

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

Active Ingredients

OCTINOXATE: 6.64%

OXYBENZONE: 1.51%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.

Warnings

Skin Cancer / Skin Aging Alert

- Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging. Rinse with water to remove. If swallowed, get medical help or contact a Poison Control Center right away.
- **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
- Apply stick following the curves of natural lip line. For added definition, use with a lip pencil

Other information

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

Inactive ingredients

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

May contain:

CI 77019 (MICA), CI 77491 (IRON OXIDES), CI 77891 (TITANIUM DIOXIDE), CI 45380 (RED 21 LAKE), CI 19140 (YELLOW 5 LAKE), CI 15850 (RED 7 LAKE), CI 45410 (RED 27 LAKE), CI 77499 (IRON OXIDES), CI 77492 (IRON OXIDES), TALC, PEG-8 METHYL ETHER TRIETHOXYLANE, CI 75470 (CARMINE).

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

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HYDRACOLOR 2 in 1

Highly moisturizing and coloring

LIPSTICK SPF 25

4 g e (.14 oz.)



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

ésika

HYDRACOLOR 2 in 1

Highly moisturizing and coloring

LIPSTICK SPF 25

4 g e (.14 oz.)

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.		Drug Facts (continued) ■ Reapply at least every 2 hours. ■ Use a water resistant sunscreen if swimming or sweating.	
Directions ■ Apply liberally and evenly 15 minutes before sun exposure. ■ Children under 6 months of age: Ask a doctor. ▶		Other information ■ Protect the product in this container from excessive heat and direct sun. Keep away from heat sources and direct sunlight. Store well and under 50°C (112°F). ▼	
Drug Facts (continued) Inactive Ingredients dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, ethylhexyl palmitate, ozokerite, water, polyethylene, polyglyceryl-3 distearate, polymethyl methacrylate, tridecyl stearate, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, caprylic/capric triglyceride, sodium starch octylsuccinate, tocopheryl acetate, phenoxylalcohol, cocos nucifera (coconut) oil, alcea barbadensis		Drug Facts (continued) leaf extract, fragrance, 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, may contain: mica, iron oxides, titanium dioxide, red 21 lake, yellow 5 lake, red 7 lake, red 27 lake, talc, peg-8 methyl ether triethoxysilane, camelline.	
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ésika		HYDRACOLOR 2 in 1 Highly moisturizing and coloring LIPSTICK SPF 25 4 g e (.14 oz.)	
Drug Facts Active Ingredients Purpose OCTINOXATE 6.6% Sunscreen OXYBENZONE 1.5% Sunscreen		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.	
Uses ■ Helps prevent sunburn.		■ For external use only.	
Warnings ■ Skin Cancer / Skin Aging Alert: Spending ▶		■ Do not use on damage or broken skin. ■ When using this product keep out of eyes. Rinse with water to remove. ▼	

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

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HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

4 g e (.14 oz.)



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

Directions
 ■ Apply liberally and evenly 15 minutes before sun exposure.
 ■ Children under 6 months of age: Ask a doctor. ▶

Drug Facts (continued)
 ■ Reapply at least every 2 hours.
 ■ Use a water resistant sunscreen if swimming or sweating.

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

Drug Facts (continued)
Inactive Ingredients dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, ethylhexyl palmitate, ezokerite, water, polyethylene, polyglyceryl-3 distearate, polymethyl methacrylate, tridecyl stearate, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, caprylic/capric triglyceride, sodium starch octenylsuccinate, tocopheryl acetate, phenoxyethanol, cocco nucifera (coconut) oil, aloë barbadensis ▶

Drug Facts (continued)
 leaf extract, fragrance, caprylyl glycol, ceramide 3, chlorphenesin, propylene glycol, limonium gerberii extract, butyrospermum parkii (shea) butter, glycine soja (soybean) oil, tocopherol, magnesium chloride, potassium chloride, silica, sodium chloride, vis visifera (grape) fruit extract, may contain: mica, iron oxides, titanium dioxide, red 21 lake, yellow 5 lake, red 7 lake, red 27 lake, talc, peg-8 methyl ether triethoxysilane, carmine, ▶

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HYDRACOLOR 2 in 1
 Highly moisturizing and coloring
 LIPSTICK SPF 25
 4 g e (.14 oz.)

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

Uses
 ■ Helps prevent sunburn.

Warnings
 ■ Skin Cancer / Skin Aging Alert: Spending ▶

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

■ For external use only.
 ■ Do not use on damage or broken skin.

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

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

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HYDRACOLOR 2 in 1
 Highly moisturizing and coloring
LIPSTICK SPF 25

4 g e (.14 oz.)



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

Directions
 ■ Apply liberally and evenly 15 minutes before sun exposure.
 ■ Children under 6 months of age: Ask a doctor. ▶

Drug Facts (continued)
 ■ Reapply at least every 2 hours.
 ■ Use a water resistant sunscreen if swimming or sweating.

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

Drug Facts (continued)
Inactive Ingredients dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, ethylhexyl palmitate, ezokerite, water, polyethylene, polyglyceryl-3 distearate, polymethyl methacrylate, tridecyl stearate, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, caprylic/capric triglyceride, sodium starch octenylsuccinate, tocopheryl acetate, phenoxyethanol, cocos nucifera (coconut) oil, aloë barbadensis ▶

Drug Facts (continued)
 leaf extract, fragrance, caprylyl glycol, ceramide 3, chlorphenesin, propylene glycol, limonium gerberii extract, butyrospermum parkii (shea) butter, glycine soja (soybean) oil, tocopherol, magnesium chloride, potassium chloride, silica, sodium chloride, vis visifera (grape) fruit extract, may contain: mica, iron oxides, titanium dioxide, red 21 lake, yellow 5 lake, red 7 lake, red 27 lake, talc, peg-8 methyl ether triethoxysilane, carmine, ▶

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HYDRACOLOR 2 in 1
 Highly moisturizing and coloring
 LIPSTICK SPF 25
 4 g e (.14 oz.)

