

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (PIMIENTA CALIENTE) - BROWN- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (ROJO DESEO) - RED- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (ROJO ESIKA) - RED- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (MARRON TOPACIO) - BROWN- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (ROSA GEOMETRIC) - PINK- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (ROSA ENCANTO) - PINK- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (MORA GLAM) - PURPLE- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (GRANATE SEDUCTOR) - PURPLE- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (BORGONA SEXY) - PURPLE- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (FRESA HOT) - PINK- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (FUCSIA CAUTIVANTE) - PINK- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (FUCSIA INTENSE) - PINK- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (NARANJA ESFERA) - ORANGE- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (ROSA NUDE) - PINK- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (PEACH NUDE) - BROWN- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (CORAL CHIC) - PINK- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (ROJO TROPICAL) - RED- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (NARANJA CITRICO) - ORANGE- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (NUDE PUNCH) - ORANGE- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (MORA ATREVIDA) - PURPLE- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (NUDE SAVANNA) - ORANGE- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (ROJO SENSUAL) - RED- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (NUDE MOCCHA) - ORANGE- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (BRONCE METALLIC) - BROWN- octinoxate and zinc oxide lipstick

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25- octinoxate and zinc oxide

Ventura Corporation LTD DUNS

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they

comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

ÉSIKA PRO HIDRACOLOR 3 IN 1 Moisturizing lipstick, color and perfecting effect SPF 25

Drug Facts

Active Ingredients	Purpose
OCTINOXATE 7.5%	Sunscreen
ZINC OXIDE 3.92%	Sunscreen

Uses

- Helps prevent sunburn.

Warnings

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

Directions

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

Other information

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

Inactive ingredients

DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL TRIMELLITATE, ISONONYL ISONONANOATE, OZOKERITE, WATER, POLYGLYCERYL-3 DIISOSTEARATE, TRIDECYL STEARATE, POLYETHYLENE, COPERNICIA CERIFERA (CARNAUBA) WAX, GLYCERIN, NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE, BUTYROSPERMUM PARKII (SHEA) BUTTER, PTFE, SODIUM STARCH OCTENYLSUCCINATE, TOCOPHERYL ACETATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, PHENOXYETHANOL, COCOS NUCIFERA (COCONUT) OIL, ALOE BARBADENSIS LEAF EXTRACT, FRAGRANCE, CERAMIDE 3, CAPRYLYL GLYCOL, CHLORPHENESIN, DIMETHICONE, TRIETHOXYCAPRYLYLSILANE, GLYCINE SOJA (SOYBEAN) OIL, LIMONIUM GERBERI EXTRACT, TRIMETHYLSILOXYSILICATE, TOCOPHEROL, MAGNESIUM CHLORIDE,

POTASSIUM CHLORIDE, SILICA, SODIUM CHLORIDE, CRAMBE MARITIMA EXTRACT, ALPHA-ISOMETHYL IONONE, d-LIMONENE, LINALOOL, AMYL CINNAMAL, CITRONELLOL.

MAY CONTAIN: RED 30 LAKE, TITANIUM DIOXIDE, IRON OXIDES, MICA, RED 27 LAKE, YELLOW 5 LAKE, RED 7 LAKE, RED 21 LAKE, TALC, BLUE 1 LAKE, CARMINE.

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

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

ésika

PRO

HIDRACOLOR

3 IN 1

Moisturizing Lipstick,
Color and Perfecting
Effect SPF 25

Net Weight

0.14 oz. e (4 g)

Drug Facts (continued)

- 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 ▶

Drug Facts (continued)

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

Other Information

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

Drug Facts (continued)

Inactive Ingredients

Dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, isononyl isononanoate, ozokerite, water, polyglyceryl-3 disostearate, tridecyl stearate, polyethylene, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, butyrospermum parkii (shea) butter, oil, sodium starch octenylsuccinate, tocopheryl acetate, capryl/capric triglyceride, phenoxyethanol, cocos nucifera (coconut) ▶

Drug Facts (continued)

ol, abo barbadensis leaf extract, fragrance, ceramide 3, caprylyl glycol, chlorphenesin, dimethicone, triethoxy-a-propylsilane, glycine soja (soybean) oil, limonium gerbert extract, trimethylsiloxysilicate, tocopherol, magnesium chloride, potassium chloride, silica, sodium chlorate, crambae maritima extract, alpha-isomethyl ionone, d-limonene, linalool, amyli cinnamal, citronellol. May Contain: red 30 lake, titanium dioxide, iron oxides, mica, red 27 lake, yellow 5 lake, red 7 lake, red 21 lake, talc, blue 1 lake, carmine. ▶

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**HIDRACOLOR
3 IN 1**
Moisturizing Lipstick,
Color and Perfecting
Effect SPF 25

Net Weight
0.14 oz. e (4 g)

Drug Facts

Active Ingredients **Purpose**

OCTINOXATE 7.5% Sunscreen
ZINC OXIDE 3.92% 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.

