

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 (MARRON GLAMOUR) - BROWN- 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 (ROSA DULZURA) - PINK- 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 (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 (FRESA COQUETA) - RED- 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 (ROSA GEOMETRIC) - PINK- octinoxate and oxybenzone lipstick

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

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

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

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

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (MARRON TOPACIO) - BROWN- octinoxate and oxybenzone lipstick

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

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (FUCSIA AMATISTA) - PINK- octinoxate and oxybenzone lipstick

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (NUDE PRISMA) - ORANGE- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (DORADO ESENCIAL) - YELLOW- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROSA ENCANTO FEMME) - PINK- 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 (ROSA ROMANTICA FEMME) - PINK- 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 (ROJO INTRIGANTE FEMME) - RED- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (PIMIENTA CALIENTE EXOTIC) - RED- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROSA ENCANTO EXOTIC) - PINK- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (CORAL CHIC EXOTIC) - ORANGE- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (FUCSIA CAUTIVANTE EXOTIC) - PINK- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROJO DESEO EXOTIC) - RED- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (FRAMBUESA MANIA EXOTIC) - PINK- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (BORGONA SEXY EXOTIC) - PURPLE- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (MARRON GLAMOUR EXOTIC) - BROWN- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25- octinoxate and oxybenzone
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 LIPSTICK SPF 25

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
OCTINOXATE 6.64 %	Sunscreen
OXYBENZONE.. 1.51 %	Sunscreen

Uses

- Helps prevent sunburn.

Warnings

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

Directions

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

Other information

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

Inactive ingredients

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 (SOYBEAN) OIL, TOCOPHEROL, MAGNESIUM CHLORIDE, POTASSIUM CHLORIDE, SILICA, SODIUM CHLORIDE, VITIS VINIFERA (GRAPE) FRUIT EXTRACT, CITRONELLOL, d-LIMONENE, BENZYL ALCOHOL, ALPHA-ISOMETHYL IONONE, LINALOOL, AMYL CINNAMAL.

MAY CONTAIN:

MICA, RED 30 LAKE, TITANIUM DIOXIDE, IRON OXIDES, YELLOW 5 LAKE, RED 21 LAKE, RED 27 LAKE, RED 7 LAKE, TALC, BLUE 1 LAKE, PEG-8 METHYL ETHER TRIETHOXSILANE, CARMINE.

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

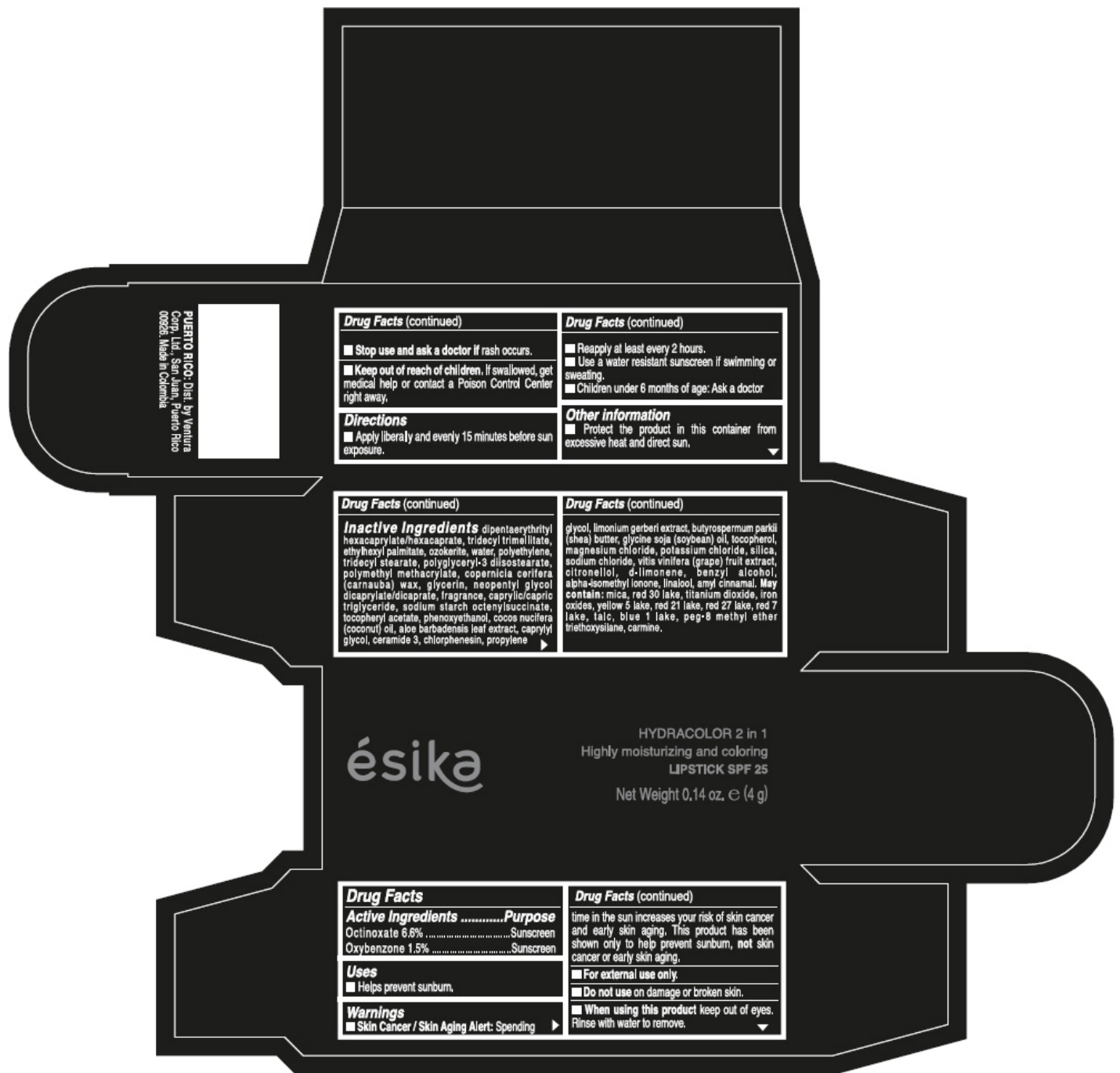
PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (PIMIENTA CALIENTE) - BROWN

