

ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 (HD MARRON TOSCANA) - BROWN- octinoxate lipst tick
ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 (HD PIMIENTA CALIENTE) - BROWN- octinoxate lipst tick
ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 (HD VINO CAUTIVANTE) - RED- octinoxate lipst tick
ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROSA VIVA) - PINK- octinoxate lipst tick
ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 (HD CORAL ENSUENO) - RED- octinoxate lipst tick
ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROJO GLAM) - RED- octinoxate lipst tick
ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 (HD CAFE HABANO) - BROWN- octinoxate lipst tick
ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 (HD FUCSIA VIBRANTE) - PINK- octinoxate lipst tick
ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 (HD DURAZNO NUDE) - PINK- octinoxate lipst tick
ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 (HD NARANJA PROVOCACION) - ORANGE- octinoxate lipst tick
ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 (HD MELON INTENSE) - PINK- octinoxate lipst tick
ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROSADO CHIC) - PINK- octinoxate lipst tick
ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 (HD CIRUELA GLAM) - RED- octinoxate lipst tick
ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 (HD FRAMBUESA ENCANTO) - RED- octinoxate lipst tick
ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 (HD MAGENTA SWEET) - PURPLE- octinoxate lipst tick
ESIKA 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.

ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20

Drug Facts

Active Ingredients

OCTINOXATE (6.8%)

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 this 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 POLYMETHYLSILSESQUOXANE, DIOLEYL TOCOPHERYL METHYLSILANOL.

May contain:

IRON OXIDES, MICA, TITANIUM DIOXIDE, YELLOW 5 LAKE, RED 30 LAKE, RED 7 LAKE, RED 27 LAKE, CALCIUM ALUMINUM BOROSILICATE, RED 6 LAKE, CARMINE, TIN OXIDE, TALC

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

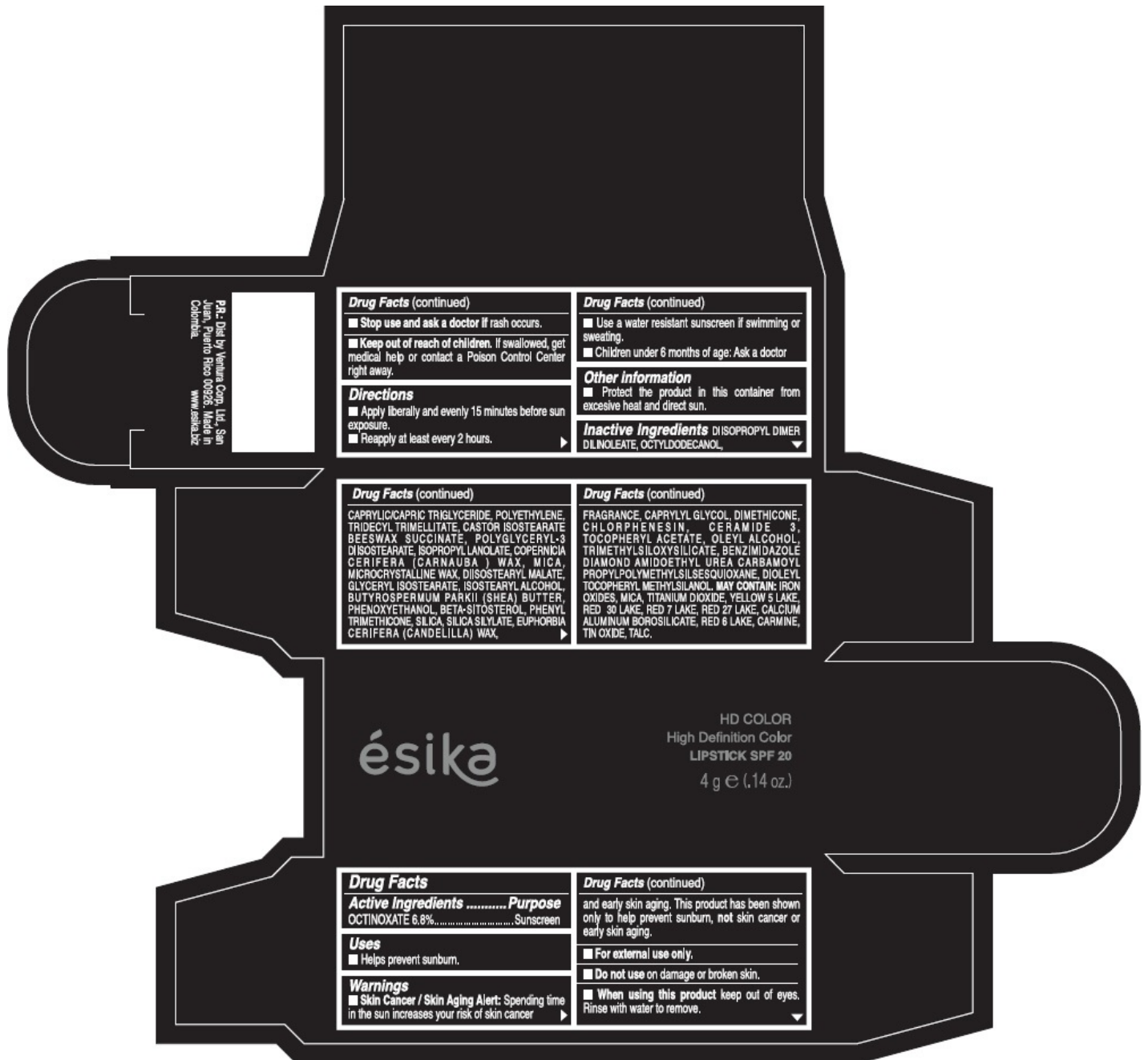
PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD MARRÓN TOSCANA) - BROWN

ésika

HD COLOR
High Definition Color

LIPSTICK SPF 20

4 g e (.14 oz.)

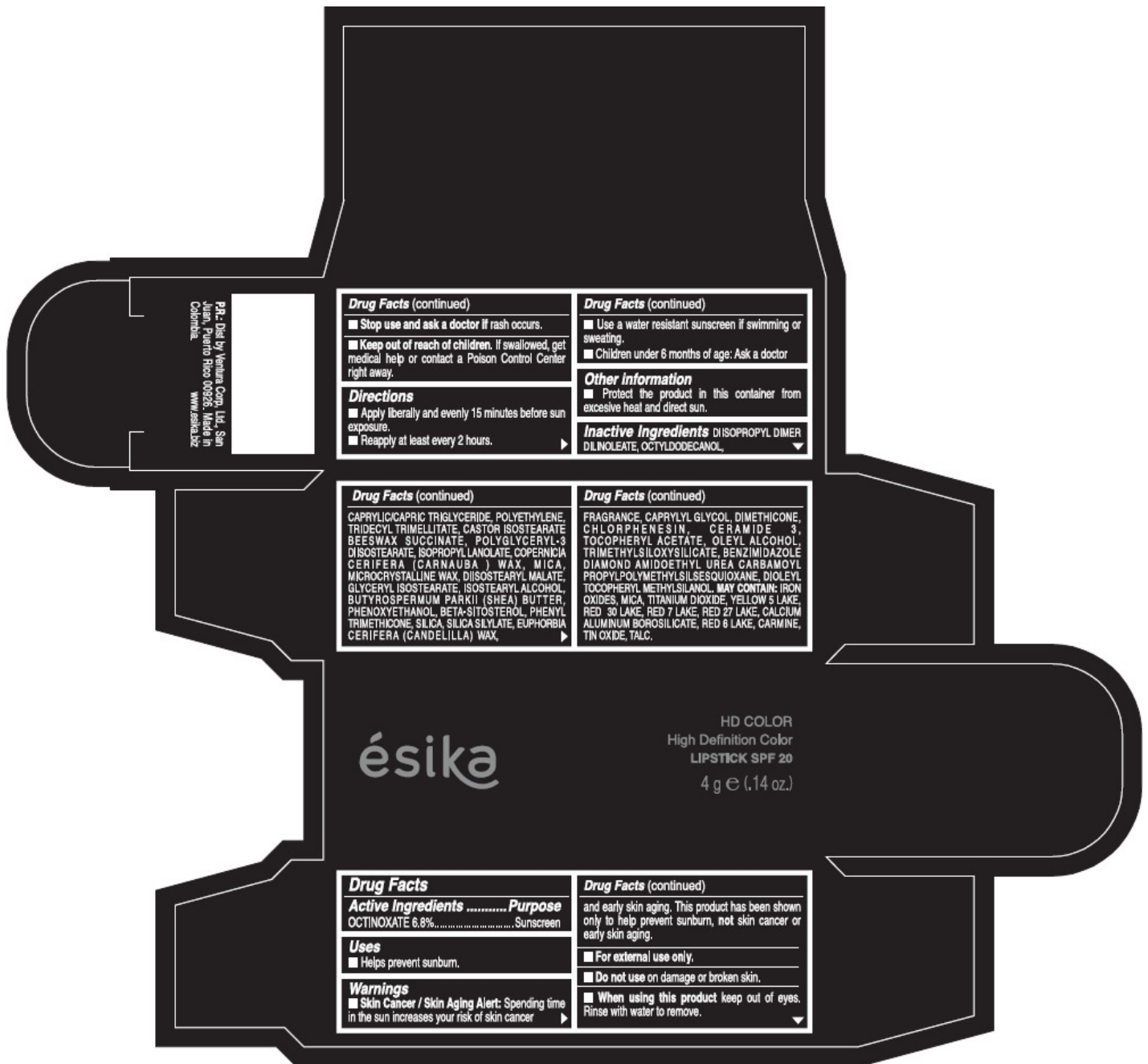


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD PIMIENTA CALIENTE) - BROWN

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

4 g e (.14 oz.)

