

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (MARRON GLAMOUR) - BROWN- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROJO DESEO) - RED- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROJO INTRIGANTE) - RED- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROJO LUJURIA) - RED- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (CORAL CHIC) - PINK- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROSA ENCANTO) - PINK- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (BORGONA SEXY) - PURPLE- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (FUCSIA CAUTIVANTE) - PINK- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (GRANATE SEDUCTOR) - PURPLE- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROSA ROMANTICA) - PINK- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (NARANJA PRIMAVERA) - ORANGE- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (FRAMBUESA MANIA) - RED- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROSA DULZURA) - PINK- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (PIMIENTA CALIENTE) - BROWN- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (CANELA NUDE) - ORANGE- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (MORA GLAM) - BROWN- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (CORAL INTENSE) - RED- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (FRESA COQUETA) - RED- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (PIMIENTA CALIENTE FEMME) - RED- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (GRANATE SEDUCTOR FEMME) - PURPLE- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (FUCSIA CAUTIVANTE FEMME) - PINK- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROSA ROMANTICA FEMME) - PINK- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROJO INTRIGANTE FEMME) - RED- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROSA ENCANTO FEMME) - PINK- octinoxate and oxybenzone lipstick
Ventura Corporation LTD

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

ÉSIKA HYDRACOLOR 2 IN 1 Highly Moisturizing and coloring SPF 25

Drug Facts

Active Ingredients	Purpose
OCTINOXATE: 6.6%	Sunscreen
OXYBENZONE: 1.5%	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. Keep away from heat sources and direct sunlight. Store well and under 50°C (112°F).

Inactive ingredients

DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL TRIMELLITATE, ETHYLHEXYL PALMITATE, OZOKERITE, WATER, POLYETHYLENE, TRIDECYL STEARATE, POLYGLYCERYL-3 DIISOSTEARATE, POLYMETHYL METHACRYLATE, COPERNICIA CERIFERA (CARNAUBA) WAX, GLYCERIN, NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE, FRAGRANCE, CAPRYLIC/CAPRIC TRIGLYCERIDE, SODIUM STARCH OCTENYLSUCCINATE, TOCOPHERYL ACETATE, PHENOXYETHANOL, COCOS NUCIFERA (COCONUT) OIL, ALOE BARBADENSIS LEAF EXTRACT, CAPRYLYL GLYCOL, CERAMIDE 3, CHLORPHENESIN, PROPYLENE GLYCOL, LIMONIUM GERBERI EXTRACT, BUTYROSPERMUM PARKII (SHEA) BUTTER, GLYCINE SOJA OIL (GLYCINE SOJA (SOYBEAN) OIL), TOCOPHEROL, MAGNESIUM CHLORIDE, POTASSIUM CHLORIDE, SILICA, SODIUM CHLORIDE, VITIS VINIFERA (GRAPE) FRUIT EXTRACT

May contain:

MICA, IRON OXIDES, TITANIUM DIOXIDE, YELLOW 5 LAKE, RED 21 LAKE, RED 7 LAKE, RED 27 LAKE, TALC, RED 30 LAKE, PEG-8 METHYL ETHER TRIETHOXYSILANE, CARMINE.

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

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (MARRON GLAMOUR) - BROWN

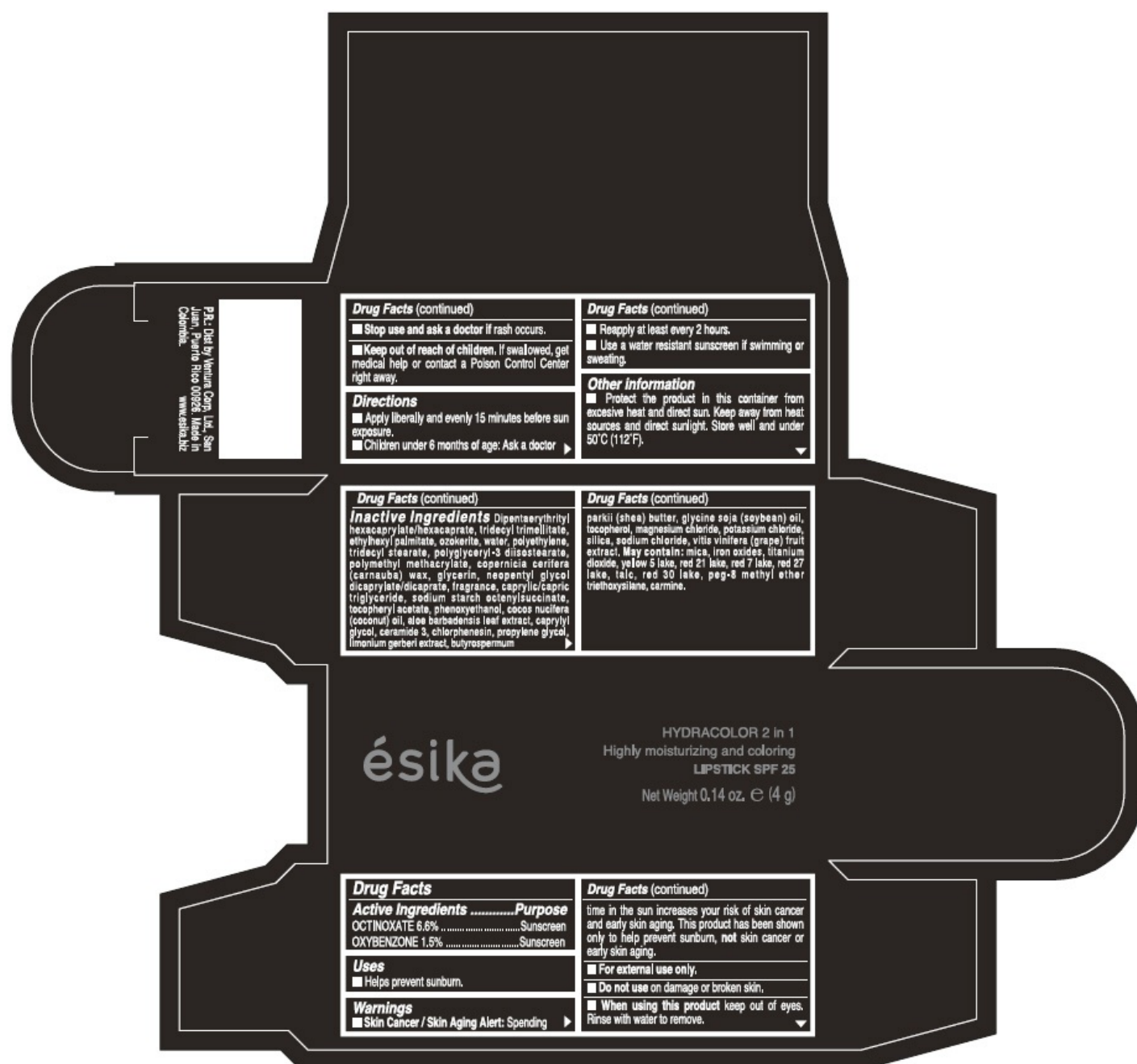
ésika

HYDRACOLOR 2 in 1

Highly moisturizing and coloring

LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)



P.R.: Dist. by Ventura 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.
- Children under 6 months of age: Ask a doctor

Drug Facts (continued)

- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.

Other information

- Protect the product in this container from excessive heat and direct sun. Keep away from heat sources and direct sunlight. Store well and under 50°C (112°F).

Drug Facts (continued)

Inactive Ingredients Dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, ethylhexyl palmitate, ozokerite, water, polyethylene, tridecyl stearate, polyglyceryl-3 diisostearate, polymethyl methacrylate, copernicia caribaea (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, fragrance, caprylic/capric triglyceride, sodium starch octenylsuccinate, tocopheryl acetate, phenoxethanol, cocos nucifera (coconut) oil, aloe barbadensis leaf extract, caprylyl glycol, ceramide 3, chlorphenesin, propylene glycol, limonium gerberi extract, butyrospermum

Drug Facts (continued)

parkii (shea) butter, glycine soja (soybean) oil, tocopherol, magnesium chloride, potassium chloride, silica, sodium chloride, vitis vinifera (grape) fruit extract. May contain: mica, iron oxides, titanium dioxide, yellow 5 lake, red 21 lake, red 7 lake, red 27 lake, talc, red 30 lake, peg-8 methyl ether triethoxysilane, carmine.

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HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25
Net Weight 0.14 oz. e (4 g)

Drug Facts

Active Ingredients **Purpose**
OCTINOXATE 6.6% Sunscreen
OXYBENZONE 1.5% Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- Skin Cancer / Skin Aging Alert: Spending

Drug Facts (continued)

time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.

For external use only.

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

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

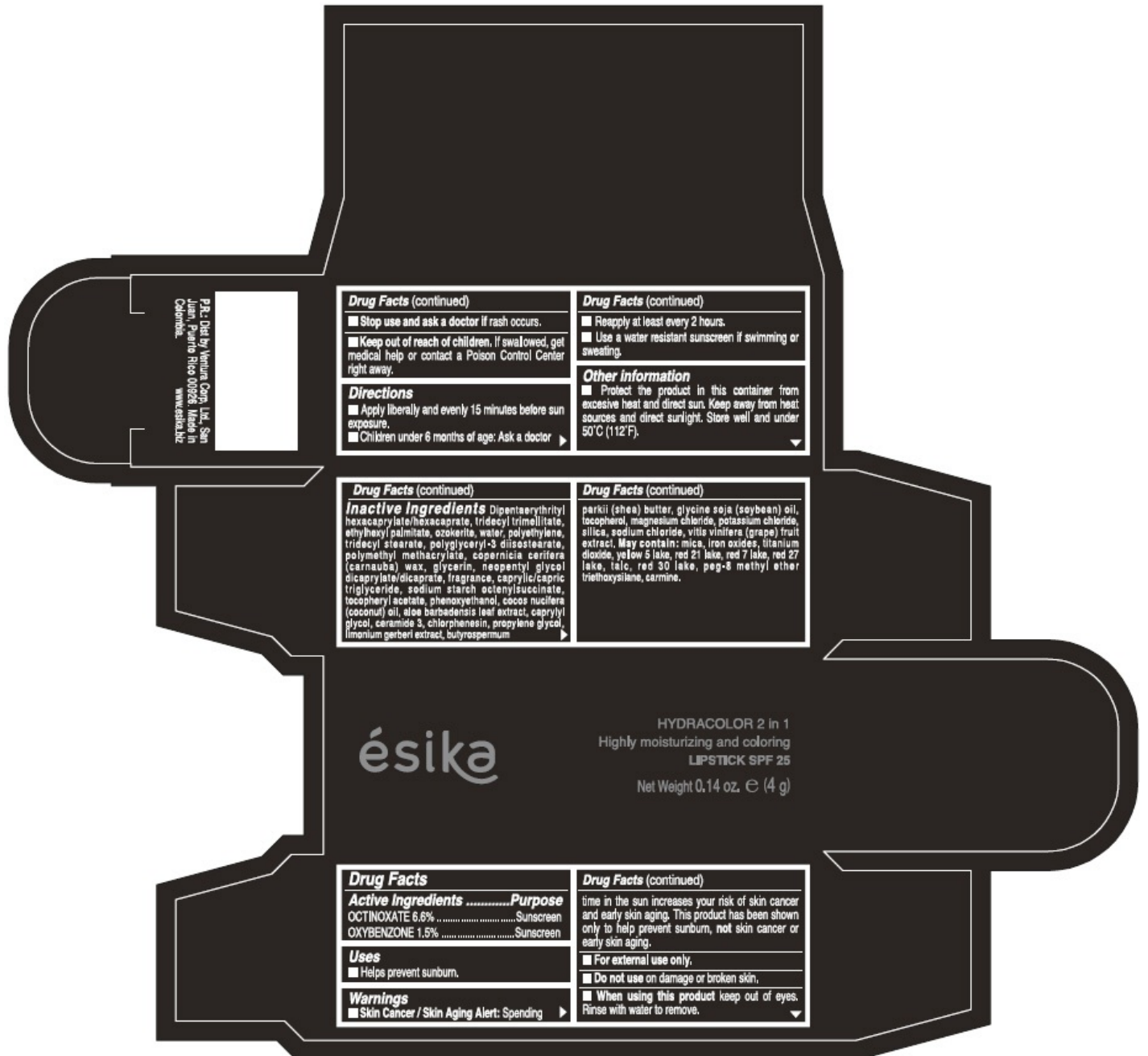
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HYDRACOLOR 2 in 1

Highly moisturizing and coloring

LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)