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 - (MARRON GLAMOUR) - BROWN

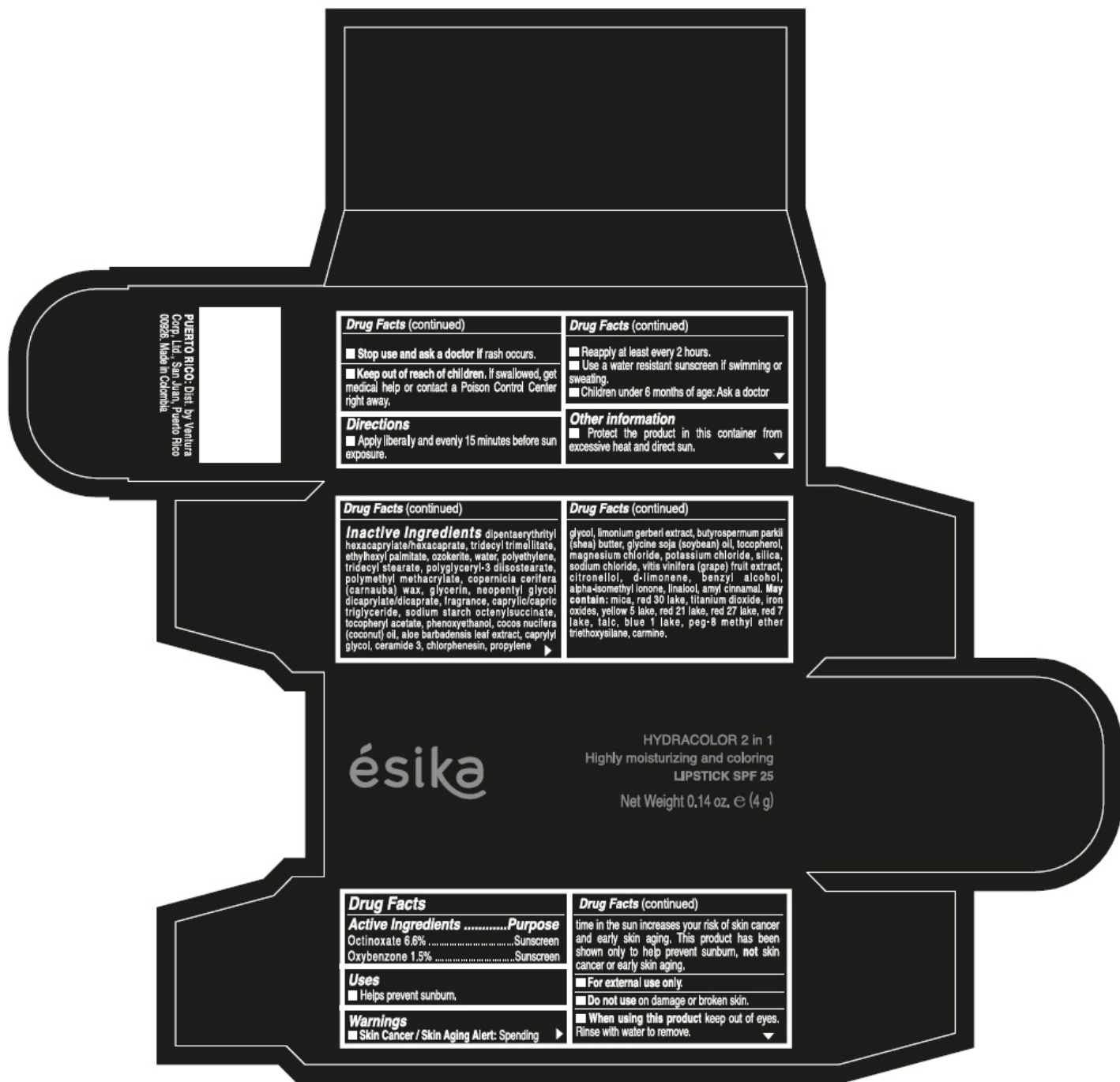
ésika

HYDRACOLOR 2 in 1

Highly moisturizing and coloring

LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

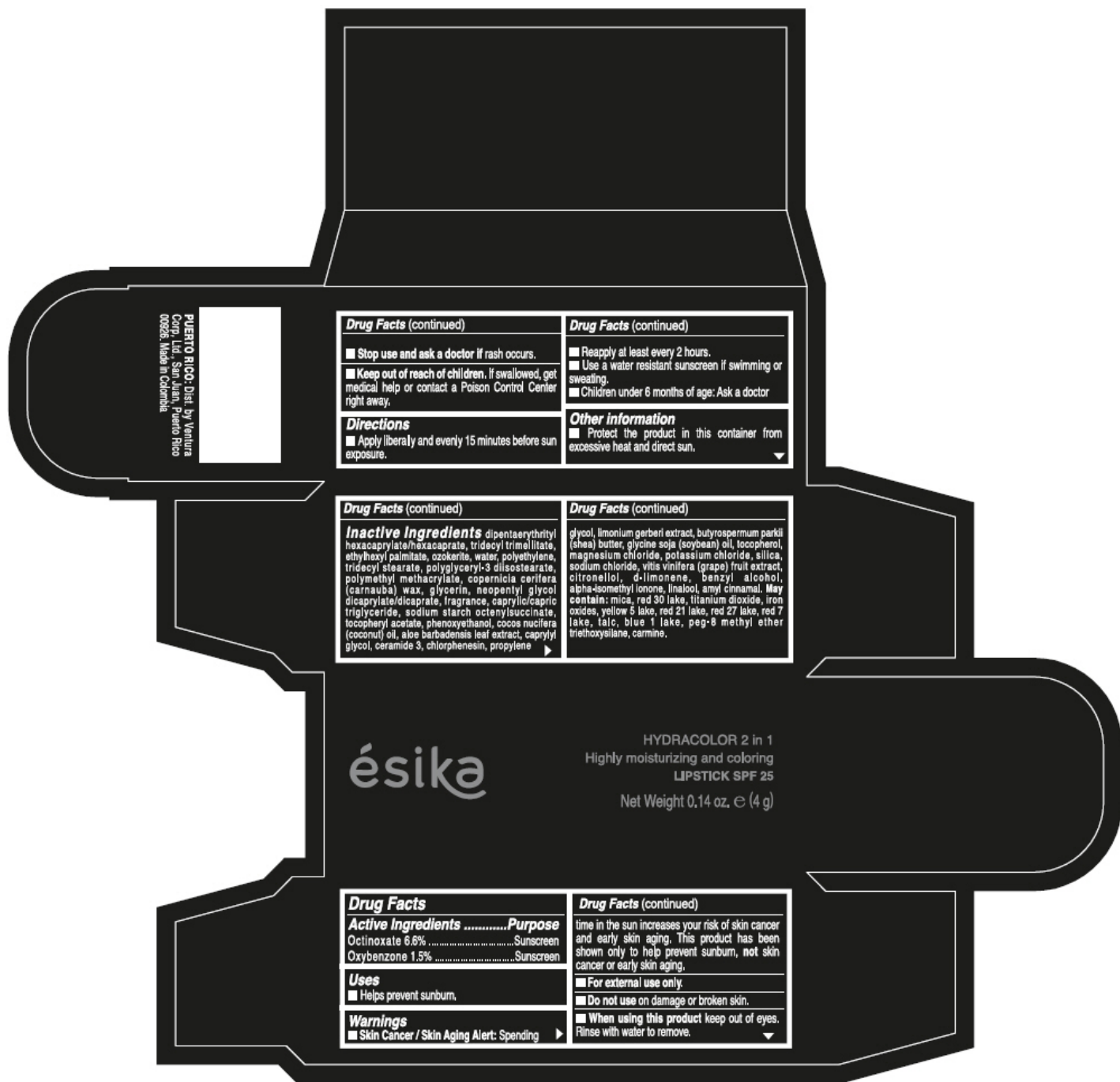


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (BORGONA SEXY) - PURPLE

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

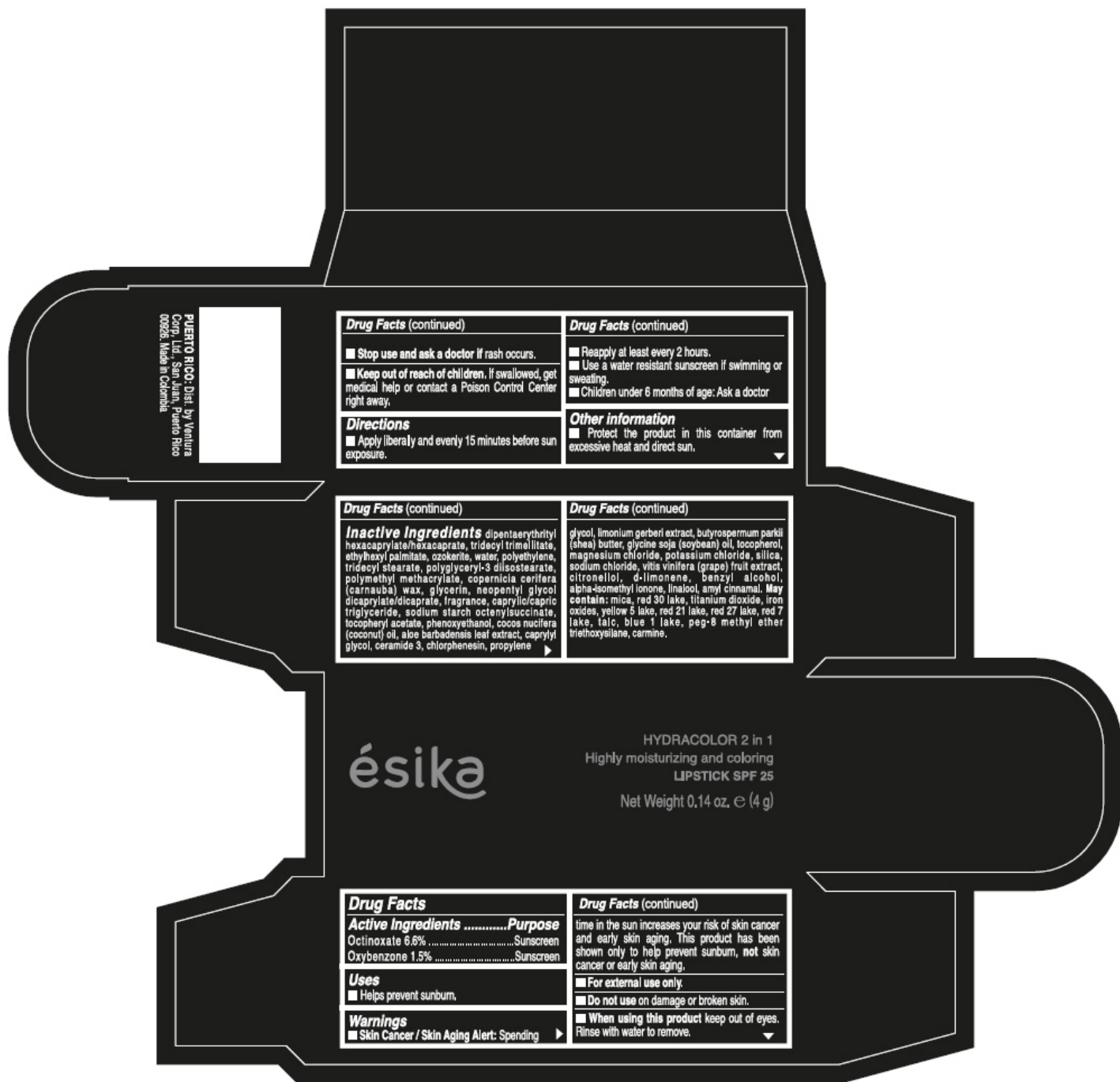


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (ROSA DULZURA) - PINK

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

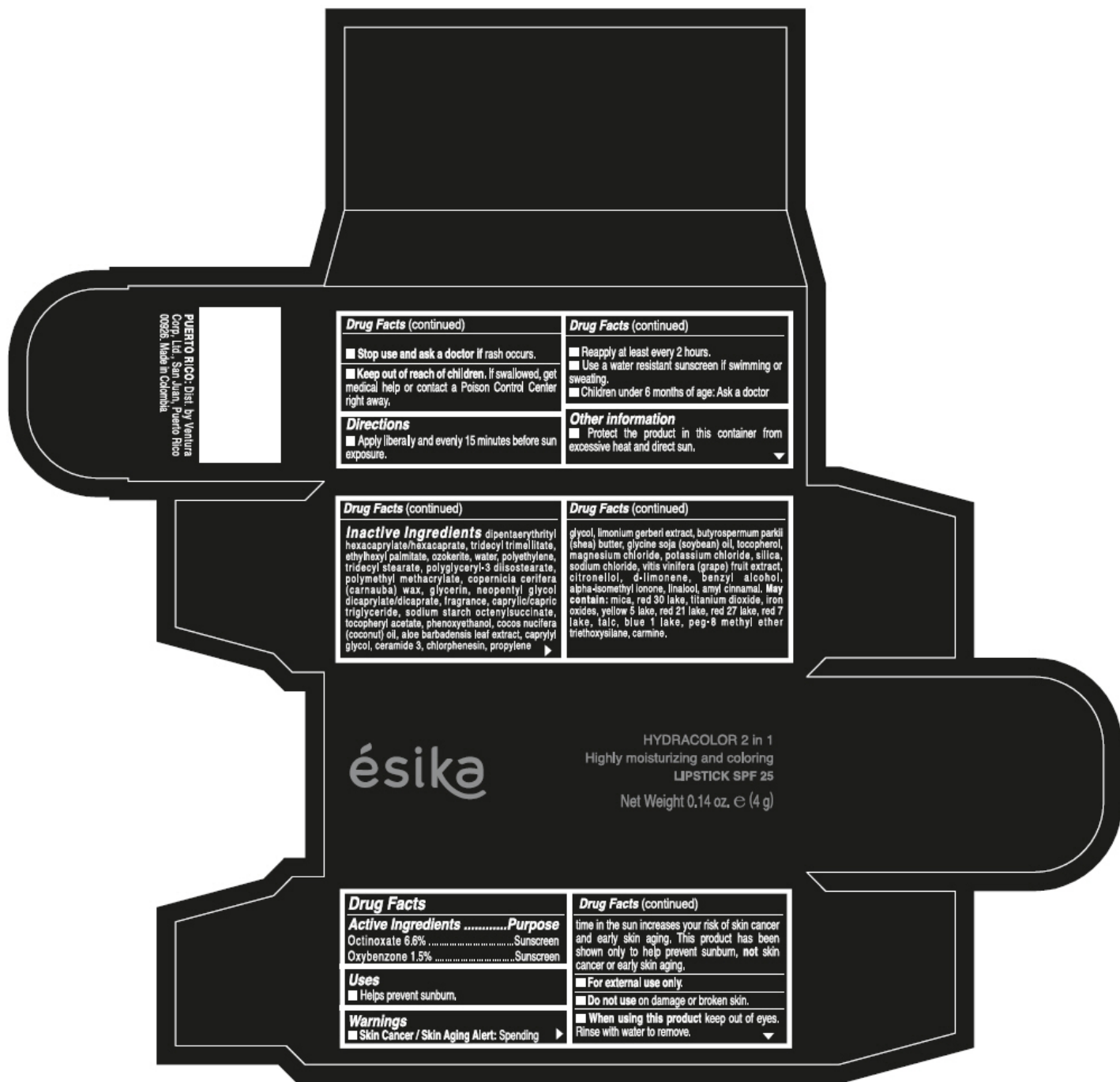


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (ROJO DESEO) - RED

ésika

HYDRACOLOR 2 in 1
 Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

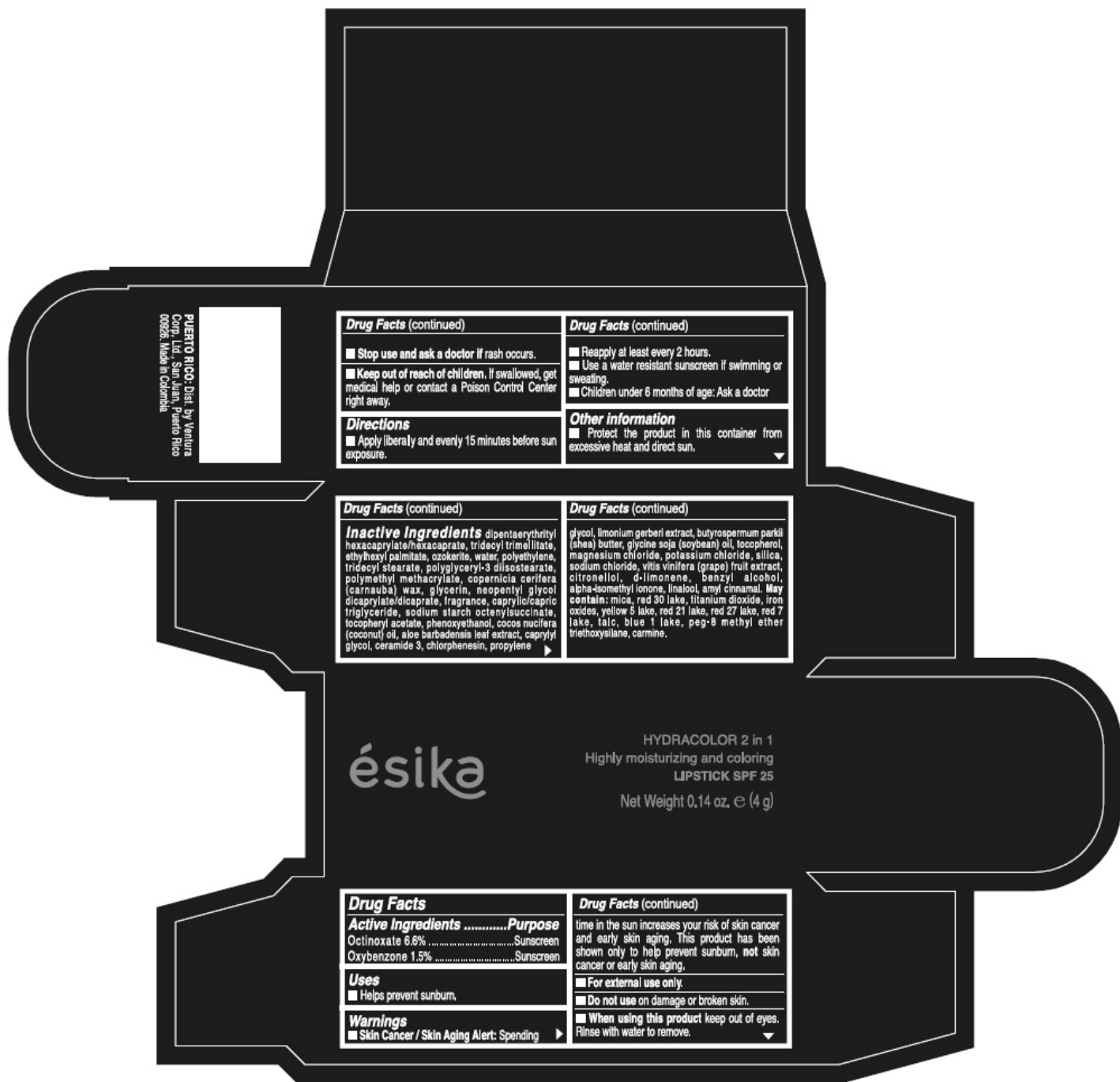


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (ROJO INTRIGANTE) - RED

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

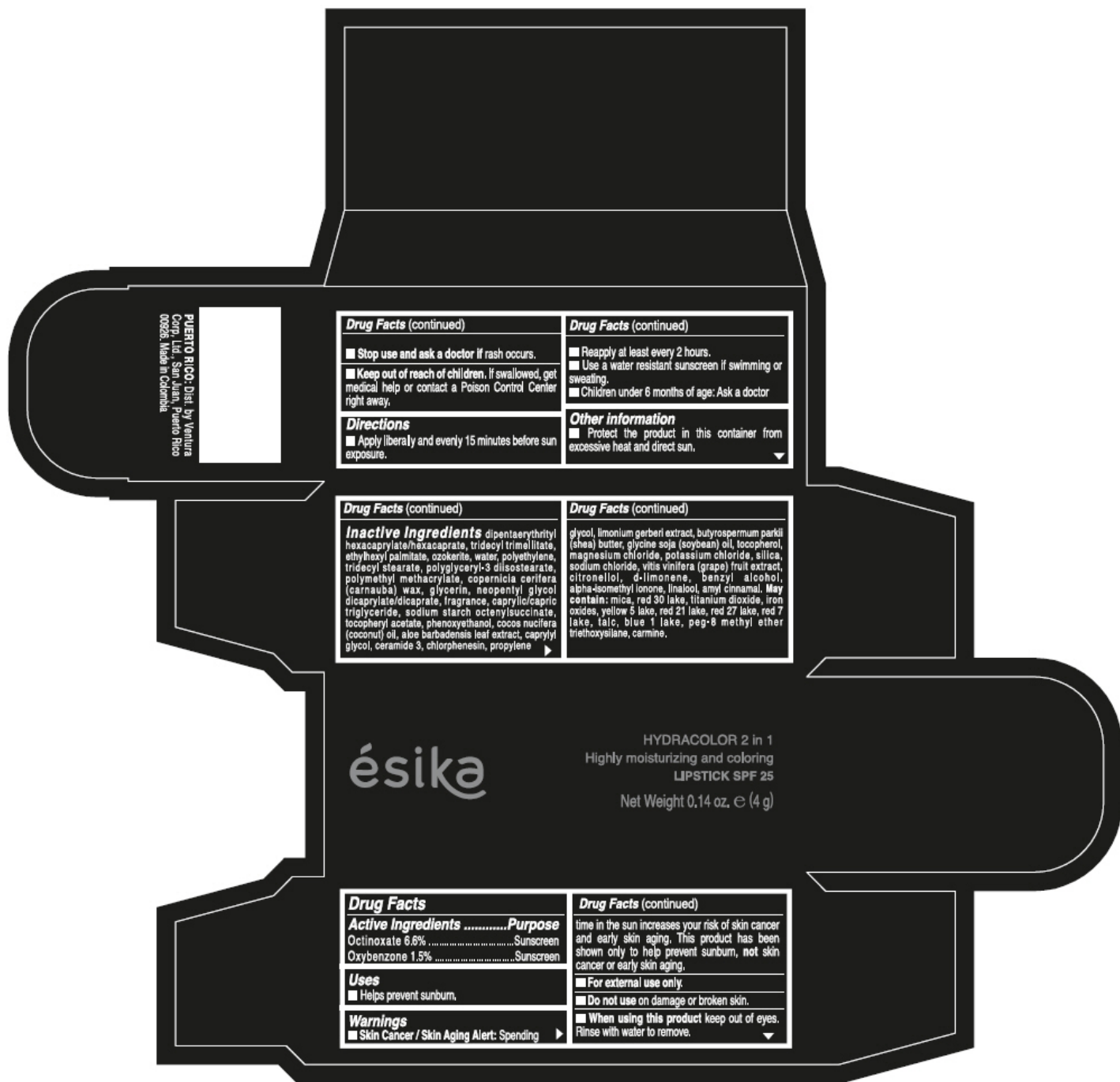


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (ROJO LUJURIA) - RED

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

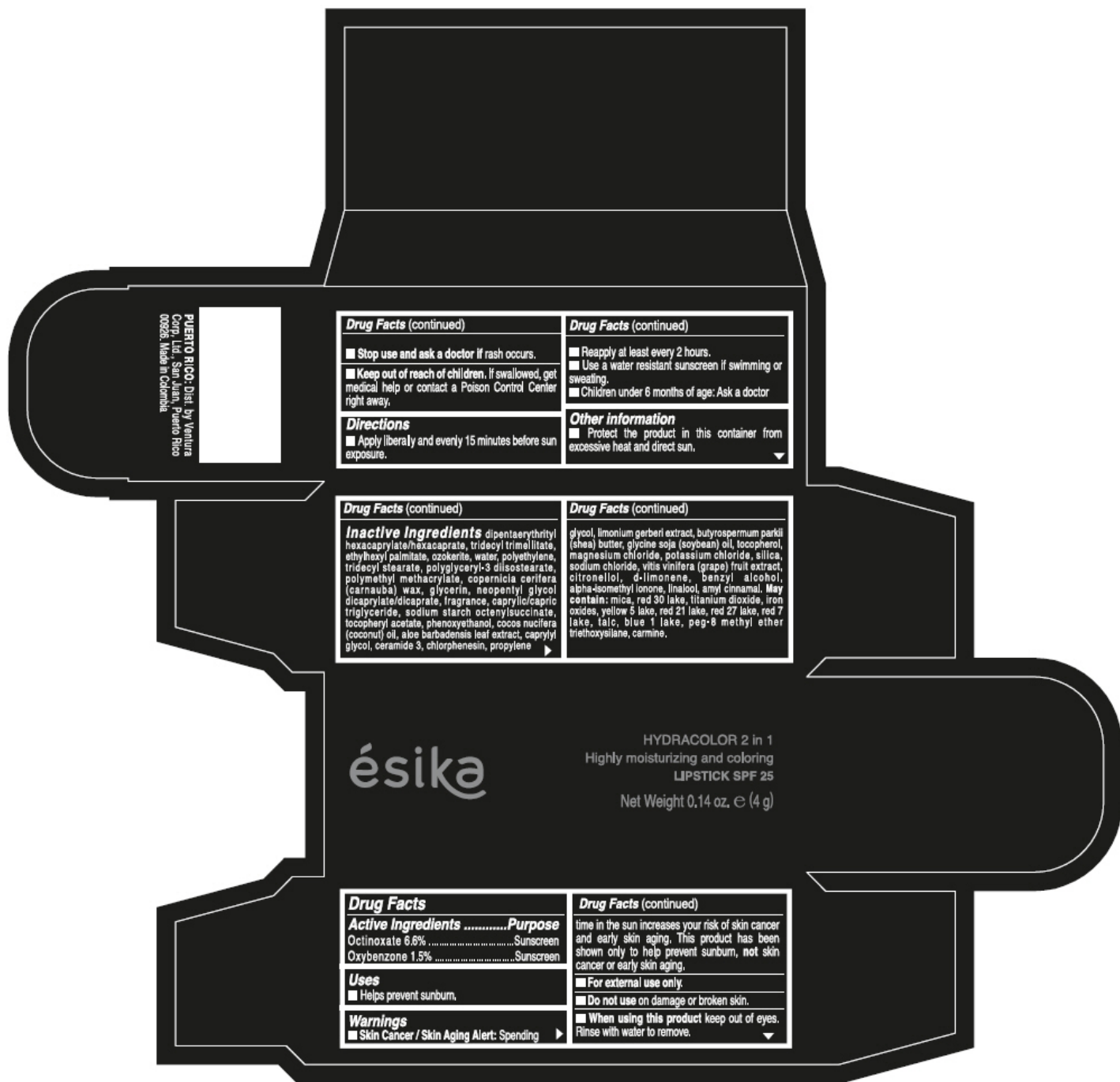


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (CORAL CHIC) - PINK

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

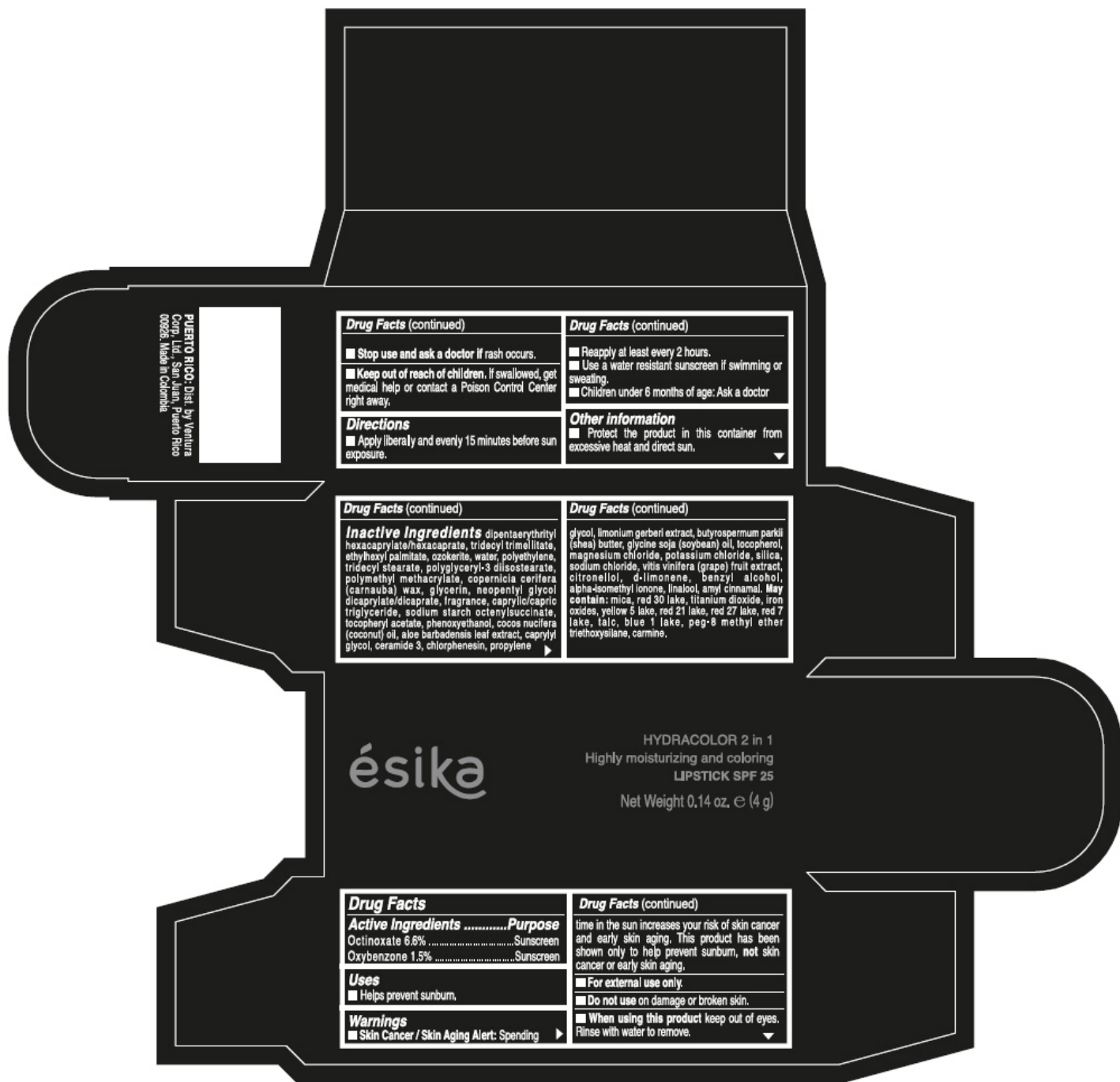


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (ROSA ENCANTO) - PINK

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

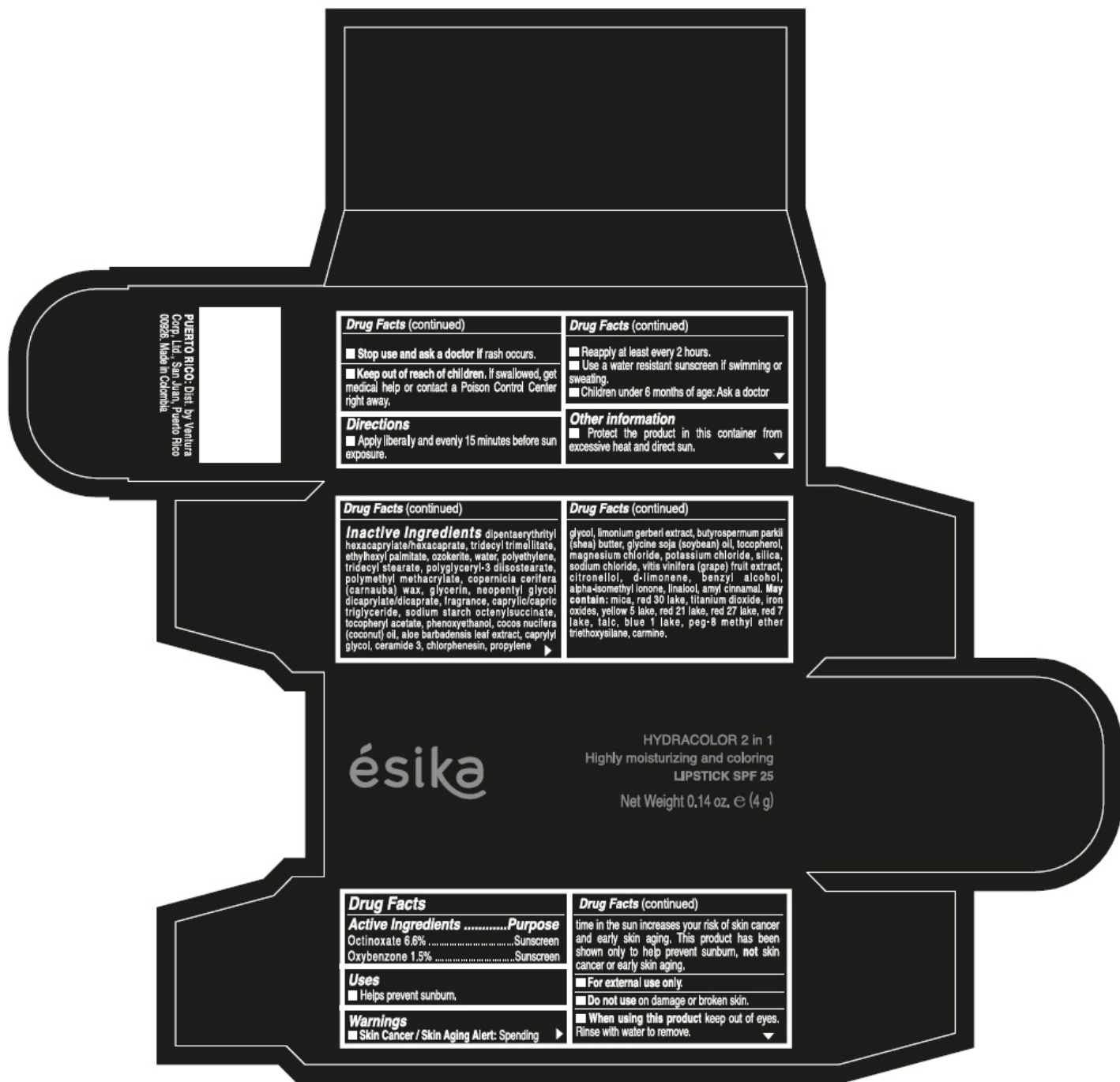


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (FUCSIA CAUTIVANTE) - PINK

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

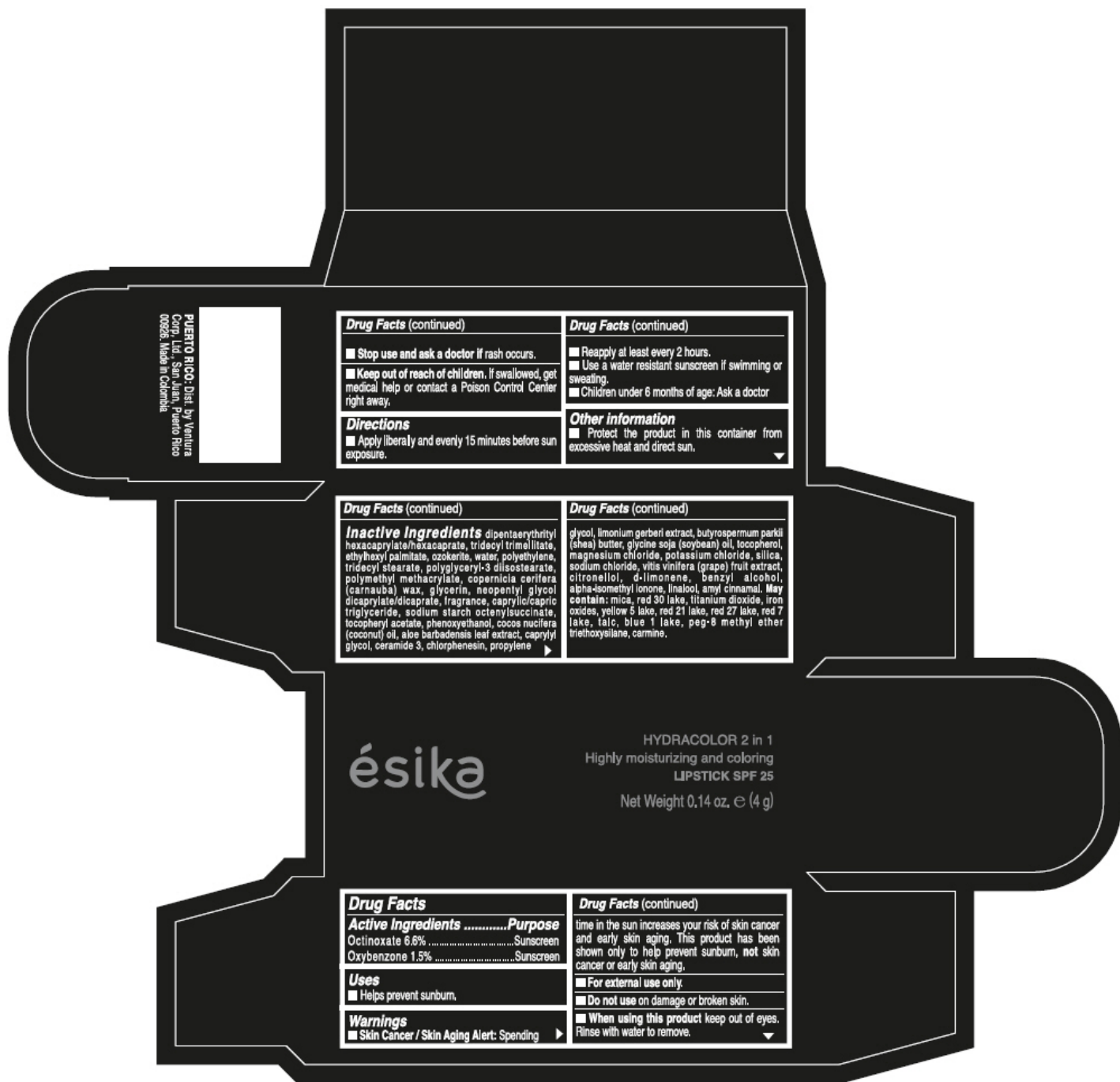