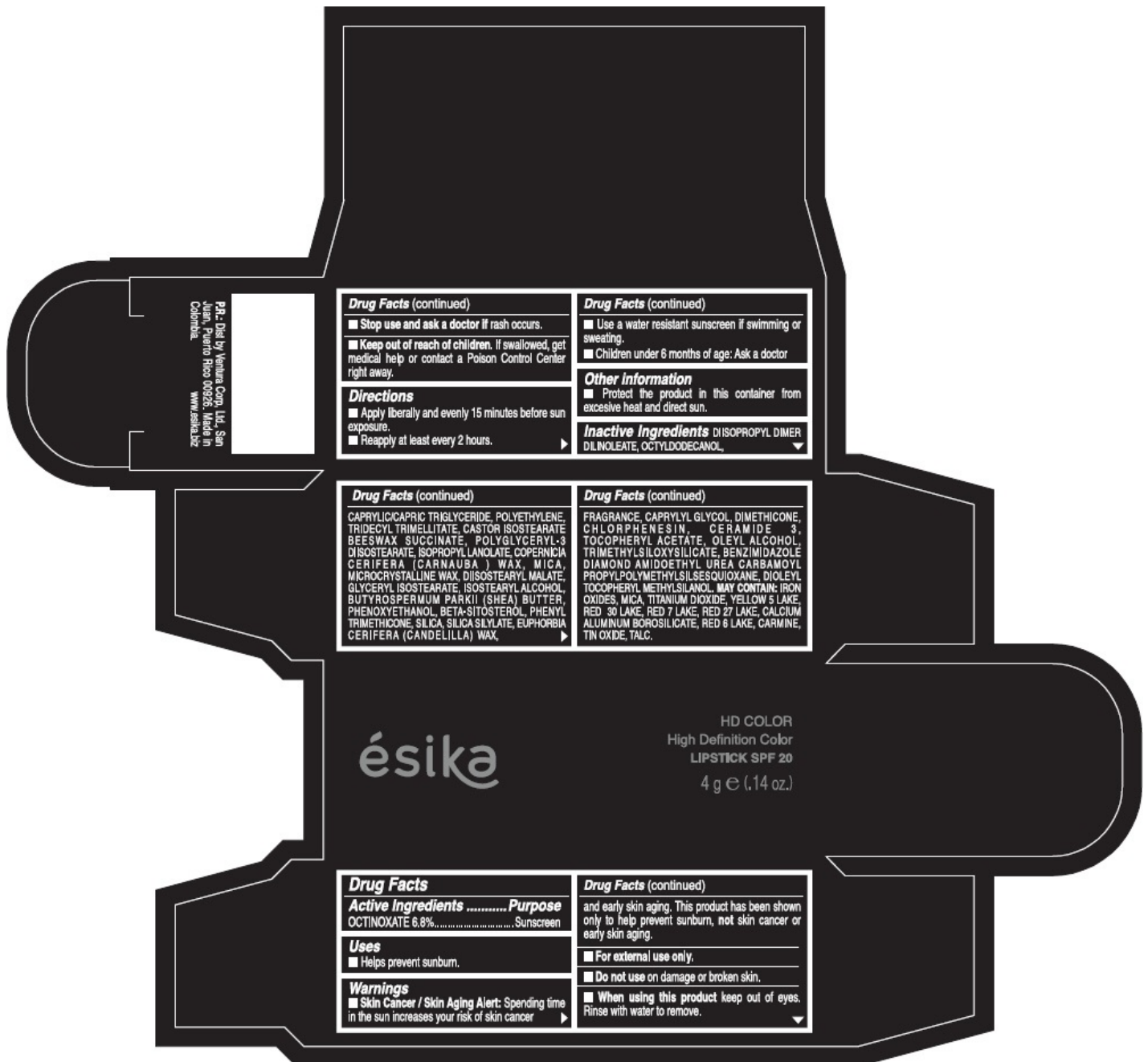


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD VINO CAUTIVANTE) - RED

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

4 g e (.14 oz.)

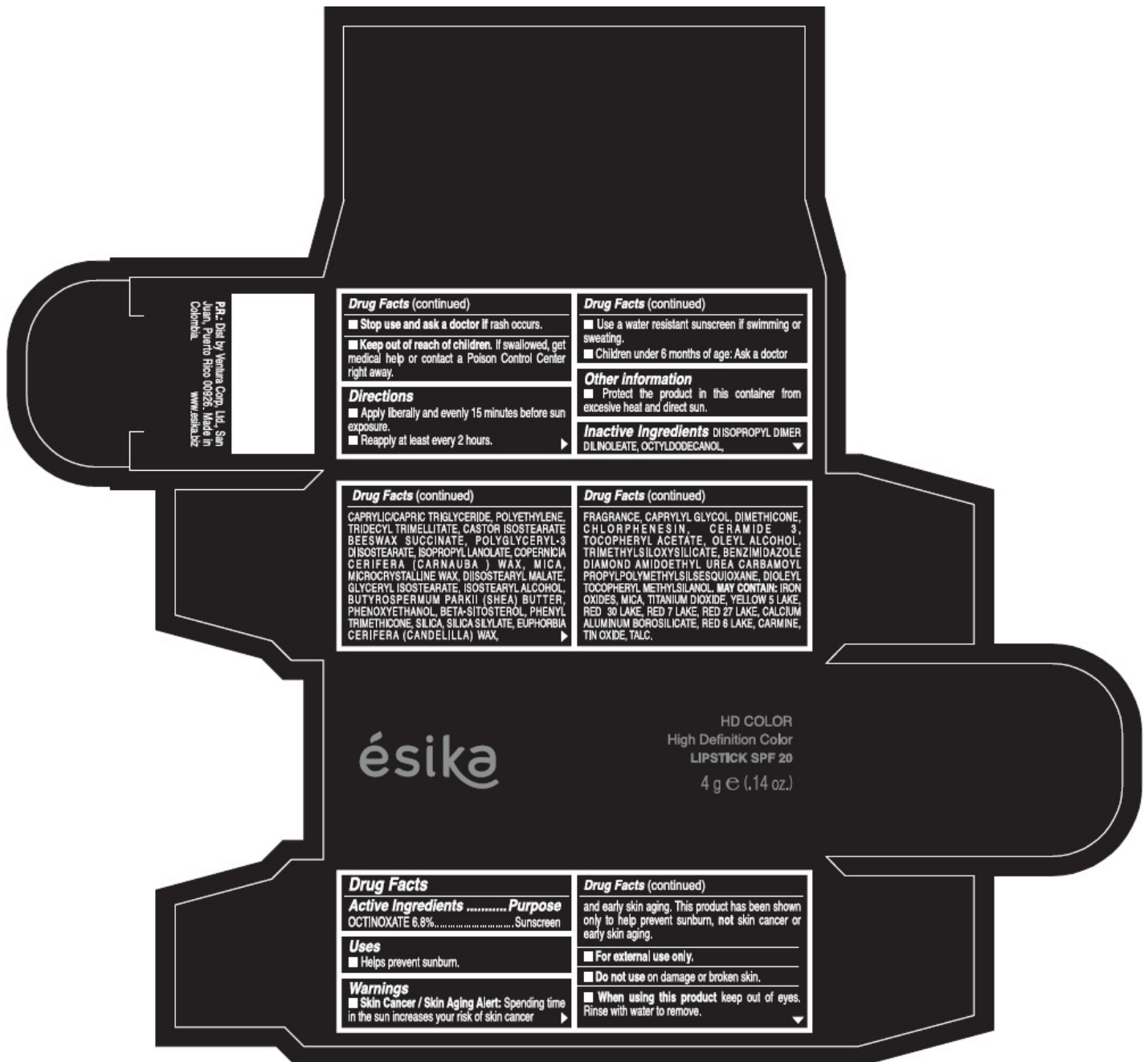


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD ROSA VIVA) - PINK

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HD COLOR
High Definition Color
LIPSTICK SPF 20

4 g e (.14 oz.)