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

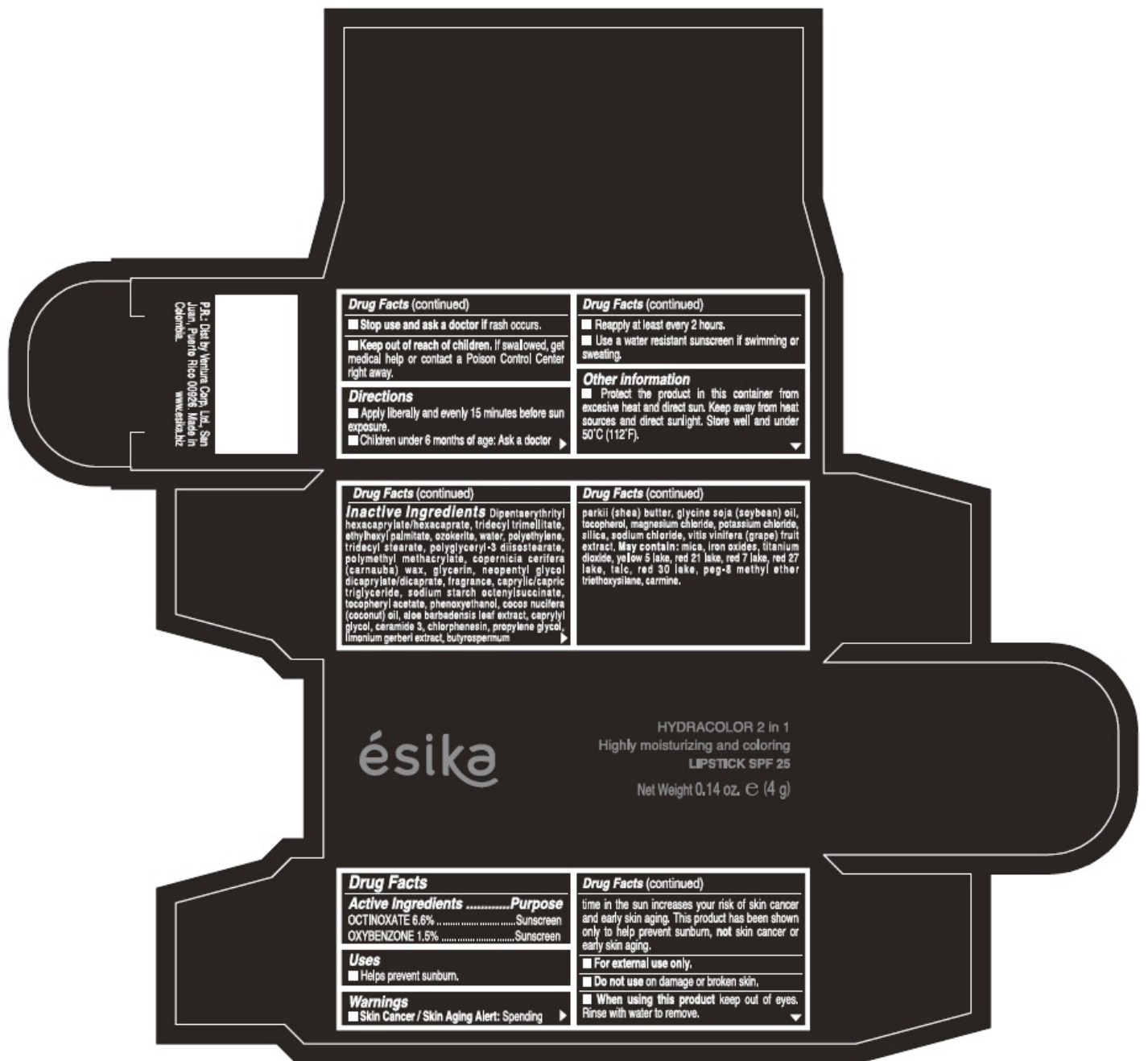
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HYDRACOLOR 2 in 1

Highly moisturizing and coloring

LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

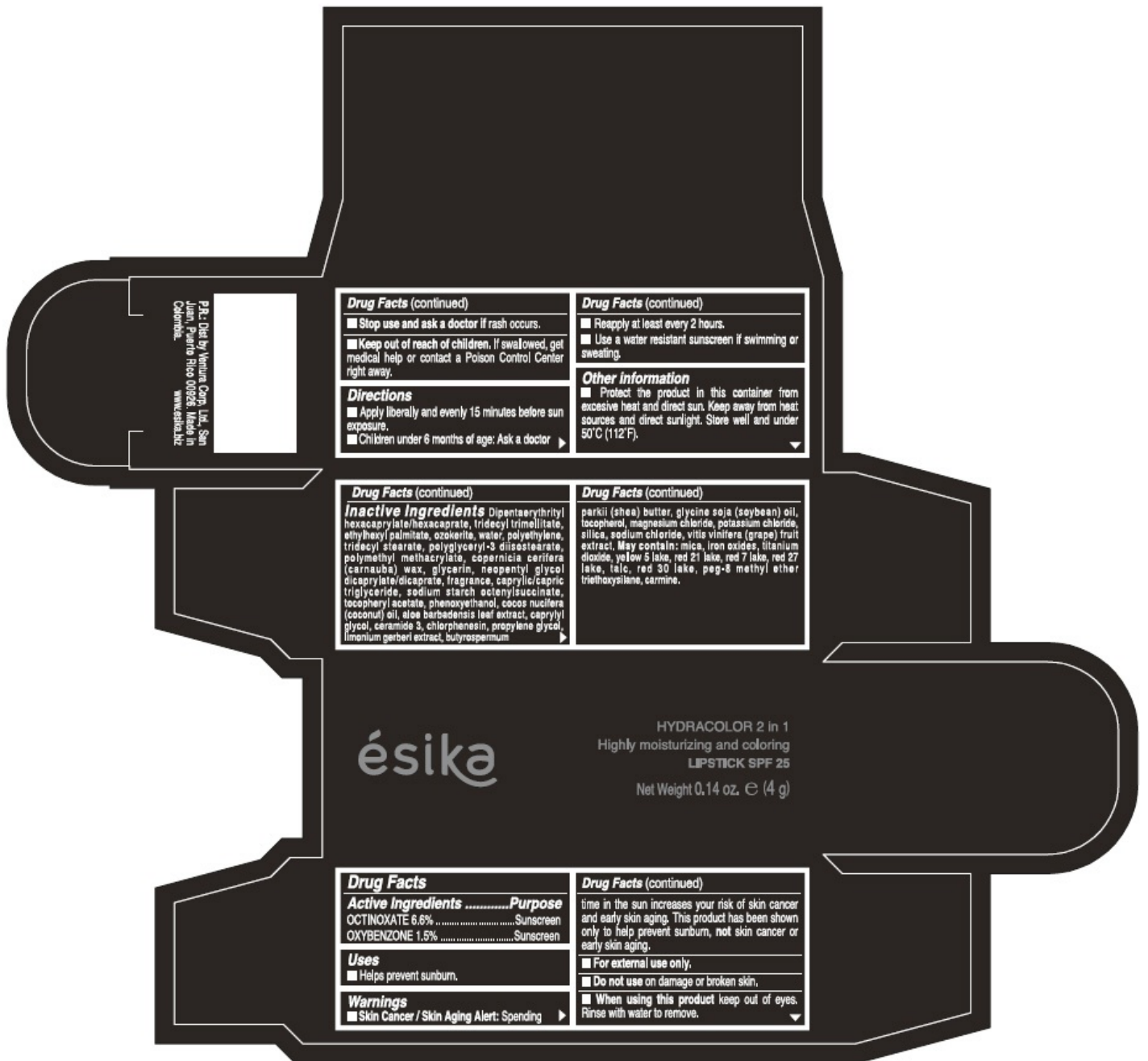


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (ROJO LUJURIA) - RED

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HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

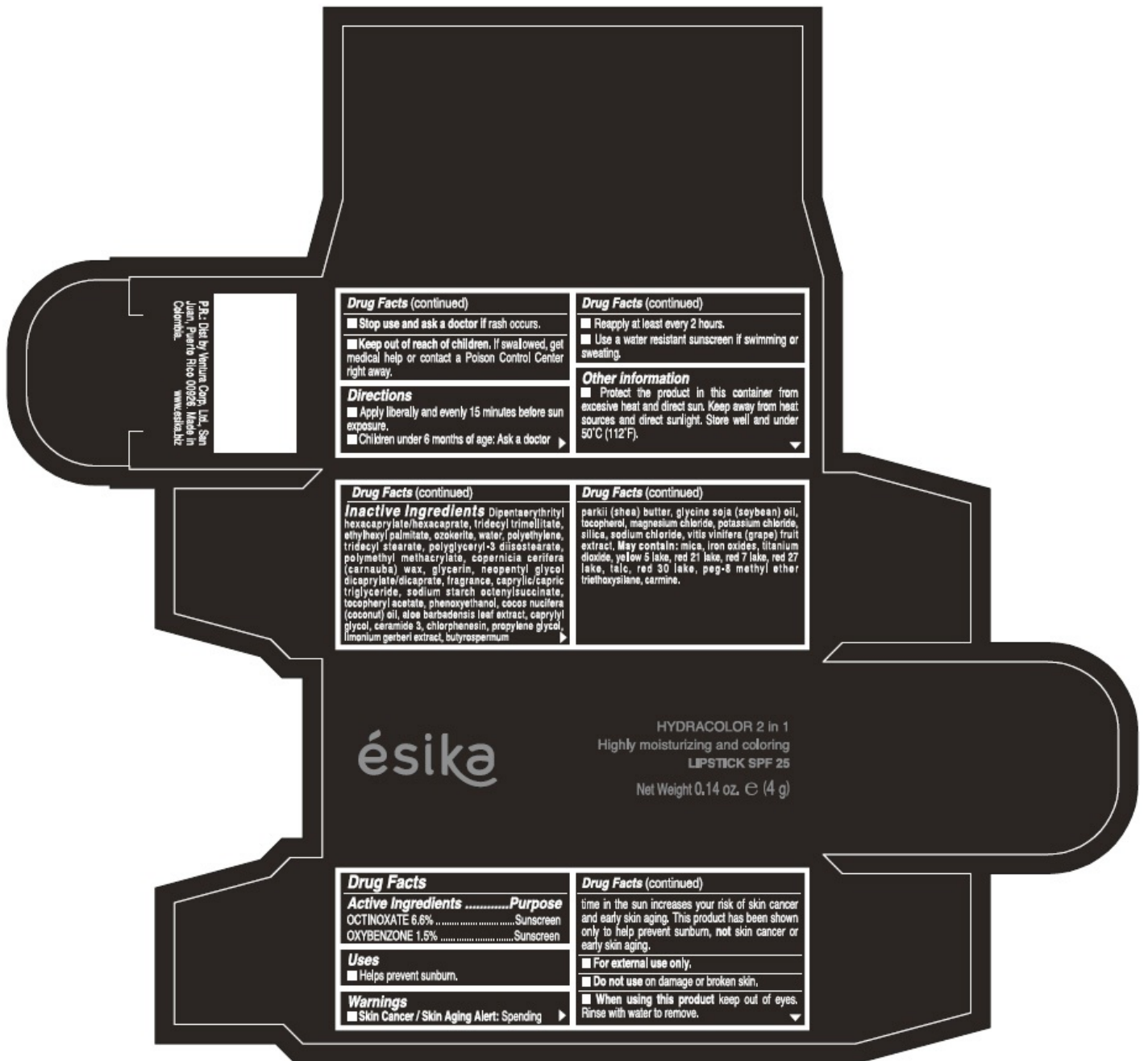


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (CORAL CHIC) - PINK

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HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