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (GRANATE SEDUCTOR) - PURPLE

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

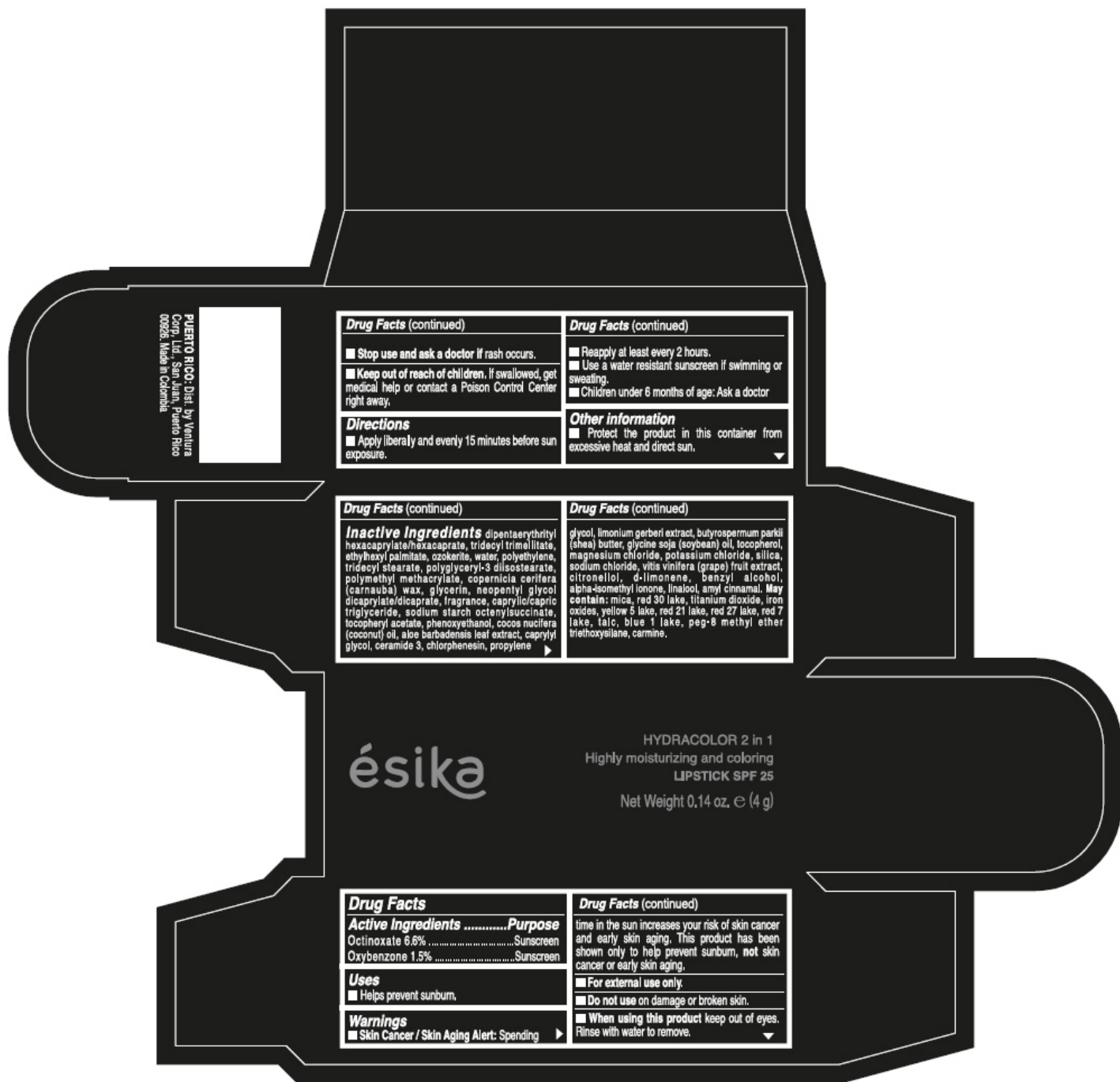


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (ROSA ROMANTICA) - PINK

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)



PUERTO RICO-Dist. by Ventura
 Corp. Ltd., San Juan, Puerto Rico
 00926. Made in Colombia

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 every 15 minutes before sun exposure.**

Drug Facts (continued)

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

Other information

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

Drug Facts (continued)

Inactive Ingredients dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, ethylhexyl palmitate, ozokerite, water, polyethylene, tridecyl stearate, polyglyceryl-3 diisostearate, polymethyl methacrylate, copernicia corifera (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

Drug Facts (continued)

glycol, limonium gerberi extract, butyrospermum parkii (shea) butter, glycine soja (soybean) oil, tocopherol, magnesium chloride, potassium chloride, silica, sodium chloride, vitis vinifera (grape) fruit extract, citronellol, δ -limonene, benzyl alcohol, alpha-isomethyl ionone, linalool, amyl cinnamal. May contain: mica, red 90 lake, titanium dioxide, iron oxides, yellow 5 lake, red 21 lake, red 27 lake, red 7 lake, talc, blue 1 lake, peg-8 methyl ether triethoxysilane, carmine.

ésika

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.

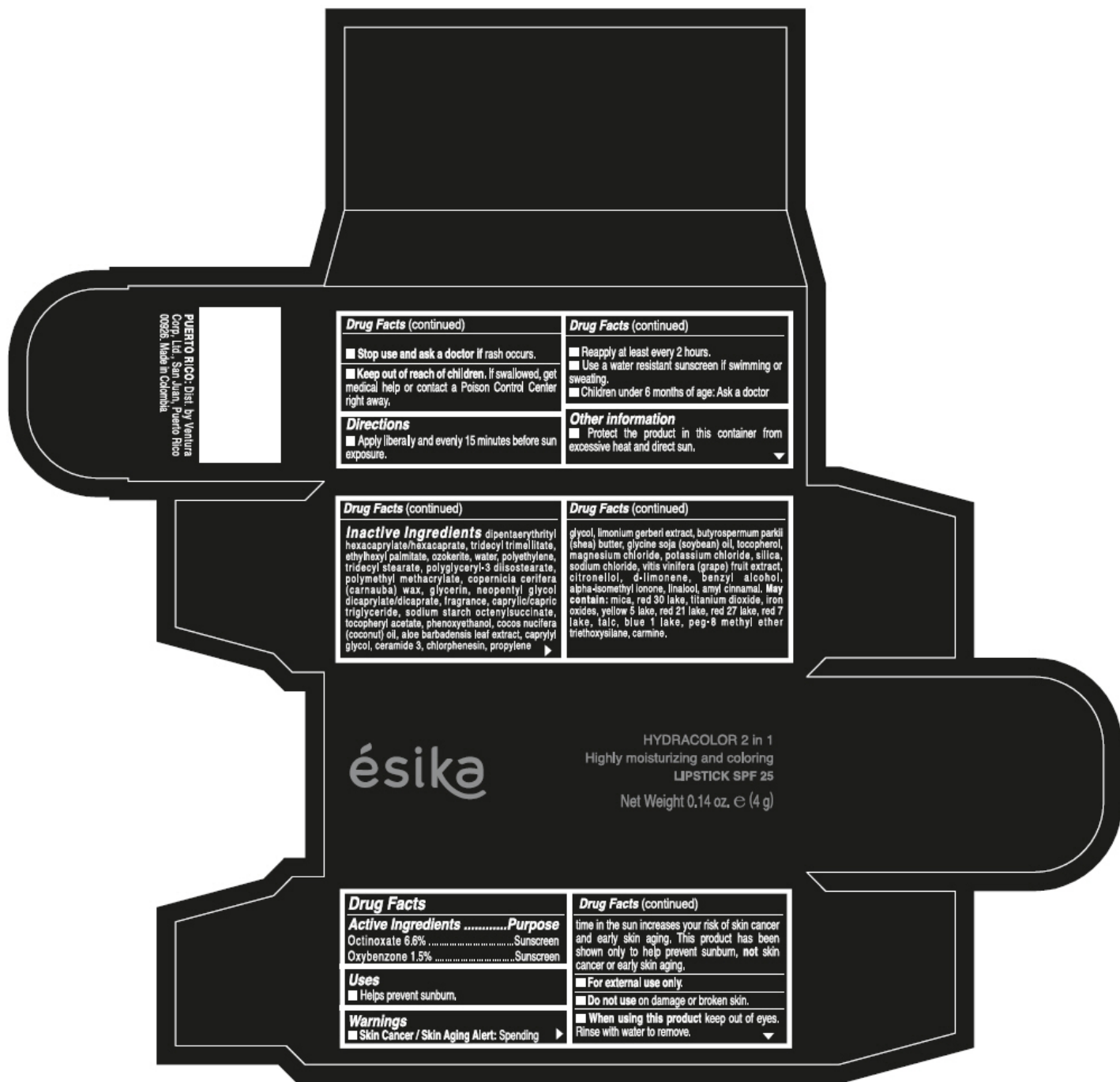
■ **For external use only.**
 ■ **Do not use on damage or broken skin.**
 ■ **When using this product keep out of eyes. Rinse with water to remove.**