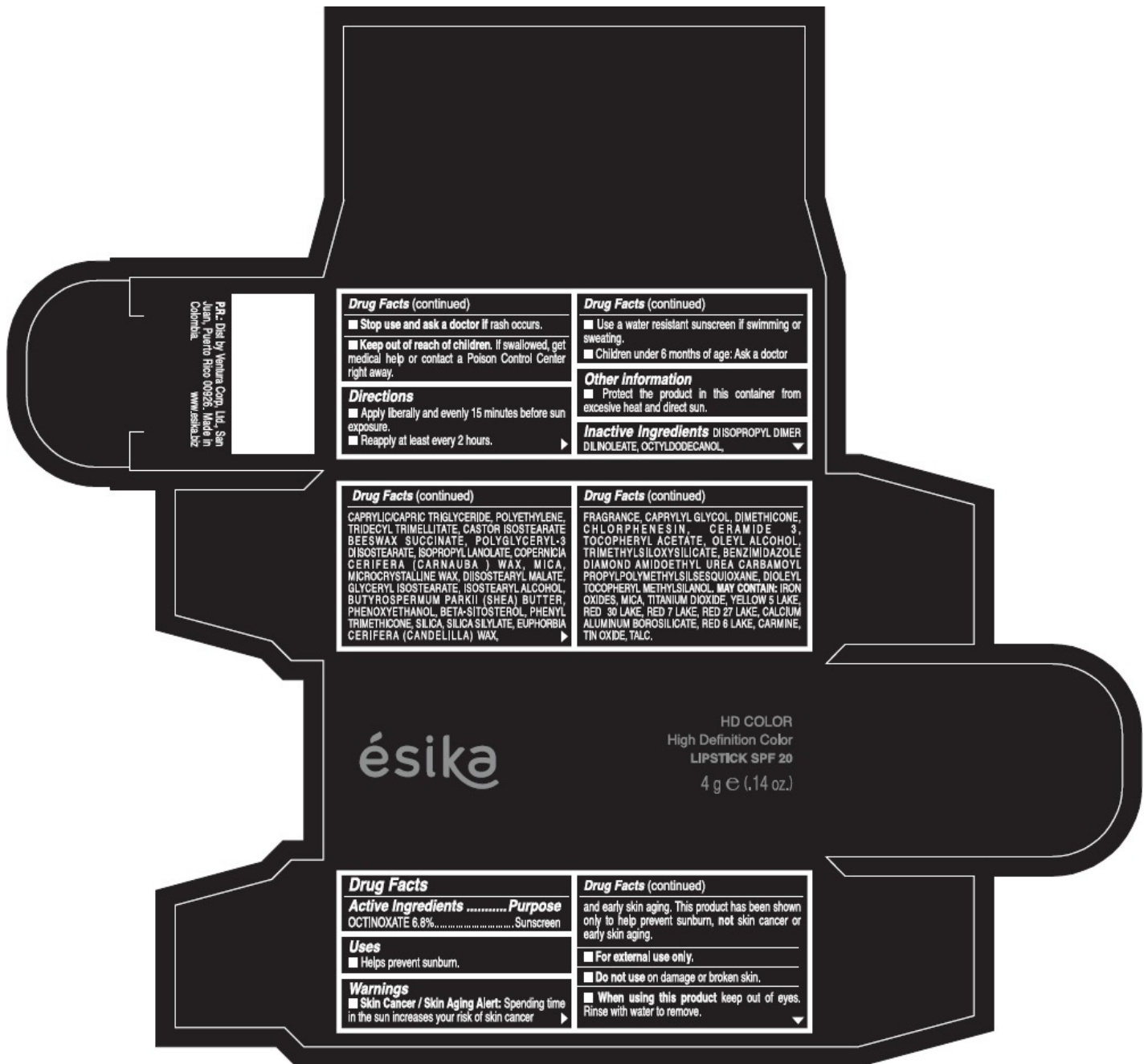


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD CORAL ENSUEÑO) - RED

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

4 g e (.14 oz.)

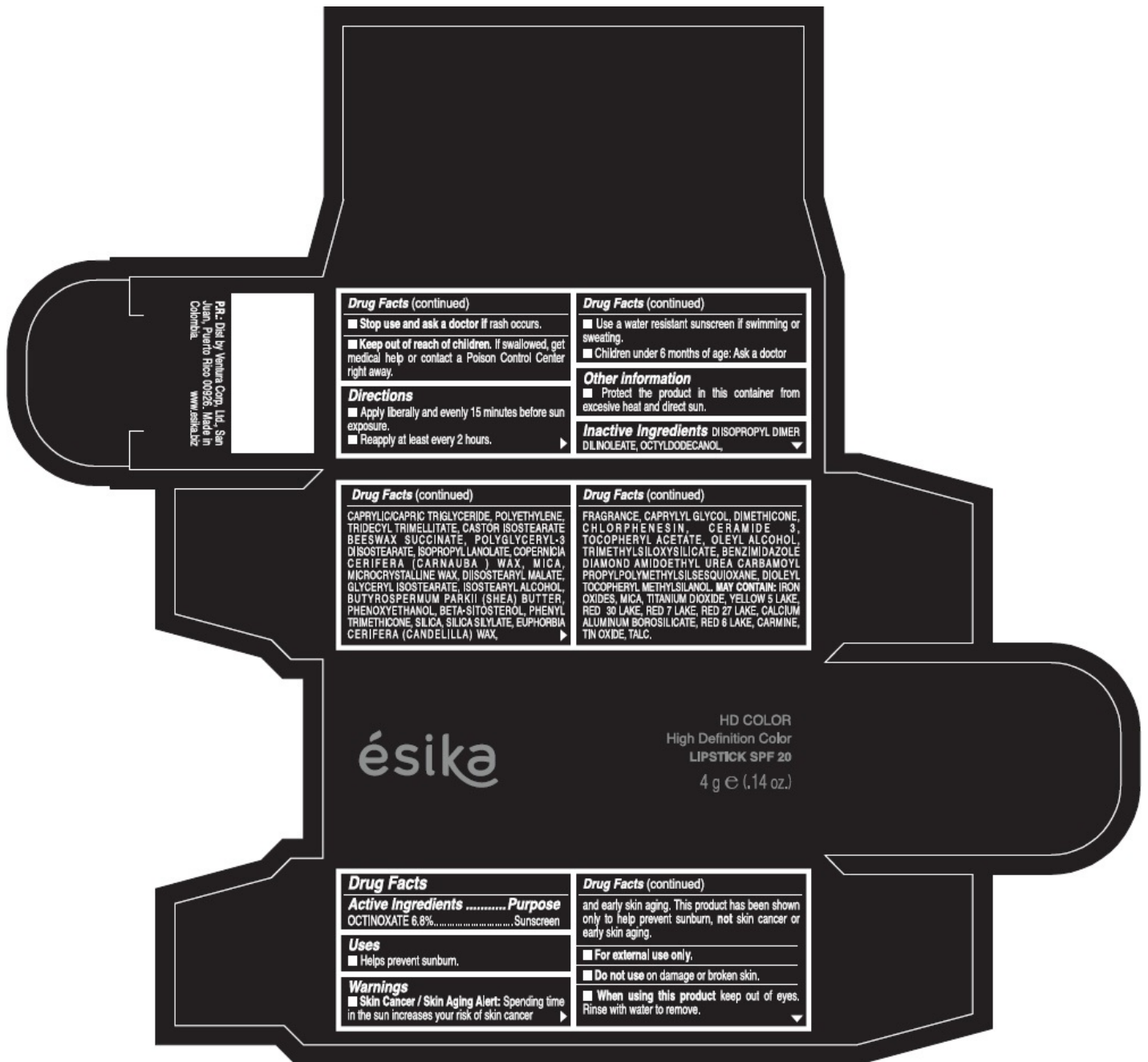


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD ROJO GLAM) - RED

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

4 g e (.14 oz.)



P.R. Dist by Mentura Corp., Ltd., San Juan, Puerto Rico 00926, Made in Colombia.
www.esika.biz

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

Directions
 ■ Apply liberally and evenly 15 minutes before sun exposure.
 ■ Reapply at least every 2 hours.

Drug Facts (continued)
 ■ 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.

Drug Facts (continued)
 CAPRYLIC/CAPRIC TRIGLYCERIDE, POLYETHYLENE TRIDECYL TRIMELLITATE, CASTOR ISOSTEARATE BEESWAX SUCCINATE, POLYGLYCERYL-3 DISOSTEARATE, ISOPROPYL ANOLATE, COPERNICIA CERIFERA (CARNAUBA) WAX, MICA, MICROCRYSTALLINE WAX, DISOSTEARYL MALATE, GLYCERYL ISOSTEARATE, ISOSTEARYL ALCOHOL, BUTYROSPERMUM PARKII (SHEA) BUTTER, PHENOXYETHANOL, BETA-SITOSTEROL, PHENYL TRIMETHICONE, SILICA, SILICA SILYLATE, EUPHORBIA CERIFERA (CANDELILLA) WAX.

Drug Facts (continued)
 FRAGRANCE, CAPRYLYL GLYCOL, DIMETHICONE, CHLORPHENESIN, CERAMIDE 3, TOCOPHERYL ACETATE, OLEYL ALCOHOL, TRIMETHYLSILOXYSILICATE, BENZIMIDAZOLE DIAMOND AMIDOTHYLUREA, CARBAMOYL PROPYLPOLYMETHYLSILSESQUOXANE, DIOLEYL TOCOPHERYL METHYLSILANOL. MAY CONTAIN: IRON OXIDES, MICA, TITANIUM DIOXIDE, YELLOW 5 LAKE, RED 30 LAKE, RED 7 LAKE, RED 27 LAKE, CALCIUM ALUMINUM BOROSILICATE, RED 6 LAKE, CARMINE, TIN OXIDE, TALC.

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HD COLOR
 High Definition Color
 LIPSTICK SPF 20
 4 g e (.14 oz.)