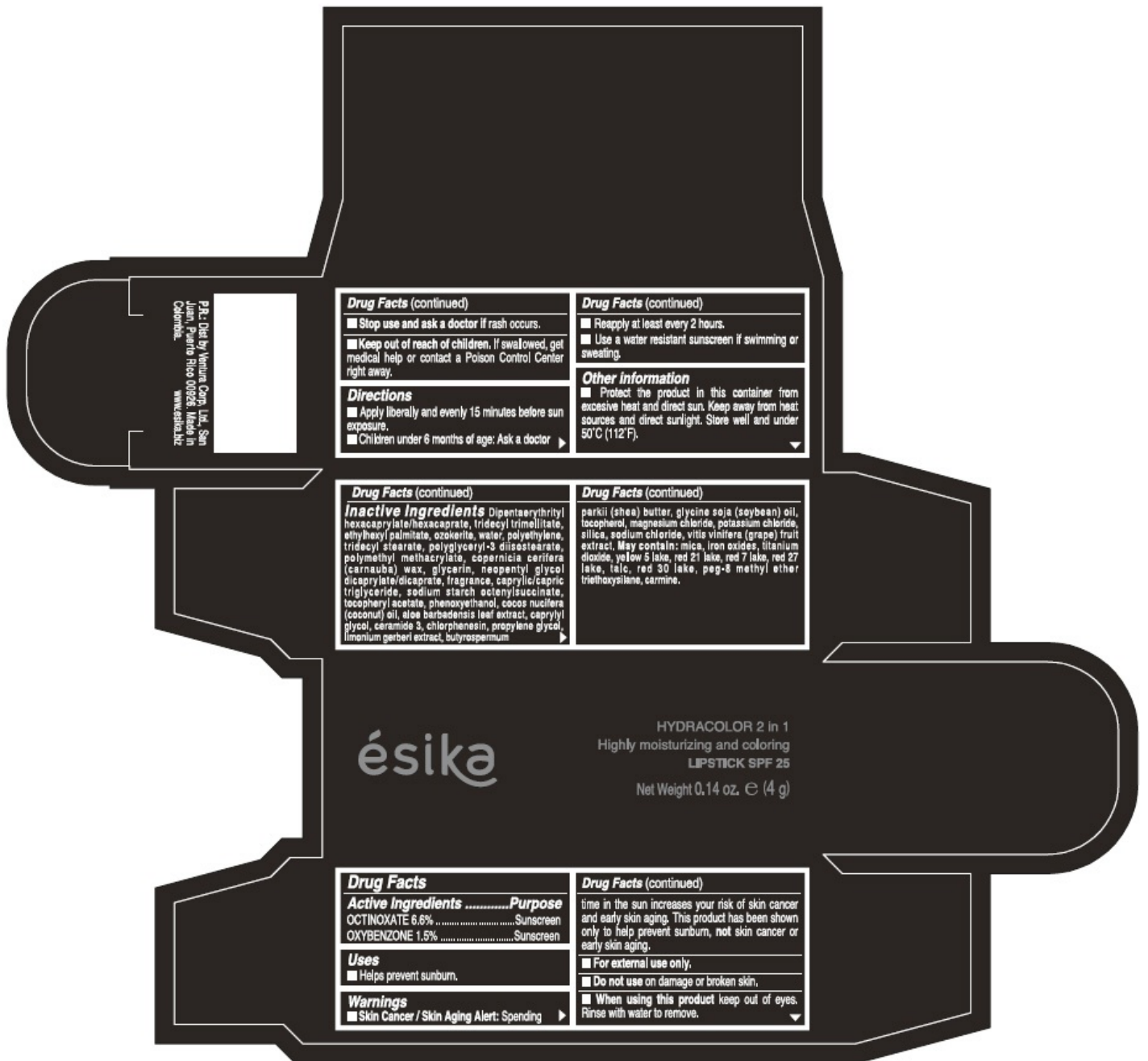


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (ROSA ENCANTO) - PINK

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HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

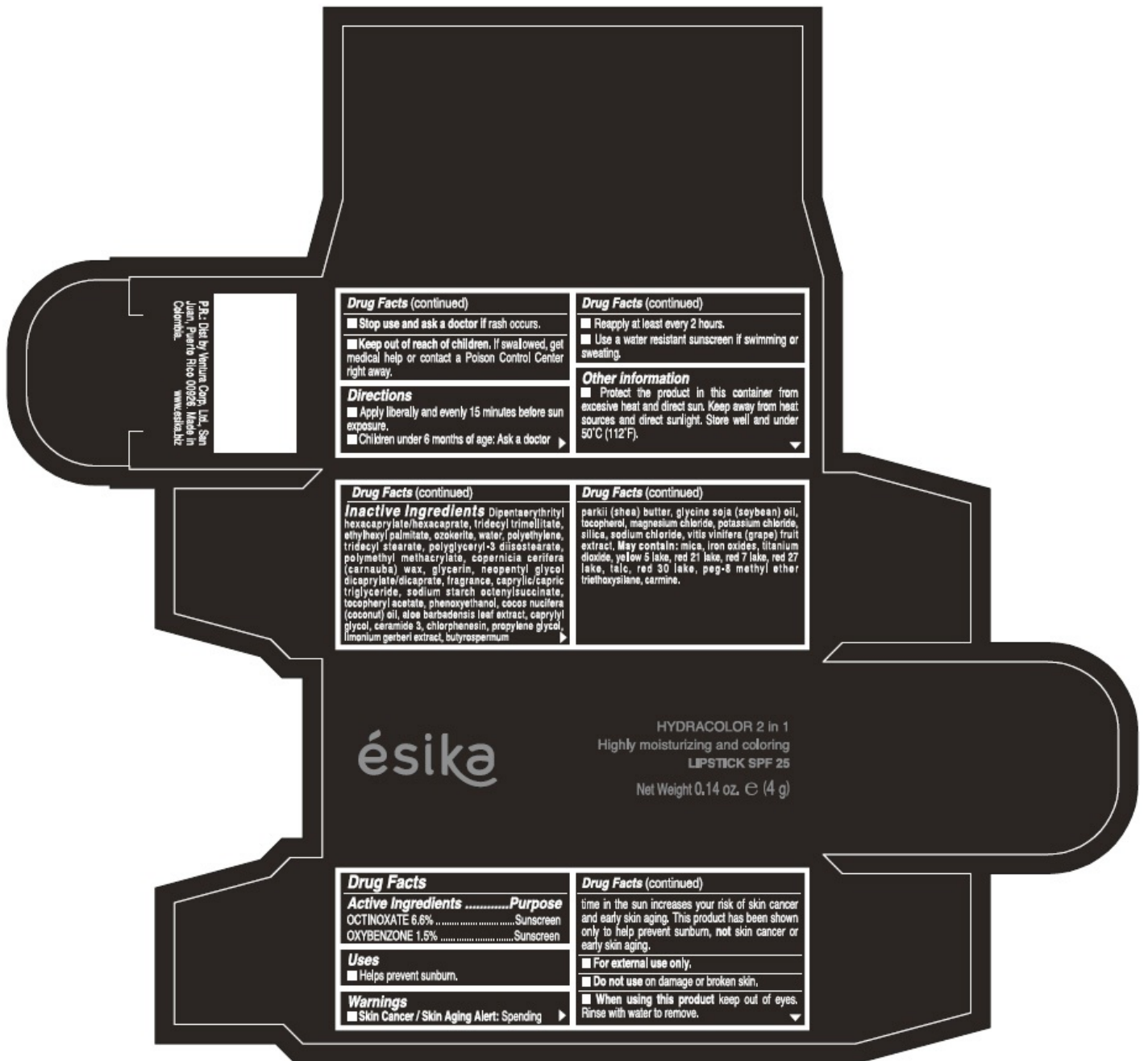


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (BORGONA SEXY) - PURPLE

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HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

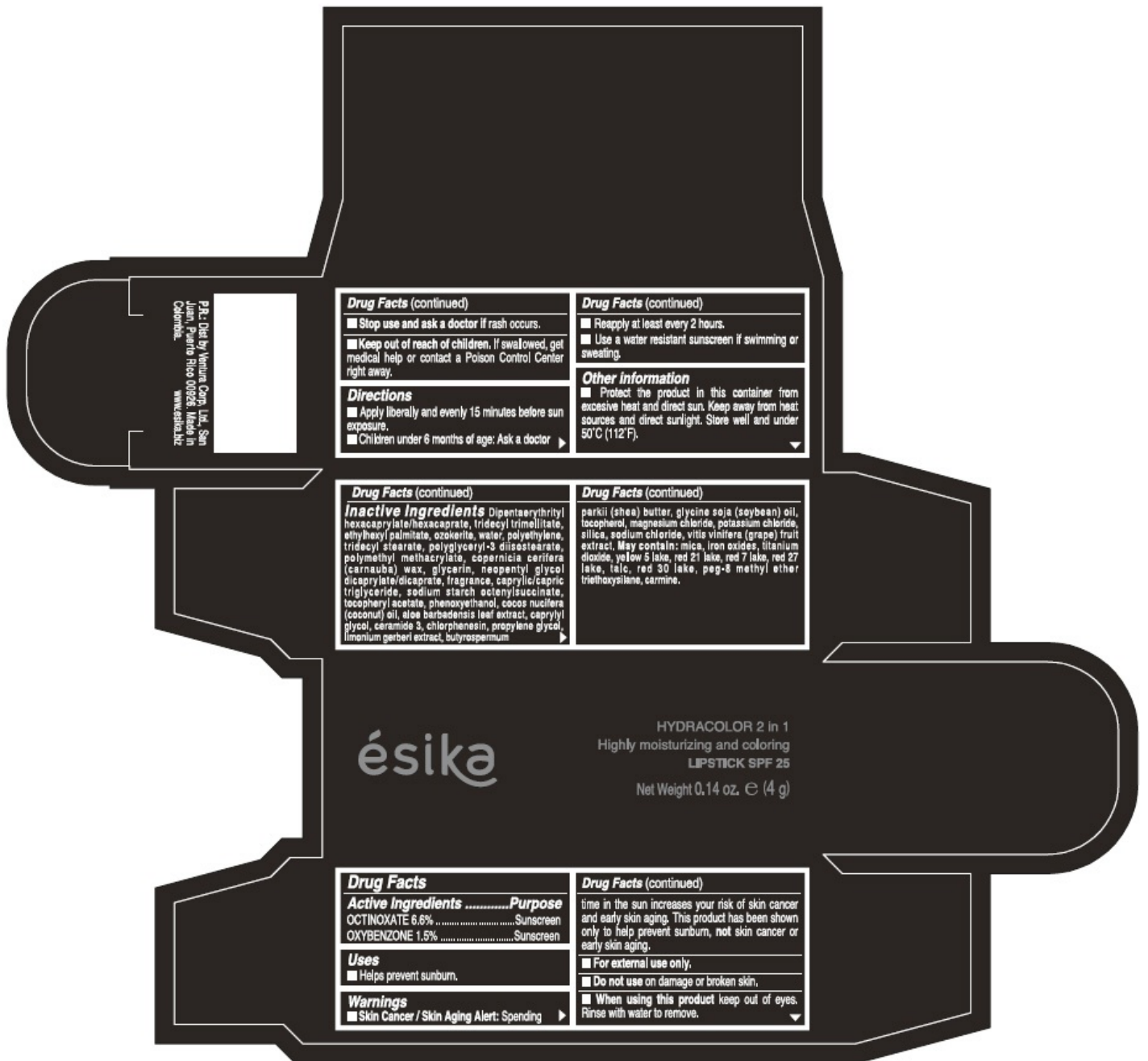


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (FUCSIA CAUTIVANTE) - PINK

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HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

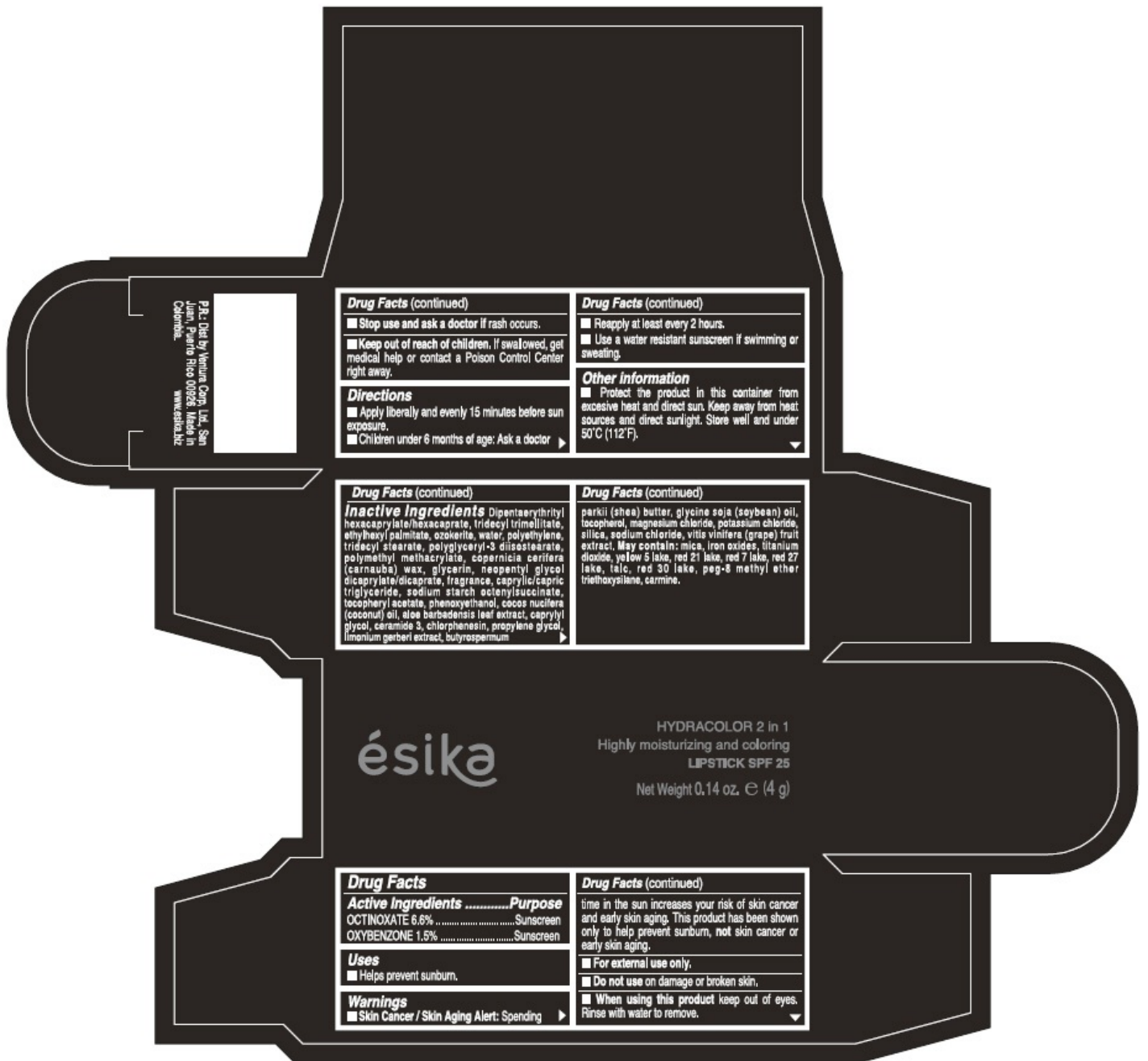


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (GRANATE SEDUCTOR) - PURPLE

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HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