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Moisturizing Lipstick,
Color and Perfecting
Effect SPF 25

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Directions

- Apply liberally and evenly 15 minutes before ▶

Drug Facts (continued)

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

Other Information

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

Drug Facts (continued)

Inactive Ingredients

Dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, isononyl isononanoate, ozokerite, water, polyglyceryl-3 distearate, tridecyl stearate, polyethylene, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, butyrospermum parkii (shea) butter, olive, sodium starch octenylsuccinate, tocopheryl acetate, capryl/capric triglyceride, phenoxyethanol, cocos nucifera (coconut) ▶

Drug Facts (continued)

ol, abo barbadensis leaf extract, fragrance, ceramide 3, caprylyl glycol, chlorphenesin, dimethicone, triethoxy-a-propylsilane, glycine soja (soybean) oil, limonium gerbert extract, trimethylsiloxysilicate, tocopherol, magnesium chloride, potassium chloride, silica, sodium chlorate, crambae maritima extract, alpha-isomethyl ionone, d-limonene, linalool, amyri cinnamal, citronellol. May Contain: red 30 lake, titanium dioxide, iron oxides, mica, red 27 lake, yellow 5 lake, red 7 lake, red 21 lake, talc, blue 1 lake, carmine. ▶

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Drug Facts (continued)

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Directions

- Apply liberally and evenly 15 minutes before ▶

Drug Facts (continued)

sun exposure.

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

Other Information

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

Drug Facts (continued)

Inactive Ingredients

Dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, isononyl isononanoate, ozokerite, water, polyglyceryl-3 disostearate, tridecyl stearate, polyethylene, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, butyrospermum caroli (shea) butter, oil, sodium starch octenylsuccinate, tocopheryl acetate, capryl/capric triglyceride, phenoxymethanol, cocos nucifera (coconut) ▶

Drug Facts (continued)

ol, aloe barbadensis leaf extract, fragrance, ceramide 3, caprylyl glycol, chlorphenesin, dimethicone, triethoxyaeropylisilane, glycine soja (soybean) oil, limonium gerbert extract, trimethylsiloxysilicate, tocopherol, magnesium chloride, potassium chloride, silica, sodium chlorate, crambae maritima extract, alpha-isomethyl ionone, d-limonene, linalool, amyri cinnamal, citronellol. May Contain: red 30 lake, titanium dioxide, iron oxides, mica, red 27 lake, yellow 5 lake, red 7 lake, red 21 lake, talc, blue 1 lake, carmine. ▶

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Drug Facts (continued)

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Other Information

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

Drug Facts (continued)

Inactive Ingredients

Dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, isononyl isononanoate, ozokerite, water, polyglyceryl-3 disostearate, tridecyl stearate, polyethylene, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, butyrospermum parkii (shea) butter, olive, sodium starch octenylsuccinate, tocopheryl acetate, capryl/capric triglyceride, phenoxyethanol, cocos nucifera (coconut) ▶

Drug Facts (continued)

ol, abo barbadensis leaf extract, fragrance, ceramide 3, caprylyl glycol, chlorphenesin, dimethicone, triethoxy-a-propylsilane, glycine soja (soybean) oil, limonium gerbert extract, trimethylsiloxysilicate, tocopherol, magnesium chloride, potassium chloride, silica, sodium chlorate, crambae maritima extract, alpha-isomethyl ionone, d-limonene, linalool, amyli cinnamal, citronellol. May Contain: red 30 lake, titanium dioxide, iron oxides, mica, red 27 lake, yellow 5 lake, red 7 lake, red 21 lake, talc, blue 1 lake, carmine. ▶

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Drug Facts (continued)

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Directions

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Drug Facts (continued)

- sun exposure.
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- Children under 6 months of age: Ask a doctor.

Other Information

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

Drug Facts (continued)

Inactive Ingredients

Dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, isononyl isononanoate, ozokerite, water, polyglyceryl-3 disostearate, tridecyl stearate, polyethylene, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, butyrospermum parkii (shea) butter, olive, sodium starch octenylsuccinate, tocopheryl acetate, capryl/capric triglyceride, phenoxyethanol, cocos nucifera (coconut) ▶

Drug Facts (continued)

ol, abo barbadensis leaf extract, fragrance, ceramide 3, caprylyl glycol, chlorphenesin, dimethicone, triethoxy-a-propylsilane, glycine soja (soybean) oil, limonum gerbert extract, trimethylsiloxysilicate, tocopherol, magnesium chloride, potassium chloride, silica, sodium chlorate, crambae maritima extract, alpha-isomethyl ionone, d-limonene, linalool, amyli cinnamal, citronellol. May Contain: red 30 lake, titanium dioxide, iron oxides, mica, red 27 lake, yellow 5 lake, red 7 lake, red 21 lake, talc, blue 1 lake, carmine. ▶

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Uses

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Drug Facts (continued)

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Effect SPF 25

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Directions

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Drug Facts (continued)

sun exposure.
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Other Information

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

Drug Facts (continued)

Inactive Ingredients

Dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, isononyl isononanoate, ozokerite, water, polyglyceryl-3 disostearate, tridecyl stearate, polyethylene, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, butyrospermum parkii (shea) butter, olive, sodium starch octenylsuccinate, tocopheryl acetate, capryl/capric triglyceride, phenoxyethanol, cocos nucifera (coconut) ▶