Drug Facts
Active Ingredients **Purpose**
 OCTINOXATE 6.8%..... 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.**

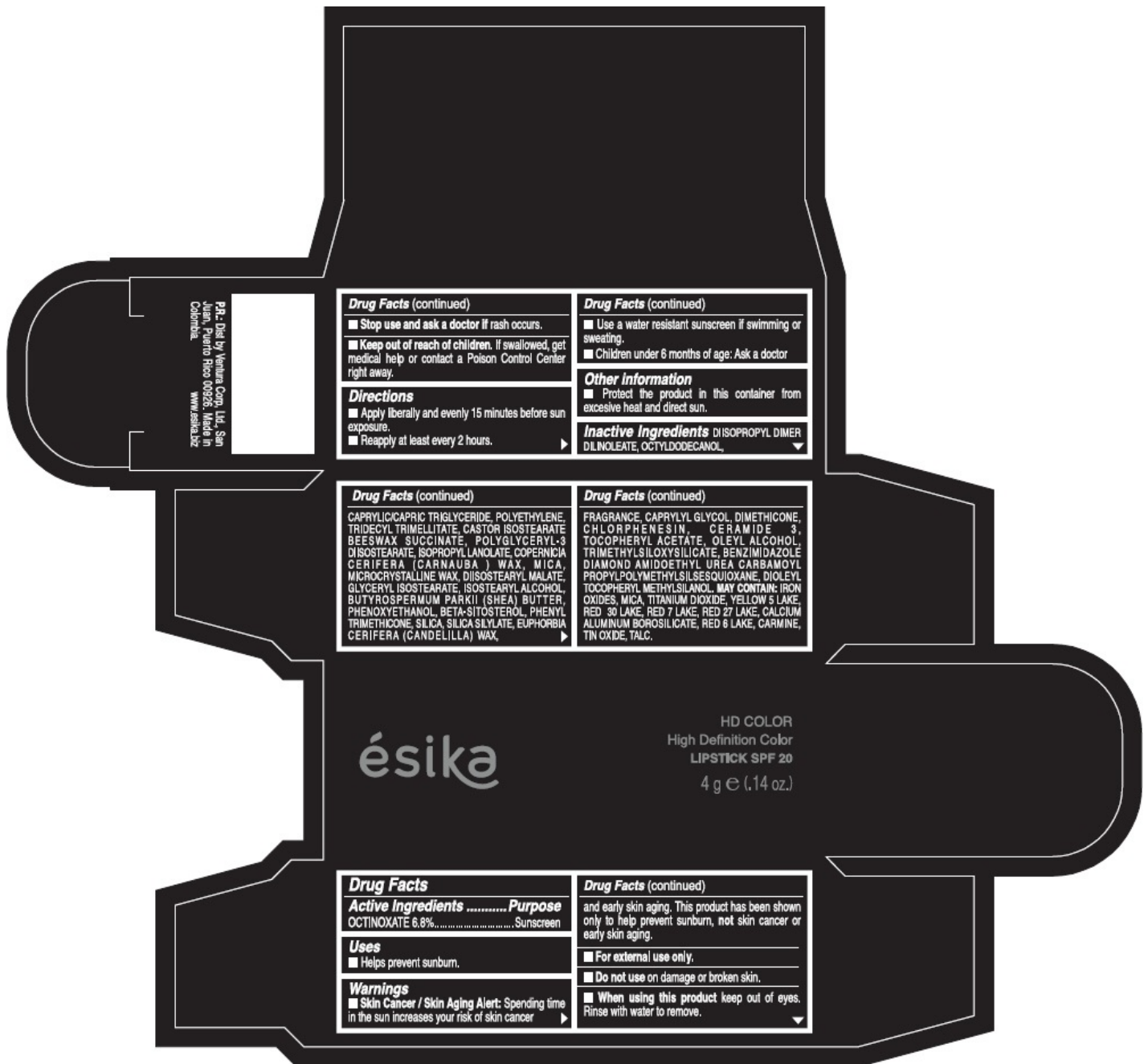
■ **Do not use** on damage or broken skin.
 ■ **When using this product** keep out of eyes. Rinse with water to remove.

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

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HD COLOR
 High Definition Color
 LIPSTICK SPF 20

4 g e (.14 oz.)

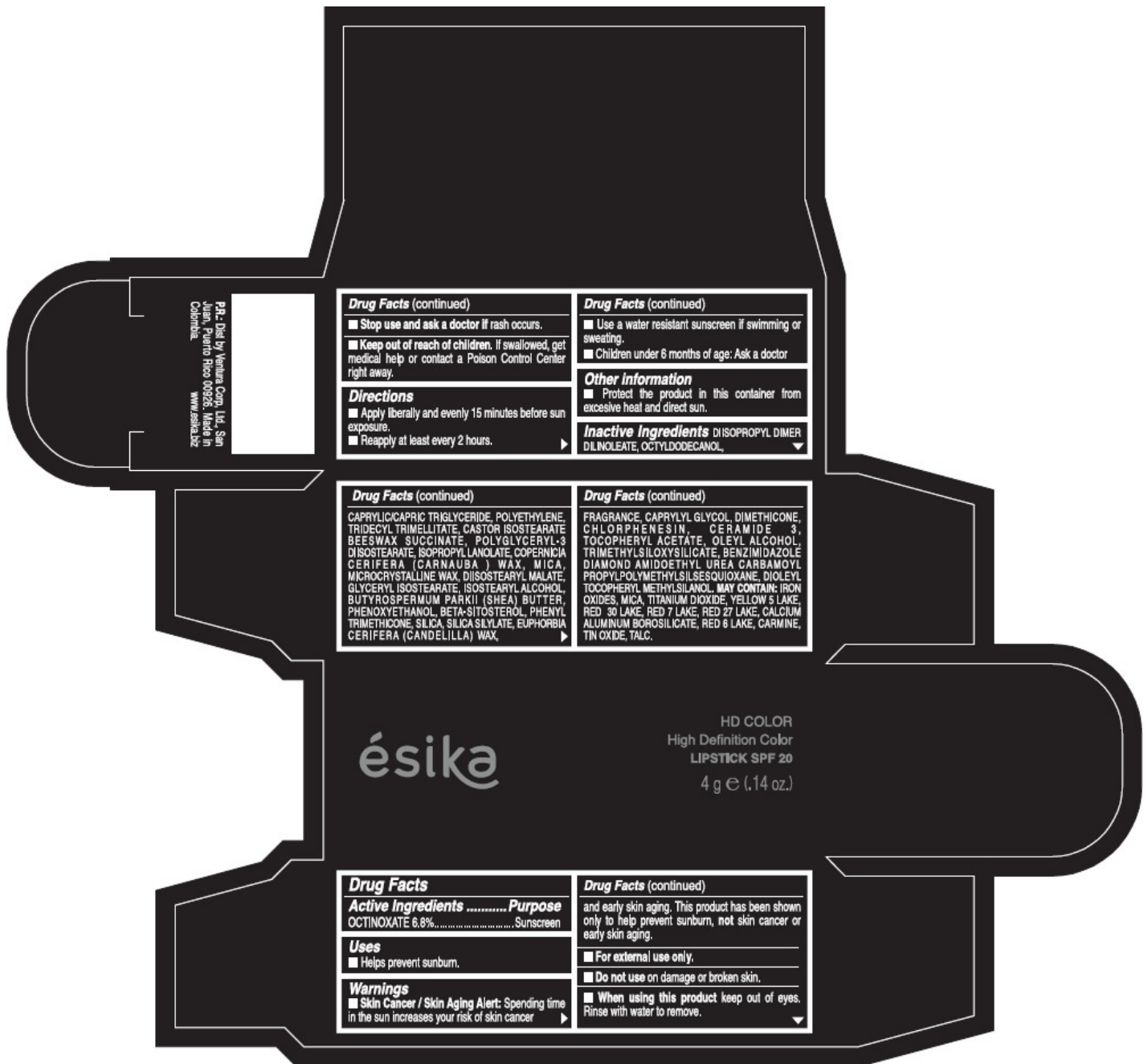


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD FUCSIA VIBRANTE) - PINK

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HD COLOR
High Definition Color
LIPSTICK SPF 20

4 g e (.14 oz.)