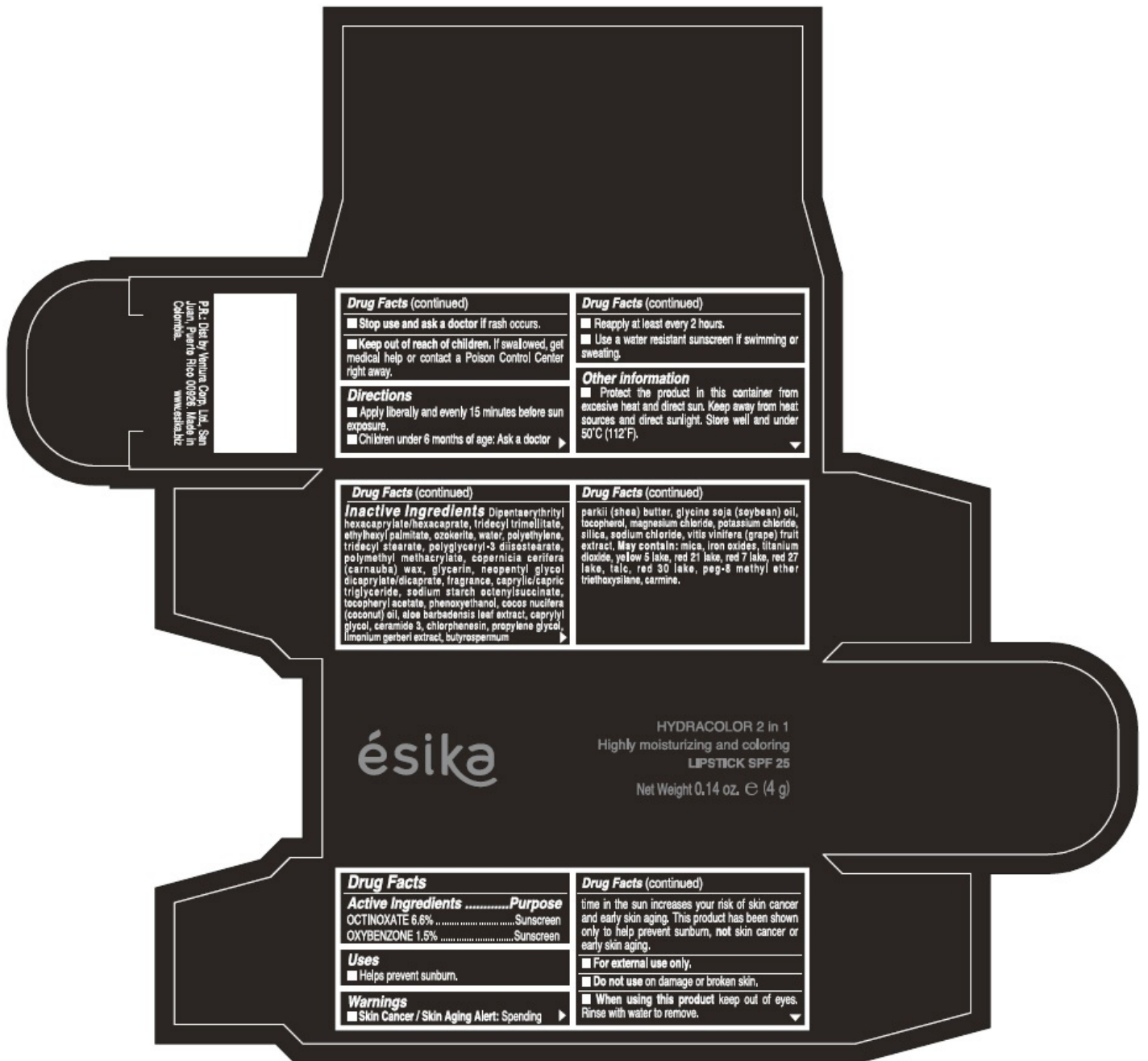


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (ROSA ROMANTICA) - PINK

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HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

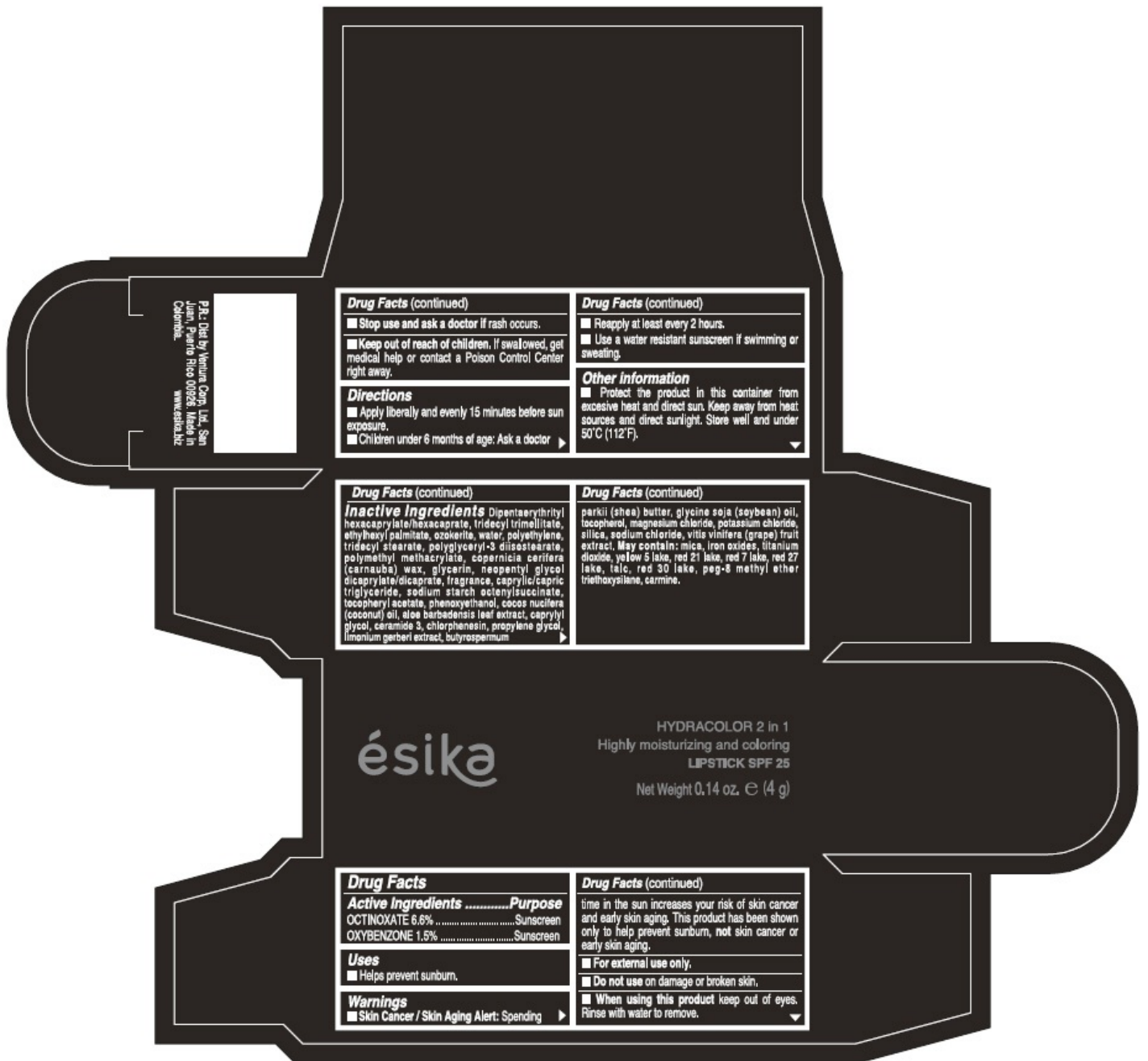


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (NARANJA PRIMAVERA) - ORANGE

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HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

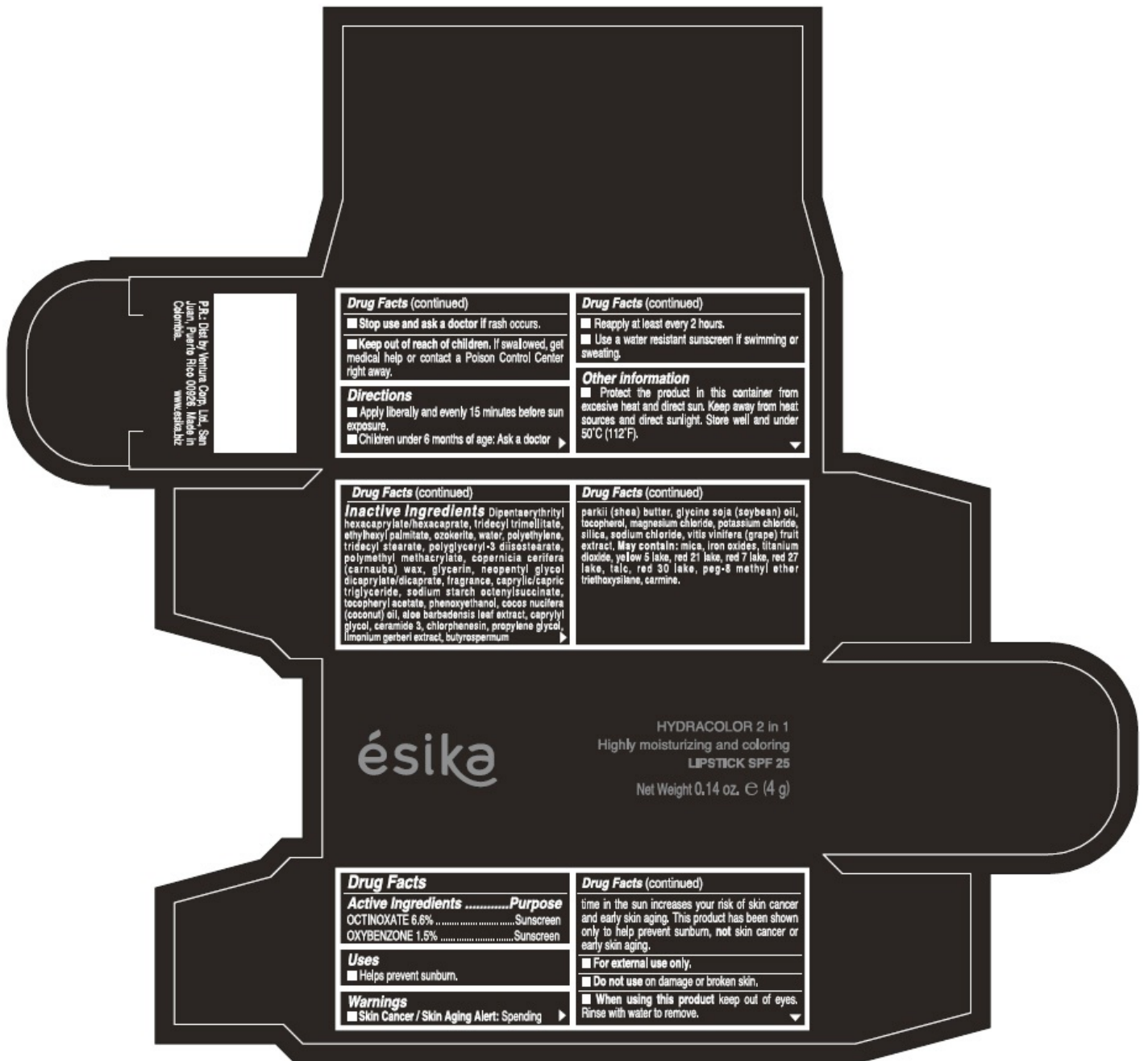


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (FRAMBUESA MANIA) - RED

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HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