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 - (CORAL CHIC) - PINK

ésika

HYDRACOLOR 2 in 1
 Highly moisturizing and coloring
LIPSTICK SPF 25

4 g e (.14 oz.)



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

Directions
 ■ Apply liberally and evenly 15 minutes before sun exposure.
 ■ Children under 6 months of age: Ask a doctor. ▶

Drug Facts (continued)
 ■ Reapply at least every 2 hours.
 ■ Use a water resistant sunscreen if swimming or sweating.

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

Drug Facts (continued)
Inactive Ingredients dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, ethylhexyl palmitate, ezokerite, water, polyethylene, polyglyceryl-3 distearate, polymethyl methacrylate, tridecyl stearate, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, caprylic/capric triglyceride, sodium starch octenylsuccinate, tocopheryl acetate, phenoxyethanol, cocos nucifera (coconut) oil, aloe barbadensis ▶

Drug Facts (continued)
 leaf extract, fragrance, 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, vis vinifera (grape) fruit extract, may contain: mica, iron oxides, titanium dioxide, red 21 lake, yellow 5 lake, red 7 lake, red 27 lake, talc, peg-8 methyl ether triethoxysilane, carmine, ▶

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HYDRACOLOR 2 in 1
 Highly moisturizing and coloring
 LIPSTICK SPF 25
 4 g e (.14 oz.)

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 - (ROSA ENCANTO) - PINK

ésika
 HYDRACOLOR 2 in 1
 Highly moisturizing and coloring
LIPSTICK SPF 25
 4 g e (.14 oz.)



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

Directions
 ■ Apply liberally and evenly 15 minutes before sun exposure.
 ■ Children under 6 months of age: Ask a doctor. ▶

Drug Facts (continued)
 ■ Reapply at least every 2 hours.
 ■ Use a water resistant sunscreen if swimming or sweating.

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

Drug Facts (continued)
Inactive Ingredients dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, ethylhexyl palmitate, ezokerite, water, polyethylene, polyglyceryl-3 distearate, polymethyl methacrylate, tridecyl stearate, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, caprylic/capric triglyceride, sodium starch octenylsuccinate, tocopheryl acetate, phenoxyethanol, cocco nucifera (coconut) oil, aloe barbadensis ▶

Drug Facts (continued)
 leaf extract, fragrance, caprylyl glycol, ceramide 3, chlorphenesin, propylene glycol, limonium gerberii extract, butyrospermum parkii (shea) butter, glycine soja (soybean) oil, tocopherol, magnesium chloride, potassium chloride, silica, sodium chloride, visis vinifera (grape) fruit extract, may contain: mica, iron oxides, titanium dioxide, red 21 lake, yellow 5 lake, red 7 lake, red 27 lake, talc, peg-8 methyl ether triethoxysilane, carmine, ▶

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HYDRACOLOR 2 in 1
 Highly moisturizing and coloring
 LIPSTICK SPF 25
 4 g e (.14 oz.)

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 - (BORGOÑA SEXY) - PURPLE

ésika

HYDRACOLOR 2 in 1
 Highly moisturizing and coloring
LIPSTICK SPF 25

4 g e (.14 oz.)



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

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

4 g e (.14 oz.)



Drug Facts (continued)

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Children under 6 months of age: Ask a doctor. ▶

Drug Facts (continued)

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

Other information

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

Drug Facts (continued)

Inactive Ingredients dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, ethylhexyl palmitate, ezokerite, water, polyethylene, polyglyceryl-3 distearate, polymethyl methacrylate, tridecyl stearate, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, caprylic/capric triglyceride, sodium starch octenylsuccinate, tocopheryl acetate, phenoxyethanol, cocos nucifera (coconut) oil, aloë barbadensis ▶

Drug Facts (continued)

leaf extract, fragrance, caprylyl glycol, ceramide 3, chlorphenesin, propylene glycol, limonium gerberii extract, butyrospermum parkii (shea) butter, glycine soja (soybean) oil, tocopherol, magnesium chloride, potassium chloride, silica, sodium chloride, vis visifera (grape) fruit extract, may contain: mica, iron oxides, titanium dioxide, red 21 lake, yellow 5 lake, red 7 lake, red 27 lake, talc, peg-8 methyl ether triethoxysilane, carmine, ▶

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HYDRACOLOR 2 in 1
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LIPSTICK SPF 25
4 g e (.14 oz.)

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.

