VIBRANTE) - PINK

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-735
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	

MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q6130CQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
PALMITIC ACID (UNII: 2V16EO95H1)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-735-14	1 in 1 BOX	02/29/2016	
1	NDC:13537-735-13	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	02/29/2016	

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD MELON

INTENSE) - PINK

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-736
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISO STEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISO STEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISO STEARATE (UNII: HYE7O27HAO)	
ISO STEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	

D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
PALMITIC ACID (UNII: 2V16EO95HI)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-736-16	1 in 1 BOX	02/29/2016	
1	NDC:13537-736-15	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	02/29/2016	

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROSADO CHIC) - PINK

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-737
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	

DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
PALMITIC ACID (UNII: 2V16EO95H1)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-737-18	1 in 1 BOX	02/29/2016	
1	NDC:13537-737-17	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	02/29/2016	

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD CIRUELA GLAM) - RED

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-738
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
PALMITIC ACID (UNII: 2V16EO95H1)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-738-20	1 in 1 BOX	02/29/2016	
1	NDC:13537-738-19	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	02/29/2016	

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD FRAMBUESA ENCANTO) - PURPLE

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-739
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	

GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)
SHEA BUTTER (UNII: K49155WL9Y)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
.BETA.-SITOSTEROL (UNII: S347WMO6M4)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
CANDELILLA WAX (UNII: WL0328HX19)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
DIMETHICONE (UNII: 92RU3N3Y1O)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BORSILICATE (UNII: 3JRB8A35M0)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)
PALMITIC ACID (UNII: 2V16EO95H1)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-739-22	1 in 1 BOX	02/29/2016	
1	NDC:13537-739-21	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	02/29/2016	

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD MAGENTA SWEET) - PURPLE

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-740
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q6130CQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
PALMITIC ACID (UNII: 2V16EO95H1)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-740-24	1 in 1 BOX	02/29/2016	
1	NDC:13537-740-23	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	02/29/2016	

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD LAVA LIPS) - ORANGE

octinoxate lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-741
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	

SHEA BUTTER (UNII: K49155WL9Y)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
.BETA.-SITOSTEROL (UNII: S347WMO6M4)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
CANDELILLA WAX (UNII: WL0328HX19)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
DIMETHICONE (UNII: 92RU3N3Y1O)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
PALMITIC ACID (UNII: 2V16EO95HI)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-741-24	1 in 1 BOX	02/29/2016	
1	NDC:13537-741-23	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	02/29/2016	

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD FRESA IMPERIAL) - RED
octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-742
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	

CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
PALMITIC ACID (UNII: 2V16EO95H1)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-742-24	1 in 1 BOX	02/29/2016	
1	NDC:13537-742-23	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	02/29/2016	

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD FUCSIA OPULENTO) - PINK

octinoxate lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-743
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISO STEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISO STEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISO STEARATE (UNII: HYE7O27HAO)	
ISO STEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)
.BETA.-SITOSTEROL (UNII: S347WMO6M4)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
CANDELILLA WAX (UNII: WL0328HX19)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
DIMETHICONE (UNII: 92RU3N3Y1O)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BORSILICATE (UNII: 3JRB8A35M0)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
PALMITIC ACID (UNII: 2V16EO95H1)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-743-24	1 in 1 BOX	02/29/2016	
1	NDC:13537-743-23	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	02/29/2016	

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD BERRY BALCANIC) - RED

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-744
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Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q6130CQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	

FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

PALMITIC ACID (UNII: 2V16EO95H1)

STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-744-24	1 in 1 BOX	02/29/2016	
1	NDC:13537-744-23	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	02/29/2016	

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROSA OBSESSION) - PINK

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-745
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	

PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
CANDELILLA WAX (UNII: WL0328HX19)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
DIMETHICONE (UNII: 92RU3N3Y1O)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)
PALMITIC ACID (UNII: 2V16EO95H1)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-745-24	1 in 1 BOX	02/29/2016	
1	NDC:13537-745-23	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	02/29/2016	

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROJO EXHUBERANTE) - RED

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-746
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
PALMITIC ACID (UNII: 2V16EO95H1)	

STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-746-24	1 in 1 BOX	02/29/2016	
1	NDC:13537-746-23	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	02/29/2016	