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

ésika

HYDRACOLOR 2 in 1
 Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

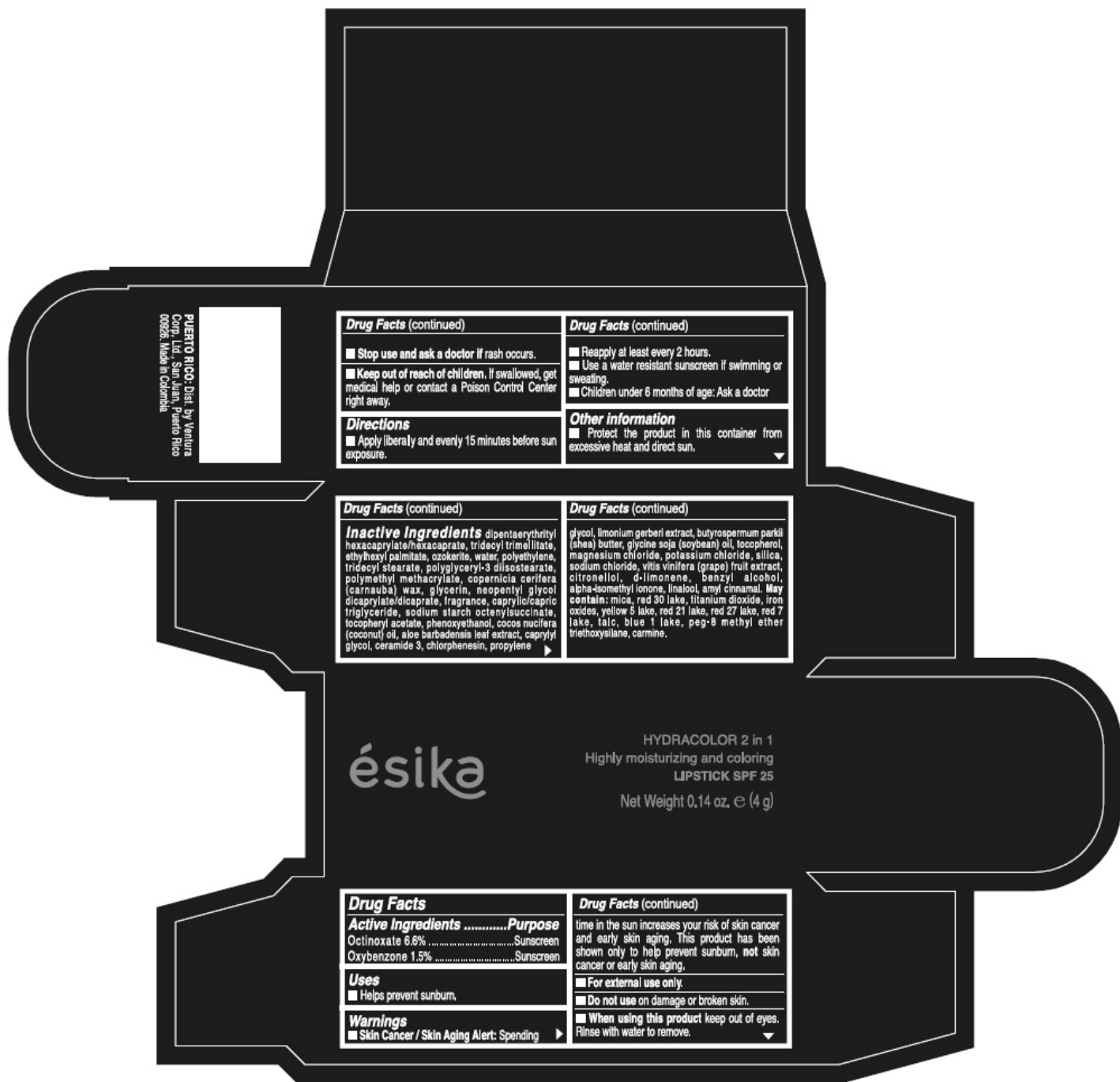


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (FRAMBUESA MANIA) - RED

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

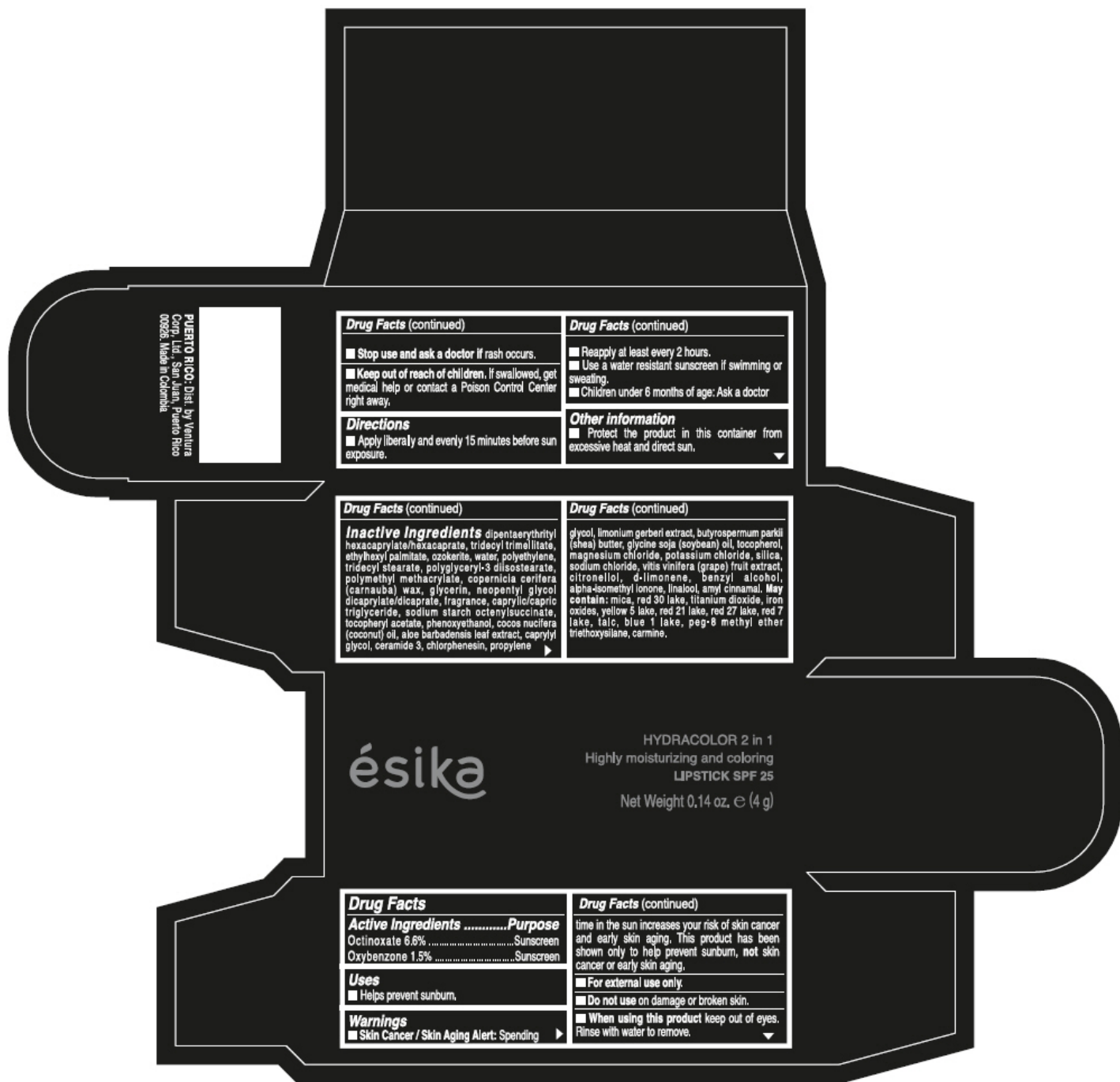


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (FRESA COQUETA) - RED

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

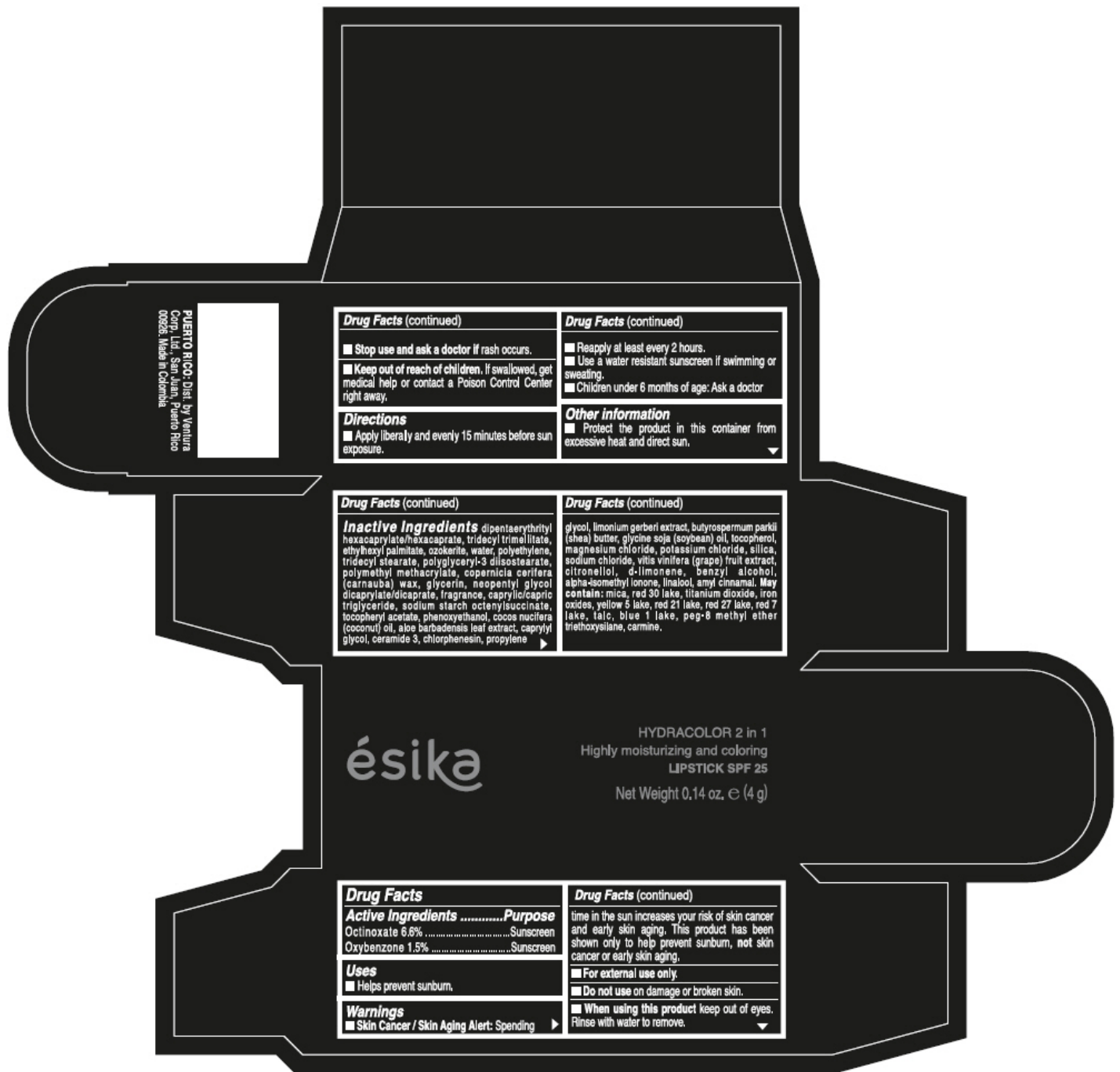


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (CANELA NUDE) - ORANGE

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

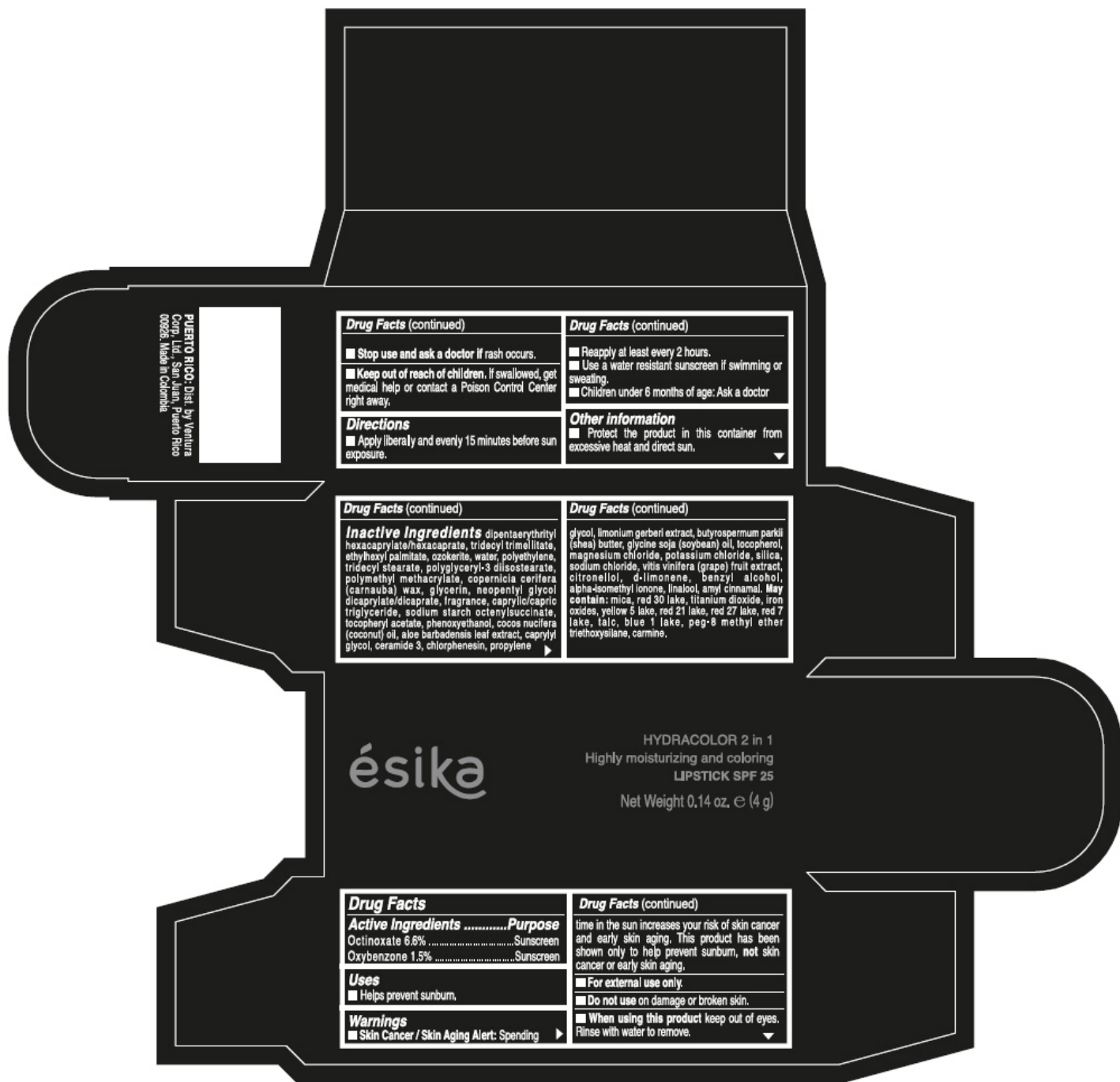


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (MORA GLAM) - BROWN

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

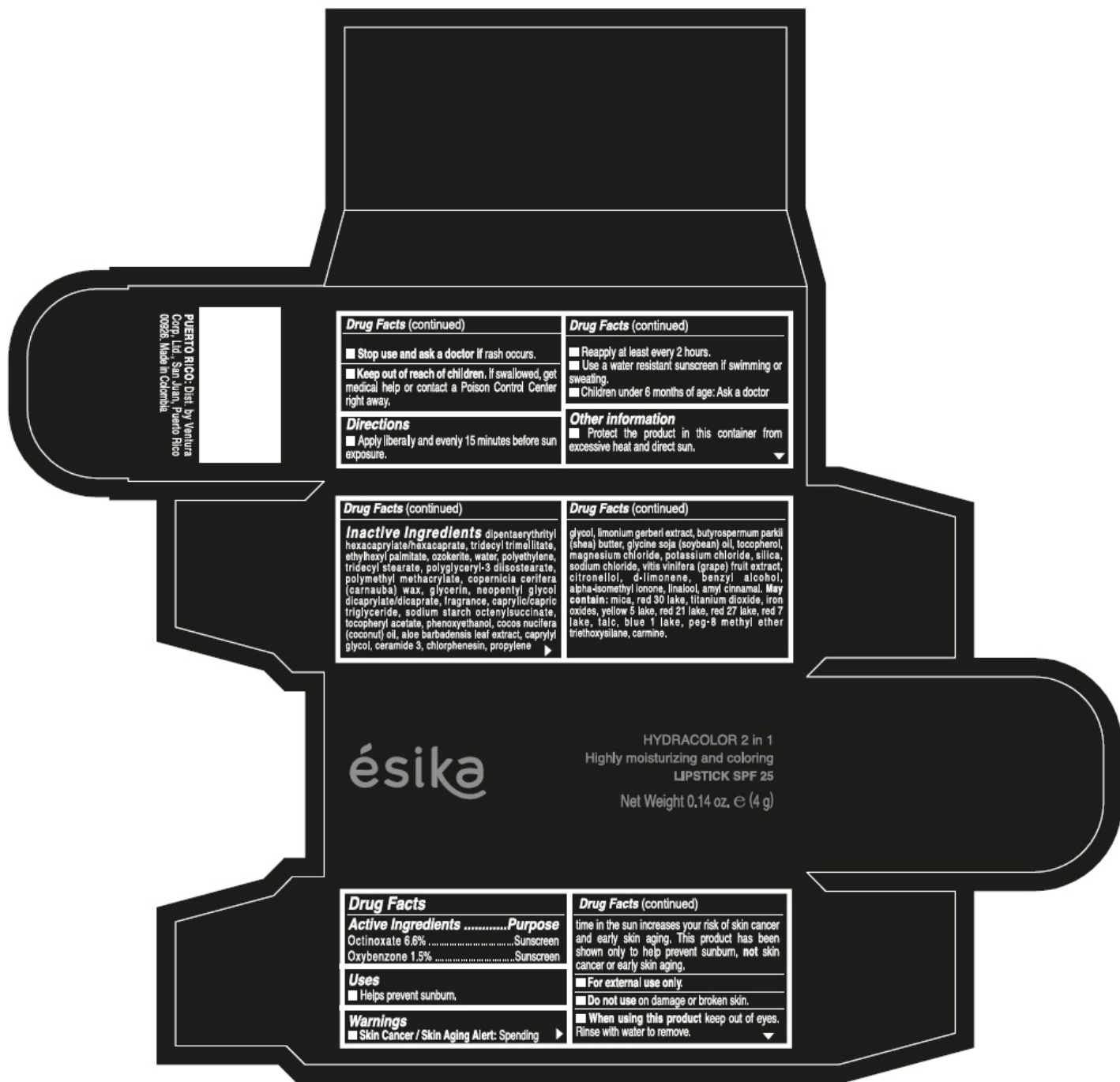


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (CORAL INTENSE) - RED

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

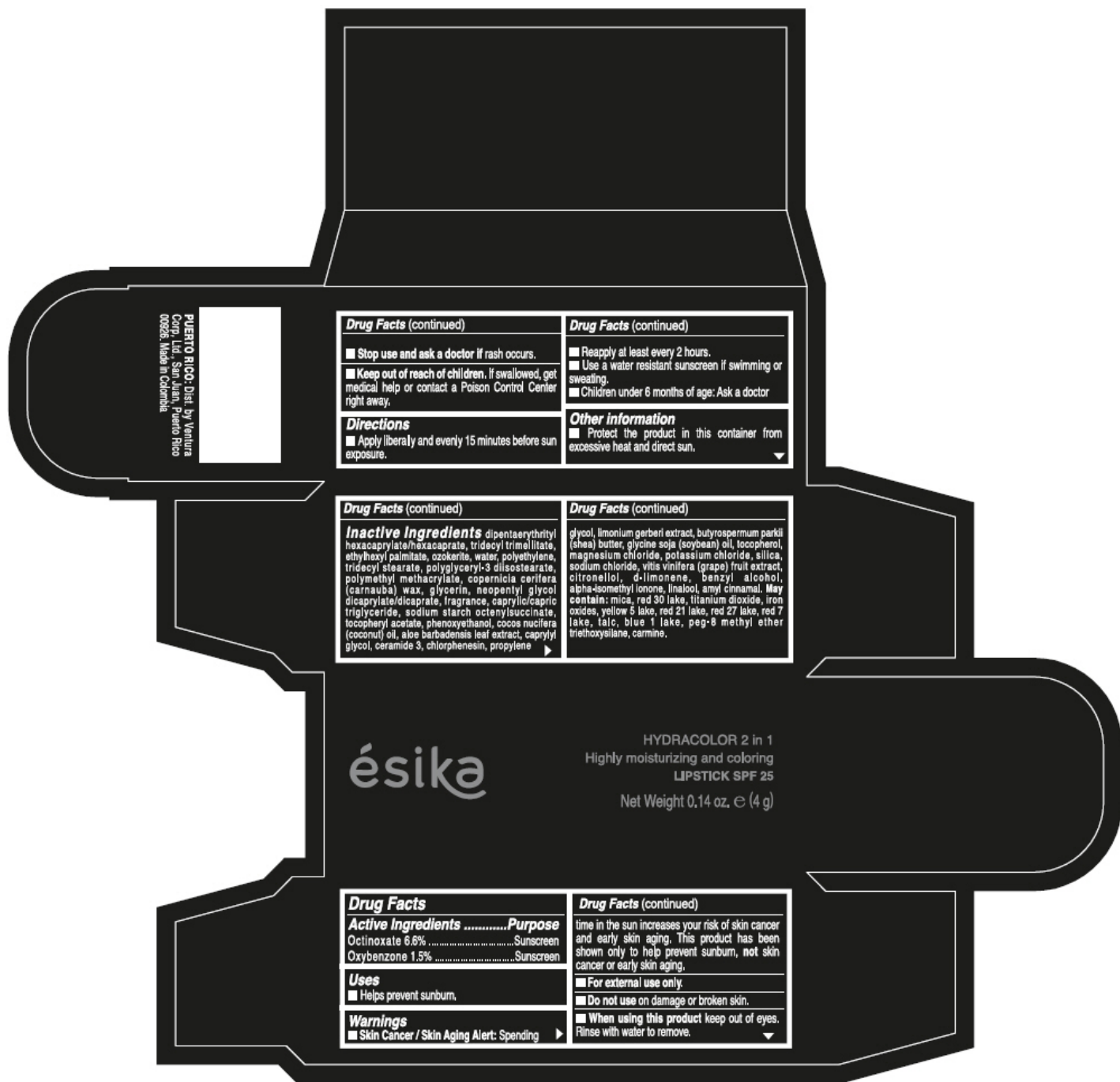


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (ROSA GEOMETRIC) - PINK

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

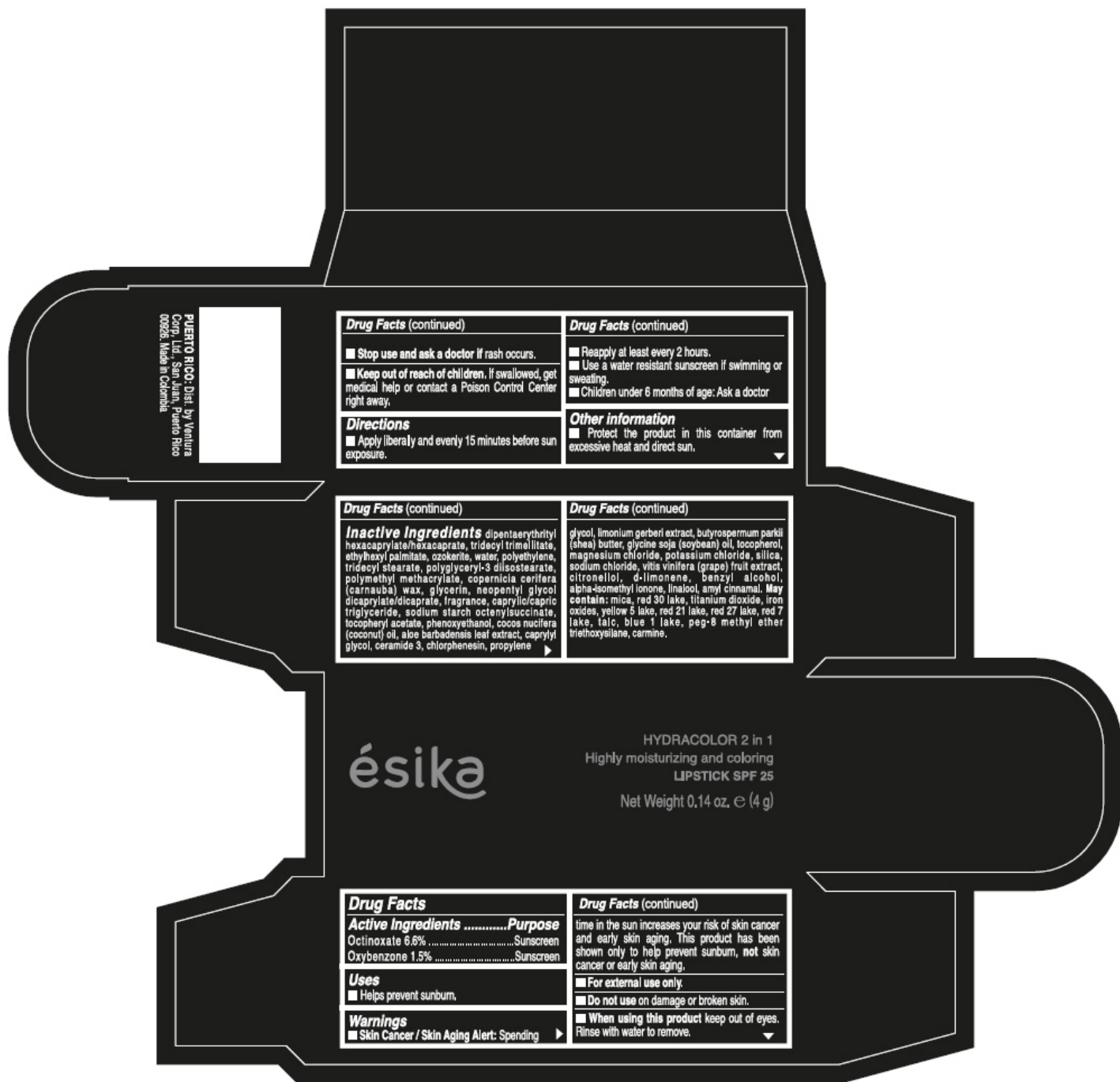


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (FUCSIA PRISMA) - RED