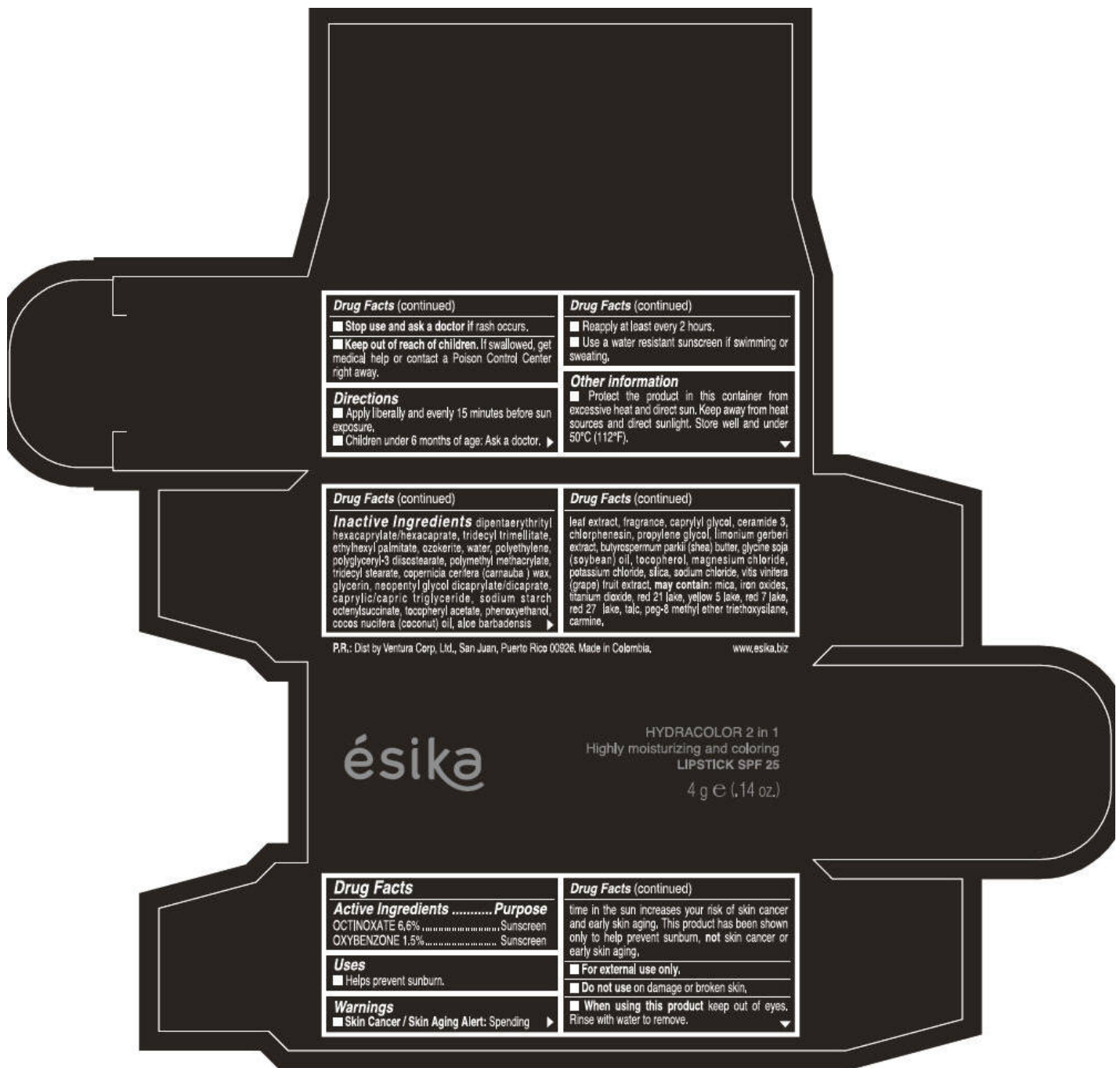
- When using this product keep out of eyes. Rinse with water to remove. ▼

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

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

4 g e (.14 oz.)

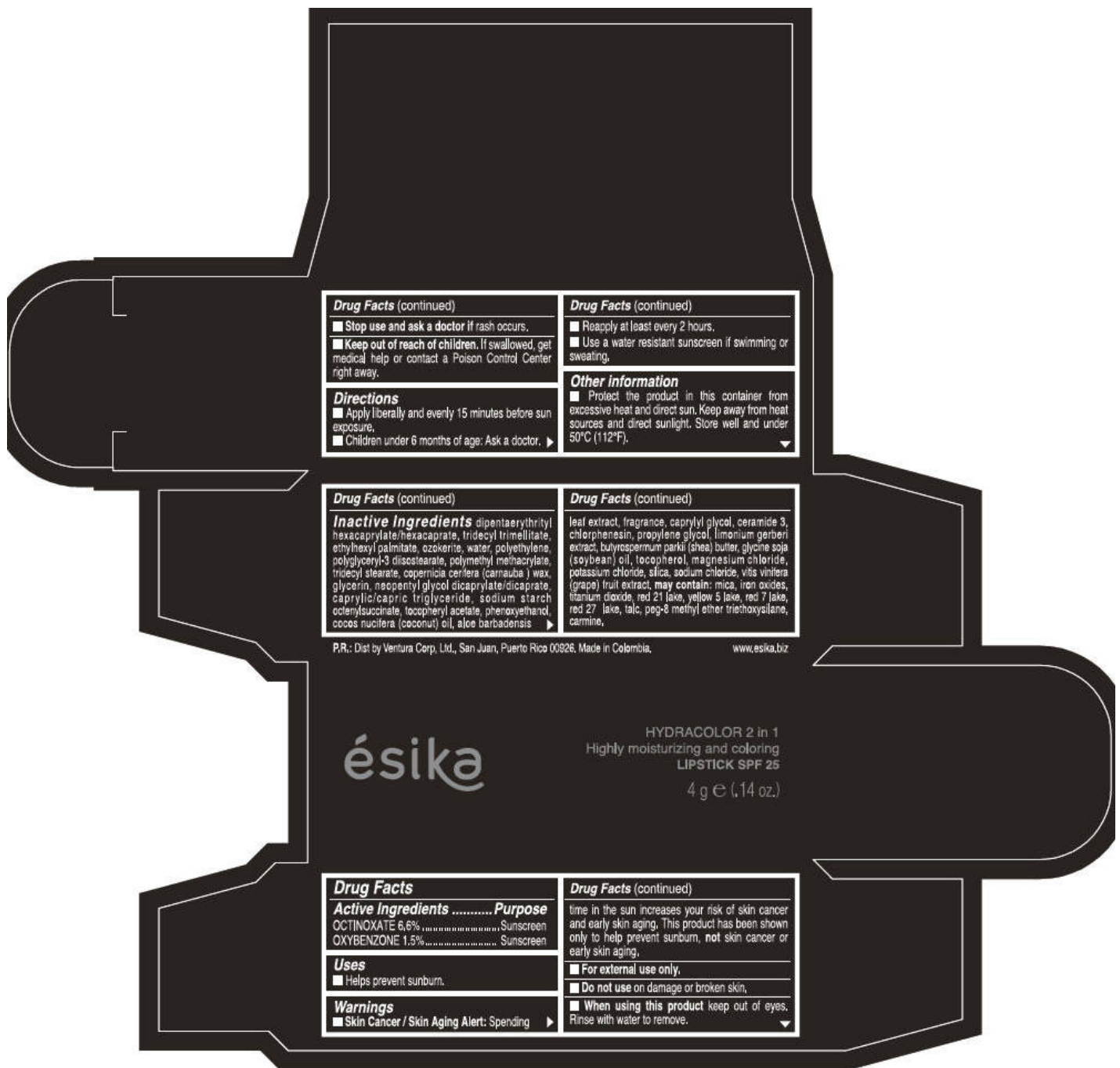


PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (ROSA ROMÁNTICA) - PINK

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

4 g e (.14 oz.)