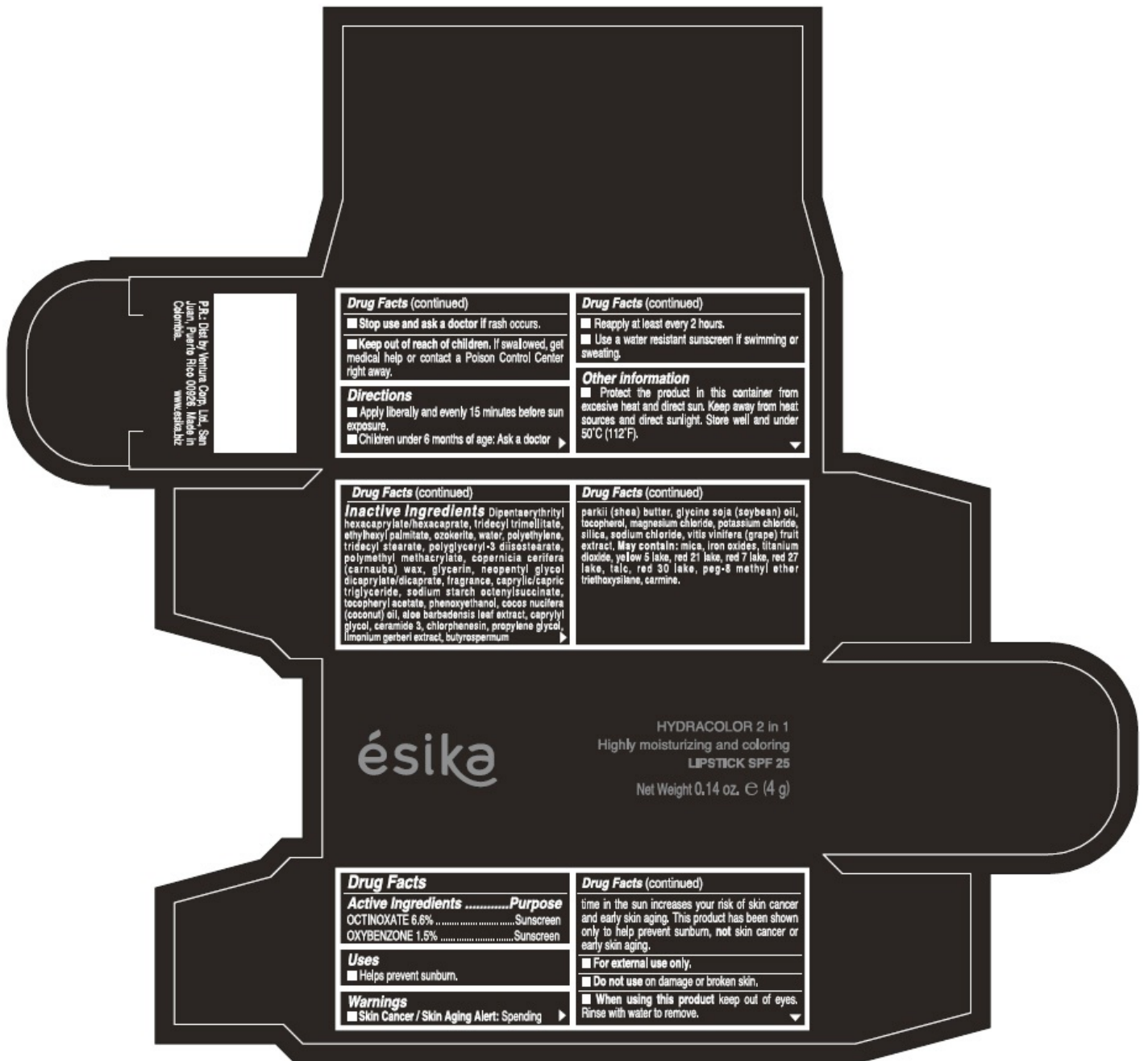


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (ROSA DULZURA) - PINK

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HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

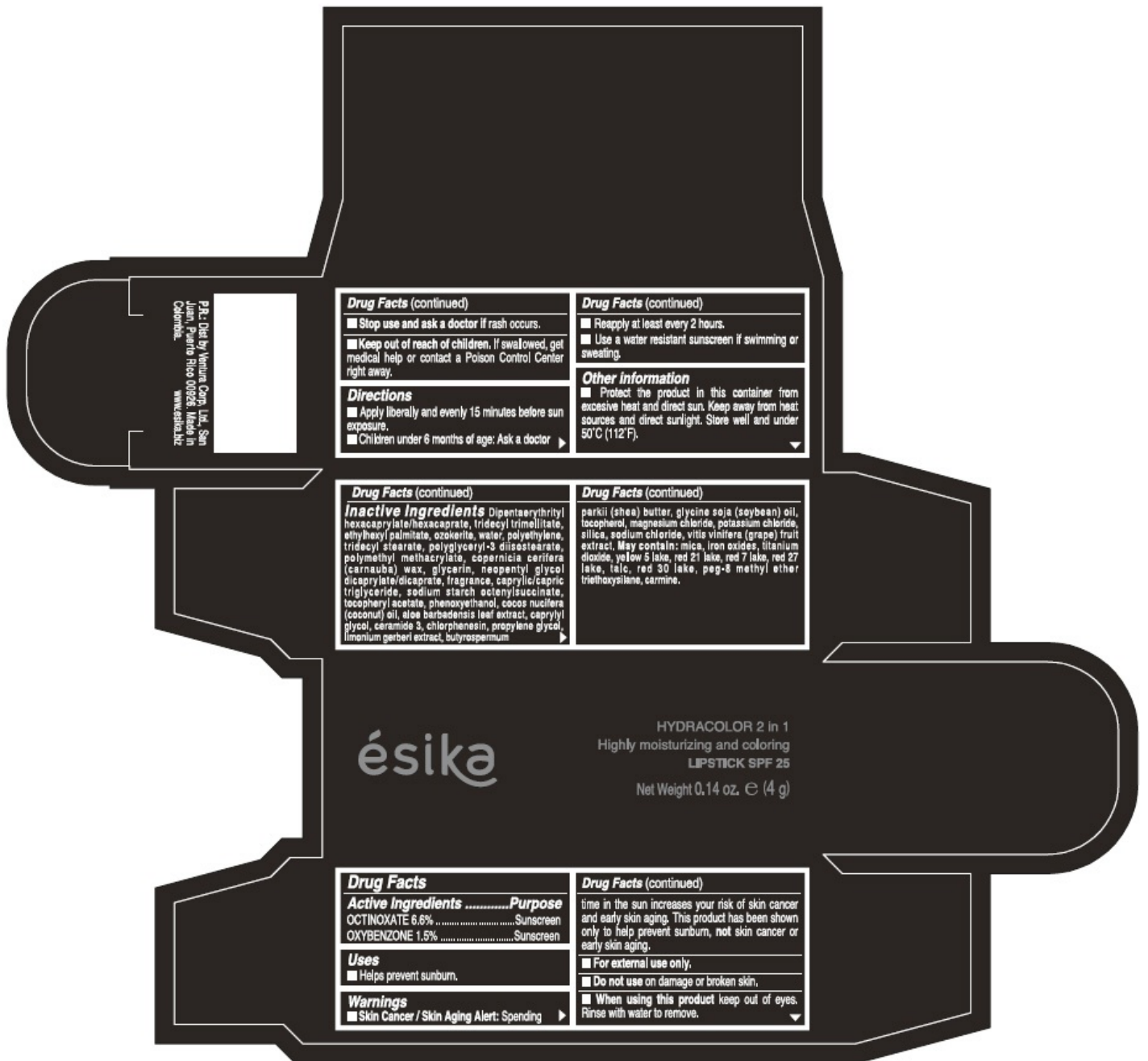


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (PIMIENTA CALIENTE) - BROWN

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HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

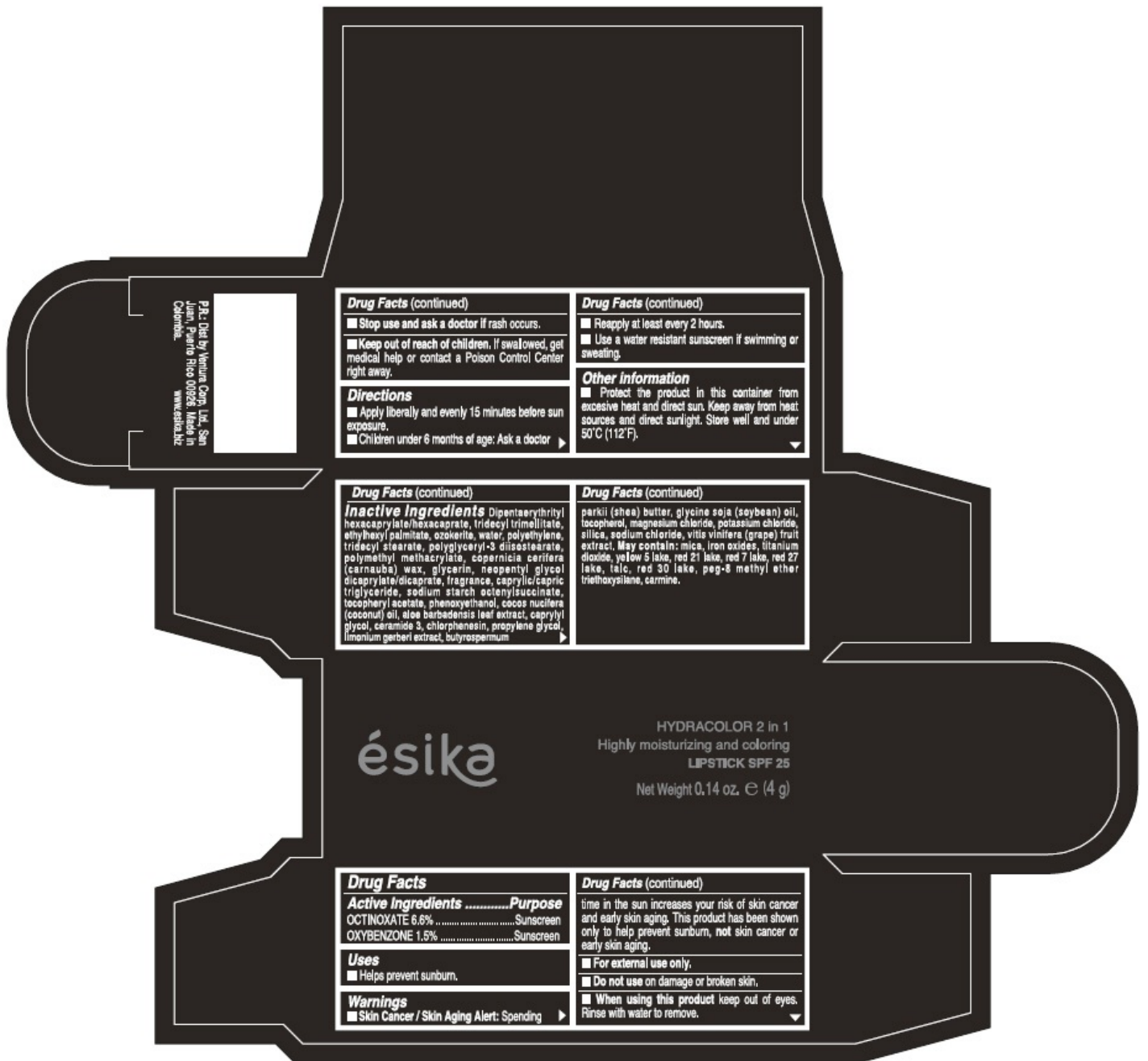


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (CANELA NUDE) - ORANGE

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HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

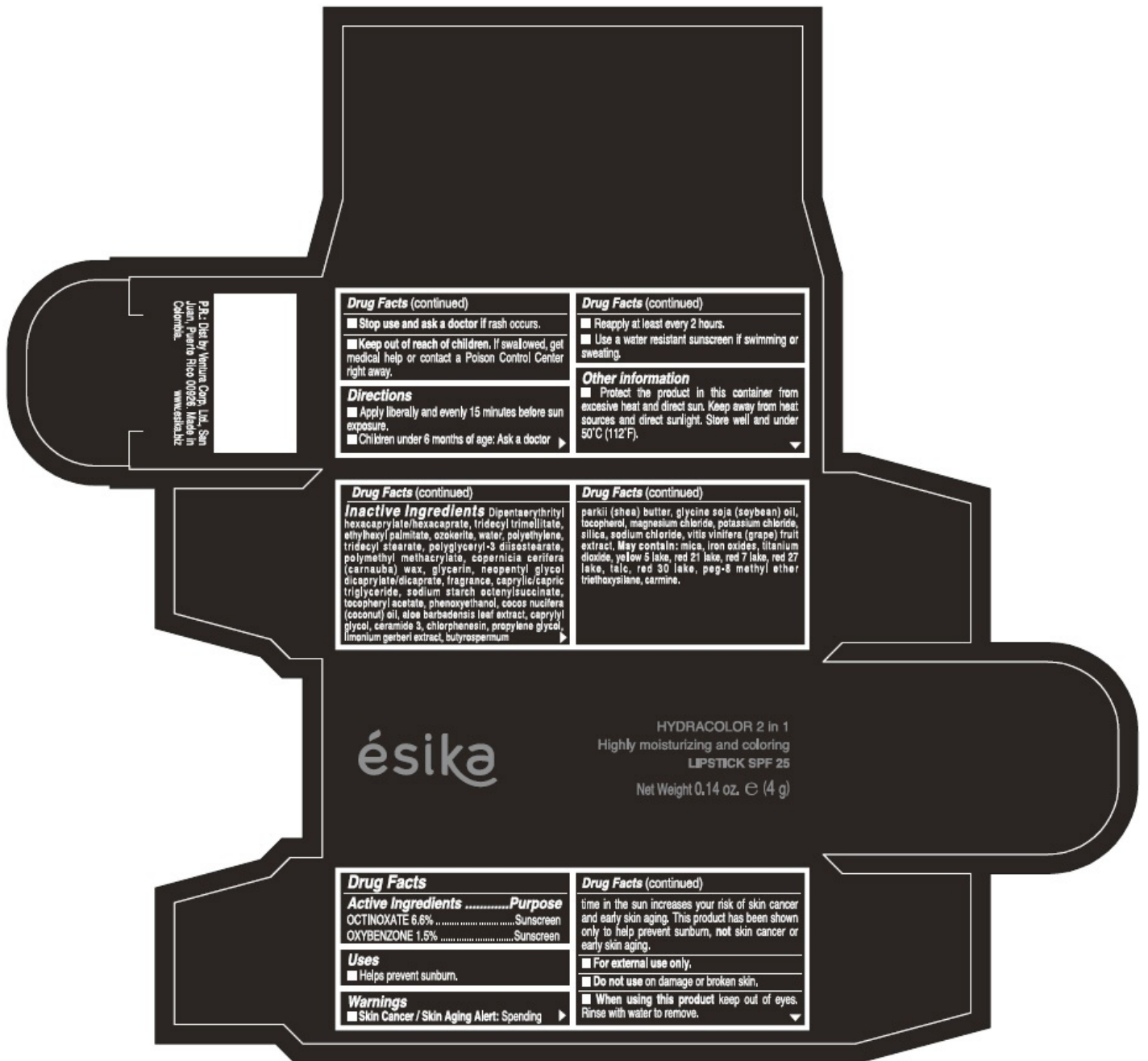


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (MORA GLAM) - BROWN

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HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