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

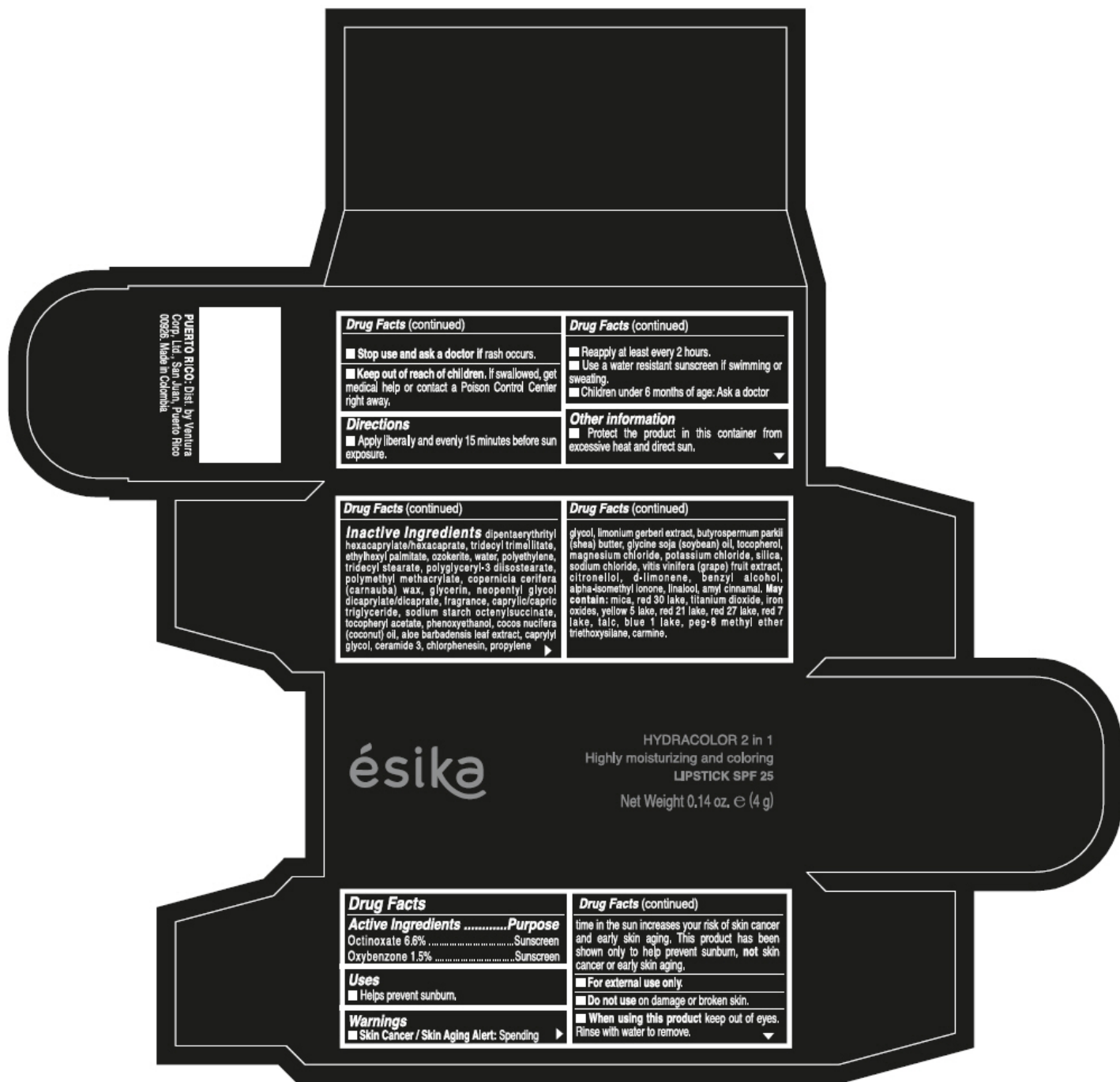


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (NARANJA ESFERA) - ORANGE

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

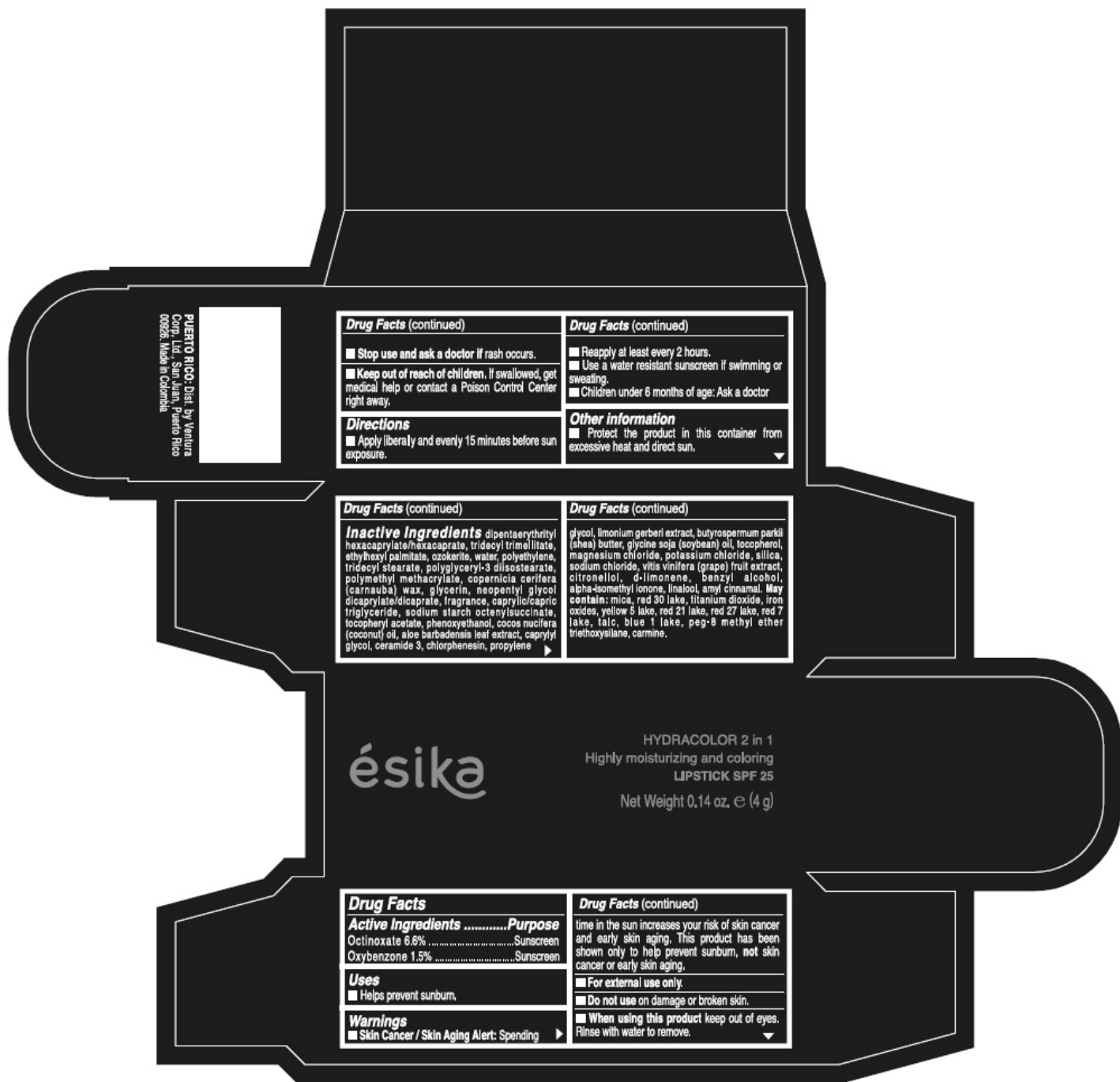


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (NUDE INFINITO) - BROWN

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

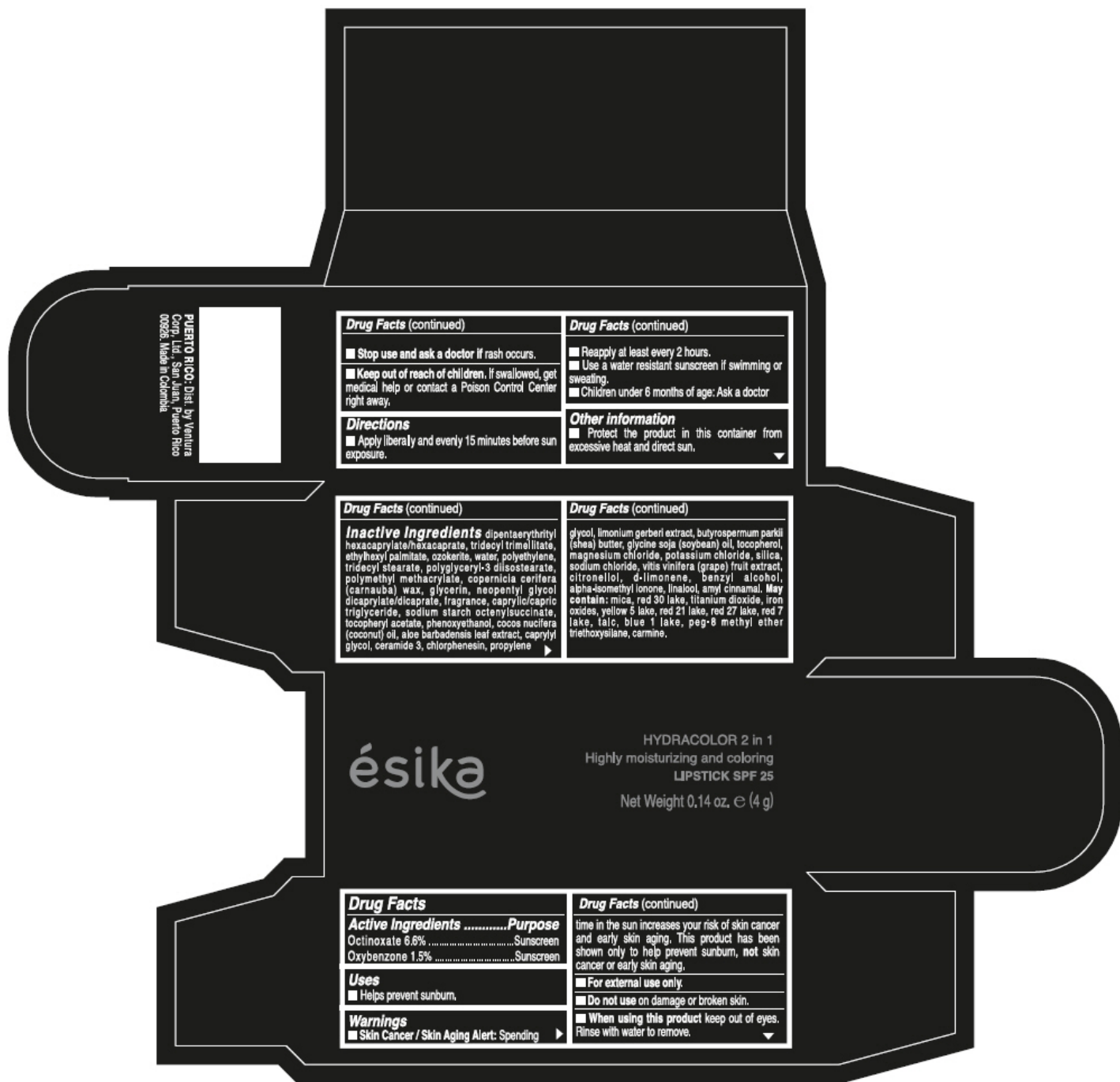


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (ROJO ESIKA) - RED

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

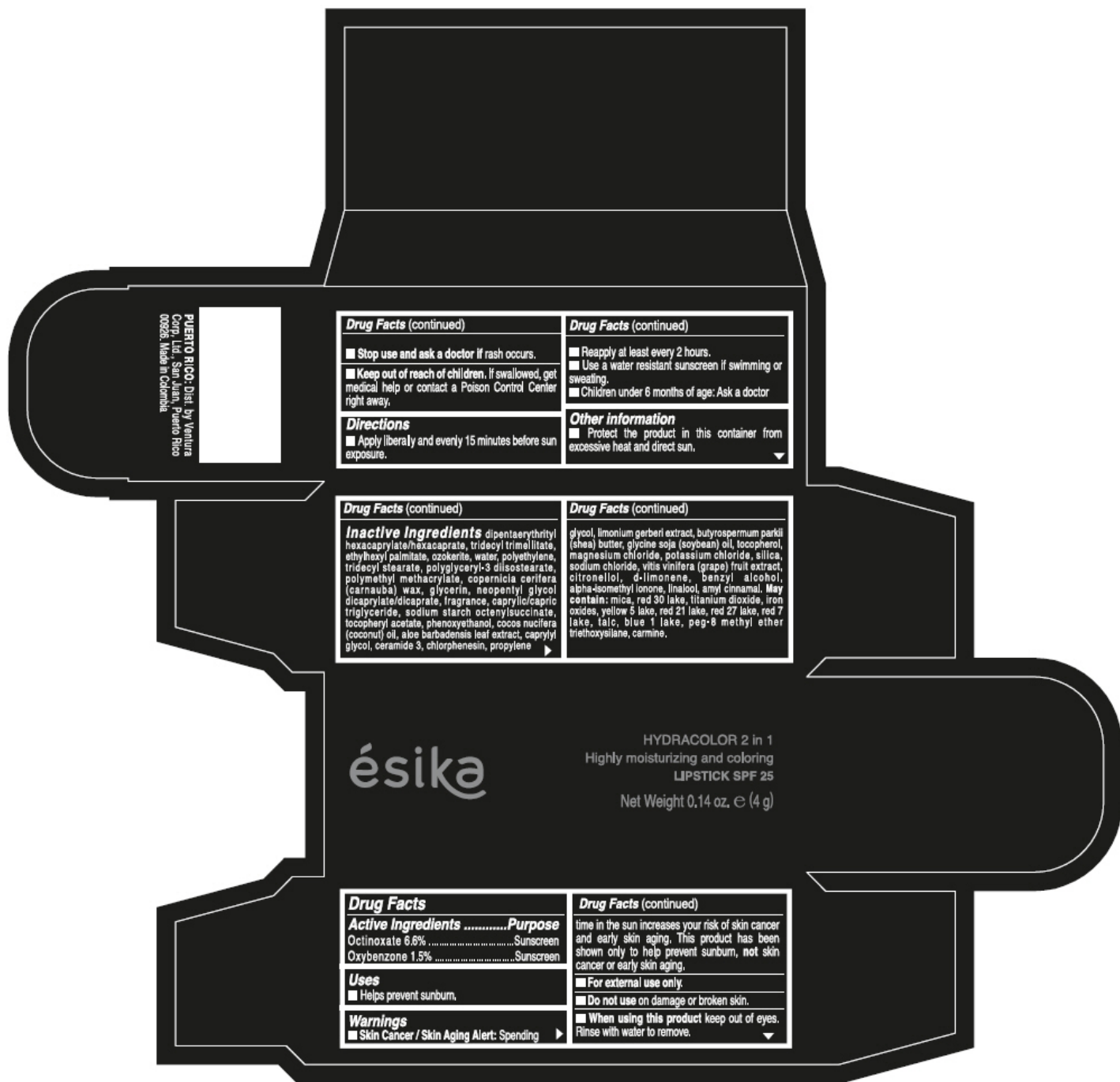


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (MARRON TOPACIO) - BROWN

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

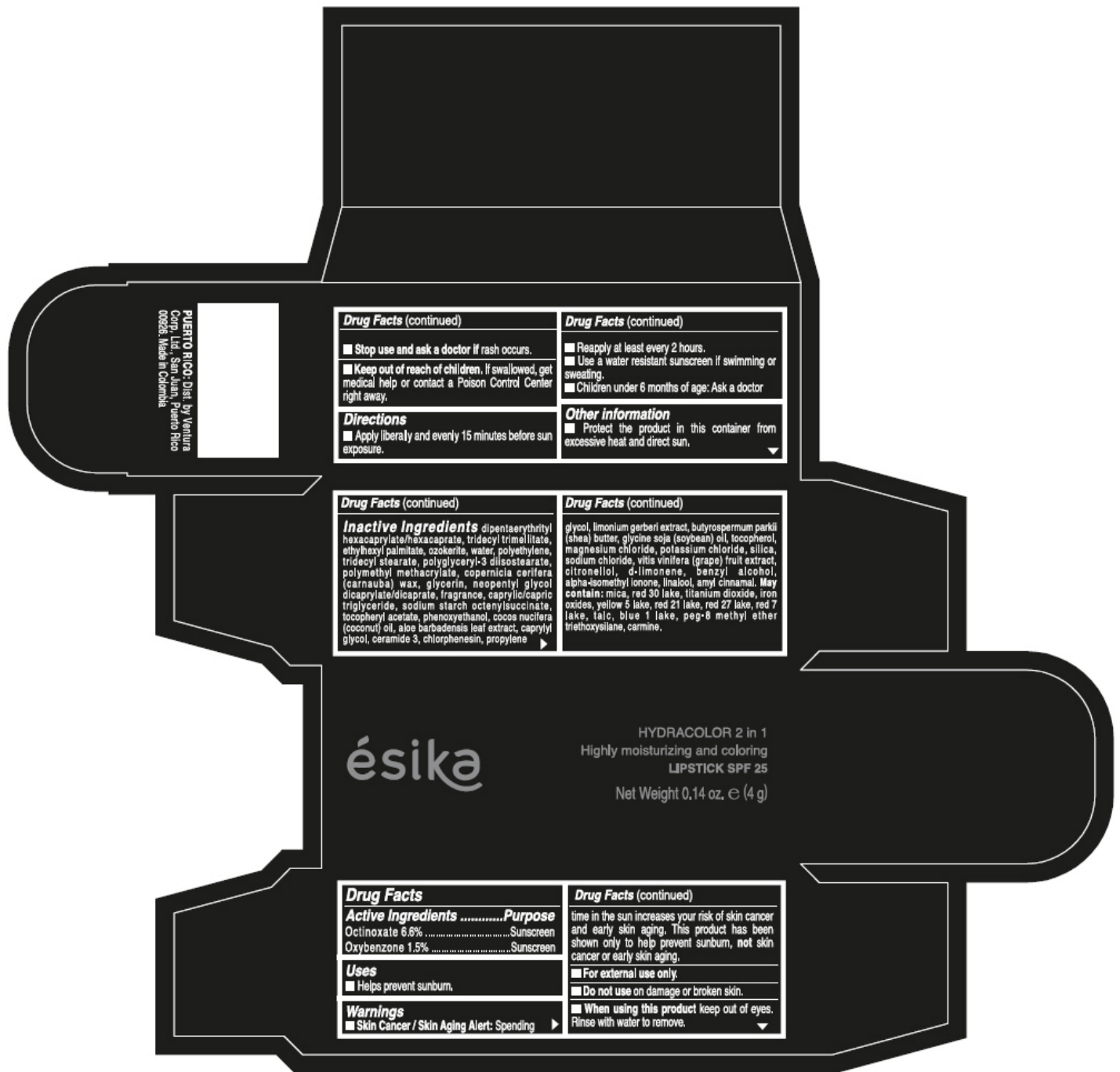


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (CORAL CUARZO) - ORANGE

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

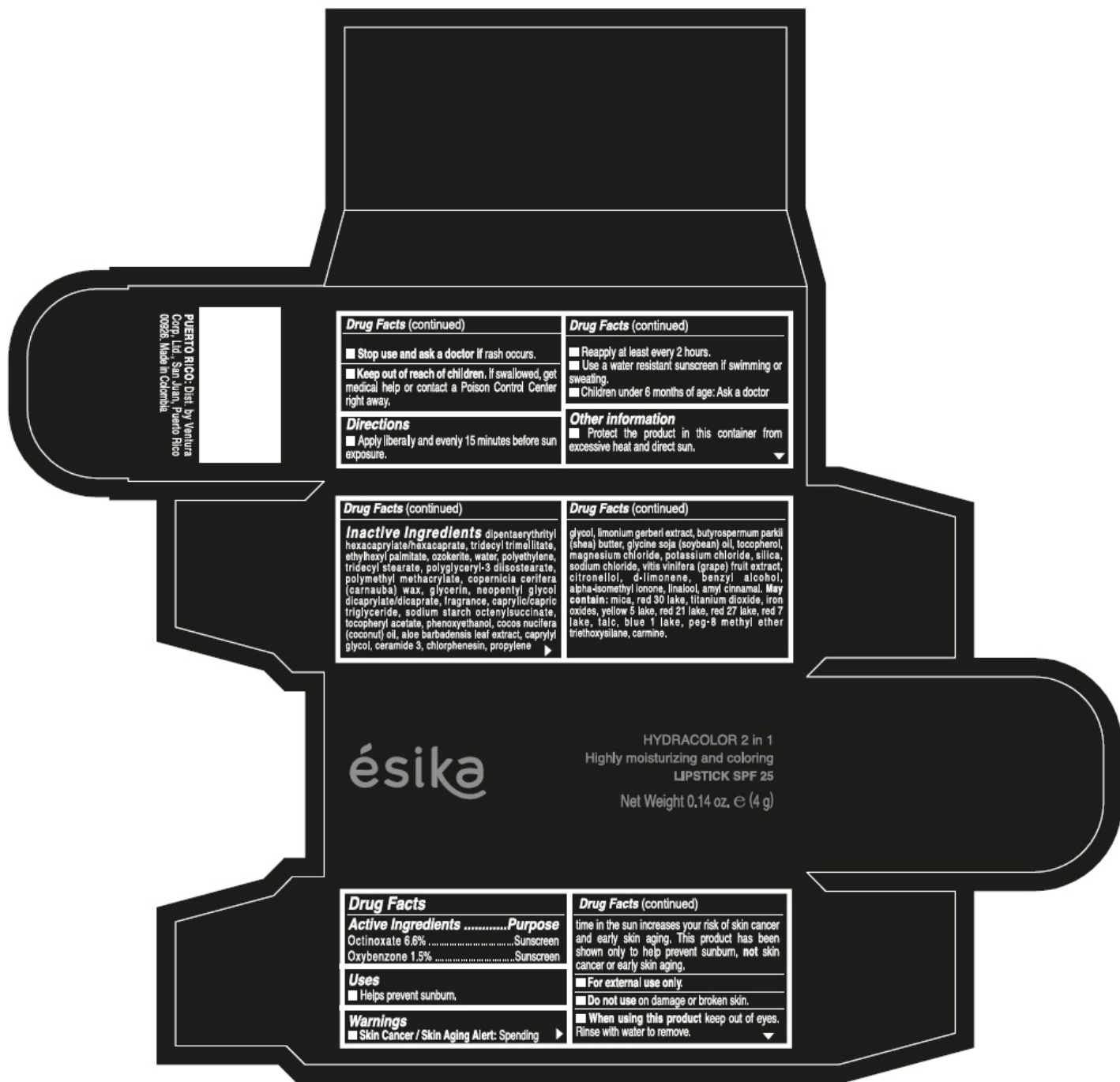


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (FUCSIA AMATISTA) - PINK

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

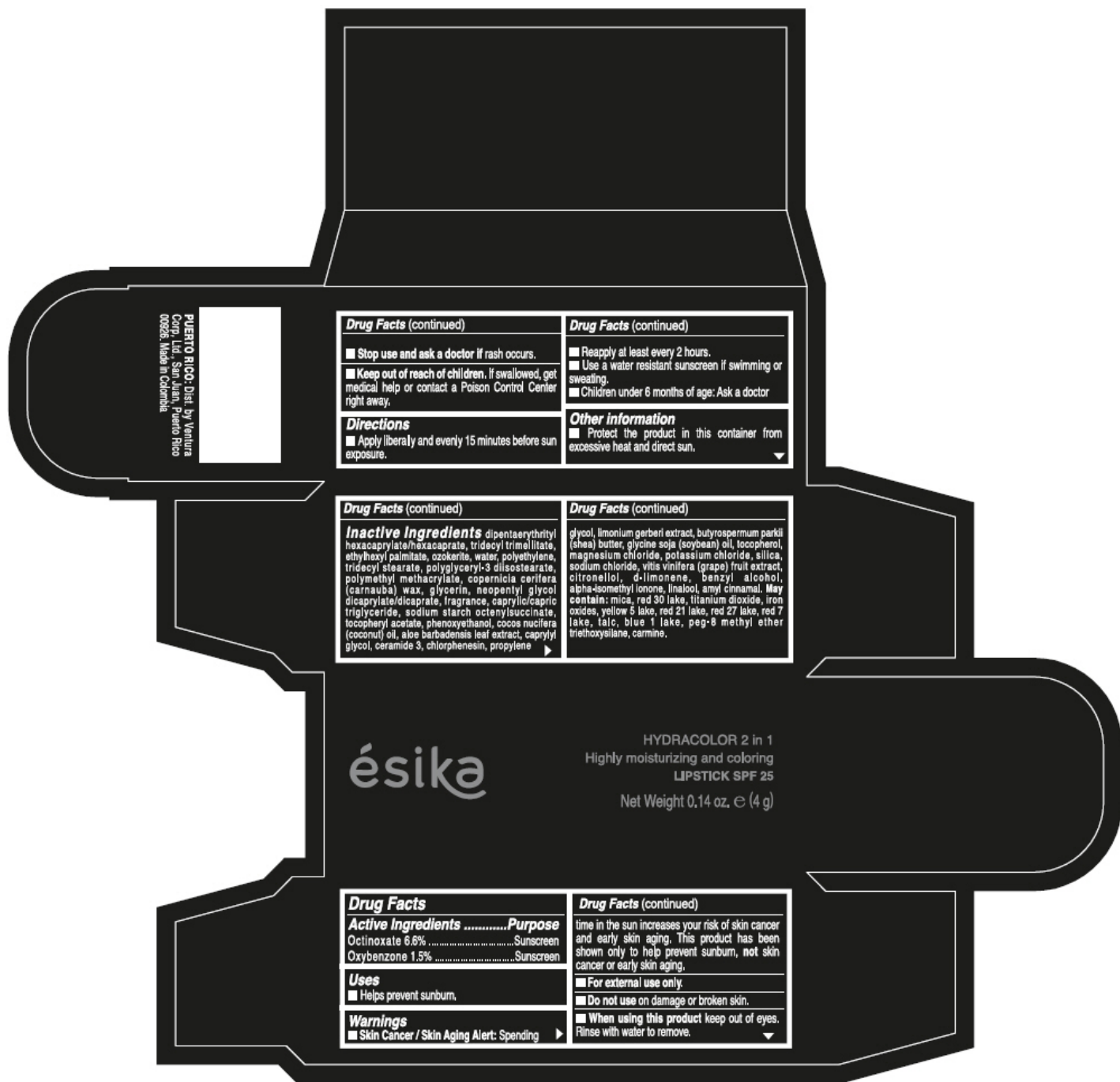


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (NUDE PRISMA) - ORANGE