Drug Facts (continued)

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Children under 6 months of age: Ask a doctor. ▶

Drug Facts (continued)

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

Other information

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

Drug Facts (continued)

Inactive Ingredients dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, ethylhexyl palmitate, ezokerite, water, polyethylene, polyglyceryl-3 distearate, polymethyl methacrylate, tridecyl stearate, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, caprylic/capric triglyceride, sodium starch octenylsuccinate, tocopheryl acetate, phenoxyethanol, cocos nucifera (coconut) oil, aloë barbadensis ▶

Drug Facts (continued)

leaf extract, fragrance, caprylyl glycol, ceramide 3, chlorphenesin, propylene glycol, limonium gerberii extract, butyrospermum parkii (shea) butter, glycine soja (soybean) oil, tocopherol, magnesium chloride, potassium chloride, silica, sodium chloride, vis visifera (grape) fruit extract, may contain: mica, iron oxides, titanium dioxide, red 21 lake, yellow 5 lake, red 7 lake, red 27 lake, talc, peg-8 methyl ether triethoxysilane, carmine, ▶

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HYDRACOLOR 2 in 1
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LIPSTICK SPF 25
4 g e (.14 oz.)

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.

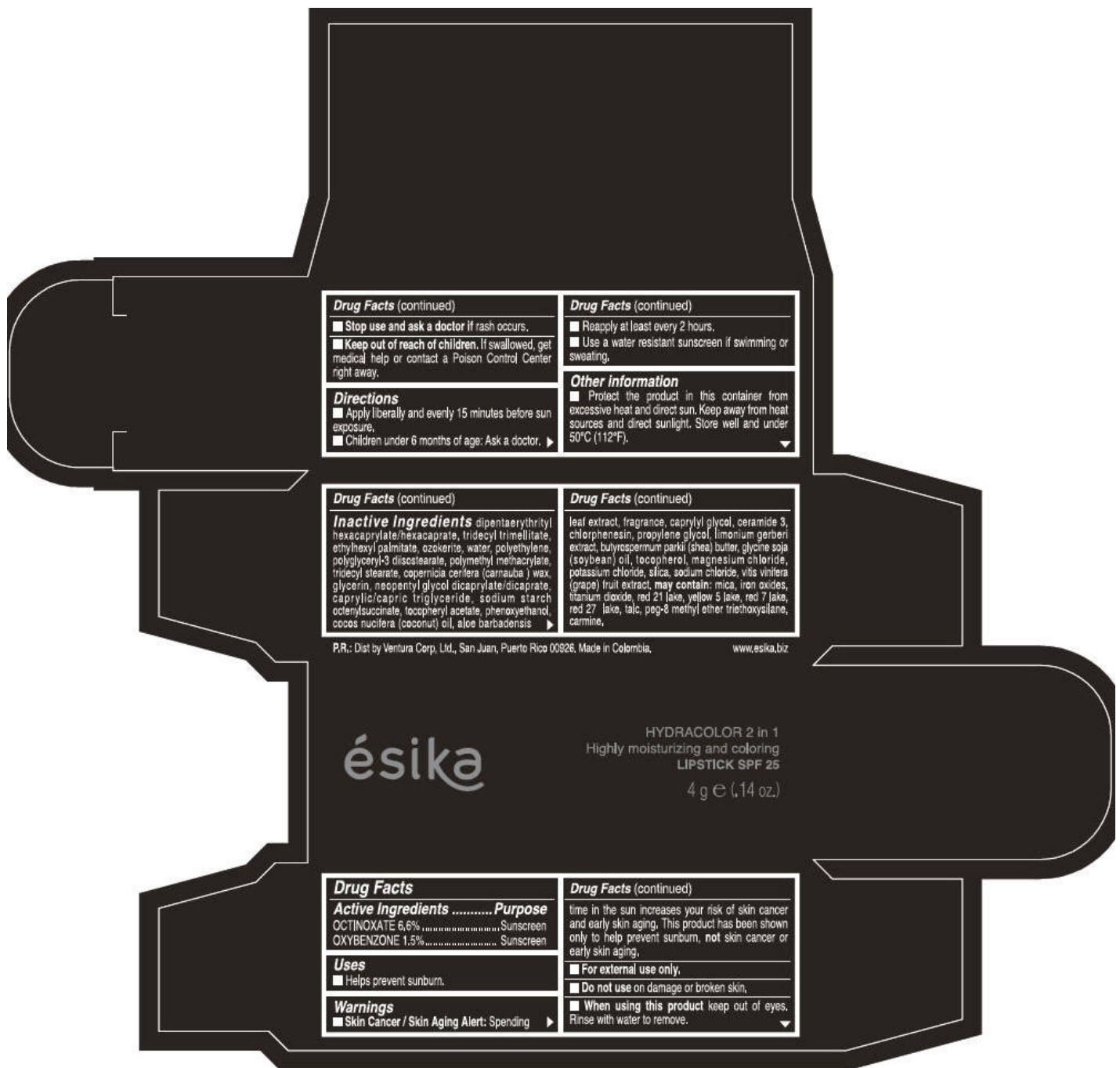
- When using this product keep out of eyes. Rinse with water to remove. ▼

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

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

4 g e (.14 oz.)



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

ésika

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

4 g e (.14 oz.)



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

Directions
 ■ Apply liberally and evenly 15 minutes before sun exposure.
 ■ Children under 6 months of age: Ask a doctor. ▶

Drug Facts (continued)
 ■ Reapply at least every 2 hours.
 ■ Use a water resistant sunscreen if swimming or sweating.