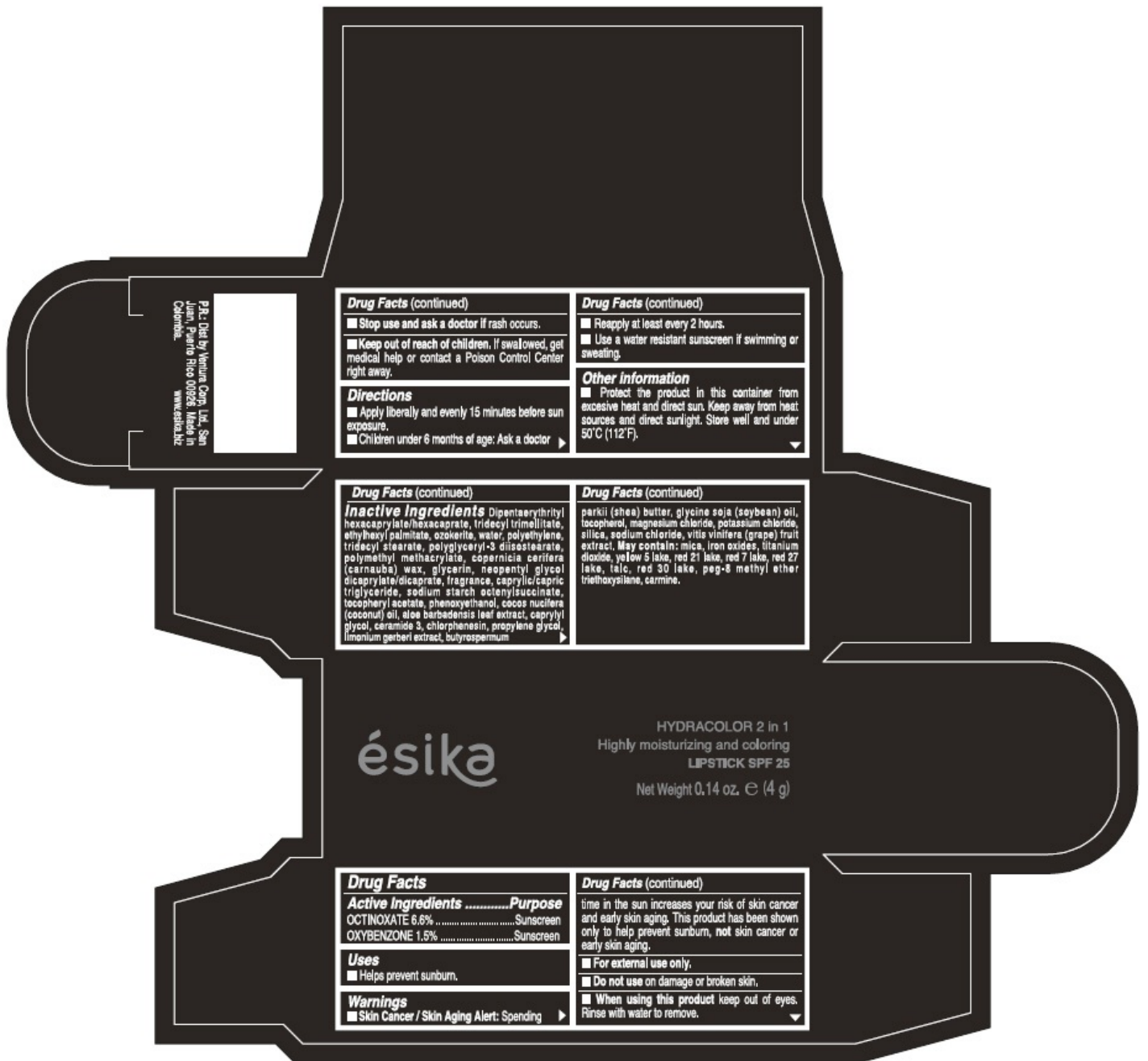


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (CORAL INTENSE) - RED

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HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

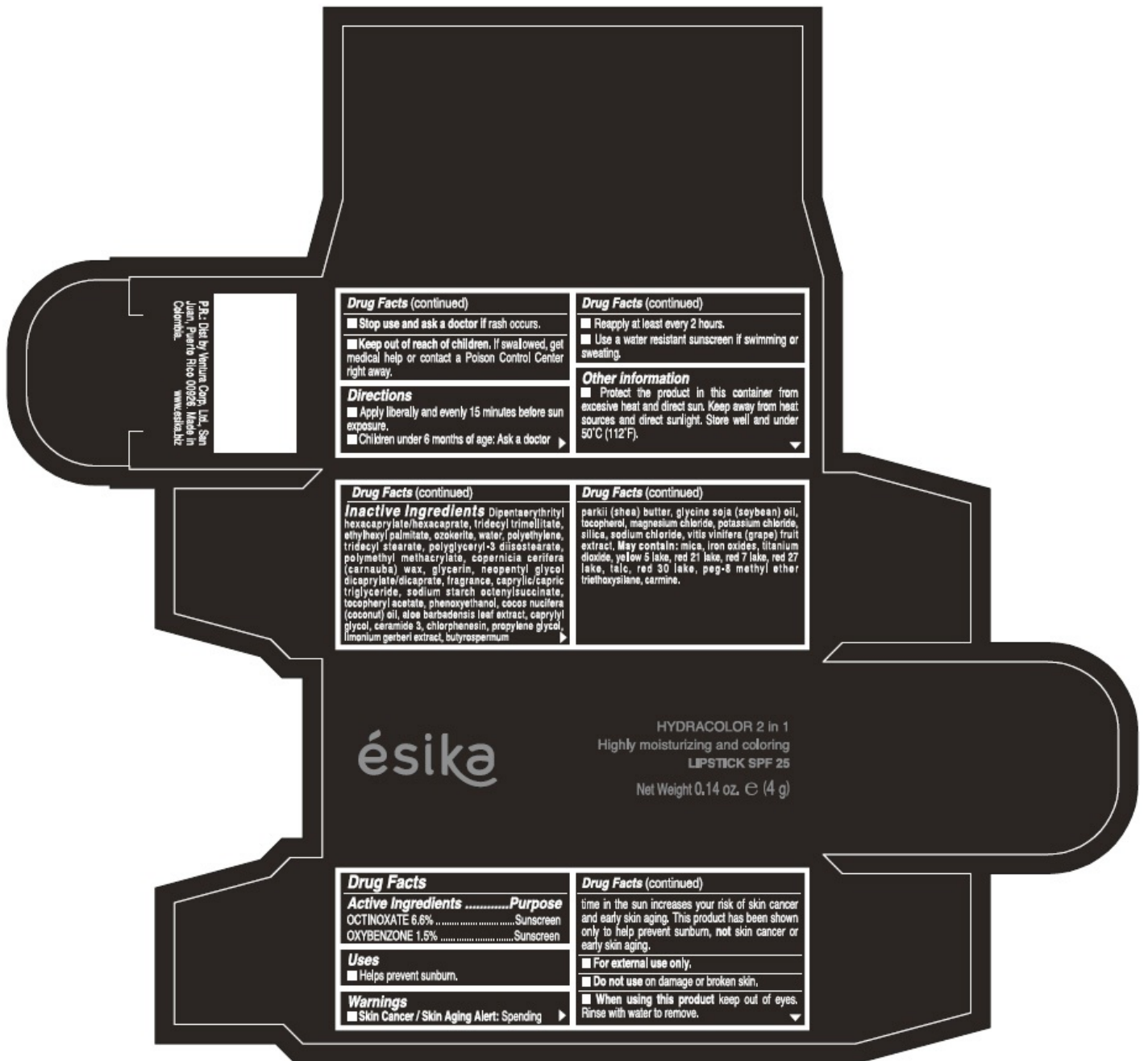


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (FRESA COQUETA) - RED

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HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

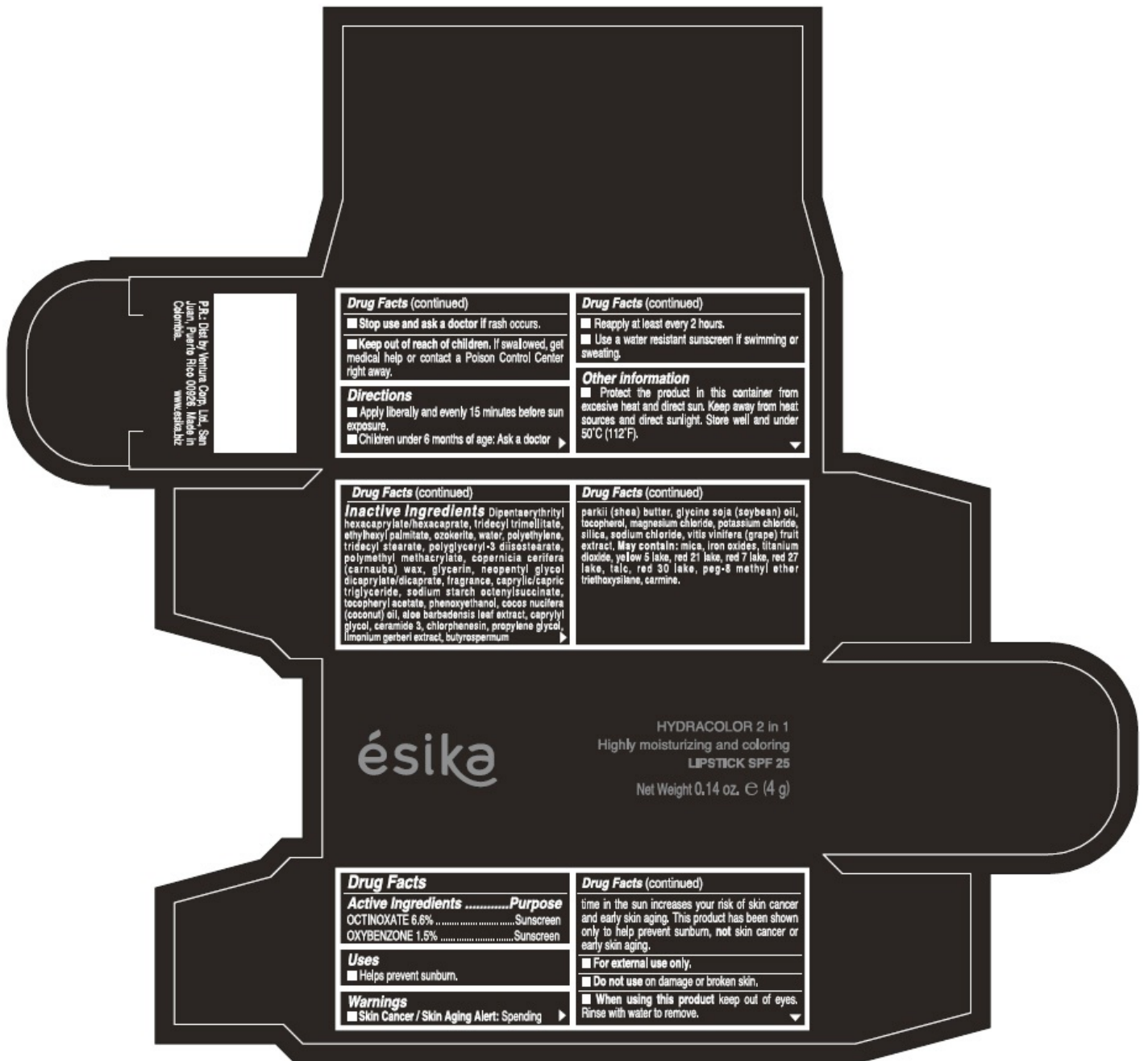


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (PIMIENTA CALIENTE FEMME) - RED