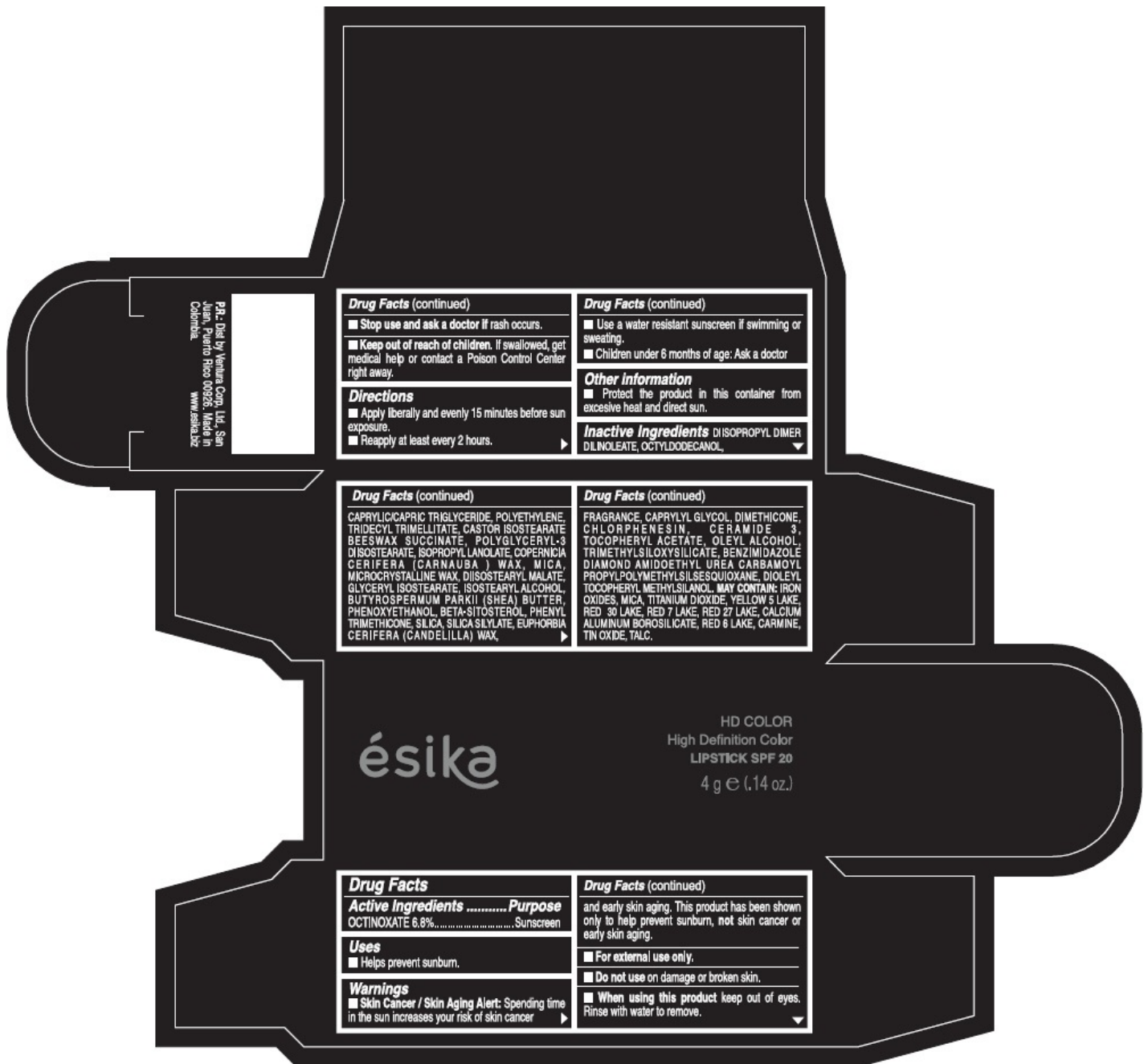


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD DURAZNO NUDE) - PINK

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HD COLOR
High Definition Color
LIPSTICK SPF 20

4 g e (.14 oz.)

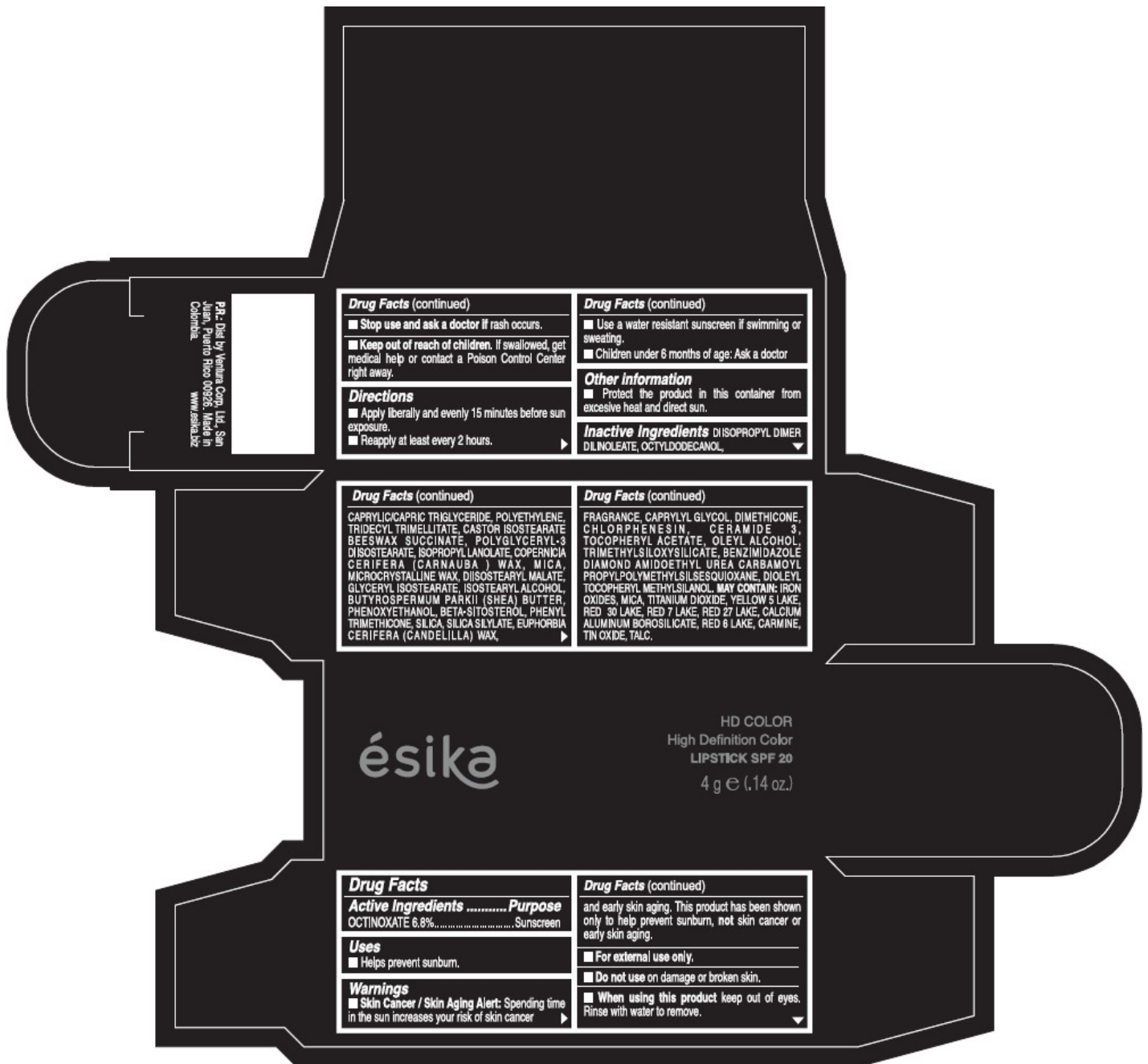


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD NARANJA PROVOCACIÓN) - ORANGE

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

4 g e (.14 oz.)

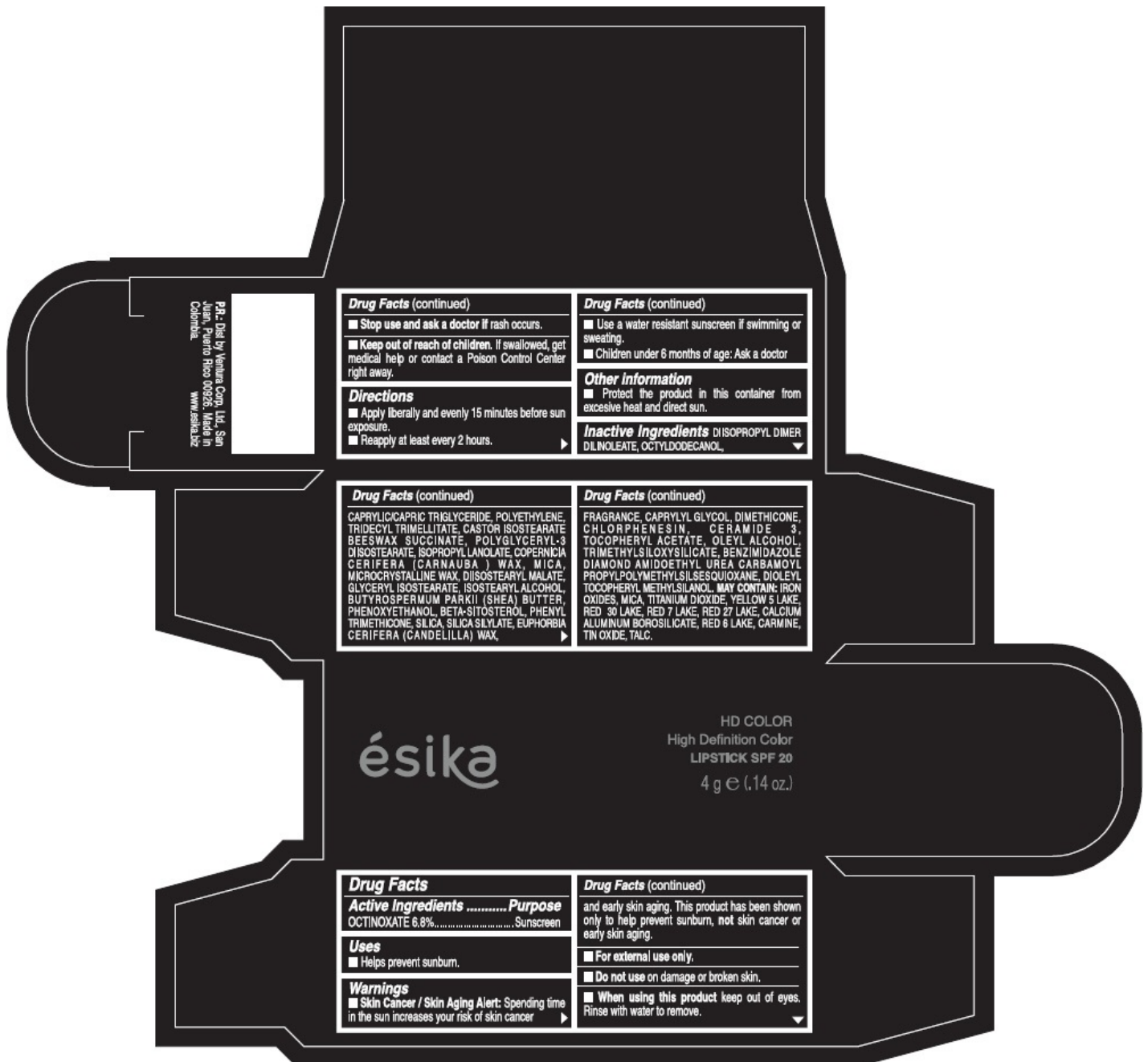


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD MELÓN INTENSE) - PINK

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

4 g e (.14 oz.)