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

Drug Facts (continued)
Inactive Ingredients dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, ethylhexyl palmitate, ezokerite, water, polyethylene, polyglyceryl-3 distearate, polymethyl methacrylate, tridecyl stearate, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, caprylic/capric triglyceride, sodium starch octenylsuccinate, tocopheryl acetate, phenoxyethanol, cocco nucifera (coconut) oil, aloe barbadensis ▶

Drug Facts (continued)
 leaf extract, fragrance, caprylyl glycol, ceramide 3, chlorphenesin, propylene glycol, limonium gerberii extract, butyrospermum parkii (shea) butter, glycine soja (soybean) oil, tocopherol, magnesium chloride, potassium chloride, silica, sodium chloride, vis visifera (grape) fruit extract, may contain: mica, iron oxides, titanium dioxide, red 21 lake, yellow 5 lake, red 7 lake, red 27 lake, talc, peg-8 methyl ether triethoxysilane, carmine, ▶

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HYDRACOLOR 2 in 1
 Highly moisturizing and coloring
 LIPSTICK SPF 25
 4 g e (.14 oz.)

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.

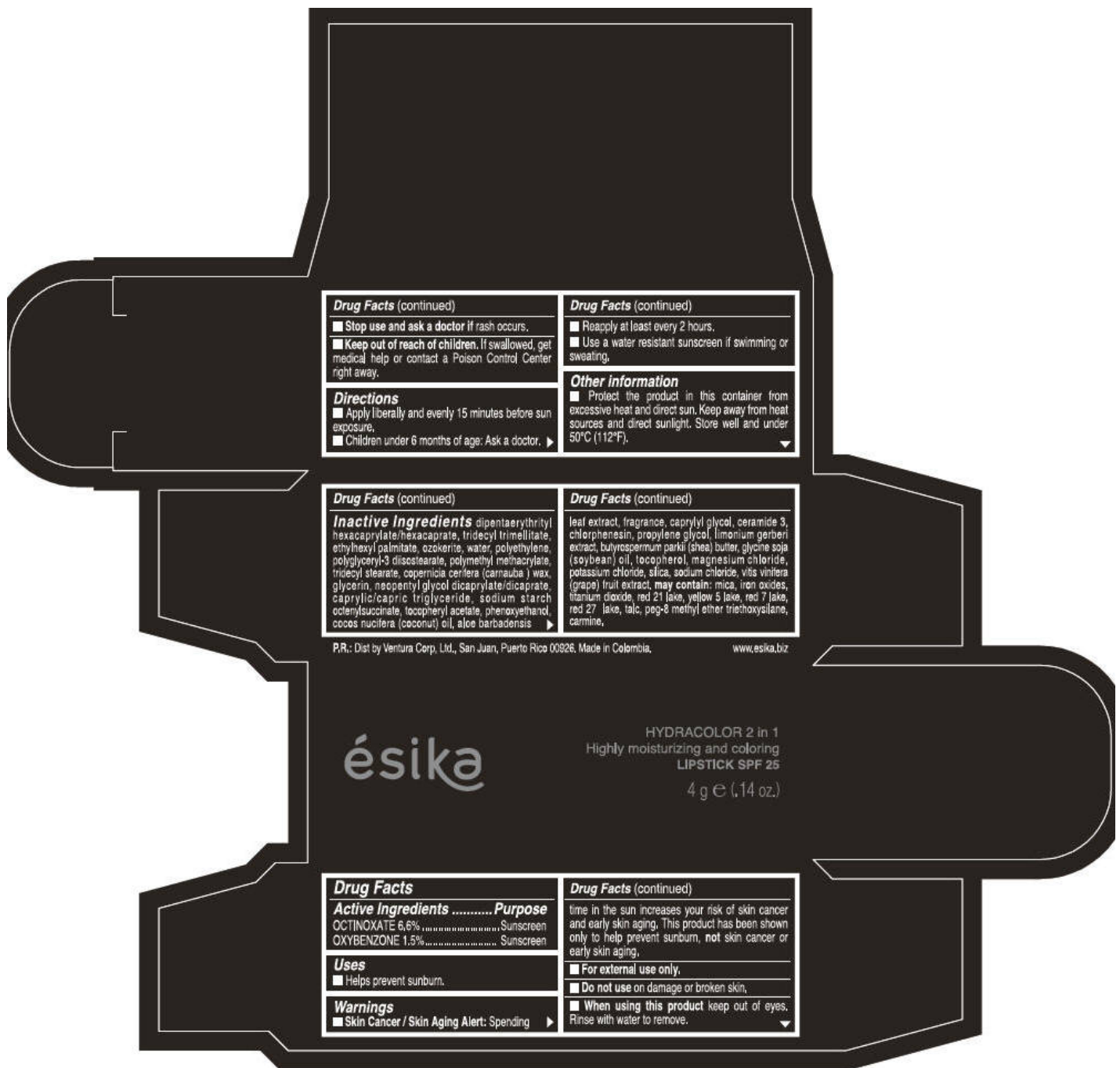
■ When using this product keep out of eyes. Rinse with water to remove. ▼

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

ésika

HYDRACOLOR 2 in 1
 Highly moisturizing and coloring
LIPSTICK SPF 25

4 g e (.14 oz.)



Drug Facts (continued)

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Children under 6 months of age: Ask a doctor. ▶

Drug Facts (continued)

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

Other information

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

Drug Facts (continued)

Inactive Ingredients dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, ethylhexyl palmitate, ezokerite, water, polyethylene, polyglyceryl-3 distearate, polymethyl methacrylate, tridecyl stearate, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, caprylic/capric triglyceride, sodium starch octenylsuccinate, tocopheryl acetate, phenoxyethanol, cocco nucifera (coconut) oil, aloë barbadensis ▶

Drug Facts (continued)

leaf extract, fragrance, 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, vis visifera (grape) fruit extract, may contain: mica, iron oxides, titanium dioxide, red 21 lake, yellow 5 lake, red 7 lake, red 27 lake, talc, peg-8 methyl ether triethoxysilane, carmine, ▼

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HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25
4 g e (.14 oz.)

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 - (PIMIENTA CALIENTE) - BROWN

ésika

HYDRACOLOR 2 in 1
Highly moisturizing and coloring
LIPSTICK SPF 25

4 g e (.14 oz.)



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

Directions
 ■ Apply liberally and evenly 15 minutes before sun exposure.
 ■ Children under 6 months of age: Ask a doctor. ▶

Drug Facts (continued)
 ■ Reapply at least every 2 hours.
 ■ Use a water resistant sunscreen if swimming or sweating.