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HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

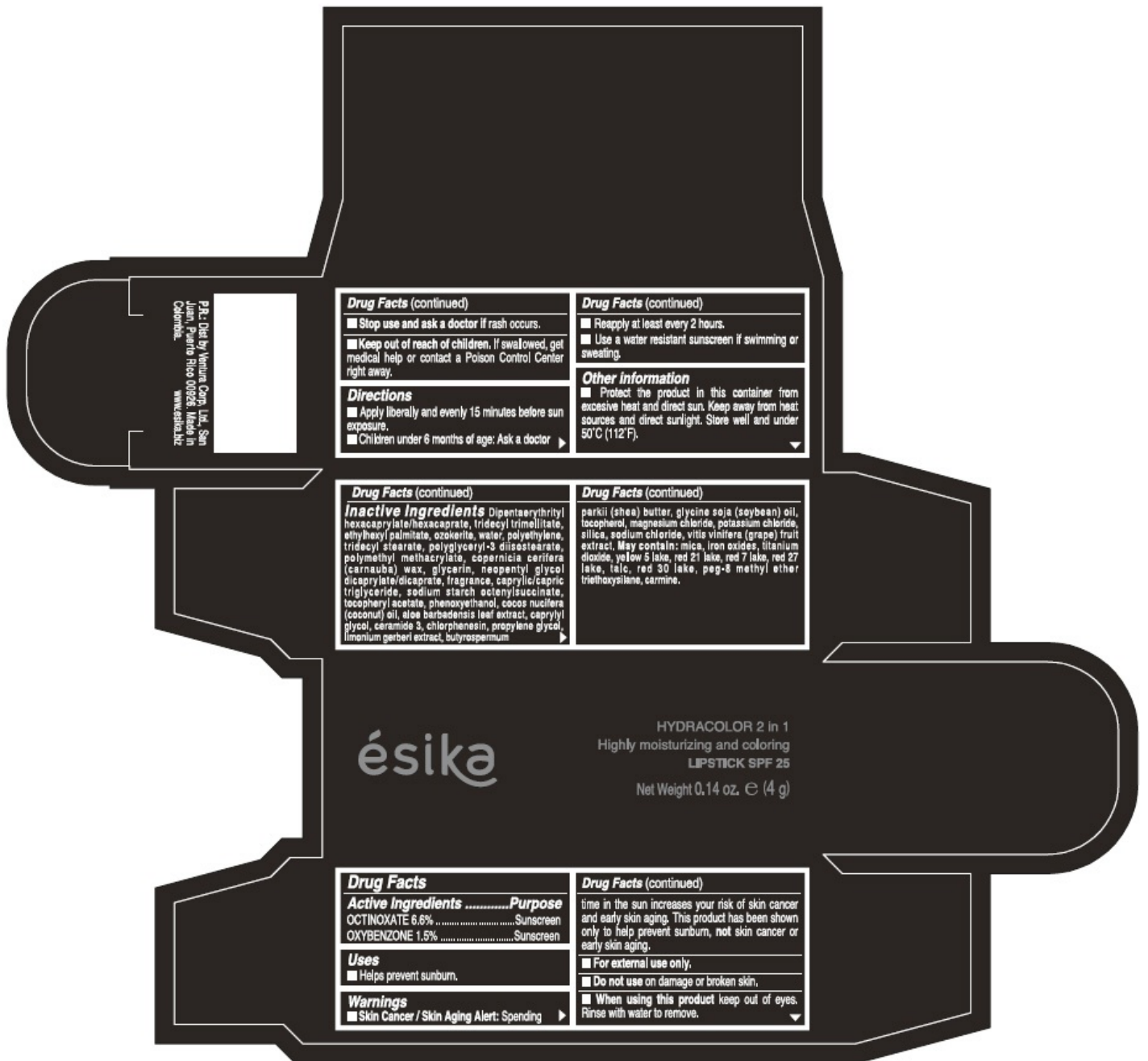


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (GRANATE SEDUCTOR FEMME) - PURPLE

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HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

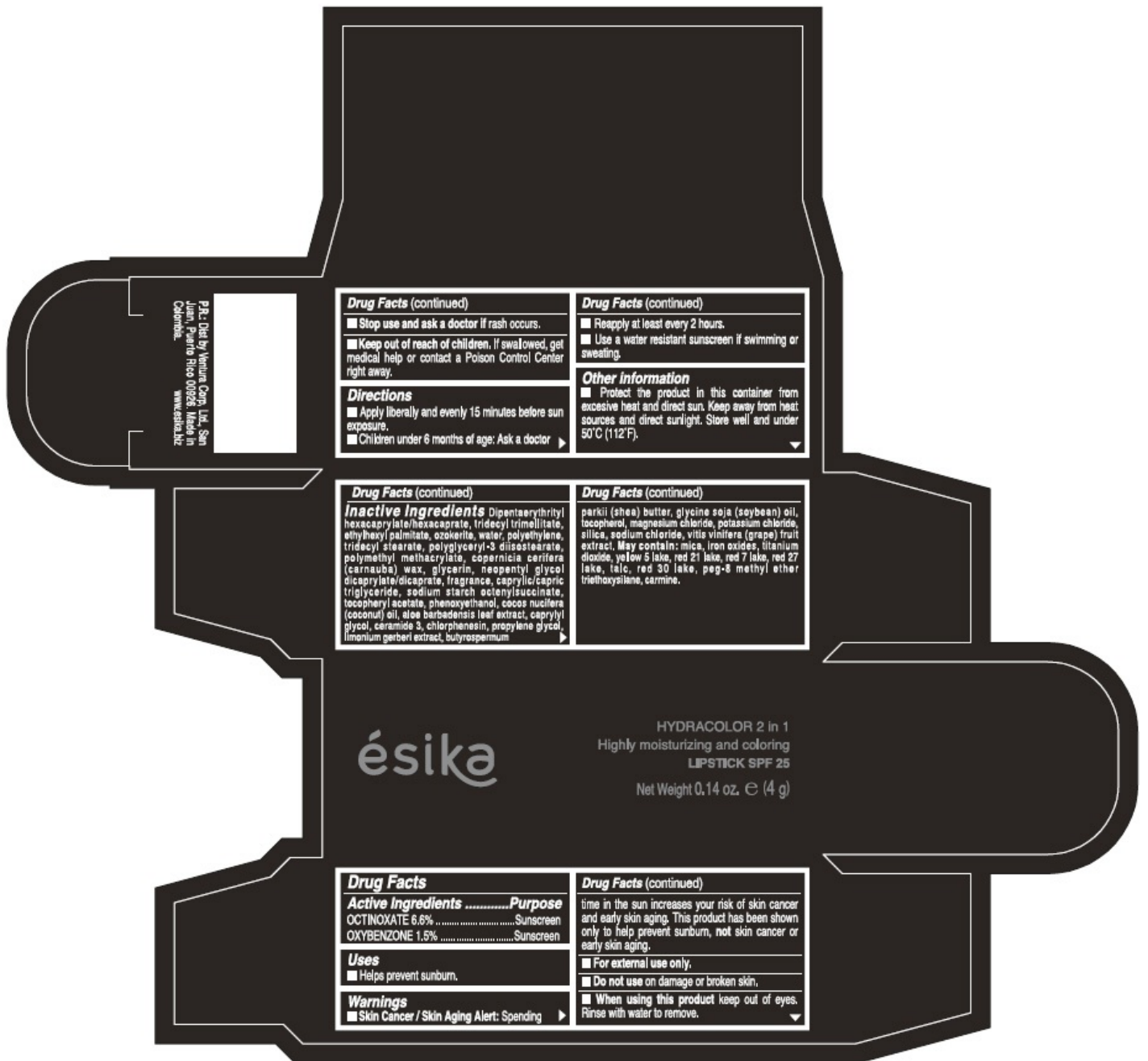


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (FUCSIA CAUTIVANTE FEMME) - PINK

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HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

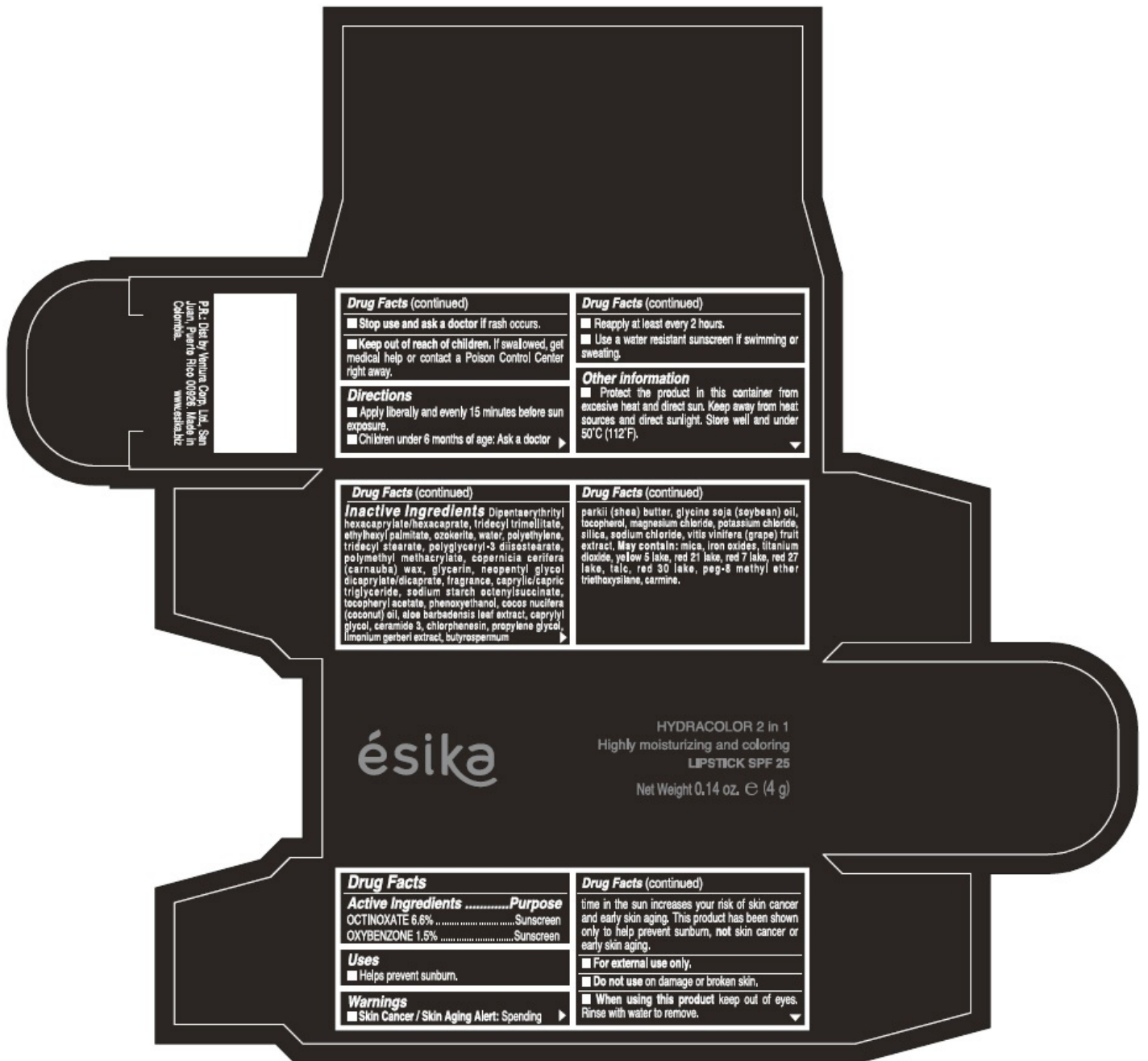


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (ROSA ROMANTICA FEMME) - PINK