Drug Facts (continued)

ol, abo barbadensis leaf extract, fragrance, ceramide 3, caprylyl glycol, chlorphenesin, dimethicone, triethoxyaerilylsilane, glycine soja (soybean) oil, limonium gerbert extract, trimethylsiloxysilicate, tocopherol, magnesium chloride, potassium chloride, silica, sodium chlorate, crambae maritima extract, alpha-isomethyl ionone, d-limonene, linalool, amyri cinnamal, citronellol. May Contain: red 30 lake, titanium dioxide, iron oxides, mica, red 27 lake, yellow 5 lake, red 7 lake, red 21 lake, talc, blue 1 lake, carmine. ▶

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Directions

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Drug Facts (continued)

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Other Information

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

Drug Facts (continued)

Inactive Ingredients

Dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, isononyl isononanoate, ozokerite, water, polyglyceryl-3 disostearate, tridecyl stearate, polyethylene, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, butyrospermum parkii (shea) butter, oil, sodium starch octenylsuccinate, tocopheryl acetate, capryl/capric triglyceride, phenoxyethanol, cocos nucifera (coconut) ▶

Drug Facts (continued)

ol, abo barbadensis leaf extract, fragrance, ceramide 3, caprylyl glycol, chlorphenesin, dimethicone, triethoxyaaprylsilane, glycine soja (soybean) oil, limonium gerbert extract, trimethylsiloxysilicate, tocopherol, magnesium chloride, potassium chloride, silica, sodium chlorate, crambae maritima extract, alpha-isomethyl ionone, d-limonene, linalool, amyri cinnamal, citronellol. May Contain: red 30 lake, titanium dioxide, iron oxides, mica, red 27 lake, yellow 5 lake, red 7 lake, red 21 lake, talc, blue 1 lake, carmine.

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 ZINC OXIDE 3.92% 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.

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

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PRO

HIDRACOLOR
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Moisturizing Lipstick,
Color and Perfecting
Effect SPF 25

Net Weight
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Drug Facts (continued)

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- Stop use and ask a doctor if rash occurs.
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Directions

- Apply liberally and evenly 15 minutes before ▶

Drug Facts (continued)

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

Other Information

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

Drug Facts (continued)

Inactive Ingredients

Dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, isononyl isononanoate, ozokerite, water, polyglyceryl-3 disostearate, tridecyl stearate, polyethylene, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, butyrospermum caroli (shea) butter, ole, sodium starch octenylsuccinate, tocopheryl acetate, capryl/capric triglyceride, phenoxyethanol, cocos nucifera (coconut) ▶

Drug Facts (continued)

ol, abo barbadensis leaf extract, fragrance, ceramide 3, caprylyl glycol, chlorphenesin, dimethicone, triethoxy-a-propylsilane, glycine soja (soybean) oil, limonium gerbert extract, trimethylsiloxysilicate, tocopherol, magnesium chloride, potassium chloride, silica, sodium chlorate, crambae maritima extract, alpha-isomethyl ionone, d-limonene, linalool, amyri cinnamal, citronellol. May Contain: red 30 lake, titanium dioxide, iron oxides, mica, red 27 lake, yellow 5 lake, red 7 lake, red 21 lake, talc, blue 1 lake, carmine. ▶

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**HIDRACOLOR
3 IN 1**
Moisturizing Lipstick,
Color and Perfecting
Effect SPF 25

Net Weight
0.14 oz. e (4 g)

Drug Facts

Active Ingredients **Purpose**
OCTINOXATE 7.5% Sunscreen
ZINC OXIDE 3.92% 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 damaged or broken skin.
- When using this product keep out of eyes. ▶

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HIDRACOLOR
3 IN 1

Moisturizing Lipstick,
Color and Perfecting
Effect SPF 25

Net Weight
0.14 oz. e (4 g)

Drug Facts (continued)

- 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 ▶

Drug Facts (continued)

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

Other Information

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

Drug Facts (continued)

Inactive Ingredients

Dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, isononyl isononanoate, ozokerite, water, polyglyceryl-3 disostearate, tridecyl stearate, polyethylene, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, butyrospermum parkii (shea) butter, oil, sodium starch octenylsuccinate, tocopheryl acetate, capryl/capric triglyceride, phenoxyethanol, cocos nucifera (coconut) ▶

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Drug Facts (continued)

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Drug Facts (continued)

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

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Drug Facts (continued)

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Drug Facts (continued)

ol, aloe barbadensis leaf extract, fragrance, ceramide 3, caprylyl glycol, chlorphenesin, dimethicone, triethoxyaeropylisilane, glycine soja (soybean) oil, limonium gerbert extract, trimethylsiloxysilicate, tocopherol, magnesium chloride, potassium chloride, silica, sodium chlorate, crambae maritima extract, alpha-isomethyl ionone, d-limonene, linalool, amyri cinamal, citronellol. May Contain: red 30 lake, titanium dioxide, iron oxides, mica, red 27 lake, yellow 5 lake, red 7 lake, red 21 lake, talc, blue 1 lake, carmine. ▶

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Active Ingredients **Purpose**
 OCTINOXATE 7.5% Sunscreen
 ZINC OXIDE 3.92% 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 damaged or broken skin.
- When using this product keep out of eyes.

ésika
PRO

HIDRACOLOR
3 IN 1

Moisturizing Lipstick,
Color and Perfecting
Effect SPF 25

Net Weight
0.14 oz. e (4 g)

Drug Facts (continued)

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 ▶

Drug Facts (continued)

sun exposure.