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

Drug Facts (continued)
Inactive Ingredients dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, ethylhexyl palmitate, ezokerite, water, polyethylene, polyglyceryl-3 distearate, polymethyl methacrylate, tridecyl stearate, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, caprylic/capric triglyceride, sodium starch octenylsuccinate, tocopheryl acetate, phenoxyethanol, cocco nucifera (coconut) oil, aloe barbadensis ▶

Drug Facts (continued)
 leaf extract, fragrance, 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, vis visifera (grape) fruit extract, may contain: mica, iron oxides, titanium dioxide, red 21 lake, yellow 5 lake, red 7 lake, red 27 lake, talc, peg-8 methyl ether triethoxysilane, carmine, ▼

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HYDRACOLOR 2 in 1
 Highly moisturizing and coloring
 LIPSTICK SPF 25
 4 g e (.14 oz.)

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 - 14 Tube Kit

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

ésika

8 g e (.28 oz.)

ésika

HYDRACOLOR 2 in 1
Highly moisturizing
and coloring LIPSTICK SPF 25



Drug Facts

Active Ingredients
 OCTINOXATE 6.5%
 OXYBENZONE 1.5%
 Sunscreen
 Sunscreen

Purpose

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.
 ■ Children under 6 months of age: Ask a doctor.

Drug Facts (continued)

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

Other Information

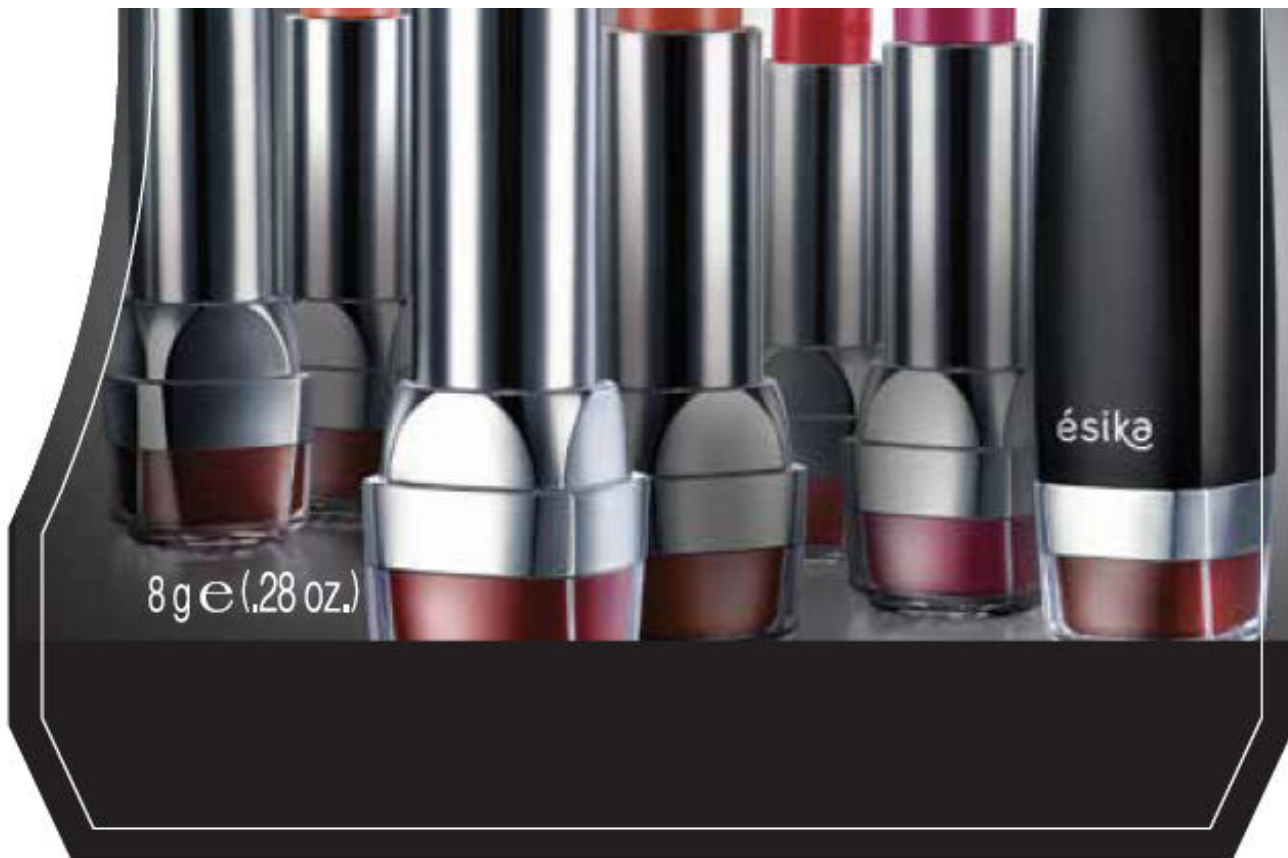
■ Protect this product in this container from excessive heat and direct sun. Keep away from heat sources and direct sunlight. Store well and under 50°C (112°F).

Inactive Ingredients

DIPENTAERYTHRITYL HEXACAPRYLATE, HEXACAPRYLATE, TRIDECYL TRIMELLITATE, ETHYLHEXYL PALMITATE, OZOKERITE, WATER, POLYETHYLENE, POLYGLYCERYL-3 DIISOSTEARATE, POLYMETHYL METHACRYLATE, TRIDECYL STEARATE, COPERNICIA GERIFERA (CARNAUBA) WAX, GLYCERIN, NEOPENTYL GLYCOL DICAPRYLATE/DICAPRYLATE, CAPRYLIC ICAPRILIC TRIGLYCERIDE, SODIUM STARCH OCTENYLSUCCINATE, TOCOPHERYL ACETATE, PHENOXYETHANOL, COCOS NUCIFERA (COCONUT) OIL, ALOE BARBADENSIS LEAF EXTRACT, FRAGRANCE, CAPRYLYL GLYCOL, CERAMIDE 3, CHLORPHENESIN, PROPYLENE GLYCOL, LIMONIN GERBERI EXTRACT, BUTYROSPERMUM PARKII (SHEA) BUTTER, GLYCINE SOJA (SOYBEAN) OIL, TOCOPHEROL, MAGNESIUM CHLORIDE, POTASSIUM CHLORIDE, SILICA, SODIUM CHLORIDE, VITIS VINIFERA (GRAPE) FRUIT EXTRACT, MAY CONTAIN: MICA, IRON OXIDES, TITANIUM DIOXIDE, RED 21 LAKE, YELLOW 6 LAKE, RED 7 LAKE, RED 27 LAKE, TALC, PEG-8 METHYL ETHER TRITHOXYSILANE, CARBAMINE.