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

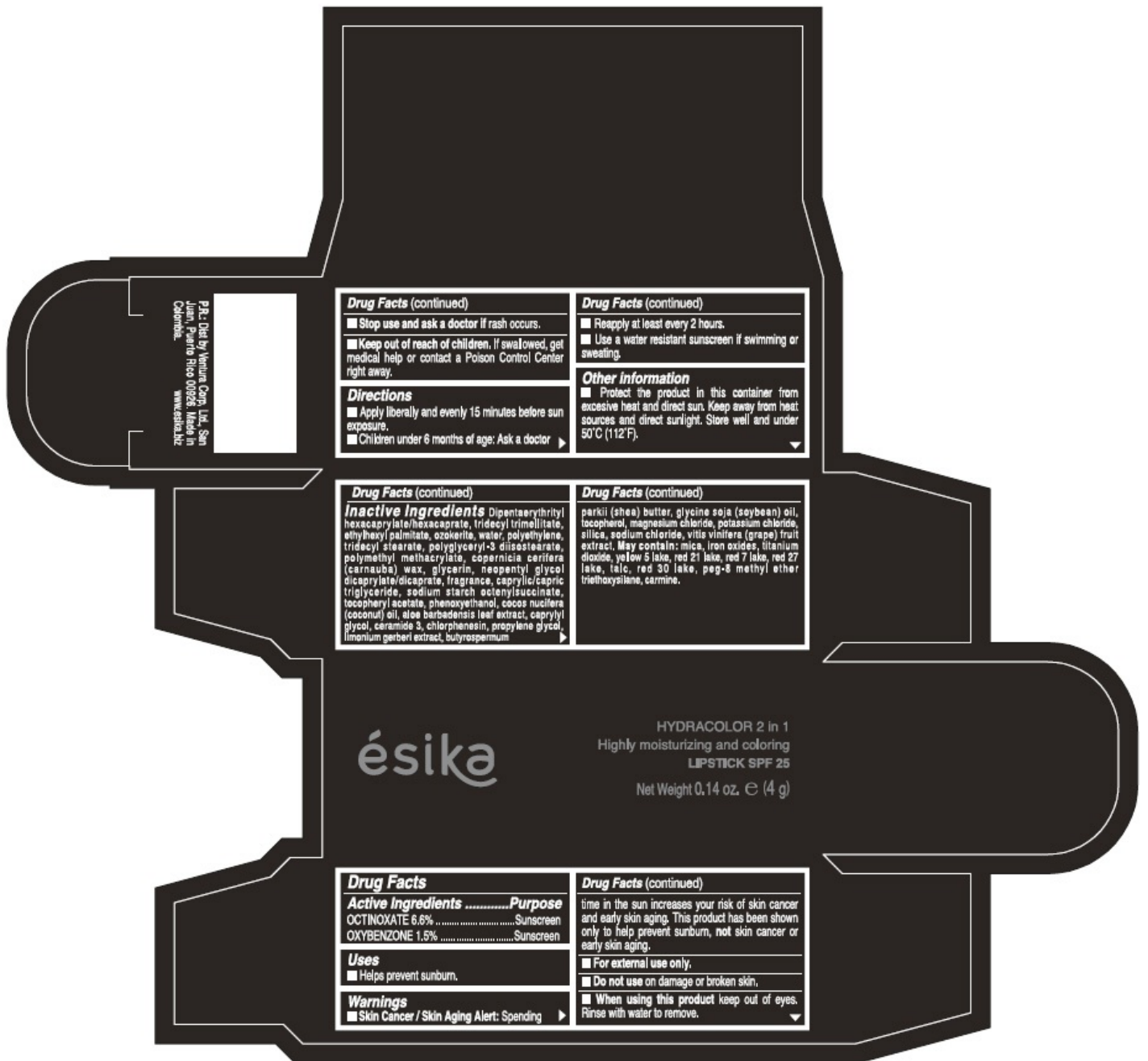


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (ROJO INTRIGANTE FEMME) - RED

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

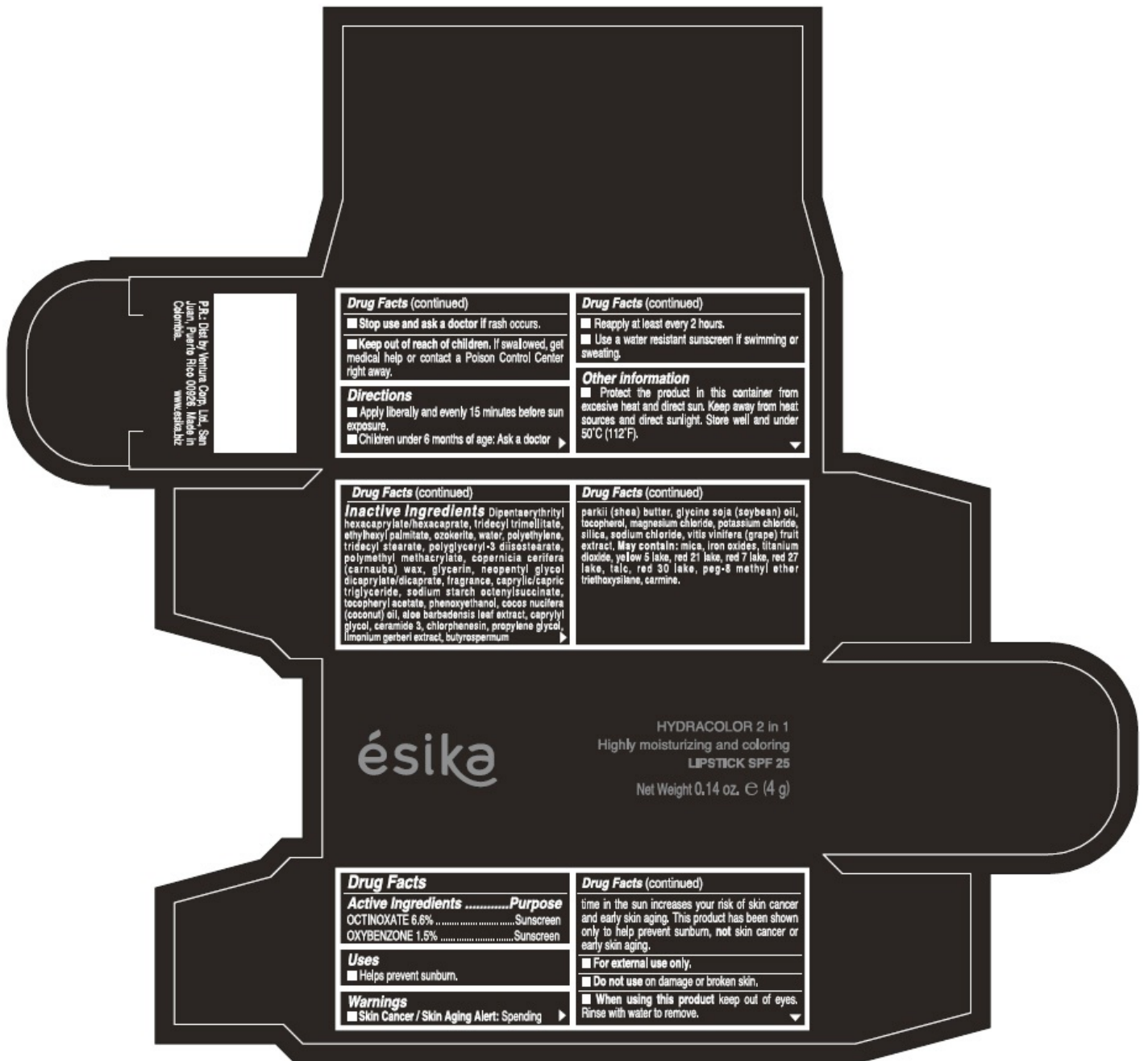


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (ROSA ENCANTO FEMME) - PINK

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)



ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (MARRON GLAMOUR) - BROWN

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-9 16
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0 Y) (Oxybenzone - UNII:95OOS7VE0 Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
TALC (UNII: 7SEV7J4R1U)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-916-02	1 in 1 BOX		
1	NDC:13537-916-01	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	09/30/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROJO DESEO) - RED

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-917
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0K00R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
D&C RED NO. 30 (UNII: 2S42T2808B)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-917-04	1 in 1 BOX		
1	NDC:13537-917-03	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	09/30/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROJO INTRIGANTE) - RED

octinoxate and oxybenzone lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-918
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
D&C RED NO. 30 (UNII: 2S42T2808B)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-918-06	1 in 1 BOX		
1	NDC:13537-918-05	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	09/30/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROJO LUJURIA) - RED
octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-919
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0K00R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

TALC (UNII: 7SEV7J4R1U)

D&C RED NO. 30 (UNII: 2S42T2808B)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-919-08	1 in 1 BOX		
1	NDC:13537-919-07	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	09/30/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (CORAL CHIC) - PINK

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-920
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
D&C RED NO. 30 (UNII: 2S42T2808B)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-920-10	1 in 1 BOX		
1	NDC:13537-920-09	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	09/30/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROSA ENCANTO) - PINK

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-921
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g

Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g
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Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0K00R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
TALC (UNII: 7SEV7J4R1U)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-921-12	1 in 1 BOX		
1	NDC:13537-921-11	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	09/30/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (BORGONA SEXY) - PURPLE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-922
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ981I0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
D&C RED NO. 30 (UNII: 2S42T2808B)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-922-14	1 in 1 BOX		
1	NDC:13537-922-13	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	09/30/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (FUCSIA CAUTIVANTE) - PINK

octinoxate and oxybenzone lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-923
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	

HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
D&C RED NO. 30 (UNII: 2S42T2808B)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-923-16	1 in 1 BOX		
1	NDC:13537-923-15	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	09/30/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (GRANATE SEDUCTOR) - PURPLE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-924
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0K00R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	

D&C RED NO. 7 (UNII: ECW0LZ41X8)

D&C RED NO. 27 (UNII: 2LRS185U6K)

TALC (UNII: 7SEV7J4R1U)

D&C RED NO. 30 (UNII: 2S42T2808B)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-924-18	1 in 1 BOX		
1	NDC:13537-924-17	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	09/30/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROSA ROMANTICA) - PINK

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-925
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
D&C RED NO. 30 (UNII: 2S42T2808B)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-925-20	1 in 1 BOX		
1	NDC:13537-925-19	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	09/30/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (NARANJA PRIMAVERA) - ORANGE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-926
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0K00R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
TALC (UNII: 7SEV7J4R1U)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-926-22	1 in 1 BOX		

1	NDC:13537-926-21	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	09/30/2014		

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (FRAMBUESA MANIA) - RED

octinoxate and oxybenzone lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-927
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	

MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
TALC (UNII: 7SEV7J4R1U)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-927-24	1 in 1 BOX		
1	NDC:13537-927-23	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	09/30/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROSA DULZURA) - PINK

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-928
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	

ETHYLHEXYL PALMITATE (UNII: 2865993309)
WATER (UNII: 059QF0KO0R)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ981I0)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
D&C RED NO. 30 (UNII: 2S42T2808B)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-928-26	1 in 1 BOX		
1	NDC:13537-928-25	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	09/30/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (PIMIENTA CALIENTE) - BROWN

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-929
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ981I0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
TALC (UNII: 7SEV7J4R1U)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-929-28	1 in 1 BOX		
1	NDC:13537-929-27	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	09/30/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (CANELA NUDE) - ORANGE
 octinoxate and oxybenzone lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-930
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
D&C RED NO. 30 (UNII: 2S42T2808B)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-930-30	1 in 1 BOX		
1	NDC:13537-930-29	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	09/30/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (MORA GLAM) - BROWN

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-931
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0K00R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
TALC (UNII: 7SEV7J4R1U)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-931-32	1 in 1 BOX		
1	NDC:13537-931-31	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	09/30/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (CORAL INTENSE) - RED

octinoxate and oxybenzone lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-932
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0K00R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	

SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
D&C RED NO. 30 (UNII: 2S42T2808B)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-932-34	1 in 1 BOX		
1	NDC:13537-932-33	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	09/30/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (FRESA COQUETA) - RED

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-933
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
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DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
ETHYLHEXYL PALMITATE (UNII: 2865993309)
WATER (UNII: 059QF0KO0R)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ981I0)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
D&C RED NO. 30 (UNII: 2S42T2808B)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-933-36	1 in 1 BOX		
1	NDC:13537-933-35	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	09/30/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (PIMIENTA CALIENTE FEMME) - RED

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-934
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98H0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
TALC (UNII: 7SEV7J4R1U)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-934-38	1 in 1 BOX		
1	NDC:13537-934-37	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	09/30/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (GRANATE SEDUCTOR FEMME) - PURPLE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-935
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98110)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
D&C RED NO. 30 (UNII: 2S42T2808B)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-935-40	1 in 1 BOX		
1	NDC:13537-935-39	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	09/30/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (FUCSIA CAUTIVANTE FEMME) - PINK

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-936
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98II0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
TALC (UNII: 7SEV7J4R1U)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-936-42	1 in 1 BOX		
1	NDC:13537-936-41	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	09/30/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROSA ROMANTICA FEMME) - PINK

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-937
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0K00R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ981I0)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
D&C RED NO. 30 (UNII: 2S42T2808B)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-937-44	1 in 1 BOX		
1	NDC:13537-937-43	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	09/30/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROJO INTRIGANTE FEMME) - RED

octinoxate and oxybenzone lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-938
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ981I0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
TALC (UNII: 7SEV7J4R1U)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-938-46	1 in 1 BOX		
1	NDC:13537-938-45	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	09/30/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROSA ENCANTO FEMME) - PINK

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-939
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.066 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.015 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0K00R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
TALC (UNII: 7SEV7J4R1U)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-939-48	1 in 1 BOX		
1	NDC:13537-939-47	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	09/30/2014	

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-916, 13537-917, 13537-918, 13537-919, 13537-920, 13537-921, 13537-922, 13537-923, 13537-924, 13537-925, 13537-926, 13537-927, 13537-928, 13537-929, 13537-930, 13537-931, 13537-932, 13537-933, 13537-934, 13537-935, 13537-936, 13537-937, 13537-938, 13537-939)

Revised: 10/2014

Ventura Corporation LTD