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

Other Information

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

Drug Facts (continued)

Inactive Ingredients

Dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, isononyl isononanoate, ozokerite, water, polyglyceryl-3 distearate, tridecyl stearate, polyethylene, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, butyrospermum parkii (shea) butter, olive, sodium starch octenylsuccinate, tocopheryl acetate, capryl/capric triglyceride, phenoxyethanol, cocos nucifera (coconut) ▶

Drug Facts (continued)

ol, abo barbadensis leaf extract, fragrance, ceramide 3, caprylyl glycol, chlorphenesin, dimethicone, triethoxyaerilysilane, glycine soja (soybean) oil, limonium gerbert extract, trimethylsiloxysilicate, tocopherol, magnesium chloride, potassium chloride, silica, sodium chlorate, crambae maritima extract, alpha-isomethyl ionone, d-limonene, linalool, amyri cinnamal, citronellol. May Contain: red 30 lake, titanium dioxide, iron oxides, mica, red 27 lake, yellow 5 lake, red 7 lake, red 21 lake, talc, blue 1 lake, carmine. ▶

PUERTO RICO: Dist. by Venture Corp, Ltd., San Juan, Puerto Rico 00926. Made in Colombia. www.esika.biz

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PRO

HIDRACOLOR
3 IN 1

Moisturizing Lipstick,
Color and Perfecting
Effect SPF 25

Net Weight
0.14 oz. e (4 g)

Drug Facts

Active Ingredients **Purpose**

OCTINOXATE 7.5% Sunscreen
ZINC OXIDE 3.92% 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.

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HIDRACOLOR
3 IN 1

Moisturizing Lipstick,
Color and Perfecting
Effect SPF 25

Net Weight
0.14 oz. e (4 g)

Drug Facts (continued)

- 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 ▶

Drug Facts (continued)

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

Other Information

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

Drug Facts (continued)

Inactive Ingredients

Dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, isononyl isononanoate, ozokerite, water, polyglyceryl-3 disostearate, tridecyl stearate, polyethylene, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, butyrospermum parkii (shea) butter, olive, sodium starch octenylsuccinate, tocopheryl acetate, capryl/capric triglyceride, phenoxyethanol, cocos nucifera (coconut) ▶

Drug Facts (continued)

ol, abo barbadensis leaf extract, fragrance, ceramide 3, caprylyl glycol, chlorphenesin, dimethicone, triethoxy-a-propylsilane, glycine soja (soybean) oil, limonum gerbert extract, trimethylsiloxysilicate, tocopherol, magnesium chloride, potassium chloride, silica, sodium chlorate, crambae maritima extract, alpha-isomethyl ionone, d-limonene, linalool, amyri cinnamal, citronellol. May Contain: red 30 lake, titanium dioxide, iron oxides, mica, red 27 lake, yellow 5 lake, red 7 lake, red 21 lake, talc, blue 1 lake, carmine. ▶

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**HIDRACOLOR
3 IN 1**
Moisturizing Lipstick,
Color and Perfecting
Effect SPF 25

Net Weight
0.14 oz. e (4 g)

Drug Facts

Active Ingredients **Purpose**
OCTINOXATE 7.5% Sunscreen
ZINC OXIDE 3.92% 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.

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ésika
PRO

HIDRACOLOR
3 IN 1

Moisturizing Lipstick,
Color and Perfecting
Effect SPF 25

Net Weight
0.14 oz. e (4 g)

Drug Facts (continued)

- 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 ▶

Drug Facts (continued)

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

Other Information

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

Drug Facts (continued)

Inactive Ingredients

Dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, isononyl isononanoate, ozokerite, water, polyglyceryl-3 disostearate, tridecyl stearate, polyethylene, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, butyrospermum parkii (shea) butter, oil, sodium starch octenylsuccinate, tocopheryl acetate, capryl/capric triglyceride, phenoxyethanol, cocos nucifera (coconut) ▶

Drug Facts (continued)

ol, aloe barbadensis leaf extract, fragrance, ceramide 3, caprylyl glycol, chlorphenesin, dimethicone, triethoxy-a-propylsilane, glycine soja (soybean) oil, limonum gerbert extract, trimethylsiloxysilicate, tocopherol, magnesium chloride, potassium chloride, silica, sodium chlorate, crambae maritima extract, alpha-isomethyl ionone, d-limonene, linalool, amyri cinnamal, citronellol. May Contain: red 30 lake, titanium dioxide, iron oxides, mica, red 27 lake, yellow 5 lake, red 7 lake, red 21 lake, talc, blue 1 lake, carmine. ▶

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**HIDRACOLOR
3 IN 1**
Moisturizing Lipstick,
Color and Perfecting
Effect SPF 25

Net Weight
0.14 oz. e (4 g)

Drug Facts

Active Ingredients **Purpose**
OCTINOXATE 7.5% Sunscreen
ZINC OXIDE 3.92% 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.