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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:13537-061
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)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	

TRIDECYL STEARATE (UNII: A8OE252M6L)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
aluminum oxide (UNII: LM26O6933)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
TALC (UNII: 7SEV7J4R1U)
CARMINIC ACID (UNII: CID8Z8N95N)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-061-02	1 in 1 BOX		
1	NDC:13537-061-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

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

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-064
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)	
WATER (UNII: 059QF0K00R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	

LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
aluminum oxide (UNII: LM26O6933)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
TALC (UNII: 7SEV7J4R1U)
CARMINIC ACID (UNII: CID8Z8N95N)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-064-04	1 in 1 BOX		
1	NDC:13537-064-03	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

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

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-065
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)
WATER (UNII: 059QF0K00R)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
TRIDECYL STEARATE (UNII: A8OE252M6L)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
aluminum oxide (UNII: LM26O6933)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
TALC (UNII: 7SEV7J4R1U)
CARMINIC ACID (UNII: CID8Z8N95N)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-065-06	1 in 1 BOX		
1	NDC:13537-065-05	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

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

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-066
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)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
aluminum oxide (UNII: LMI26O6933)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
TALC (UNII: 7SEV7J4R1U)
CARMINIC ACID (UNII: CID8Z8N95N)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-066-08	1 in 1 BOX		
1	NDC:13537-066-07	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

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

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-067
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)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ981I0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
aluminum oxide (UNII: LM26O6933)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
TALC (UNII: 7SEV7J4R1U)	
CARMINIC ACID (UNII: CID8Z8N95N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-067-10	1 in 1 BOX		
1	NDC:13537-067-09	4 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

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

octinoxate and oxybenzone lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-068
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)	
WATER (UNII: 059QF0K00R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	

SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
aluminum oxide (UNII: LM26O6933)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
TALC (UNII: 7SEV7J4R1U)
CARMINIC ACID (UNII: CID8Z8N95N)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-068-12	1 in 1 BOX		
1	NDC:13537-068-11	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

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

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-069
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)		
WATER (UNII: 059QF0KO0R)		
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)		
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)		
TRIDECYL STEARATE (UNII: A8OE252M6L)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
GLYCERIN (UNII: PDC6A3C0OX)		
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
COCONUT OIL (UNII: Q9L0O73W7L)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
CAPRYLYL GLYCOL (UNII: 00YIU5438U)		
CERAMIDE 3 (UNII: 4370DF050B)		
CHLORPHENESIN (UNII: I670DAL4SZ)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SHEA BUTTER (UNII: K49155WL9Y)		
SOYBEAN OIL (UNII: 241ATL177A)		
TOCOPHEROL (UNII: R0ZB2556P8)		
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)		
POTASSIUM CHLORIDE (UNII: 660YQ98110)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
WINE GRAPE (UNII: 3GOV20705G)		
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)		
LIMONENE, (+)- (UNII: GFD7C86Q1W)		
LINALOOL, (+/-)- (UNII: D81QY6I88E)		
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)		
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)		
MICA (UNII: V8A1AW0880)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
D&C RED NO. 21 (UNII: 08744Z6JNY)		
aluminum oxide (UNII: LM26O6933)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		
D&C RED NO. 7 (UNII: ECW0LZ41X8)		
D&C RED NO. 27 (UNII: 2LRS185U6K)		
FERROSFERRIC OXIDE (UNII: XM0M87F357)		
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)		
TALC (UNII: 7SEV7J4R1U)		

CARMINIC ACID (UNII: CID8Z8N95N)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-069-14	1 in 1 BOX		
1	NDC:13537-069-13	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

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

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-070
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)	
WATER (UNII: 059QF0K00R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ981I0)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
aluminum oxide (UNII: LMI26O6933)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
TALC (UNII: 7SEV7J4R1U)
CARMINIC ACID (UNII: CID8Z8N95N)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-070-16	1 in 1 BOX		
1	NDC:13537-070-15	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

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

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-071
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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)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
aluminum oxide (UNII: LMI26O6933)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	

D&C RED NO. 27 (UNII: 2LRS185U6K)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
TALC (UNII: 7SEV7J4R1U)	
CARMINIC ACID (UNII: CID8Z8N95N)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-071-18	1 in 1 BOX		
1	NDC:13537-071-17	4 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

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

octinoxate and oxybenzone lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-072
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)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
aluminum oxide (UNII: LM26O6933)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
TALC (UNII: 7SEV7J4R1U)
CARMINIC ACID (UNII: CID8Z8N95N)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-072-20	1 in 1 BOX		
1	NDC:13537-072-19	4 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

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

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-073
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)	
WATER (UNII: 059QF0K00R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
MICA (UNII: V8A1AW0880)	

FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
aluminum oxide (UNII: LM26O6933)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
TALC (UNII: 7SEV7J4R1U)
CARMINIC ACID (UNII: CID8Z8N95N)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-073-22	1 in 1 BOX		
1	NDC:13537-073-21	4 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

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

octinoxate and oxybenzone lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-074
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)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	

TRIDECYL STEARATE (UNII: A8OE252M6L)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
aluminum oxide (UNII: LM26O6933)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
TALC (UNII: 7SEV7J4R1U)
CARMINIC ACID (UNII: CID8Z8N95N)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-074-24	1 in 1 BOX		
1	NDC:13537-074-23	4 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