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

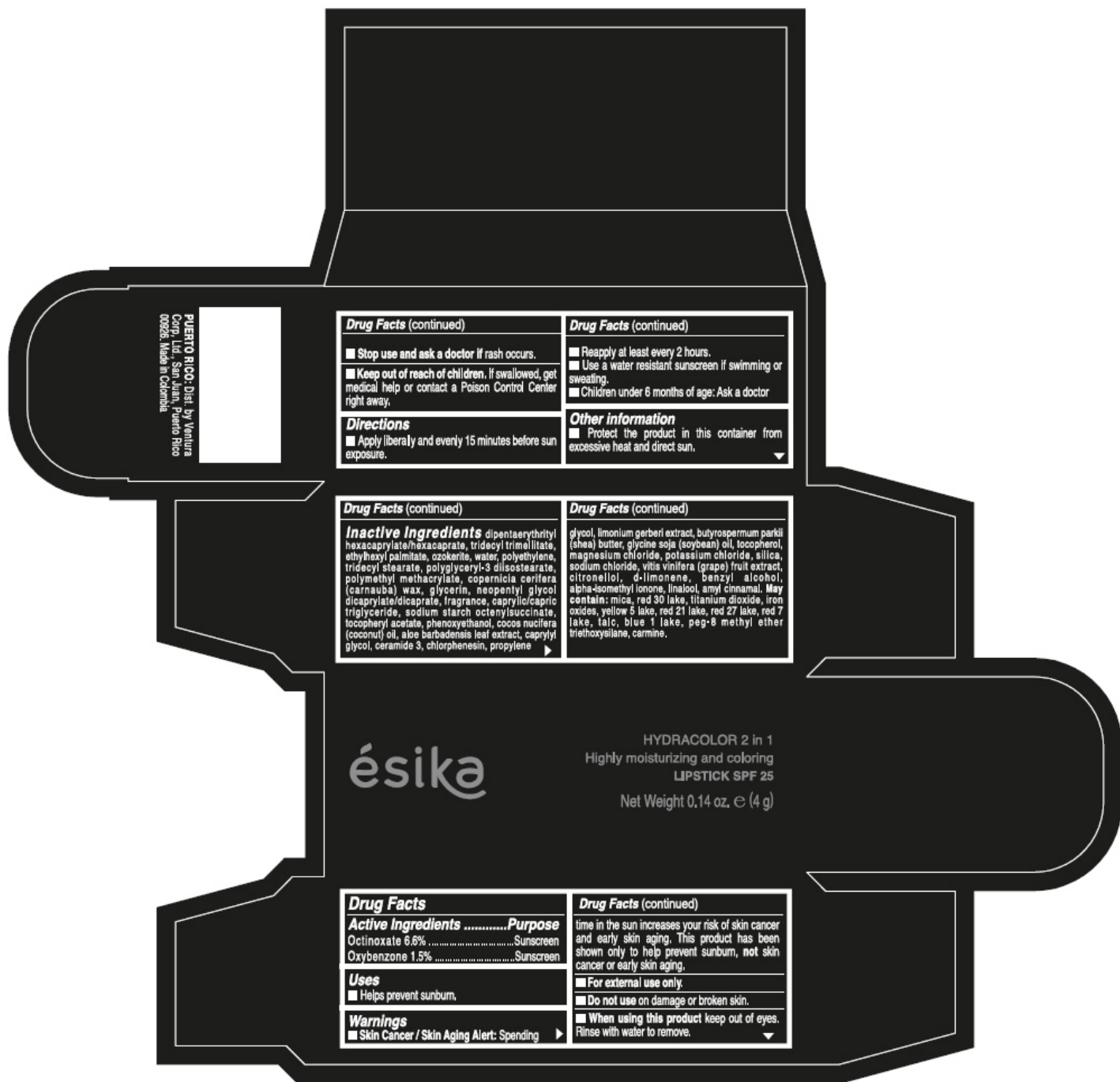


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (DORADO ESENCIAL) - YELLOW

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

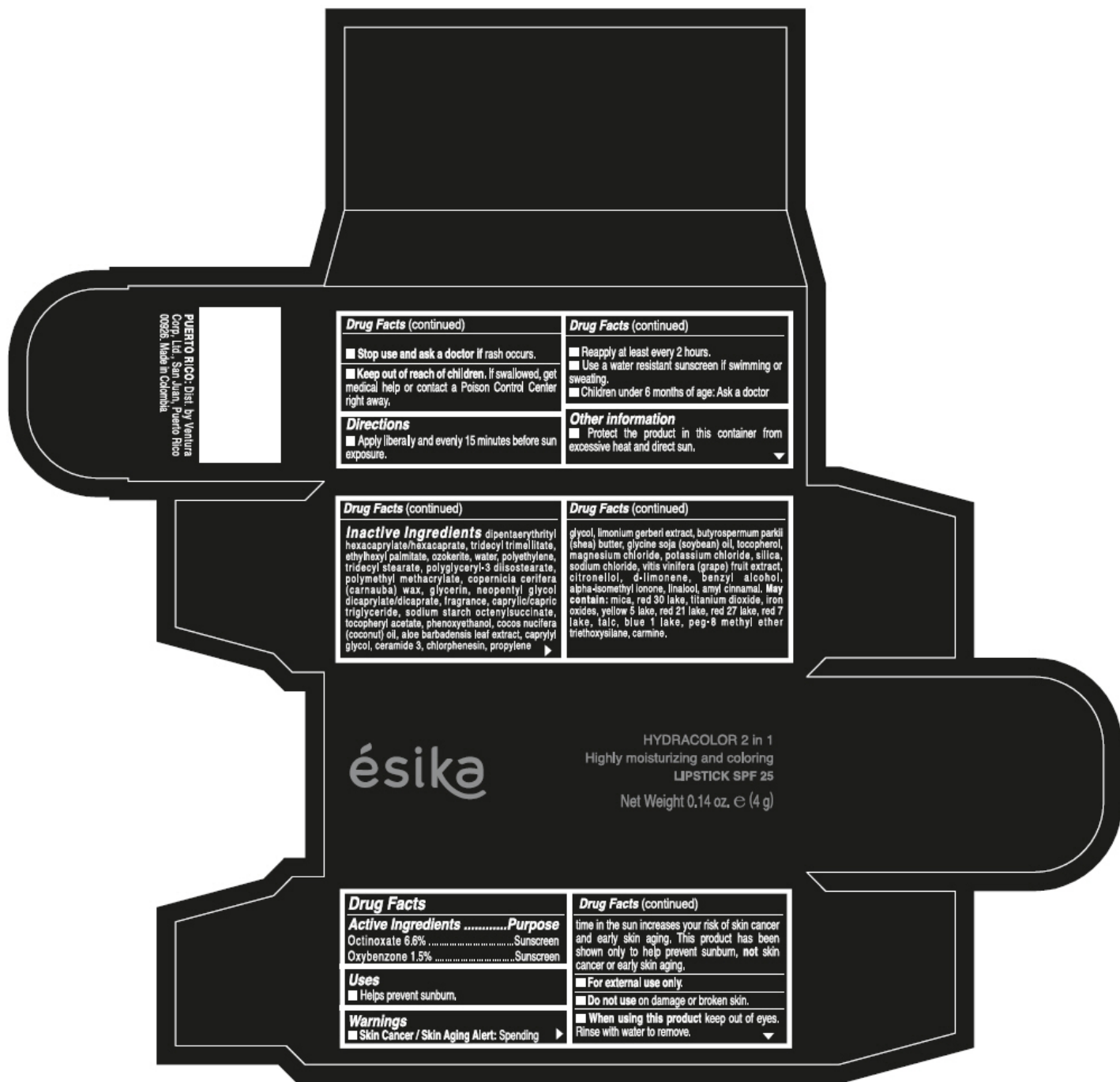


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (ROSA ENCANTO FEMME) - PINK

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

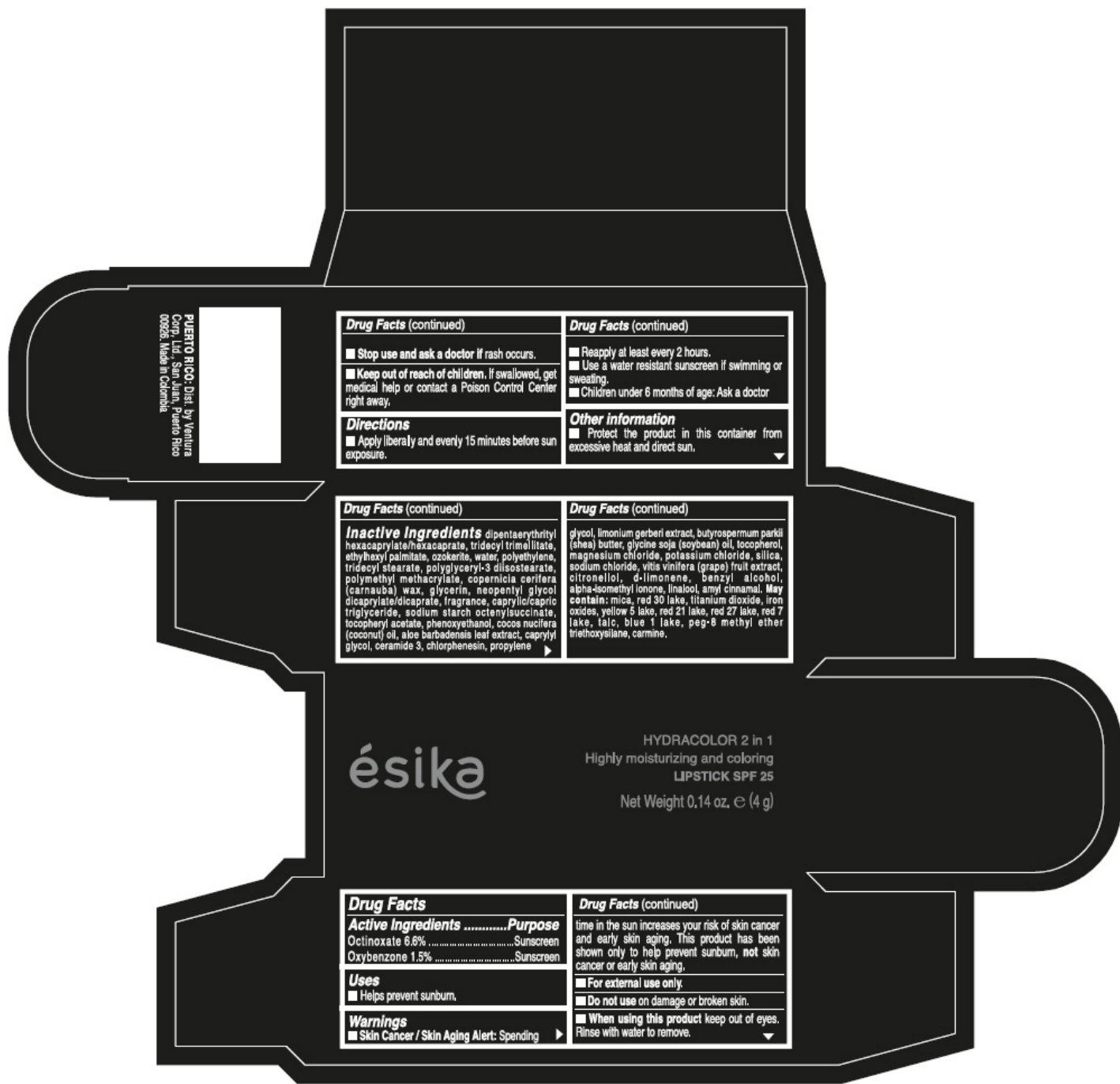


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (PIMIENTA CALIENTE FEMME) - RED

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

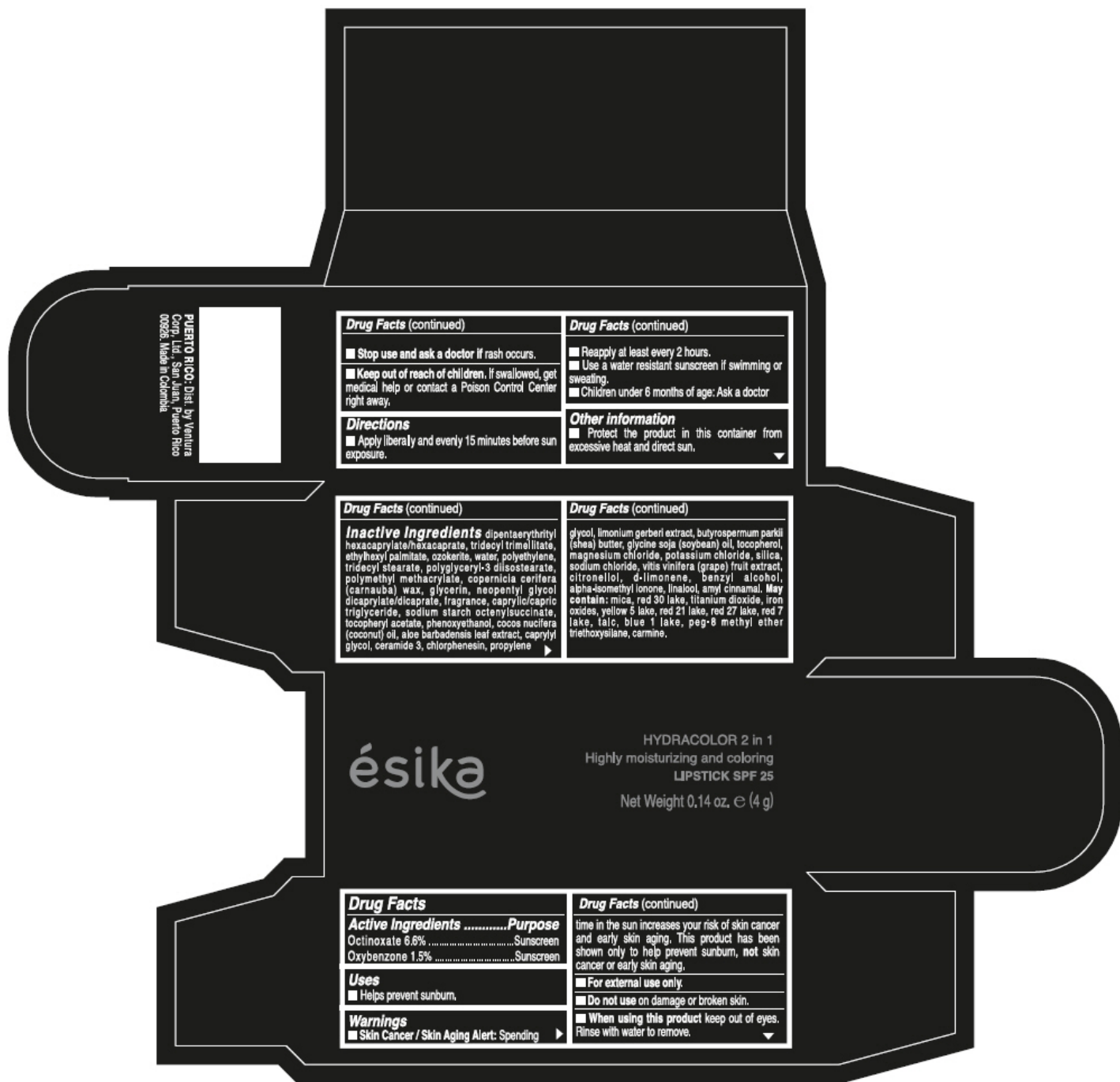


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (GRANATE SEDUCTOR FEMME) - PURPLE

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

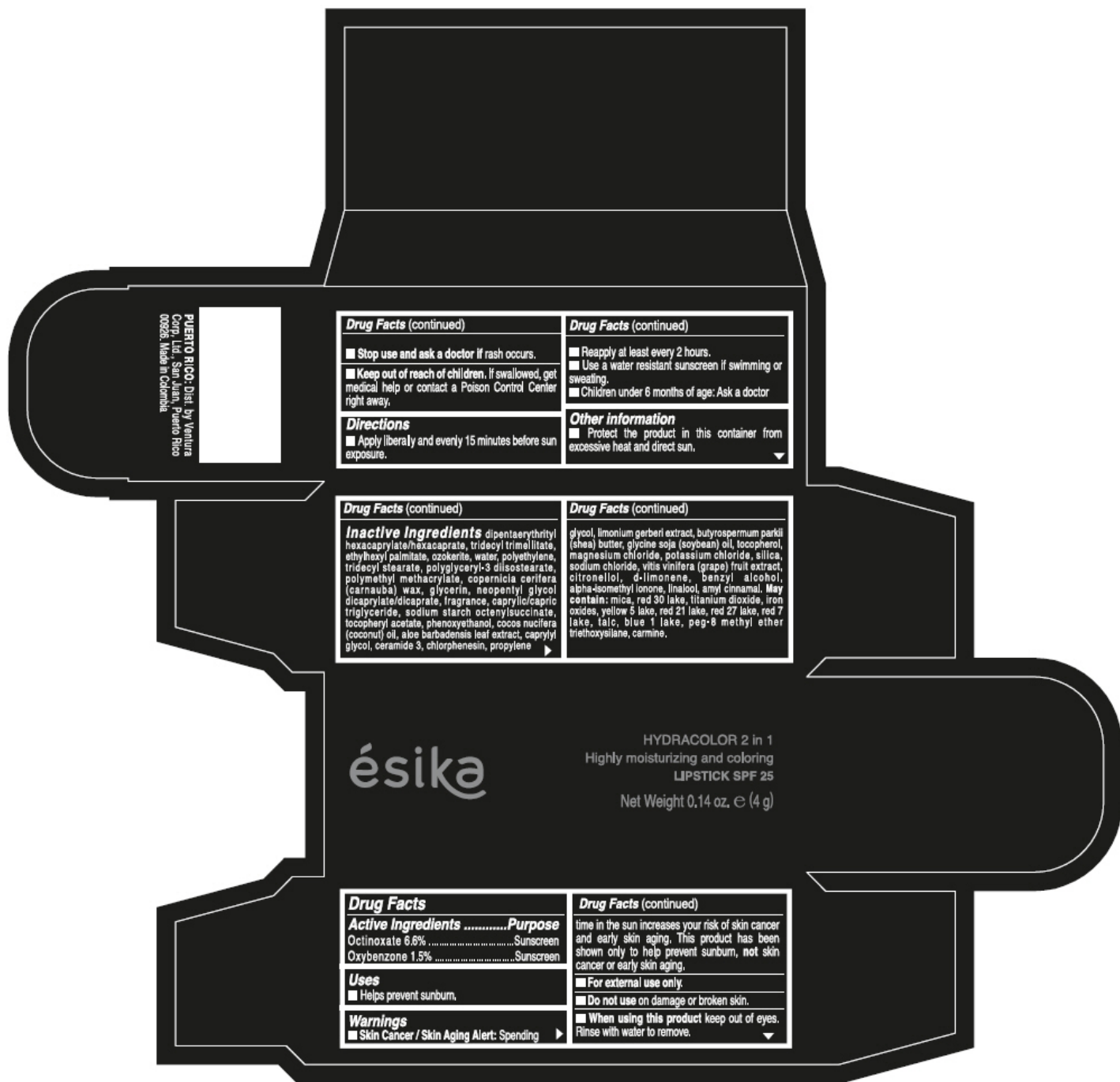


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (ROSA ROMANTICA FEMME) - PINK

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

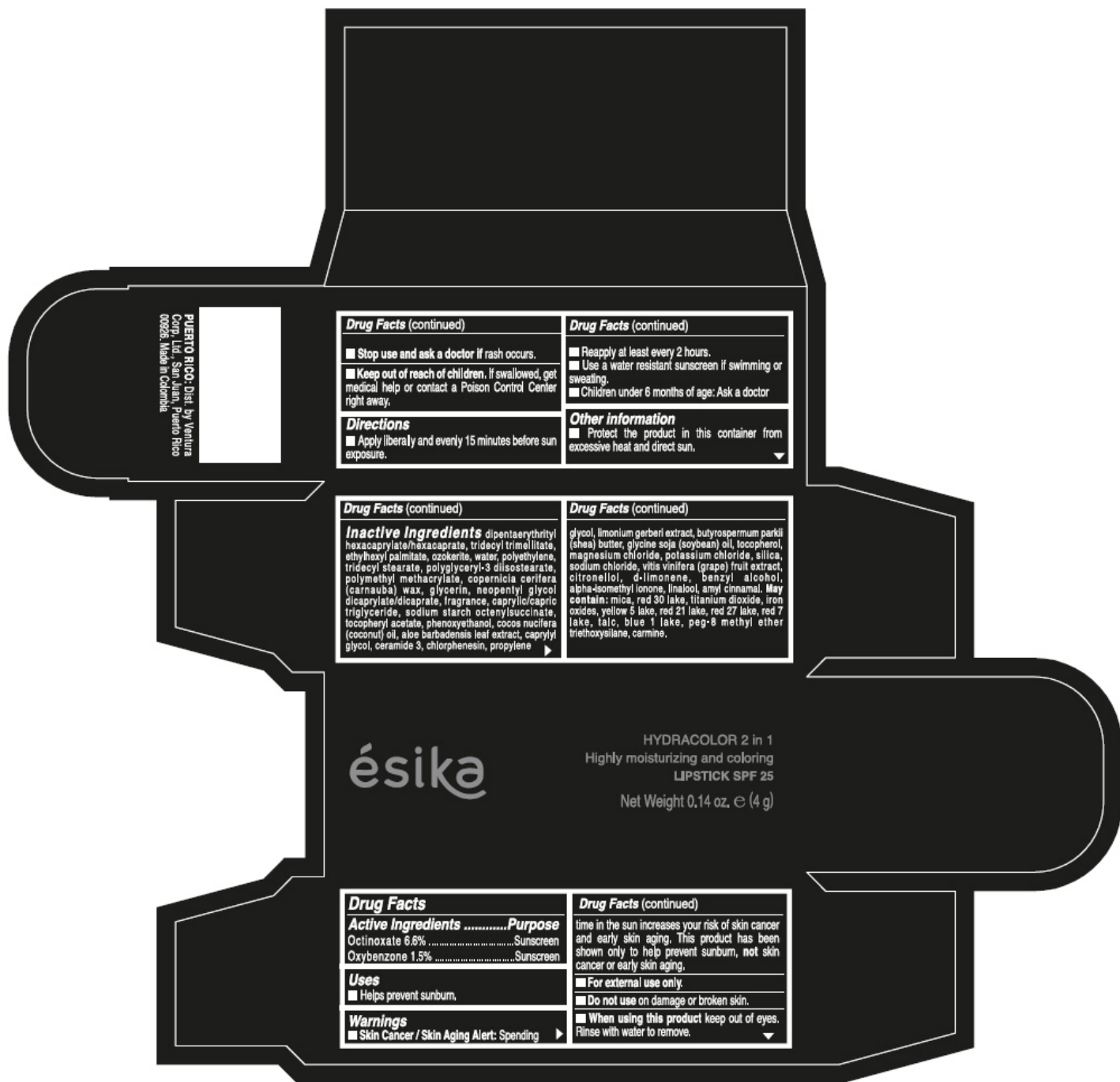


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (FUCSIA CAUTIVANTE FEMME) - PINK

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

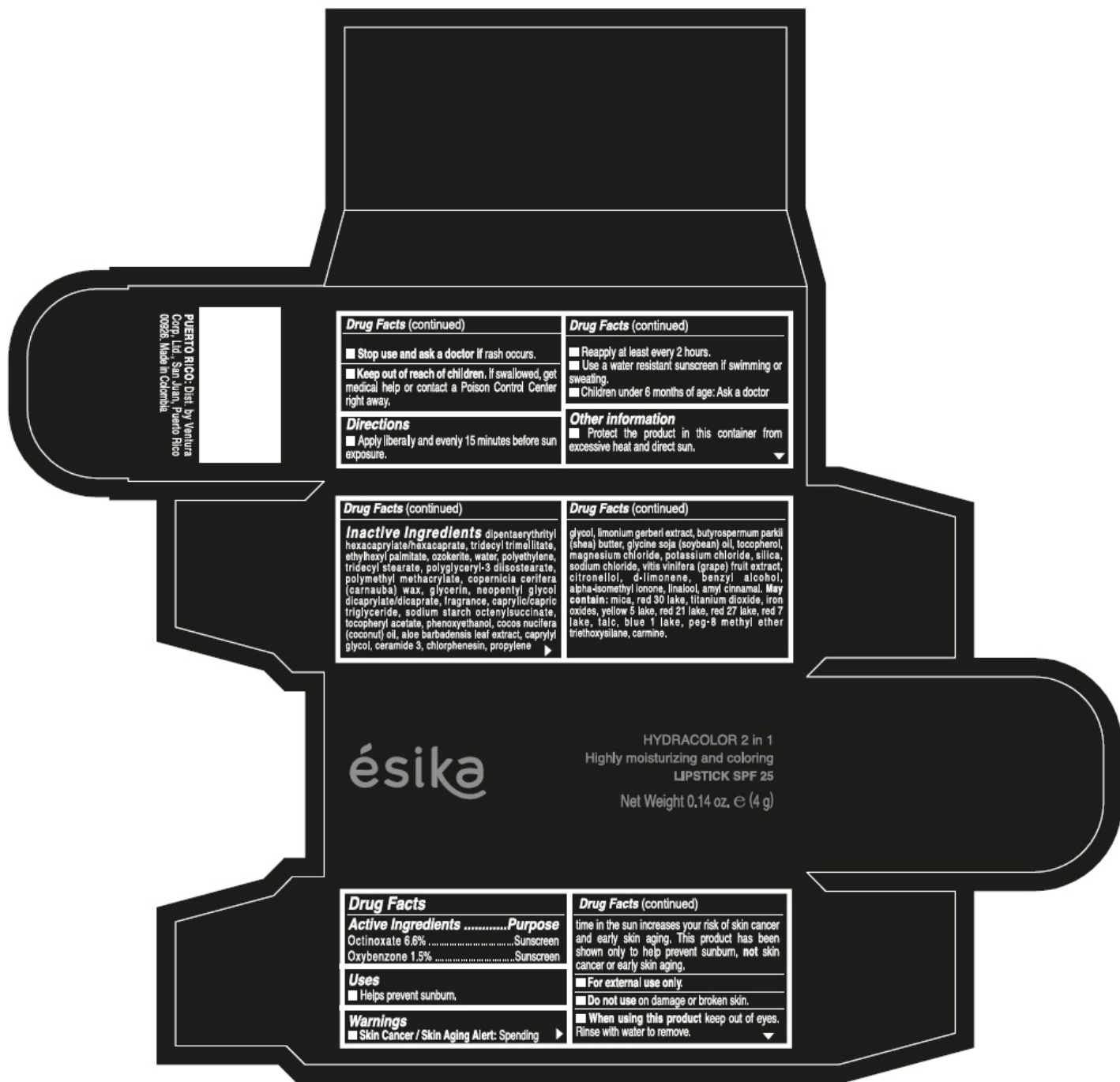


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (ROJO INTRIGANTE FEMME) - RED