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HIDRACOLOR
3 IN 1

Moisturizing Lipstick,
Color and Perfecting
Effect SPF 25

Net Weight
0.14 oz. e (4 g)

Drug Facts (continued)

Rinse with water to remove.
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Directions

■ Apply liberally and evenly 15 minutes before ▶

Drug Facts (continued)

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

Other Information

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

Drug Facts (continued)

Inactive Ingredients

Dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, isononyl isononanoate, ozokerite, water, polyglyceryl-3 disostearate, tridecyl stearate, polyethylene, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, butyrospermum parkii (shea) butter, olive, sodium starch octenylsuccinate, tocopheryl acetate, capryl/capric triglyceride, phenoxyethanol, cocos nucifera (coconut) ▶

Drug Facts (continued)

ol, abo barbadensis leaf extract, fragrance, ceramide 3, caprylyl glycol, chlorphenesin, dimethicone, triethoxyacetylglutamine, glycine soja (soybean) oil, limonium gerbert extract, trimethylsiloxysilicate, tocopherol, magnesium chloride, potassium chloride, silica, sodium chlorate, crambae maritima extract, alpha-isomethyl ionone, d-limonene, linalool, amyri cinamal, citronellol. May Contain: red 30 lake, titanium dioxide, iron oxides, mica, red 27 lake, yellow 5 lake, red 7 lake, red 21 lake, talc, blue 1 lake, carmine. ▶

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HIDRACOLOR
3 IN 1
Moisturizing Lipstick,
Color and Perfecting
Effect SPF 25

Net Weight
0.14 oz. e (4 g)

Drug Facts

Active Ingredients **Purpose**
OCTINOXATE 7.5% Sunscreen
ZINC OXIDE 3.92% 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.

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- Do not use on damaged or broken skin.
- When using this product keep out of eyes. ▶

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HIDRACOLOR
3 IN 1

Moisturizing Lipstick,
Color and Perfecting
Effect SPF 25

Net Weight
0.14 oz. e (4 g)

Drug Facts (continued)

- 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 ▶

Drug Facts (continued)

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

Other Information

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

Drug Facts (continued)

Inactive Ingredients

Dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, isononyl isononanoate, ozokerite, water, polyglyceryl-3 disostearate, tridecyl stearate, polyethylene, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, butyrospermum parkii (shea) butter, oil, sodium starch octenylsuccinate, tocopheryl acetate, capryl/capric triglyceride, phenoxymethanol, cocos nucifera (coconut) ▶

Drug Facts (continued)

ol, abo barbadensis leaf extract, fragrance, ceramide 3, caprylyl glycol, chlorphenesin, dimethicone, triethoxy-a-propylsilane, glycine soja (soybean) oil, limonium gerbert extract, trimethylsiloxysilicate, tocopherol, magnesium chloride, potassium chloride, silica, sodium chlorate, crambae maritima extract, alpha-isomethyl ionone, d-limonene, linalool, amyri cinnamal, citronellol. May Contain: red 30 lake, titanium dioxide, iron oxides, mica, red 27 lake, yellow 5 lake, red 7 lake, red 21 lake, talc, blue 1 lake, carmine. ▶

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**HIDRACOLOR
3 IN 1**
Moisturizing Lipstick,
Color and Perfecting
Effect SPF 25

Net Weight
0.14 oz. e (4 g)

Drug Facts

Active Ingredients **Purpose**
OCTINOXATE 7.5% Sunscreen
ZINC OXIDE 3.92% 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 damaged or broken skin.
- When using this product keep out of eyes. ▶

ésika
PRO

HIDRACOLOR
3 IN 1

Moisturizing Lipstick,
Color and Perfecting
Effect SPF 25

Net Weight
0.14 oz. e (4 g)

Drug Facts (continued)

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 ▶

Drug Facts (continued)

sun exposure.

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

Other Information

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

Drug Facts (continued)

Inactive Ingredients

Dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, isomyl isononanoate, ozokerite, water, polyglyceryl-3 disostearate, tridecyl stearate, polyethylene, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, butyrospermum parkii (shea) butter, ole, sodium starch octenylsuccinate, tocopheryl acetate, capryl/capric triglyceride, phenoxyethanol, cocos nucifera (coconut) ▶

Drug Facts (continued)

ol, abo barbadensis leaf extract, fragrance, ceramide 3, caprylyl glycol, chlorphenesin, dimethicone, triethoxya-propylsilane, glycine soja (soybean) oil, limonium gerbert extract, trimethylsiloxysilicate, tocopherol, magnesium chloride, potassium chloride, silica, sodium chlorate, crambae maritima extract, alpha-isomethyl ionone, d-limonene, linalool, amyli cinnamal, citronellol. May Contain: red 30 lake, titanium dioxide, iron oxides, mica, red 27 lake, yellow 5 lake, red 7 lake, red 21 lake, talc, blue 1 lake, carmine.

PUERTO RICO: Dist. by Venture Corp, Ltd., San Juan, Puerto Rico 00926. Made in Colombia. www.esika.biz



HIDRACOLOR
3 IN 1
Moisturizing Lipstick,
Color and Perfecting
Effect SPF 25

Net Weight
0.14 oz. e (4 g)

Drug Facts

Active Ingredients **Purpose**

OCTINOXATE 7.5% Sunscreen
ZINC OXIDE 3.92% 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 damaged or broken skin.
- When using this product keep out of eyes. ▶

HIDRACOLOR 3 IN 1

Moisturizing **Lipstick**,
Color and Perfecting Effect SPF 25

ésika
PRO

Net Wt. 0.28 oz. e (8 g)