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20

octinoxate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-747
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-747-28	1 in 1 KIT	02/29/2016	12/01/2018
1	NDC:13537-747-27	1 in 1 BOX		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	0.43 g
Part 2	1 TUBE	0.43 g
Part 3	1 TUBE	0.43 g
Part 4	1 TUBE	0.43 g
Part 5	1 TUBE	0.43 g
Part 6	1 TUBE	0.43 g
Part 7	1 TUBE	0.43 g
Part 8	1 TUBE	0.43 g
Part 9	1 TUBE	0.43 g
Part 10	1 TUBE	0.43 g
Part 11	1 TUBE	0.43 g
Part 12	1 TUBE	0.43 g
Part 13	1 TUBE	0.43 g
Part 14	1 TUBE	0.43 g

Part 15	1 TUBE	0.43 g
Part 16	1 TUBE	0.43 g
Part 17	1 TUBE	0.43 g
Part 18	1 TUBE	0.43 g

Part 1 of 18

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD PIMIENTA CALIENTE) - BROWN

octinoxate lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)
PALMITIC ACID (UNII: 2V16EO95H1)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.43 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/29/2016	12/01/2018

Part 2 of 18

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD VINO CAUTIVANTE) - BROWN

octinoxate lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q6130CQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
PALMITIC ACID (UNII: 2V16EO95H1)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.43 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/29/2016	12/01/2018

Part 3 of 18

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROSA VIVA) - PINK

octinoxate lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)
PALMITIC ACID (UNII: 2V16EO95H1)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.43 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/29/2016	12/01/2018

Part 4 of 18

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD CORAL ENSUENO) - RED

octinoxate lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q6130CQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
PALMITIC ACID (UNII: 2V16EO95H1)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.43 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/29/2016	12/01/2018

Part 5 of 18

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROJO GLAM) - RED

octinoxate lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)
PALMITIC ACID (UNII: 2V16EO95HI)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.43 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/29/2016	12/01/2018

Part 6 of 18

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD CAFE HABANO) - BROWN

octinoxate lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q6130CQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
PALMITIC ACID (UNII: 2V16EO95H1)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.43 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/29/2016	12/01/2018

Part 7 of 18

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD FUCSIA VIBRANTE) - PINK

octinoxate lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)
PALMITIC ACID (UNII: 2V16EO95H1)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.43 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/29/2016	12/01/2018

Part 8 of 18

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD MELON INTENSE) - PINK

octinoxate lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q6130CQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
PALMITIC ACID (UNII: 2V16EO95H1)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.43 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/29/2016	12/01/2018

Part 9 of 18

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROSADO CHIC) - PINK

octinoxate lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)
PALMITIC ACID (UNII: 2V16EO95H1)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.43 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/29/2016	12/01/2018

Part 10 of 18

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD CIRUELA GLAM) - RED

octinoxate lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q6130CQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
PALMITIC ACID (UNII: 2V16EO95H1)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.43 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/29/2016	12/01/2018

Part 11 of 18

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD FRAMBUESA ENCANTO) - PURPLE

octinoxate lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)
PALMITIC ACID (UNII: 2V16EO95H1)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.43 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/29/2016	12/01/2018

Part 12 of 18

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD MAGENTA SWEET) - PURPLE

octinoxate lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q6130CQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
PALMITIC ACID (UNII: 2V16EO95H1)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.43 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/29/2016	12/01/2018

Part 13 of 18

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD LAVA LIPS) - ORANGE

octinoxate lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)
PALMITIC ACID (UNII: 2V16EO95H1)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.43 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/29/2016	12/01/2018

Part 14 of 18

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD FRESA IMPERIAL) - RED

octinoxate lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q6130CQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
PALMITIC ACID (UNII: 2V16EO95H1)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.43 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/29/2016	12/01/2018

Part 15 of 18

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD FUCSIA OPULENTO) - PINK

octinoxate lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)
PALMITIC ACID (UNII: 2V16EO95H1)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.43 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/29/2016	12/01/2018

Part 16 of 18

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD BERRY BALCANIC) - RED

octinoxate lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q6130CQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
PALMITIC ACID (UNII: 2V16EO95H1)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.43 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/29/2016	12/01/2018

Part 17 of 18

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROSA OBSESSION) - PINK

octinoxate lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)
PALMITIC ACID (UNII: 2V16EO95H1)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.43 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/29/2016	12/01/2018

Part 18 of 18

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROJO EXHUBERANTE) - RED

octinoxate lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
PALMITIC ACID (UNII: 2V16EO95H1)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.43 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

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OTC monograph final	part352	02/29/2016	12/01/2018

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/29/2016	12/01/2018

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-729, 13537-730, 13537-731, 13537-732, 13537-733, 13537-734, 13537-735, 13537-736, 13537-737, 13537-738, 13537-739, 13537-740, 13537-741, 13537-742, 13537-743, 13537-744, 13537-745, 13537-746, 13537-747)

Revised: 12/2018

Ventura Corporation LTD