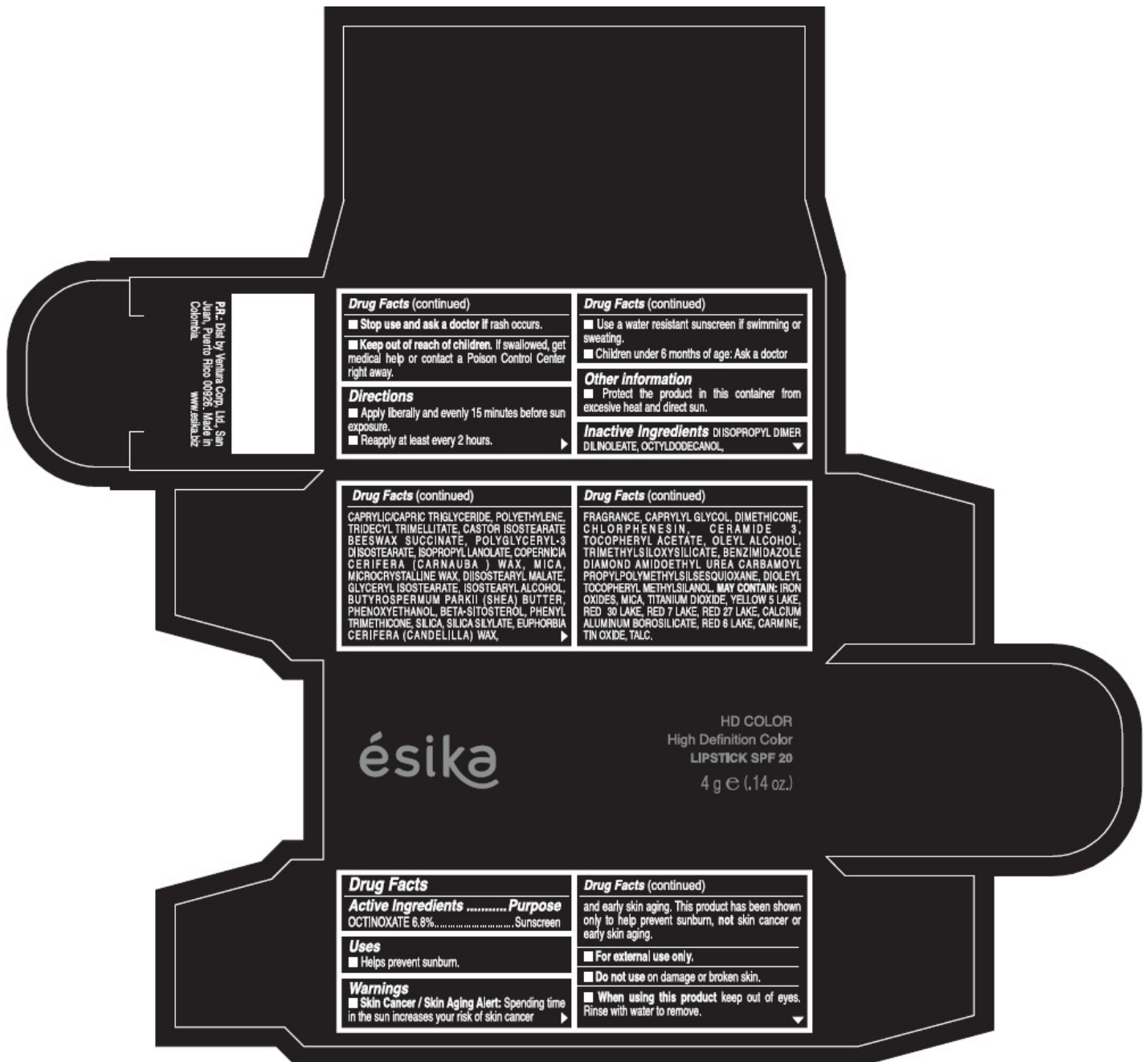


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD ROSADO CHIC) - PINK

ésika

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

4 g e (.14 oz.)

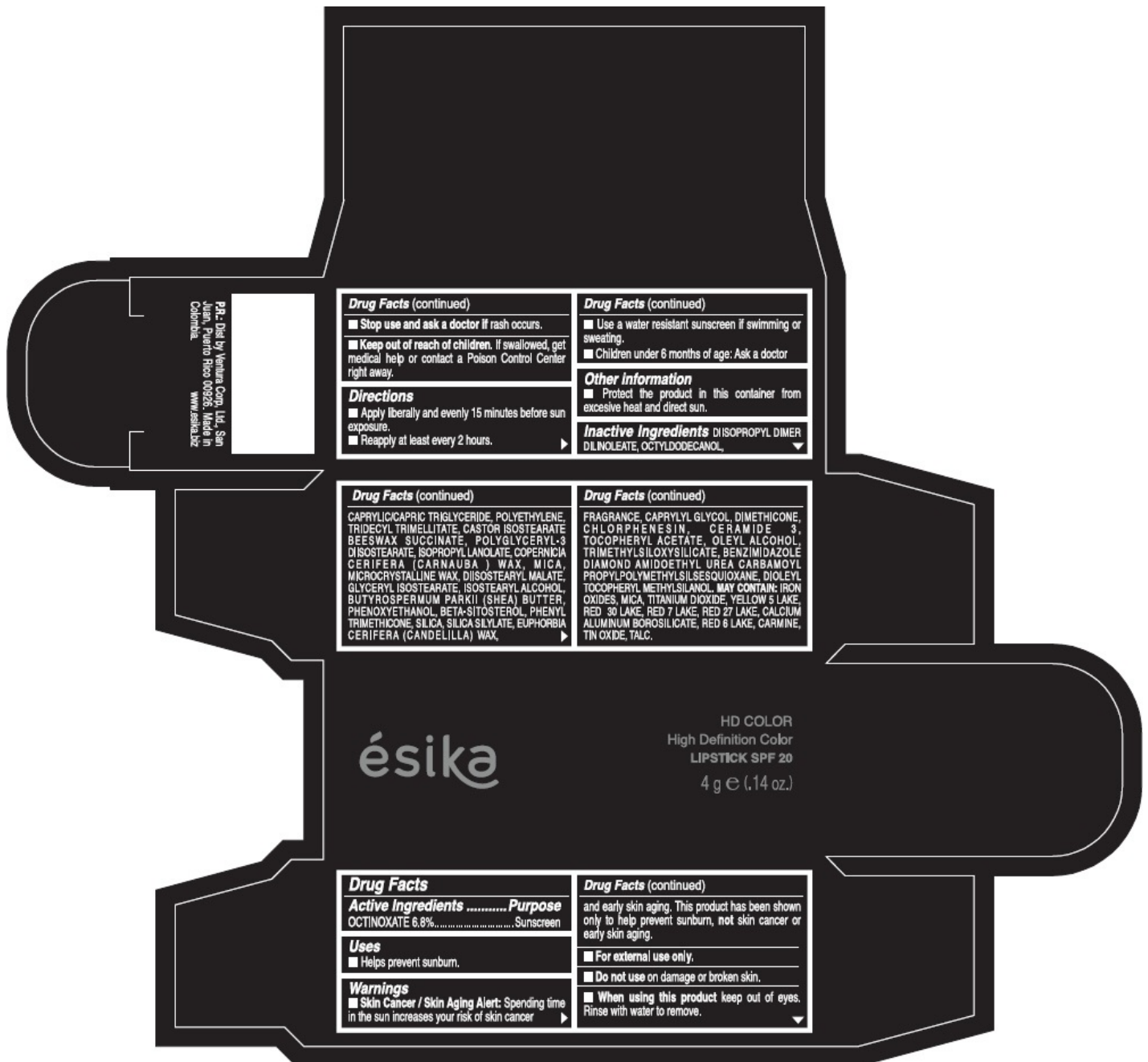


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD CIRUELA GLAM) - RED

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

4 g e (.14 oz.)