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

Inactive Ingredients DIPENTAERYTHRYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL TRIMELLITATE, ISONONYL ISONONANOATE, OZOKERITE, WATER, POLYGLYCERYL-3 DIISOSTEARATE, TRIDECYL STEARATE, POLYETHYLENE GLYCERIN, COPERNICIA CERIFERA (CARNAUBA) WAX, BUTYROSPERMUM PARKII (SHEA) BUTTER, NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE, PTFE, SODIUM STARCH OCTENYL SUCCINATE, TOCOPHERYL ACETATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, PHENOXYETHANOL, COCOS NUCLIFERA (COCONUT) OIL, CAPRYLYL GLYCOL, CHLORPHENESIN, TRIETHOXYCAPRYLYLSILANE, GLYCINE SOJA (SOYBEAN) OIL, DIMETHICONE, LIMONIUM GERBERI EXTRACT, TOCOPHEROL, MAGNESIUM CHLORIDE, POTASSIUM CHLORIDE, SILICA, SODIUM CHLORIDE, TRIMETHYLSILOXYLICATE, GRAMBE MARITIMA EXTRACT, ALPHA-ISOMETHYL IONONE, 4-LIMONENE, UNACCOL AMYL CINNAMYL CITRONELLOL, MAY CONTAIN: RED 30 LAKE, TITANIUM DIOXIDE, IRON OXIDES, MICA, RED 27 LAKE, YELLOW 6 LAKE, RED 7 LAKE, RED 21 LAKE, TALC, BLUE 1 LAKE, CARMINI.

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

Drug Facts (continued)
■ Use a water resistant sunscreen if swimming or sweating.
■ Children under 6 months of age: Ask a doctor.

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

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

Uses
■ Helps prevent sunburn.

Drug Facts
Active Ingredients
Octinoxate 7.5% Sunscreen
Zinc Oxide 3.92% Sunscreen

HIDRACOLOR 3 IN 1
Moisturizing Lipstick,
Color and Perfecting Effect SPF 25

ésika
PRO

Net Wt. 0.28 oz. e (8 g)

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (PIMIENTA CALIENTE) - BROWN

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-958
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISO STEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
SHEA BUTTER (UNII: K49155WL9Y)
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CERAMIDE NP (UNII: 4370DF050B)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
DIMETHICONE (UNII: 92RU3N3Y1O)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-958-02	1 in 1 BOX	07/12/2016	
1	NDC:13537-958-01	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (ROJO DESEO) - RED

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-959
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98H0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-959-04	1 in 1 BOX	07/12/2016	
1	NDC:13537-959-03	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (ROJO ESIKA) - RED

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-960
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

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

ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)
CERESIN (UNII: Q1LS2UJO3A)
WATER (UNII: 059QF0KO0R)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
TRIDECYL STEARATE (UNII: A8OE252M6L)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
SHEA BUTTER (UNII: K49155WL9Y)
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CERAMIDE NP (UNII: 4370DF050B)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
DIMETHICONE (UNII: 92RU3N3Y1O)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-960-06	1 in 1 BOX	07/12/2016	
1	NDC:13537-960-05	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (MARRON TOPACIO) - BROWN

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-966
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0K00R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	

TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98H0)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-966-08	1 in 1 BOX	07/12/2016	
1	NDC:13537-966-07	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (ROSA GEOMETRIC) - PINK

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-967
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ981I0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-967-10	1 in 1 BOX	07/12/2016	
1	NDC:13537-967-09	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (ROSA ENCANTO) - PINK

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-968
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

CERAMIDE NP (UNII: 4370DF050B)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
DIMETHICONE (UNII: 92RU3N3Y1O)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98110)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-968-12	1 in 1 BOX	07/12/2016	
1	NDC:13537-968-11	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (MORA GLAM) - PURPLE
 octinoxate and zinc oxide lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-969
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-969-14	1 in 1 BOX	07/12/2016	
1	NDC:13537-969-13	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (GRANATE SEDUCTOR) - PURPLE

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-970
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	

POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CERAMIDE NP (UNII: 4370DF050B)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
DIMETHICONE (UNII: 92RU3N3Y1O)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98H0)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-970-18	1 in 1 BOX	07/12/2016	
1	NDC:13537-970-17	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (BORGONA SEXY) - PURPLE

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-971
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ981I0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	

.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-971-20	1 in 1 BOX	07/12/2016	
1	NDC:13537-971-19	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (FRESA HOT) - PINK

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-972
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	

POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
TRIDECYL STEARATE (UNII: A8OE252M6L)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
SHEA BUTTER (UNII: K49155WL9Y)
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CERAMIDE NP (UNII: 4370DF050B)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
DIMETHICONE (UNII: 92RU3N3Y1O)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98110)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6188E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-972-22	1 in 1 BOX	07/12/2016	
1	NDC:13537-972-21	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (FUCSIA CAUTIVANTE) - PINK

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-973
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-973-24	1 in 1 BOX	07/12/2016	
1	NDC:13537-973-23	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (FUCSIA INTENSE) - PINK

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-974
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98110)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-974-24	1 in 1 BOX	07/12/2016	
1	NDC:13537-974-23	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (NARANJA ESFERA) - ORANGE

octinoxate and zinc oxide lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-975
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

CHLORPHENESIN (UNII: I670DAL4SZ)
DIMETHICONE (UNII: 92RU3N3Y1O)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-975-24	1 in 1 BOX	07/12/2016	
1	NDC:13537-975-23	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (ROSA NUDE) - PINK