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

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-075
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)	
WATER (UNII: 059QF0K00R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	

LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
aluminum oxide (UNII: LMI26O6933)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
TALC (UNII: 7SEV7J4R1U)
CARMINIC ACID (UNII: CID8Z8N95N)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-075-26	1 in 1 BOX		
1	NDC:13537-075-25	4 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

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

octinoxate and oxybenzone lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-076
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)
WATER (UNII: 059QF0KO0R)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
TRIDECYL STEARATE (UNII: A8OE252M6L)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ981I0)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
aluminum oxide (UNII: LM26O6933)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
TALC (UNII: 7SEV7J4R1U)
CARMINIC ACID (UNII: CID8Z8N95N)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-076-28	1 in 1 BOX		
1	NDC:13537-076-27	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25

octinoxate and oxybenzone kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-077
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-077-29	1 in 1 CASE		
2	NDC:13537-077-30	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 CASE	0.57 g
Part 2	1 CASE	0.57 g
Part 3	1 CASE	0.57 g
Part 4	1 CASE	0.57 g
Part 5	1 CASE	0.57 g
Part 6	1 CASE	0.57 g
Part 7	1 CASE	0.57 g
Part 8	1 CASE	0.57 g
Part 9	1 CASE	0.57 g
Part 10	1 CASE	0.57 g
Part 11	1 CASE	0.57 g
Part 12	1 CASE	0.57 g
Part 13	1 CASE	0.57 g
Part 14	1 CASE	0.57 g

Part 1 of 14

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)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	

aluminum oxide (UNII: LM26O6933)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
TALC (UNII: 7SEV7J4R1U)	
CARMINIC ACID (UNII: CID8Z8N95N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.57 g in 1 CASE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

Part 2 of 14

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROJO DESEO) - 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)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

GLYCERIN (UNII: PDC6A3C00X)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98110)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
aluminum oxide (UNII: LM26O6933)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
TALC (UNII: 7SEV7J4R1U)
CARMINIC ACID (UNII: CID8Z8N95N)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.57 g in 1 CASE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

Part 3 of 14

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROJO INTRIGANTE) - 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)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98110)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	

.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
aluminum oxide (UNII: LM26O6933)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
TALC (UNII: 7SEV7J4R1U)
CARMINIC ACID (UNII: CID8Z8N95N)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.57 g in 1 CASE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

Part 4 of 14

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROJO LUJURIA) - 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)
WATER (UNII: 059QF0KO0R)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
TRIDECYL STEARATE (UNII: A8OE252M6L)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ981I0)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
aluminum oxide (UNII: LM26O6933)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
TALC (UNII: 7SEV7J4R1U)
CARMINIC ACID (UNII: CID8Z8N95N)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.57 g in 1 CASE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

Part 5 of 14

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)	
WATER (UNII: 059QF0K00R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
aluminum oxide (UNII: LM26O6933)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
TALC (UNII: 7SEV7J4R1U)
CARMINIC ACID (UNII: CID8Z8N95N)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.57 g in 1 CASE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

Part 6 of 14

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (ROSA ENCANTO) - 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)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ981I0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
aluminum oxide (UNII: LM26O6933)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
TALC (UNII: 7SEV7J4R1U)	
CARMINIC ACID (UNII: CID8Z8N95N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.57 g in 1 CASE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

Part 7 of 14

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)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
aluminum oxide (UNII: LM26O6933)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
TALC (UNII: 7SEV7J4R1U)
CARMINIC ACID (UNII: CID8Z8N95N)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.57 g in 1 CASE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

Part 8 of 14

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (FUCSIA CAUTIVANTE) - 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)	
WATER (UNII: 059QF0K00R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
aluminum oxide (UNII: LM26O6933)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
TALC (UNII: 7SEV7J4R1U)	
CARMINIC ACID (UNII: CID8Z8N95N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.57 g in 1 CASE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

Part 9 of 14

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)	
WATER (UNII: 059QF0K00R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
aluminum oxide (UNII: LM26O6933)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
TALC (UNII: 7SEV7J4R1U)
CARMINIC ACID (UNII: CID8Z8N95N)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.57 g in 1 CASE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

Part 10 of 14

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: 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)	
WATER (UNII: 059QF0K00R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
MICA (UNII: V8A1AW0880)	

FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
aluminum oxide (UNII: LM26O6933)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
TALC (UNII: 7SEV7J4R1U)
CARMINIC ACID (UNII: CID8Z8N95N)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.57 g in 1 CASE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

Part 11 of 14

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (NARANJA PRIMAVERA) - 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)	
WATER (UNII: 059QF0K00R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231QV8)
TRIDECYL STEARATE (UNII: A8OE252M6L)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
aluminum oxide (UNII: LM26O6933)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
TALC (UNII: 7SEV7J4R1U)
CARMINIC ACID (UNII: CID8Z8N95N)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.57 g in 1 CASE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

Part 12 of 14

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING SPF 25 (FRAMBUESA MANIA) - 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)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98H0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	

Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
aluminum oxide (UNII: LM26O6933)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
TALC (UNII: 7SEV7J4R1U)
CARMINIC ACID (UNII: CID8Z8N95N)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.57 g in 1 CASE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

Part 13 of 14

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)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98II0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
aluminum oxide (UNII: LMI26O6933)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
TALC (UNII: 7SEV7J4R1U)	
CARMINIC ACID (UNII: CID8Z8N95N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.57 g in 1 CASE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

Part 14 of 14

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

TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98H0)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
Isomethyl-.Alpha.-Ionone (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 21 (UNII: 08744Z6JNY)
aluminum oxide (UNII: LM26O6933)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
TALC (UNII: 7SEV7J4R1U)
CARMINIC ACID (UNII: CID8Z8N95N)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.57 g in 1 CASE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/03/2014	

Labeler - Ventura Corporation LTD (602751344)

Establishment			
Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-061, 13537-064, 13537-065, 13537-066, 13537-067, 13537-068, 13537-069, 13537-070, 13537-071, 13537-072, 13537-073, 13537-074, 13537-075, 13537-076, 13537-077)