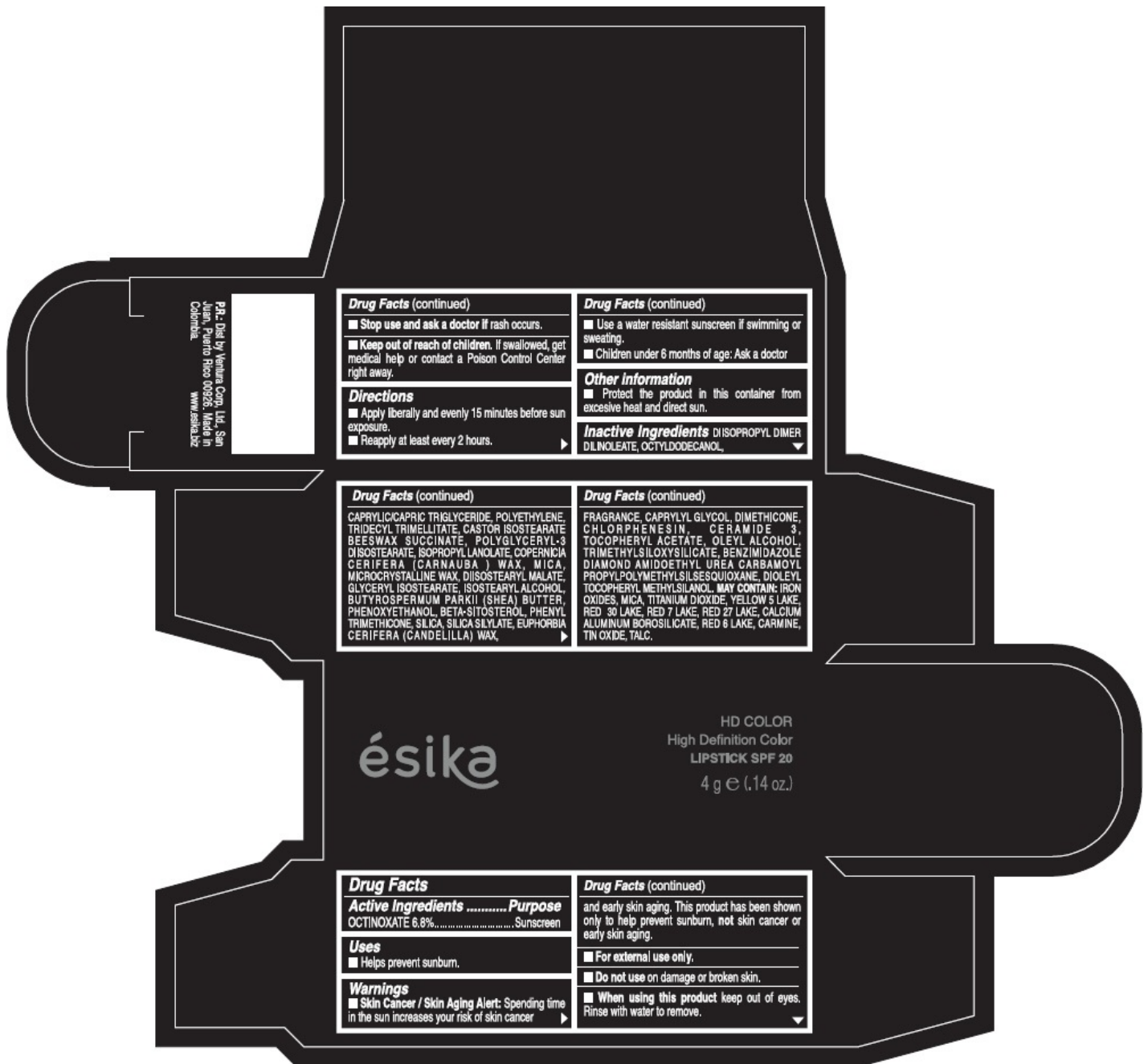


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD FRAMBUESA ENCANTO) - RED

ésika

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

4 g e (.14 oz.)

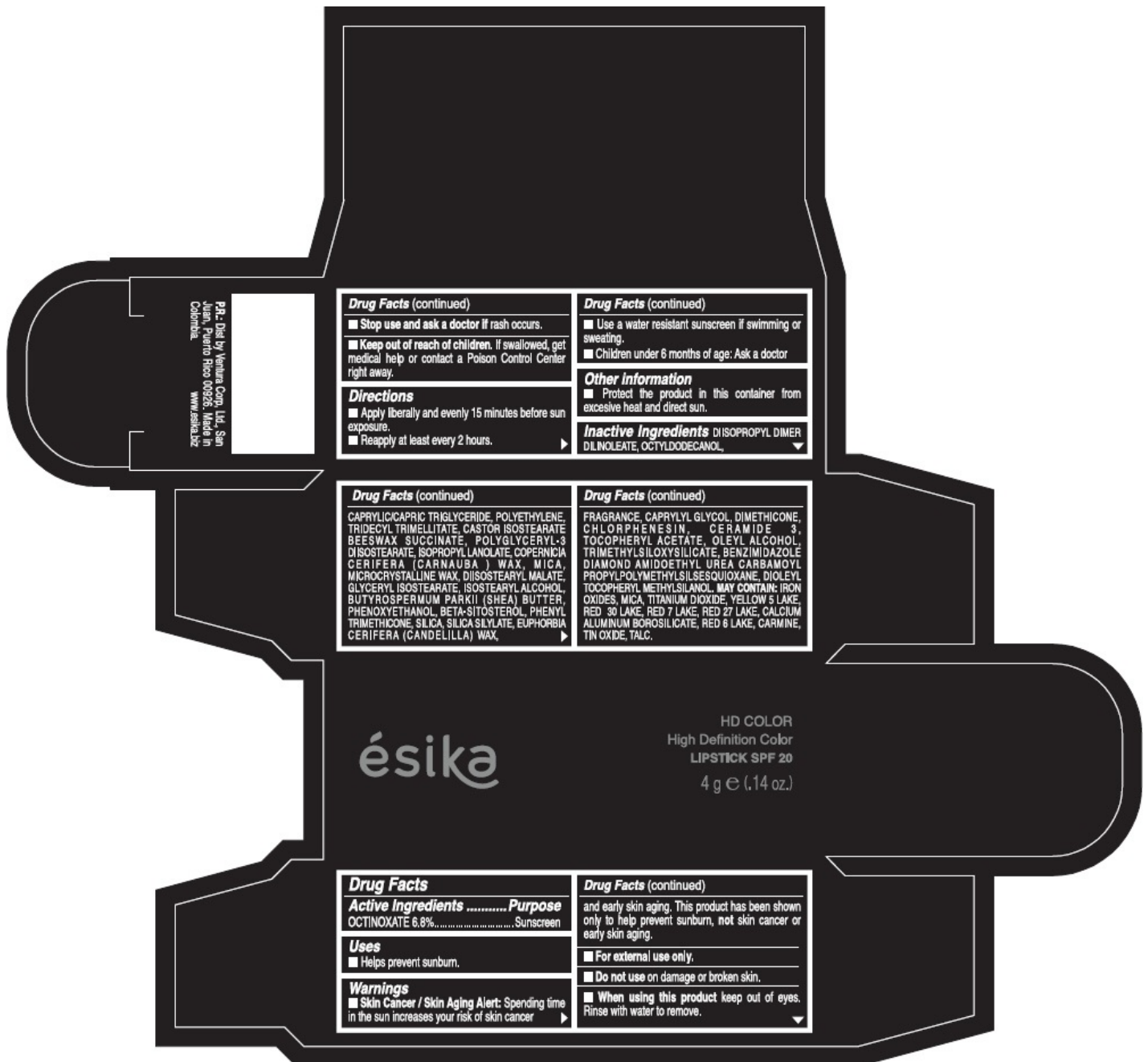


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (HD MAGENTA SWEET) - PURPLE

ésika

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

4 g e (.14 oz.)



PRINCIPAL DISPLAY PANEL - Kit Carton

HD COLOR
HIGH DEFINITION COLOR LIPSTICK
SPF 20

ésika

Net Weight
 0.275 oz. e (7.8 g)



www.esika.biz

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

Inactive Ingredients DIISOPROPYL DIMER DILINOLATE, OCTYLODECANOL, CAPRYL/CAPRIC TRIGLYCERIDE, POLYETHYLENE TRIDECYL TRIMELLATE, CASTOR ISOSTEARATE BEESWAX SUCCINATE, CERIUM OXIDE, IRON OXIDES, MICA, TITANIUM DIOXIDE, YELLOW 6 LAKE, RED 30 LAKE, RED 27 LAKE, CALCIUM ALUMINUM BORSILICATE, RED 8 LAKE, CAPRAMINE, TIN OXIDE, TALC.

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

Drug Facts (continued)
■ Children under 6 months of age: Ask a doctor.

- Use a water resistant sunscreen if swimming or sweating.
- Reapply at least every 2 hours.
- Apply liberally and evenly 15 minutes before sun exposure.

Directions

- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
- Stop use and ask a doctor if rash occurs.
- When using this product keep out of eyes. Rinse with water to remove.
- Do not use on damaged or broken skin.
- For external use only.

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.

- Helps prevent sunburn.

Uses

Active Ingredients Sunscreen
OCTINOXATE (6.8%)

Drug Facts

HD COLOR
HIGH DEFINITION COLOR LIPSTICK
SPF 20

ésika

HASTA **5**
VECES MÁS

INTENSIDAD DE COLOR EN TUS LABIOS*

Net Weight
0.275 oz. e (7.8 g)

*Resultados obtenidos en Evaluación mediante panel de Jueces Sensoriales comparando el Labial HD de Érika con otros productos del mercado.

ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 (HD MARRON TOSCANA) - BROWN

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-001
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 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 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 30 (UNII: 2S42T2808B)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
D&C RED NO. 6 (UNII: 481744A4O)
STANNIC OXIDE (UNII: KM7N50LOS6)
TALC (UNII: 7SEV7J4R1U)
ALUMINUM OXIDE (UNII: LM26O6933)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-001-02	1 in 1 BOX		
1	NDC:13537-001-01	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	04/03/2014	

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

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-002
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 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
D&C RED NO. 6 (UNII: 481744AI4O)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
TALC (UNII: 7SEV7J4R1U)	
ALUMINUM OXIDE (UNII: LM26O6933)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-002-04	1 in 1 BOX		
1	NDC:13537-002-03	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	04/03/2014	

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

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-003
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 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 30 (UNII: 2S42T2808B)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)
D&C RED NO. 6 (UNII: 481744A140)
STANNIC OXIDE (UNII: KM7N50LOS6)
TALC (UNII: 7SEV7J4R1U)
ALUMINUM OXIDE (UNII: LM26O6933)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-003-06	1 in 1 BOX		
1	NDC:13537-003-05	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	04/03/2014	

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

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-004
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: 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 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 30 (UNII: 2S42T2808B)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)
D&C RED NO. 6 (UNII: 481744AI4O)
STANNIC OXIDE (UNII: KM7N50LOS6)
TALC (UNII: 7SEV7J4R1U)
ALUMINUM OXIDE (UNII: LM26O6933)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-004-08	1 in 1 BOX		
1	NDC:13537-004-07	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	04/03/2014	

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

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-005
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 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
D&C RED NO. 6 (UNII: 481744A14O)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
TALC (UNII: 7SEV7J4R1U)	
ALUMINUM OXIDE (UNII: LM26O6933)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-005-10	1 in 1 BOX		

1	NDC:13537-005-09	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	04/03/2014		

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

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-006
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 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

OLEYL ALCOHOL (UNII: 172F2WN8DV)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 30 (UNII: 2S42T2808B)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
D&C RED NO. 6 (UNII: 481744A4O)
STANNIC OXIDE (UNII: KM7N50LOS6)
TALC (UNII: 7SEV7J4R1U)
ALUMINUM OXIDE (UNII: LM26O6933)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-006-12	1 in 1 BOX		
1	NDC:13537-006-11	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	04/03/2014	

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

octinoxate lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-007
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 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 30 (UNII: 2S42T2808B)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
D&C RED NO. 6 (UNII: 481744A4O)
STANNIC OXIDE (UNII: KM7N50LOS6)
TALC (UNII: 7SEV7J4R1U)
ALUMINUM OXIDE (UNII: LM26O6933)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-007-14	1 in 1 BOX		
1	NDC:13537-007-13	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	04/03/2014	

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

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-008
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 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)	
D&C RED NO. 6 (UNII: 481744AI4O)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
TALC (UNII: 7SEV7J4R1U)	
ALUMINUM OXIDE (UNII: LM26O6933)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-008-16	1 in 1 BOX		
1	NDC:13537-008-15	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	04/03/2014	

ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 (HD DURAZNO NUDE) - PINK
 octinoxate lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-009
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 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 30 (UNII: 2S42T2808B)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
D&C RED NO. 6 (UNII: 481744A14O)
STANNIC OXIDE (UNII: KM7N50LOS6)
TALC (UNII: 7SEV7J4R1U)
ALUMINUM OXIDE (UNII: LMI26O6933)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-009-18	1 in 1 BOX		
1	NDC:13537-009-17	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	04/03/2014	

ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 (HD NARANJA PROVOCACION) - ORANGE

octinoxate lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-016
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: 461N10614Y)	
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 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 30 (UNII: 2S42T2808B)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
D&C RED NO. 6 (UNII: 481744AI4O)
STANNIC OXIDE (UNII: KM7N50LOS6)
TALC (UNII: 7SEV7J4R1U)
ALUMINUM OXIDE (UNII: LMI26O6933)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-016-20	1 in 1 BOX		
1	NDC:13537-016-19	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	04/03/2014	

**ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 (HD MELON INTENSE)
- PINK**
octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-017
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 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)	
D&C RED NO. 6 (UNII: 481744AI4O)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
TALC (UNII: 7SEV7J4R1U)	
ALUMINUM OXIDE (UNII: LM26O6933)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-017-22	1 in 1 BOX		
1	NDC:13537-017-21	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	04/03/2014	

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

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-018
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 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 30 (UNII: 2S42T2808B)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
D&C RED NO. 6 (UNII: 481744AI4O)
STANNIC OXIDE (UNII: KM7N50LOS6)
TALC (UNII: 7SEV7J4R1U)
ALUMINUM OXIDE (UNII: LM26O6933)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-018-24	1 in 1 BOX		
1	NDC:13537-018-23	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	04/03/2014	

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

octinoxate lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-024
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 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 30 (UNII: 2S42T2808B)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
D&C RED NO. 6 (UNII: 481744A14O)
STANNIC OXIDE (UNII: KM7N50LOS6)
TALC (UNII: 7SEV7J4R1U)
ALUMINUM OXIDE (UNII: LM26O6933)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-024-26	1 in 1 BOX		
1	NDC:13537-024-25	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	04/03/2014	

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

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-030
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 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)	
D&C RED NO. 6 (UNII: 481744AI4O)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
TALC (UNII: 7SEV7J4R1U)	

ALUMINUM OXIDE (UNII: LM26O6933)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-030-28	1 in 1 BOX		
1	NDC:13537-030-27	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	04/03/2014	

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

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-029
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 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)	
D&C RED NO. 6 (UNII: 481744AI4O)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
TALC (UNII: 7SEV7J4R1U)	
ALUMINUM OXIDE (UNII: LM26O6933)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-029-28	1 in 1 BOX		
1	NDC:13537-029-27	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	04/03/2014	

ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20

octinoxate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-236
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-236-32	2 in 1 CARTON		
1	NDC:13537-236-31	1 in 1 TUBE		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	7.8 g

Part 2	1 TUBE	7.8 g
Part 3	1 TUBE	7.8 g
Part 4	1 TUBE	7.8 g
Part 5	1 TUBE	7.8 g
Part 6	1 TUBE	7.8 g
Part 7	1 TUBE	7.8 g
Part 8	1 TUBE	7.8 g
Part 9	1 TUBE	7.8 g
Part 10	1 TUBE	7.8 g
Part 11	1 TUBE	7.8 g
Part 12	1 TUBE	7.8 g

Part 1 of 12

ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 HD MARRON TOSCANA - 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 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 30 (UNII: 2S42T2808B)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
D&C RED NO. 6 (UNII: 481744A4O)
STANNIC OXIDE (UNII: KM7N50LOS6)
TALC (UNII: 7SEV7J4R1U)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		7.8 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	05/15/2015	

Part 2 of 12

ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 HD PIMIENTA CALIENTE - 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 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
CALCIUM ALUMINUM BORSILICATE (UNII: 3JRB8A35M0)	
D&C RED NO. 6 (UNII: 481744AI4O)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
TALC (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		7.8 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	05/15/2015	

Part 3 of 12

ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 HD VINO CAUTIVANTE - 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 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
D&C RED NO. 6 (UNII: 481744A4O)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
TALC (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		7.8 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	05/15/2015	

Part 4 of 12

ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 HD ROSA VIVA - 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: 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 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)	
D&C RED NO. 6 (UNII: 481744AI4O)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
TALC (UNII: 7SEV7J4R1U)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		7.8 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	05/15/2015	

Part 5 of 12

ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 HD CORAL ENSUENO - 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 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 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
D&C RED NO. 6 (UNII: 481744A4O)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
TALC (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		7.8 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	05/15/2015	

Part 6 of 12

ESIKA 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: Q6130CQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)	
D&C RED NO. 6 (UNII: 481744A14O)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
TALC (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		7.8 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	05/15/2015	

Part 7 of 12

ESIKA 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: 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 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 30 (UNII: 2S42T2808B)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
D&C RED NO. 6 (UNII: 481744A14O)
STANNIC OXIDE (UNII: KM7N50LOS6)
TALC (UNII: 7SEV7J4R1U)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		7.8 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	05/15/2015	

Part 8 of 12

ESIKA 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 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
D&C RED NO. 6 (UNII: 481744AI4O)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
TALC (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		7.8 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	05/15/2015	

Part 9 of 12

ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 HD DURAZNO NUDE - 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: 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 3 (UNII: 4370DF050B)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 30 (UNII: 2S42T2808B)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
D&C RED NO. 6 (UNII: 481744A14O)
STANNIC OXIDE (UNII: KM7N50LOS6)
TALC (UNII: 7SEV7J4R1U)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		7.8 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	05/15/2015	

Part 10 of 12

ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 HD NARANJA PROVOCACION - 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 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 30 (UNII: 2S42T2808B)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
D&C RED NO. 6 (UNII: 481744AI4O)
STANNIC OXIDE (UNII: KM7N50LOS6)
TALC (UNII: 7SEV7J4R1U)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		7.8 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	05/15/2015	

Part 11 of 12

ESIKA 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 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
D&C RED NO. 6 (UNII: 481744AI4O)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
TALC (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		7.8 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	05/15/2015	

Part 12 of 12

ESIKA HD COLOR HIGH DEFINITION COLOR SPF 20 HD CIRUELA 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 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 30 (UNII: 2S42T2808B)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
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OTC MONOGRAPH FINAL	part352	05/15/2015	

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-001, 13537-002, 13537-003, 13537-004, 13537-005, 13537-006, 13537-007, 13537-008, 13537-009, 13537-016, 13537-017, 13537-018, 13537-024, 13537-030, 13537-029, 13537-236)