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-976
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+) - (UNII: GFD7C86Q1W)	
LINALOOL, (+/-) - (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R) - (UNII: P01OUT964K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	

D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-976-24	1 in 1 BOX	07/12/2016	
1	NDC:13537-976-23	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (PEACH NUDE) - BROWN

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-977
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
PHENOXYETHANOL (UNII: HE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CERAMIDE NP (UNII: 4370DF050B)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
DIMETHICONE (UNII: 92RU3N3Y1O)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ981I0)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-977-24	1 in 1 BOX	07/12/2016	
1	NDC:13537-977-23	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (CORAL CHIC) - PINK
 octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-978
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-978-24	1 in 1 BOX	07/12/2016	
1	NDC:13537-978-23	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (ROJO TROPICAL) - RED

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-979
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	

HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
SHEA BUTTER (UNII: K49155WL9Y)
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CERAMIDE NP (UNII: 4370DF050B)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
DIMETHICONE (UNII: 92RU3N3Y1O)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-979-24	1 in 1 BOX	07/12/2016	
1	NDC:13537-979-23	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (NARANJA CITRICO) - ORANGE

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-980
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98110)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-980-24	1 in 1 BOX	07/12/2016	
1	NDC:13537-980-23	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (NUDE PUNCH) - ORANGE

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-981
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

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

TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)
CERESIN (UNII: Q1LS2UJO3A)
WATER (UNII: 059QF0KO0R)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
TRIDECYL STEARATE (UNII: A8OE252M6L)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
SHEA BUTTER (UNII: K49155WL9Y)
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CERAMIDE NP (UNII: 4370DF050B)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
DIMETHICONE (UNII: 92RU3N3Y1O)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ981I0)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-981-24	1 in 1 BOX	07/12/2016	

1	NDC:13537-981-23	4 g in 1 TUBE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part352	07/12/2016		

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (MORA ATREVIDA) - PURPLE
 octinoxate and zinc oxide lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-982
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ981I0)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-982-24	1 in 1 BOX	07/12/2016	
1	NDC:13537-982-23	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (NUDE SAVANNA) - ORANGE

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-983
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ981I0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-983-24	1 in 1 BOX	07/12/2016	
1	NDC:13537-983-23	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (ROJO SENSUAL) - RED

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-984
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CERAMIDE NP (UNII: 4370DF050B)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
DIMETHICONE (UNII: 92RU3N3Y1O)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98110)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-984-24	1 in 1 BOX	07/12/2016	
1	NDC:13537-984-23	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (NUDE MOCCHA) - ORANGE

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-985
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98H0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-985-24	1 in 1 BOX	07/12/2016	
1	NDC:13537-985-23	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (BRONCE METALLIC) - BROWN

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-986
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
SHEA BUTTER (UNII: K49155WL9Y)
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CERAMIDE NP (UNII: 4370DF050B)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
DIMETHICONE (UNII: 92RU3N3Y1O)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-986-24	1 in 1 BOX	07/12/2016	
1	NDC:13537-986-23	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25

octinoxate and zinc oxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-987
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-987-28	3 in 1 BOX	07/12/2016	
1	NDC:13537-987-27	1 in 1 TUBE		

Quantity of Parts

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

Part 24	1 TUBE	8 g
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Part 1 of 24

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (PIMIENTA CALIENTE) - BROWN

octinoxate and zinc oxide lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	

MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Part 2 of 24

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (ROJO DESEO) - RED

octinoxate and zinc oxide 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	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98H0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Part 3 of 24

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (ROJO ESIKA) - RED

octinoxate and zinc oxide lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)
CERAMIDE NP (UNII: 4370DF050B)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
DIMETHICONE (UNII: 92RU3N3Y1O)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98H0)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Part 4 of 24

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (MARRON TOPACIO) - BROWN
 octinoxate and zinc oxide lipstick

Product Information

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

MICA (UNII: V8A1AW0880)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Part 5 of 24

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (ROSA GEOMETRIC) - PINK

octinoxate and zinc oxide 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	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

GLYCERIN (UNII: PDC6A3C00X)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
SHEA BUTTER (UNII: K49155WL9Y)
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CERAMIDE NP (UNII: 4370DF050B)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
DIMETHICONE (UNII: 92RU3N3Y1O)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Part 6 of 24

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (ROSA ENCANTO) - PINK

octinoxate and zinc oxide lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ981I0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	

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

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Part 7 of 24

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (MORA GLAM) - PURPLE

octinoxate and zinc oxide lipstick

Product Information	
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	

TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)
CERESIN (UNII: Q1LS2UJO3A)
WATER (UNII: 059QF0KO0R)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
TRIDECYL STEARATE (UNII: A8OE252M6L)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
SHEA BUTTER (UNII: K49155WL9Y)
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CERAMIDE NP (UNII: 4370DF050B)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
DIMETHICONE (UNII: 92RU3N3Y1O)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ981I0)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Part 8 of 24

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (GRANATE SEDUCTOR) - PURPLE

octinoxate and zinc oxide lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Part 9 of 24

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (BORGONA SEXY) - PURPLE
 octinoxate and zinc oxide lipstick