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

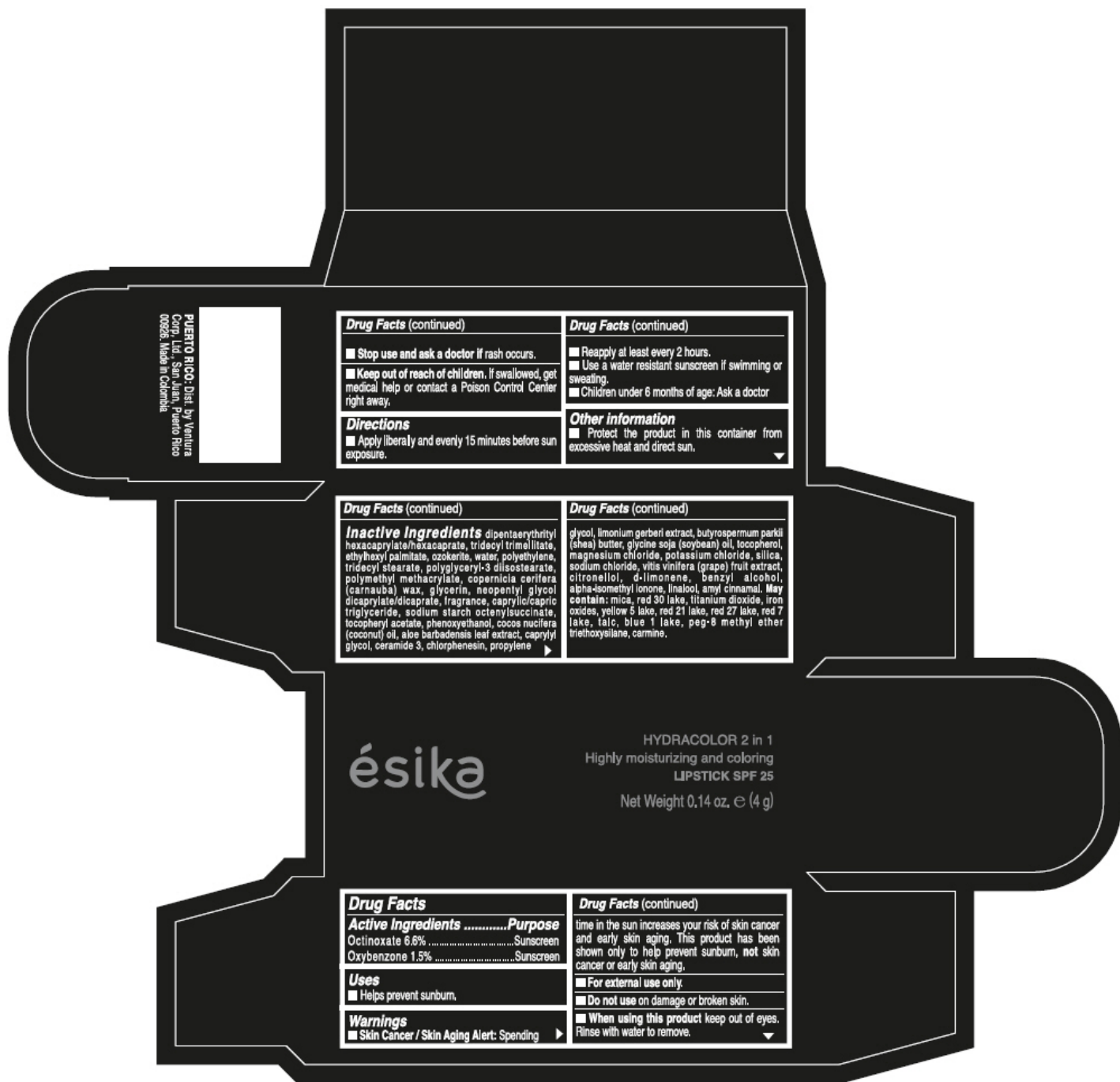


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (PIMIENTA CALIENTE EXOTIC) - RED

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

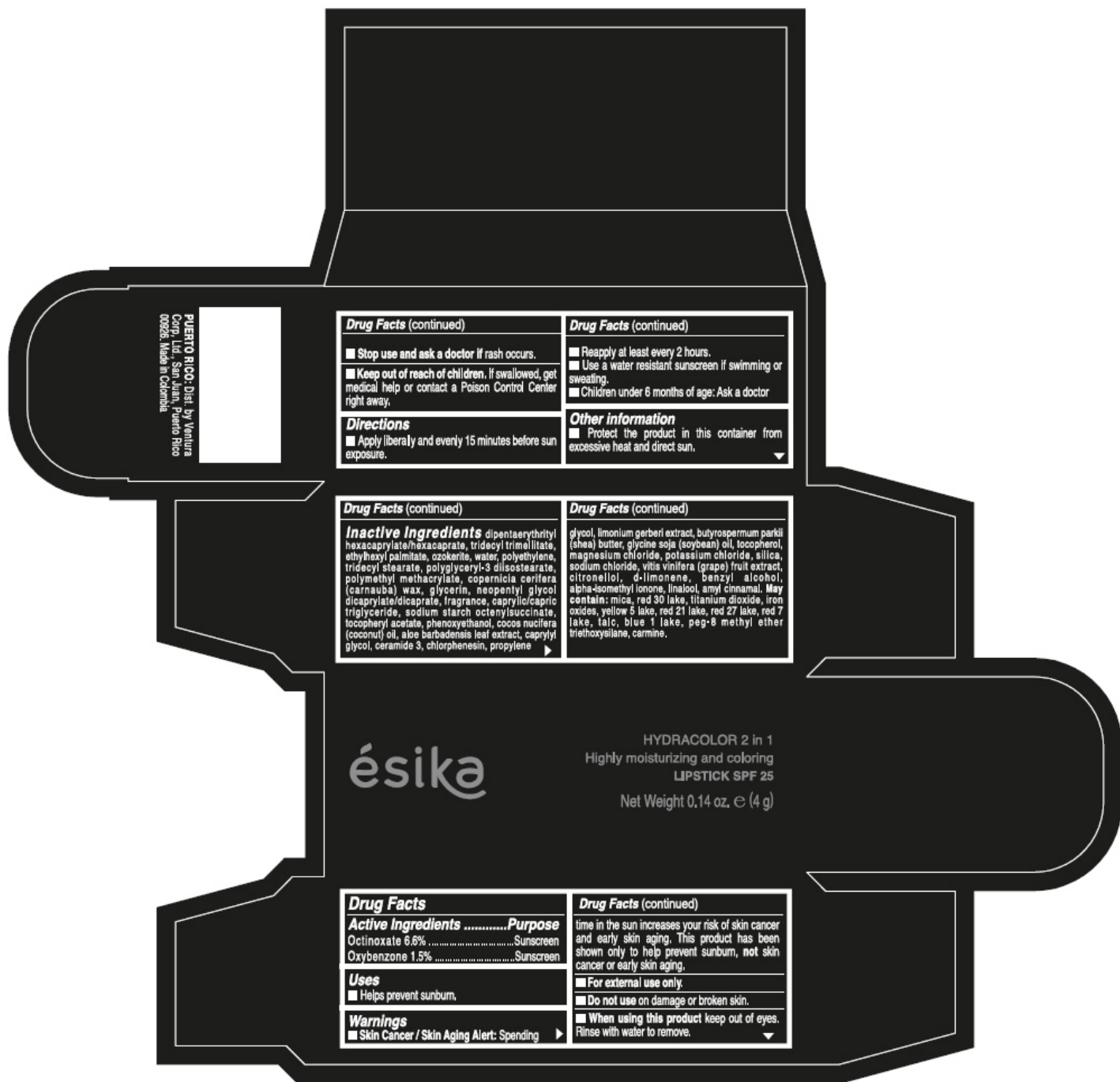


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (ROSA ENCANTO EXOTIC) - PINK

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

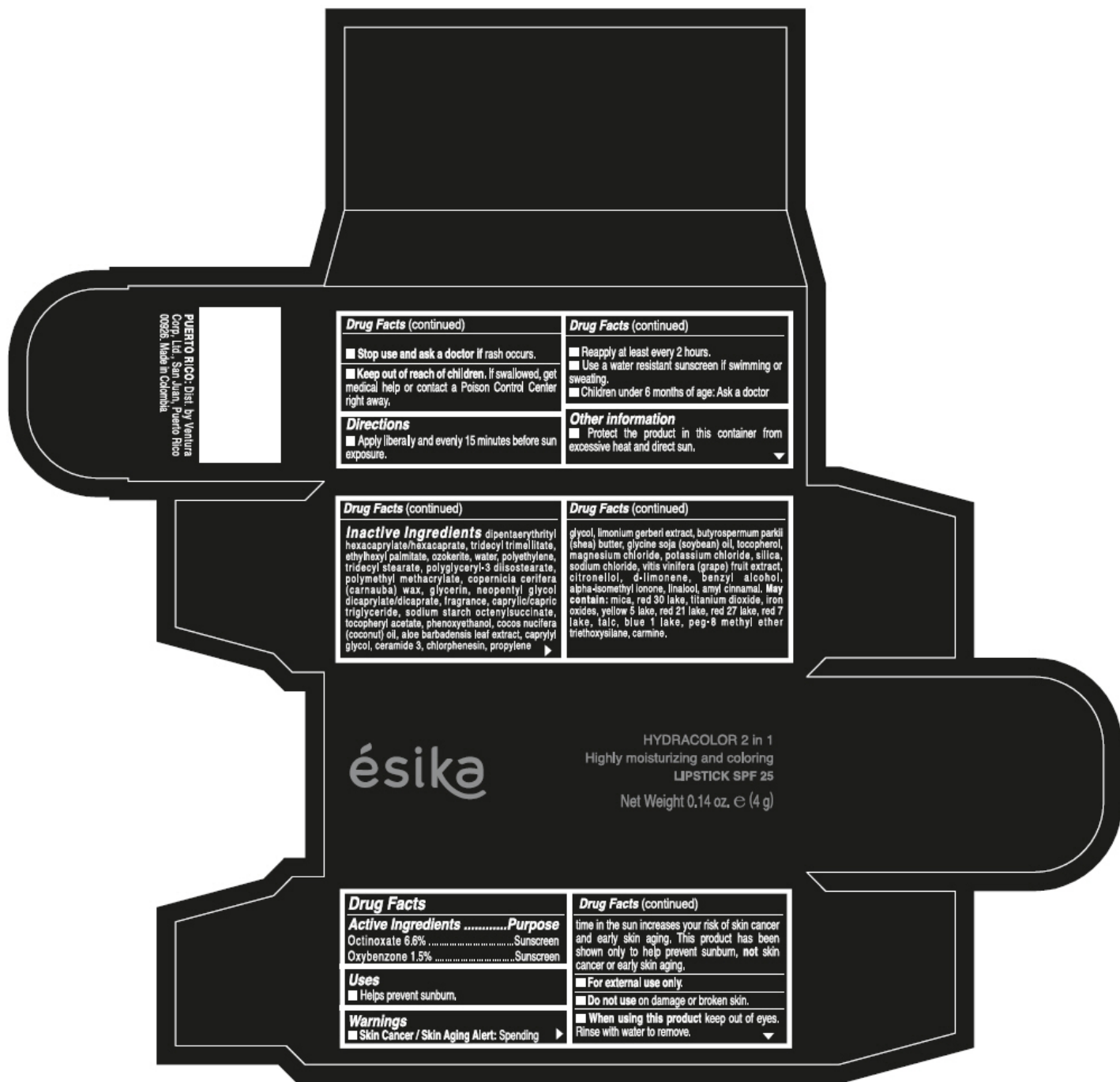


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (CORAL CHIC EXOTIC) - ORANGE

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)



PUERTO RICO-Dist. by Ventura Corp. Ltd., San Juan, Puerto Rico 00926. Made in Colombia

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 every 15 minutes before sun exposure.

Drug Facts (continued)

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

Other information

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

Drug Facts (continued)

Inactive Ingredients dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, ethylhexyl palmitate, ozokerite, water, polyethylene, tridecyl stearate, polyglyceryl-3 diisostearate, polymethyl methacrylate, copernicia corifera (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

Drug Facts (continued)

glycol, limonium gerberi extract, butyrospermum parkii (shea) butter, glycine soja (soybean) oil, tocopherol, magnesium chloride, potassium chloride, silica, sodium chloride, vitis vinifera (grape) fruit extract, citronellol, δ -limonene, benzyl alcohol, alpha-isomethyl ionone, linalool, amyl cinnamal. May contain: mica, red 90 lake, titanium dioxide, iron oxides, yellow 5 lake, red 21 lake, red 27 lake, red 7 lake, talc, blue 1 lake, peg-8 methyl ether triethoxysilane, carmine.

ésika

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.**

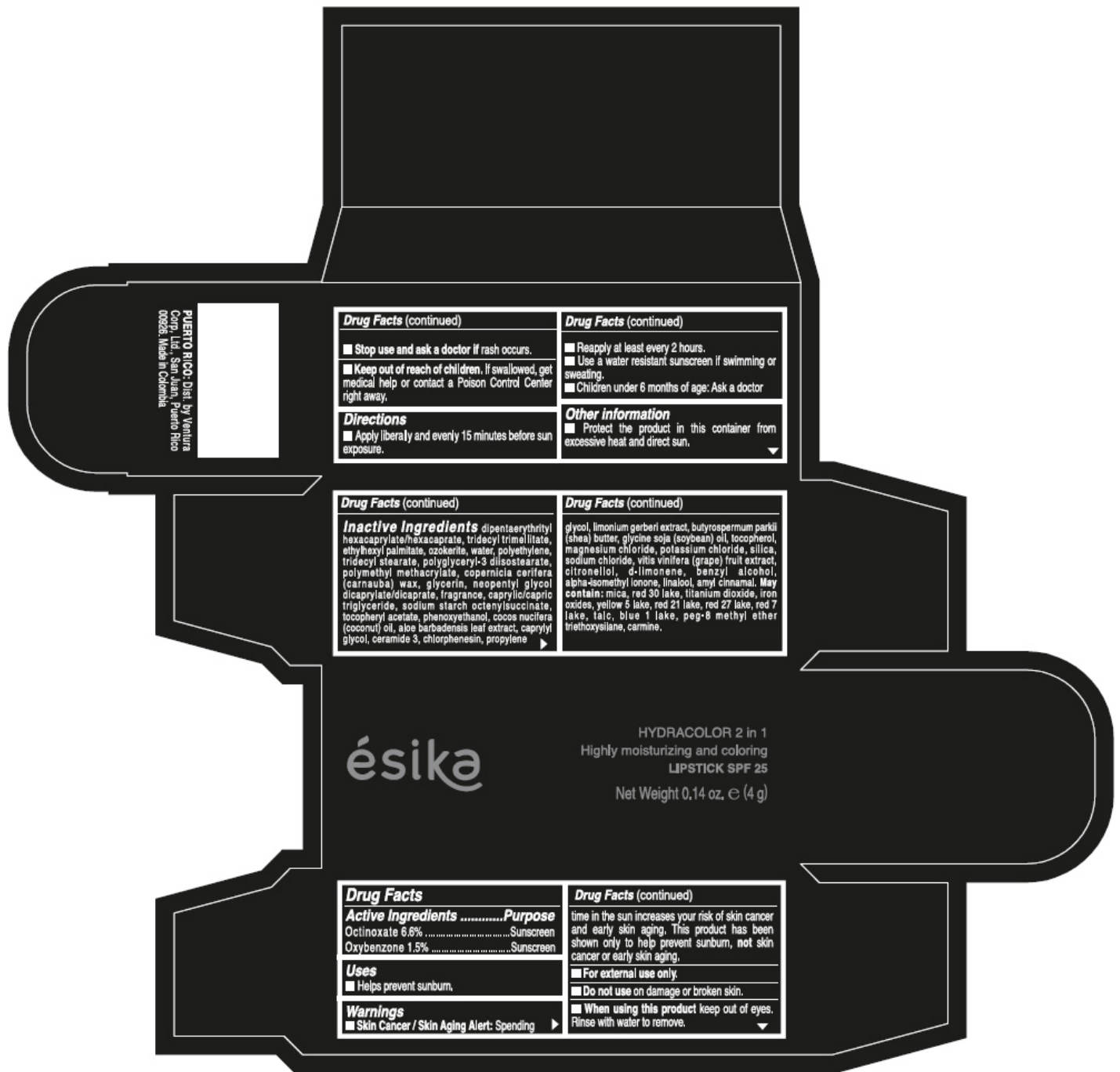
■ **When using this product keep out of eyes.** Rinse with water to remove.

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

ésika

HYDRACOLOR 2 in 1
 Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

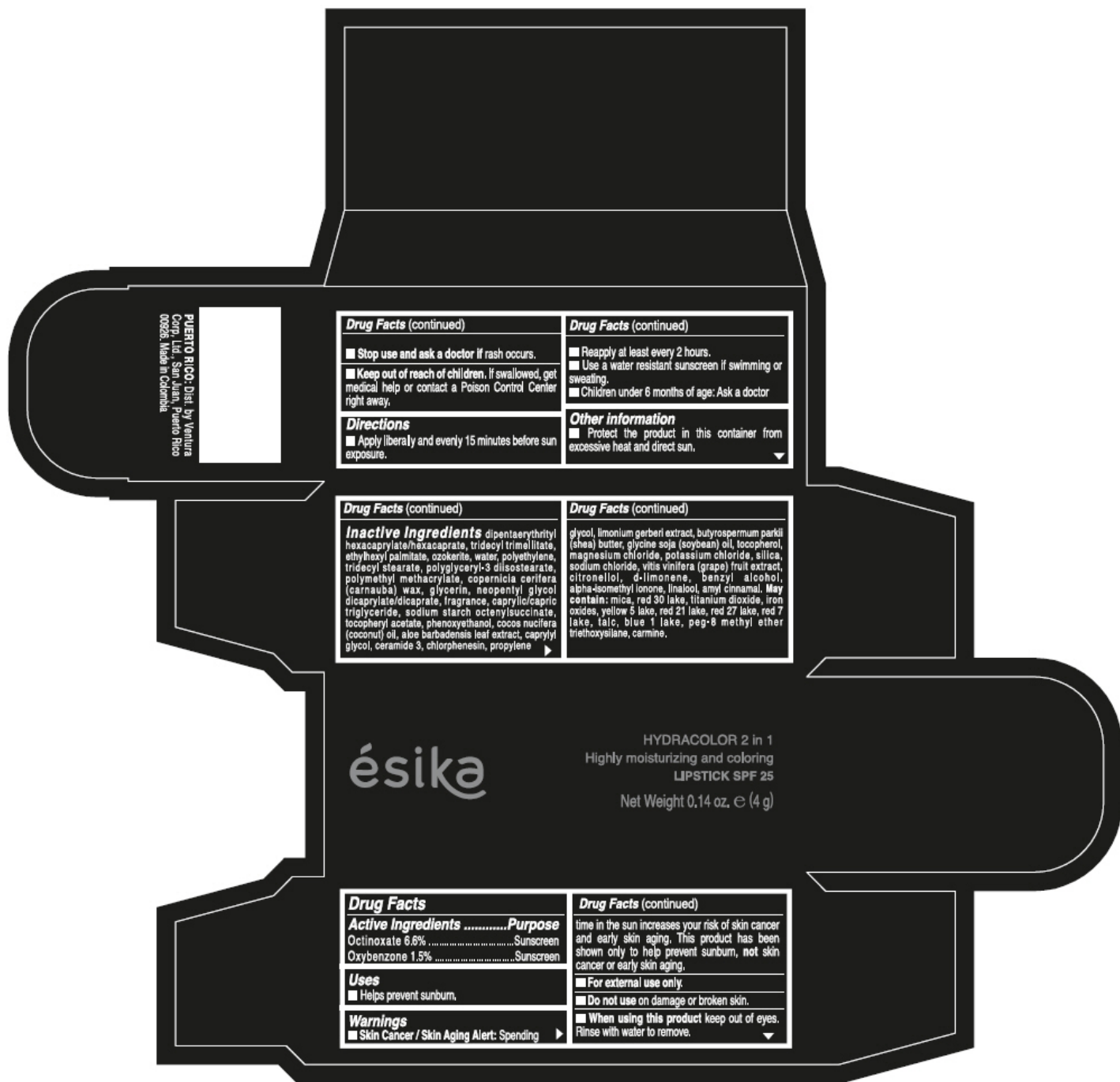


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (ROJO DESEO EXOTIC) - RED

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

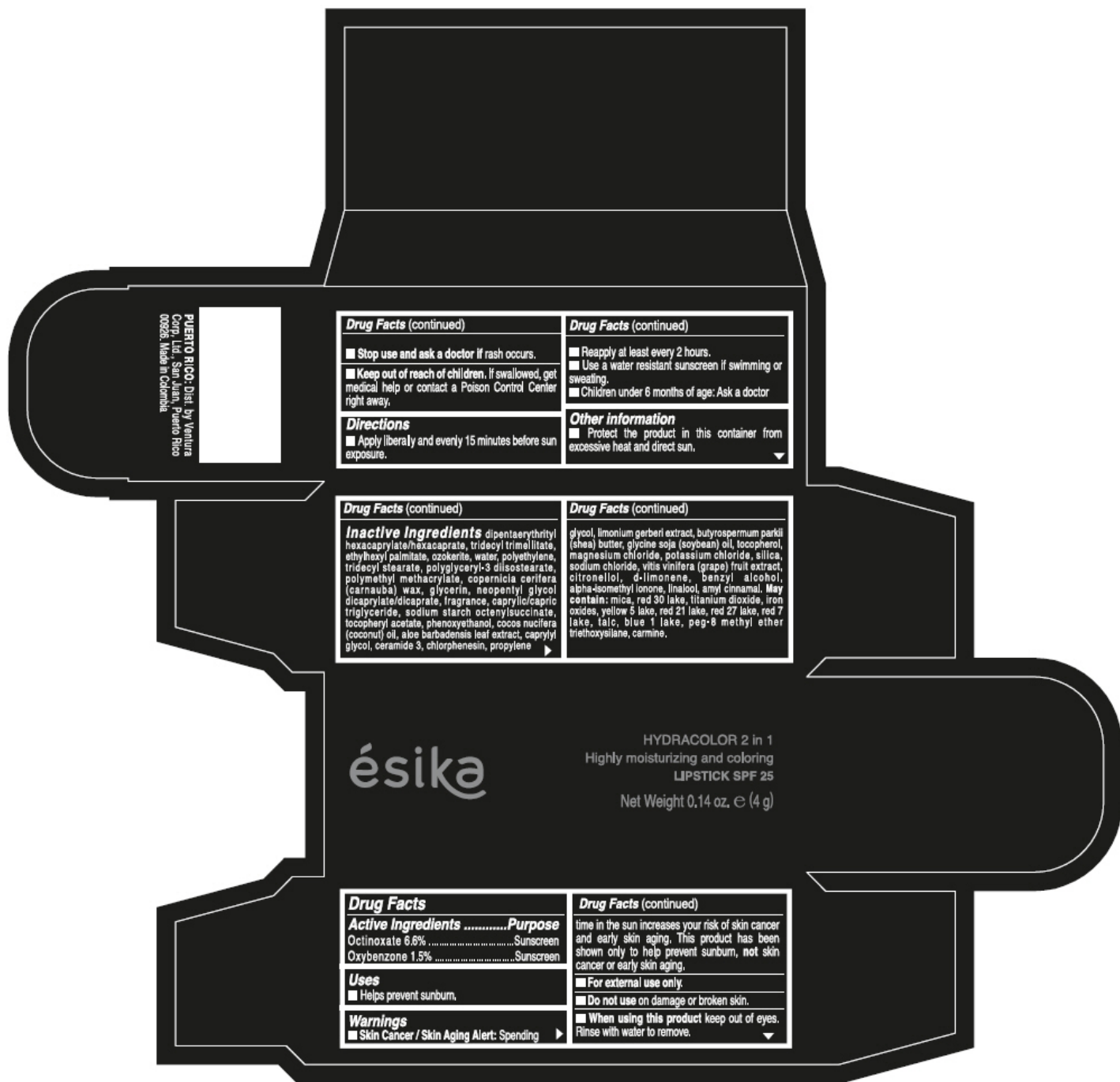


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (FRAMBUESA MANIA EXOTIC) - PINK

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

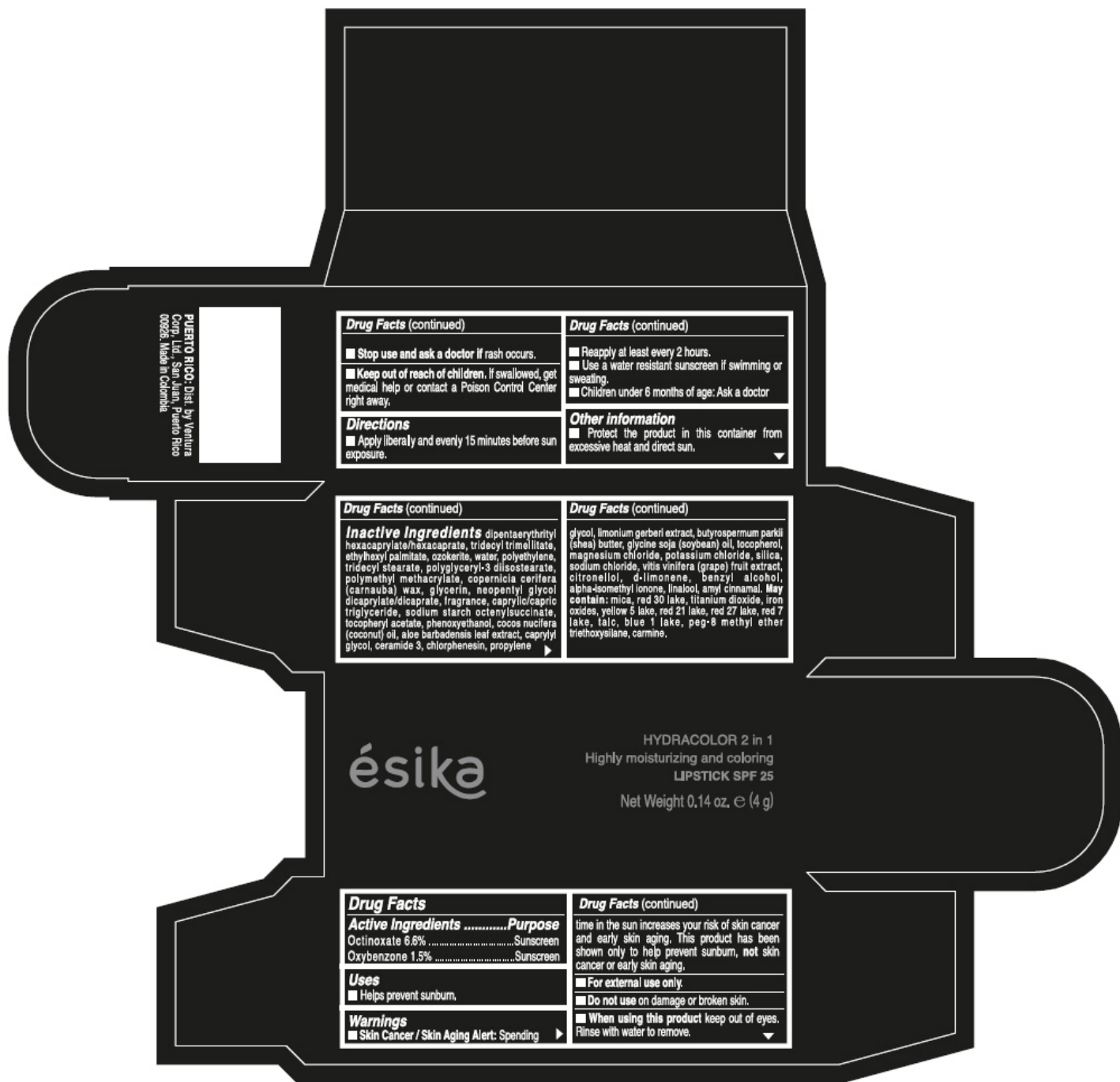


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (BORGONA SEXY EXOTIC) - PURPLE

ésika

HYDRACOLOR 2 in 1
 Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

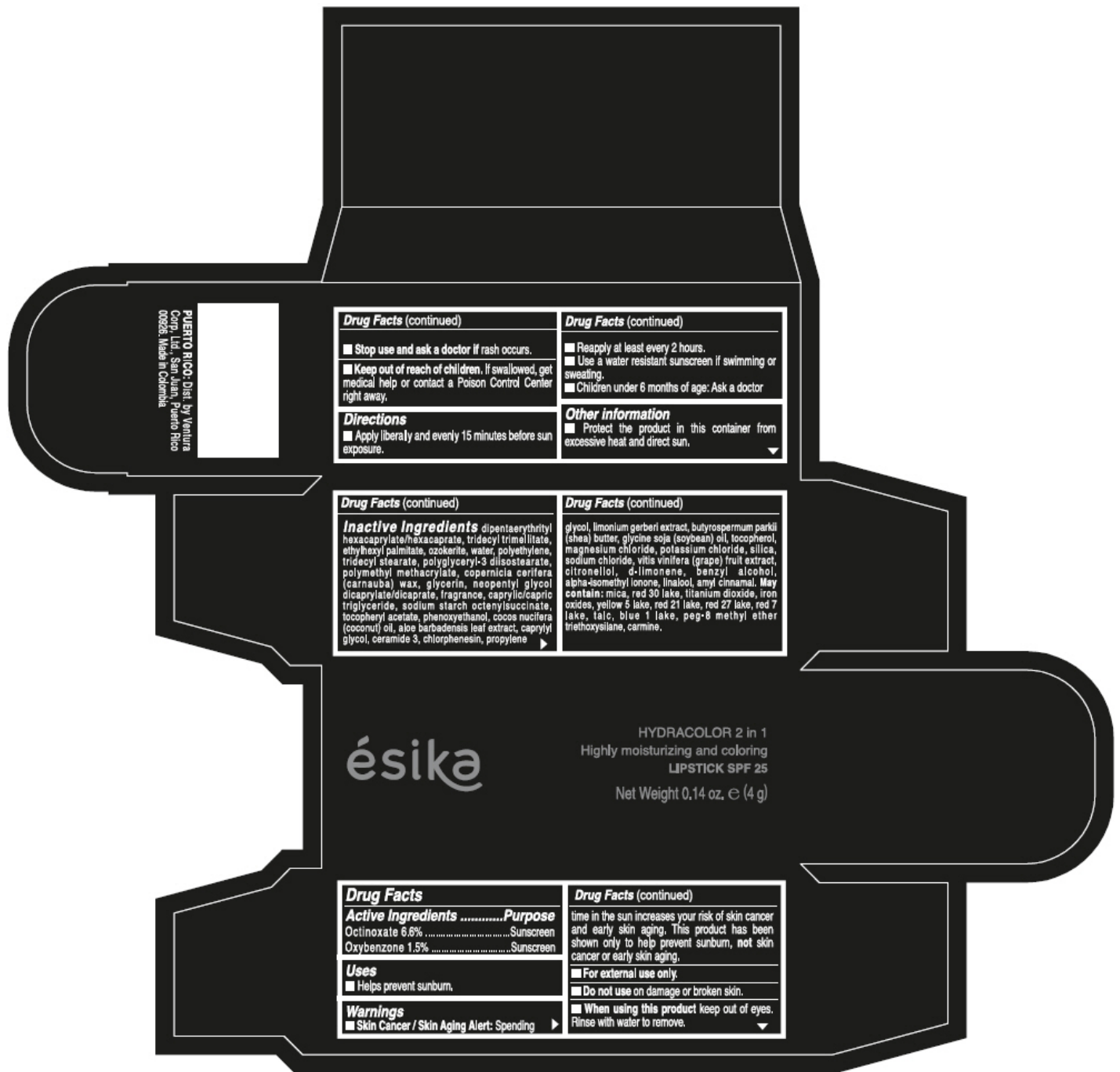


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (MARRON GLAMOUR EXOTIC) - BROWN

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

Net Weight 0.14 oz. e (4 g)

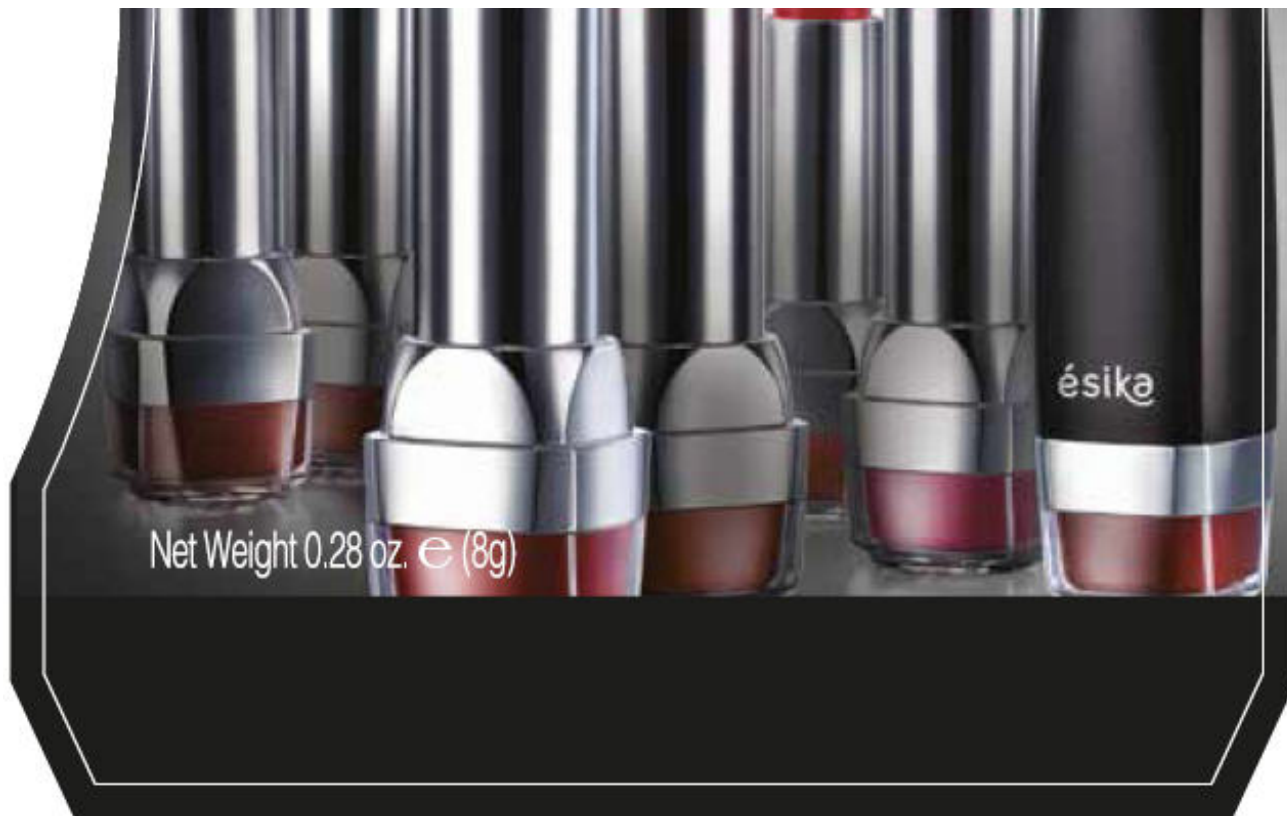


PRINCIPAL DISPLAY PANEL - Kit Carton

HYDRACOLOR 2 in 1
 Highly moisturizing
 and coloring **LIPSTICK SPF 25**

ésika

Net Weight 0.28 oz. e (8g)



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:13537-475
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	

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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-475-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-475-01	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	11/09/2016	

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:13537-476
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	

LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-476-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-476-01	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	11/09/2016	

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:13537-477
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 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)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:13537-477-02	1 in 1 BOX	11/09/2016
1	NDC:13537-477-01	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	11/09/2016	

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:13537-478
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-478-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-478-01	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	11/09/2016	

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:13537-479
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231QV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	

D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-479-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-479-01	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	11/09/2016	

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:13537-880
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-880-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-880-01	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	11/09/2016	

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:13537-804
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-804-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-804-01	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	11/09/2016	

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:13537-805
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	

CERESIN (UNII: Q1LS2UJO3A)
WATER (UNII: 059QF0KO0R)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-805-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-805-01	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	11/09/2016	

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:13537-806
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-806-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-806-01	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	11/09/2016	

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:13537-807
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g

OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)

OXYBENZONE

0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-807-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-807-01	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	11/09/2016	

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:13537-808
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-808-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-808-01	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	11/09/2016	

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:13537-809
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0K00R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-809-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-809-01	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	11/09/2016	

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:13537-810
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	

POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-810-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-810-01	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	11/09/2016	

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:13537-811
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	

.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-811-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-811-01	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	11/09/2016	

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:13537-812
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-812-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-812-01	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	11/09/2016	

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:13537-813
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-813-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-813-01	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	11/09/2016	

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:13537-814
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

D&C RED NO. 21 (UNII: 08744Z6JNY)

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

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

TALC (UNII: 7SEV7J4R1U)

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-814-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-814-01	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	11/09/2016	

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:13537-815
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-815-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-815-01	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	11/09/2016	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25

(ROSA GEOMETRIC) - PINK

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-816
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-816-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-816-01	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	11/09/2016	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (FUCSIA PRISMA) - RED

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-817
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	

CERESIN (UNII: Q1LS2UJO3A)
WATER (UNII: 059QF0KO0R)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-817-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-817-01	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	11/09/2016	

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

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-818
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-818-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-818-01	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	11/09/2016	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (NUDE INFINITO) - BROWN

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-819
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g

OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)

OXYBENZONE

0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-819-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-819-01	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	11/09/2016	

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

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-820
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-820-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-820-01	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	11/09/2016	

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

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-821
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-821-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-821-01	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	11/09/2016	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (CORAL CUARZO) - ORANGE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-822
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	

POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-822-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-822-01	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	11/09/2016	

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

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-823
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	

.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-823-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-823-01	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	11/09/2016	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (NUDE PRISMA) - ORANGE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-824
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-824-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-824-01	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	11/09/2016	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (DORADO ESENCIAL) - YELLOW

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-825
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-825-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-825-01	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	11/09/2016	

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:13537-826
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

D&C RED NO. 21 (UNII: 08744Z6JNY)

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

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

TALC (UNII: 7SEV7J4R1U)

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-826-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-826-01	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	11/09/2016	

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:13537-827
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-827-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-827-01	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	11/09/2016	

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:13537-828
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-828-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-828-01	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	11/09/2016	

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:13537-829
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	

CERESIN (UNII: Q1LS2UJO3A)
WATER (UNII: 059QF0KO0R)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-829-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-829-01	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	11/09/2016	

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:13537-830
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-830-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-830-01	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	11/09/2016	

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:13537-831
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g

OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)

OXYBENZONE

0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-831-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-831-01	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	11/09/2016	

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

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-832
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-832-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-832-01	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	11/09/2016	

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

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-833
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-833-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-833-01	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	11/09/2016	

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

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-834
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	

POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-834-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-834-01	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	11/09/2016	

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

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-835
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	

.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-835-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-835-01	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	11/09/2016	

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

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-836
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISO STEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-836-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-836-01	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	11/09/2016	

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

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-837
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-837-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-837-01	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	11/09/2016	

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

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-838
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

D&C RED NO. 21 (UNII: 08744Z6JNY)

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

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

TALC (UNII: 7SEV7J4R1U)

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-838-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-838-01	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	11/09/2016	

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

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-839
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-839-02	1 in 1 BOX	11/09/2016	
1	NDC:13537-839-01	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	11/09/2016	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF

octinoxate and oxybenzone kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-840
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-840-02	2 in 1 BOX	11/09/2016	
1	NDC:13537-840-01	1 in 1 TUBE		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	8 g
Part 2	1 TUBE	8 g
Part 3	1 TUBE	8 g
Part 4	1 TUBE	8 g
Part 5	1 TUBE	8 g
Part 6	1 TUBE	8 g
Part 7	1 TUBE	8 g
Part 8	1 TUBE	8 g
Part 9	1 TUBE	8 g
Part 10	1 TUBE	8 g
Part 11	1 TUBE	8 g
Part 12	1 TUBE	8 g
Part 13	1 TUBE	8 g
Part 14	1 TUBE	8 g
Part 15	1 TUBE	8 g
Part 16	1 TUBE	8 g
Part 17	1 TUBE	8 g
Part 18	1 TUBE	8 g
Part 19	1 TUBE	8 g
Part 20	1 TUBE	8 g
Part 21	1 TUBE	8 g
Part 22	1 TUBE	8 g
Part 23	1 TUBE	8 g
Part	1 TUBE	8 g

24	1 TUBE	8 g
Part 25	1 TUBE	8 g
Part 26	1 TUBE	8 g
Part 27	1 TUBE	8 g
Part 28	1 TUBE	8 g
Part 29	1 TUBE	8 g
Part 30	1 TUBE	8 g
Part 31	1 TUBE	8 g
Part 32	1 TUBE	8 g
Part 33	1 TUBE	8 g
Part 34	1 TUBE	8 g
Part 35	1 TUBE	8 g
Part 36	1 TUBE	8 g
Part 37	1 TUBE	8 g
Part 38	1 TUBE	8 g
Part 39	1 TUBE	8 g
Part 40	1 TUBE	8 g
Part 41	1 TUBE	8 g
Part 42	1 TUBE	8 g

Part 1 of 42

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

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 2 of 42

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

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 3 of 42

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

octinoxate and oxybenzone lipstick

Product Information**Route of Administration**

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	

D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 4 of 42

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

octinoxate and oxybenzone 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	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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
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Part 5 of 42**ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROJO DESEO) - RED**

octinoxate and oxybenzone lipstick

Product Information**Route of Administration** TOPICAL**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 6 of 42

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

octinoxate and oxybenzone 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	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 7 of 42

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

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 8 of 42

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

octinoxate and oxybenzone lipstick

Product Information**Route of Administration**

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	

D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 9 of 42

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

octinoxate and oxybenzone 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	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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
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Part 10 of 42**ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (FUCSIA CAUTIVANTE) - PINK**

octinoxate and oxybenzone lipstick

Product Information**Route of Administration** TOPICAL**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 11 of 42

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

octinoxate and oxybenzone 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	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 12 of 42

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

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 13 of 42

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

octinoxate and oxybenzone lipstick

Product Information**Route of Administration**

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	

D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 14 of 42

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

octinoxate and oxybenzone 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	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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
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Part 15 of 42**ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (FRESA COQUETA) - RED**

octinoxate and oxybenzone lipstick

Product Information**Route of Administration** TOPICAL**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 16 of 42

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

octinoxate and oxybenzone 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	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 17 of 42

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

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 18 of 42

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

octinoxate and oxybenzone lipstick

Product Information**Route of Administration**

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	

D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 19 of 42

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

octinoxate and oxybenzone 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	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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
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Part 20 of 42**ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (FUCSIA PRISMA) - RED**

octinoxate and oxybenzone lipstick

Product Information**Route of Administration** TOPICAL**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 21 of 42

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

octinoxate and oxybenzone 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	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 22 of 42

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (NUDE INFINITO) - BROWN

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 23 of 42

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

octinoxate and oxybenzone lipstick

Product Information**Route of Administration**

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	

D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 24 of 42

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

octinoxate and oxybenzone 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	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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
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Part 25 of 42**ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (CORAL CUARZO) - ORANGE**

octinoxate and oxybenzone lipstick

Product Information**Route of Administration** TOPICAL**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 26 of 42

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

octinoxate and oxybenzone 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	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 27 of 42

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (NUDE PRISMA) - ORANGE

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 28 of 42

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (DORADO ESENCIAL) - YELLOW

octinoxate and oxybenzone lipstick

Product Information**Route of Administration**

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	

D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 29 of 42

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

octinoxate and oxybenzone 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	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
POLY(METHYL METHACRYLATE; 45000 MW) (UNII: Z47NNT4J11)
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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
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Part 30 of 42**ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (PIMIENTA CALIENTE FEMME) - RED**

octinoxate and oxybenzone lipstick

Product Information**Route of Administration** TOPICAL**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 31 of 42

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

octinoxate and oxybenzone 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	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 32 of 42

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

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 33 of 42

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

octinoxate and oxybenzone lipstick

Product Information**Route of Administration**

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	

D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 34 of 42

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

octinoxate and oxybenzone 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	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
POLY(METHYL METHACRYLATE; 45000 MW) (UNII: Z47NNT4J11)
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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
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Part 35 of 42**ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (PIMIENTA CALIENTE EXOTIC) - RED**

octinoxate and oxybenzone lipstick

Product Information**Route of Administration** TOPICAL**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 36 of 42

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

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 37 of 42

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

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 38 of 42

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

octinoxate and oxybenzone lipstick

Product Information**Route of Administration**

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	

D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 39 of 42

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

octinoxate and oxybenzone 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	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
POLY(METHYL METHACRYLATE; 45000 MW) (UNII: Z47NNT4J11)
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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
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Part 40 of 42**ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (FRAMBUESA MANIA EXOTIC) - PINK**

octinoxate and oxybenzone lipstick

Product Information**Route of Administration** TOPICAL**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
MICA (UNII: V8A1AW0880)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 41 of 42

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

octinoxate and oxybenzone 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	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Part 42 of 42

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

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
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 NP (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)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	11/09/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/09/2016	

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-475, 13537-476, 13537-477, 13537-478, 13537-479, 13537-880, 13537-804, 13537-805, 13537-806, 13537-807, 13537-808, 13537-809, 13537-810, 13537-811, 13537-812, 13537-813, 13537-814, 13537-815, 13537-816, 13537-817, 13537-818, 13537-819, 13537-820, 13537-821, 13537-822, 13537-823, 13537-824, 13537-825, 13537-826, 13537-827, 13537-828, 13537-829, 13537-830, 13537-831, 13537-832, 13537-833, 13537-834, 13537-835, 13537-836, 13537-837, 13537-838, 13537-839, 13537-840)

Revised: 11/2016

Ventura Corporation LTD