Product Information	
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g
Inactive Ingredients		
Ingredient Name	Strength	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)		
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)		
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)		
CERESIN (UNII: Q1LS2UJO3A)		
WATER (UNII: 059QF0KO0R)		
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)		
TRIDECYL STEARATE (UNII: A8OE252M6L)		
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
GLYCERIN (UNII: PDC6A3C0OX)		
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)		
SHEA BUTTER (UNII: K49155WL9Y)		
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)		
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
PHENOXYETHANOL (UNII: HE492ZZ3T)		
COCONUT OIL (UNII: Q9L0O73W7L)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
CERAMIDE NP (UNII: 4370DF050B)		
CAPRYLYL GLYCOL (UNII: 00YIU5438U)		
CHLORPHENESIN (UNII: I670DAL4SZ)		
DIMETHICONE (UNII: 92RU3N3Y1O)		
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)		
SOYBEAN OIL (UNII: 241ATL177A)		
TOCOPHEROL (UNII: R0ZB2556P8)		
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)		
POTASSIUM CHLORIDE (UNII: 660YQ98I10)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)		
LIMONENE, (+)- (UNII: GFD7C86Q1W)		
LINALOOL, (+/-)- (UNII: D81QY6I88E)		
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)		
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)		
D&C RED NO. 30 (UNII: 2S42T2808B)		
ALUMINUM OXIDE (UNII: LM26O6933)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
MICA (UNII: V8A1AW0880)		
D&C RED NO. 27 (UNII: 2LRS185U6K)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		
D&C RED NO. 7 (UNII: ECW0LZ41X8)		
D&C RED NO. 21 (UNII: 08744Z6JNY)		

TALC (UNII: 7SEV7J4R1U)

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Part 10 of 24

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (FRESA HOT) - PINK

octinoxate and zinc oxide lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CERAMIDE NP (UNII: 4370DF050B)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
DIMETHICONE (UNII: 92RU3N3Y1O)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Part 11 of 24

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (FUCSIA CAUTIVANTE) - PINK

octinoxate and zinc oxide lipstick

Product Information

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ981I0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Part 12 of 24

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (FUCSIA INTENSE) - PINK

octinoxate and zinc oxide 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	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	

TRIDECYL STEARATE (UNII: A8OE252M6L)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
SHEA BUTTER (UNII: K49155WL9Y)
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CERAMIDE NP (UNII: 4370DF050B)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
DIMETHICONE (UNII: 92RU3N3Y1O)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98II0)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Part 13 of 24

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (NARANJA ESFERA) - ORANGE

octinoxate and zinc oxide lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98110)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Part 14 of 24

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (ROSA NUDE) - PINK

octinoxate and zinc oxide 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	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISO STEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98H0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Part 15 of 24**ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (PEACH NUDE) - BROWN**

octinoxate and zinc oxide lipstick

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

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

CERAMIDE NP (UNII: 4370DF050B)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
DIMETHICONE (UNII: 92RU3N3Y1O)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98110)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Part 16 of 24

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (CORAL CHIC) - PINK
 octinoxate and zinc oxide lipstick

Product Information	
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98H0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	

D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Part 17 of 24

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (ROJO TROPICAL) - RED

octinoxate and zinc oxide 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	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	

NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
SHEA BUTTER (UNII: K49155WL9Y)
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CERAMIDE NP (UNII: 4370DF050B)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
DIMETHICONE (UNII: 92RU3N3Y1O)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98H0)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (NARANJA CITRICO) - ORANGE

octinoxate and zinc oxide lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98H0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Part 19 of 24

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (NUDE PUNCH) - ORANGE

octinoxate and zinc oxide 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	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

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

ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)
CERESIN (UNII: Q1LS2UJO3A)
WATER (UNII: 059QF0KO0R)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
TRIDECYL STEARATE (UNII: A8OE252M6L)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
SHEA BUTTER (UNII: K49155WL9Y)
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CERAMIDE NP (UNII: 4370DF050B)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
DIMETHICONE (UNII: 92RU3N3Y1O)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Part 20 of 24

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (MORA ATREVIDA) - PURPLE

octinoxate and zinc oxide 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	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	

SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Part 21 of 24

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (NUDE SAVANNA) - ORANGE

octinoxate and zinc oxide lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ981I0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Part 22 of 24

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (ROJO SENSUAL) - RED

octinoxate and zinc oxide lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CERAMIDE NP (UNII: 4370DF050B)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
DIMETHICONE (UNII: 92RU3N3Y1O)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Part 23 of 24

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (NUDE MOCCHA) - ORANGE
 octinoxate and zinc oxide lipstick

Product Information**Route of Administration**

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Part 24 of 24

ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25 (BRONCE METALLIC) - BROWN

octinoxate and zinc oxide 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	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0K00R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	

HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
SHEA BUTTER (UNII: K49155WL9Y)
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CERAMIDE NP (UNII: 4370DF050B)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
DIMETHICONE (UNII: 92RU3N3Y1O)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
D&C RED NO. 21 (UNII: 08744Z6JNY)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/12/2016	

Labeler - Ventura Corporation LTD DUNS (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-958, 13537-959, 13537-960, 13537-966, 13537-967, 13537-968, 13537-969, 13537-970, 13537-971, 13537-972, 13537-973, 13537-974, 13537-975, 13537-976, 13537-977, 13537-978, 13537-979, 13537-980, 13537-981, 13537-982, 13537-983, 13537-984, 13537-985, 13537-986, 13537-987)

Revised: 11/2018

Ventura Corporation LTD DUNS