

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MARRON GLAMOUR) - BROWN-
octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO DESEO) - RED- octinoxate and
oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO INTRIGANTE) - RED- octinoxate and
oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO LUJURIA) - RED- octinoxate and
oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL CHIC) - PINK- octinoxate and
oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ENCANTO) - PINK- octinoxate and
oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (BORGONA SEXY) - PURPLE- octinoxate
and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA CAUTIVANTE) - PINK- octinoxate
and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (GRANATE SEDUCTOR) - PURPLE-
octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ROMANTICA) - PINK- octinoxate
and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NARANJA PRIMAVERA) - ORANGE-
octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FRAMBUESA MANIA) - RED- octinoxate
and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA DULZURA) - PINK- octinoxate and
oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (PIMIENTA CALIENTE) - BROWN-
octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CANELA NUDE) - ORANGE- octinoxate and
oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MORA GLAM) - BROWN- octinoxate and
oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL INTENSE) - RED- octinoxate and
oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FRESA COQUETA) - RED- octinoxate and
oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (PIMIENTA CALIENTE FEMME) - RED-
octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (GRANATE SEDUCTOR FEMME) - PURPLE-
octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA CAUTIVANTE FEMME) - PINK-
octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ROMANTICA FEMME) - PINK-
octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO INTRIGANTE FEMME) - RED-
octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ENCANTO FEMME) - PINK-
octinoxate and oxybenzone lipstick**

**ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA GEOMETRIC) - PINK- octinoxate and
oxybenzone lipstick**

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA PRISMA) - RED- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NARANJA ESFERA) - ORANGE- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NUDE INFINITO) - BROWN- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO ESIKA) - ORANGE- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MARRON TOPACIO) - BROWN- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA AMATISTA) - RED- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL QUARZO) - ORANGE- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NUDE PRISMA) - BEIGE- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 SPF 25 (DORADO ESENCIAL) - YELLOW- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 SPF 25 (PIMIENTA CALIENTE EXOTIC) - BROWN- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ENCANTO EXOTIC) - PINK- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL CHIC EXOTIC) - PINK- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA CAUTIVANTE EXOTIC) - PINK- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO DESEO EXOTIC) - BROWN- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FRAMBUESA MANIA EXOTIC) - RED- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 SPF 25 (BORGONA SEXY EXOTIC) - PURPLE- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MARRON GLAMOR EXOTIC) - BROWN- octinoxate and oxybenzone lipstick
ESIKA HYDRACOLOR 2 IN 1 SPF 25- octinoxate and oxybenzone
Ventura Corporation LTD

ESIKA HYDRACOLOR 2 IN 1 HIGHLY MOISTURIZING AND COLORING LIPSTICK SPF 25

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
Octinoxate 6.64 %	Sunscreen
Oxybenzone 1.51 %	Sunscreen

Uses

- Helps prevent sunburn.

Warnings

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

Contains Oxybenzone

Directions

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

Other information

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

Inactive ingredients

DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL TRIMELLITATE, ETHYLHEXYL PALMITATE, OZOKERITE, WATER, POLYETHYLENE, TRIDECYL STEARATE, POLYGLYCERYL-3 DIISOSTEARATE, POLYMETHYL METHACRYLATE, COPERNICIA CERIFERA (CARNAUBA) WAX, GLYCERIN, NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE, FRAGRANCE, CAPRYLIC/CAPRIC TRIGLYCERIDE, SODIUM STARCH OCTENYLSUCCINATE, TOCOPHERYL ACETATE, PHENOXYETHANOL, COCOS NUCIFERA (COCONUT) OIL, ALOE BARBADENSIS LEAF EXTRACT, CAPRYLYL GLYCOL, CERAMIDE 3, CHLORPHENESIN, PROPYLENE GLYCOL, LIMONIUM GERBERI EXTRACT, BUTYROSPERMUM PARKII (SHEA) BUTTER, GLYCINE SOJA (SOYBEAN) OIL, TOCOPHEROL, MAGNESIUM CHLORIDE, POTASSIUM CHLORIDE, SILICA, SODIUM CHLORIDE, VITIS VINIFERA (GRAPE) FRUIT EXTRACT. **MAY CONTAIN** :MICA, TITANIUM DIOXIDE, RED 30 LAKE, IRON OXIDES, YELLOW 5 LAKE, RED 21 LAKE, RED 27 LAKE, RED 7 LAKE, TALC, BLUE 1 LAKE, PEG-8 METHYL ETHER TRIETHOXYSILANE, CARMINE.

PRINCIPAL DISPLAY PANEL - Kit Carton

HYDRACOLOR 2 IN 1

Highly Moisturizing and Coloring
LipstickSPF 25

ésika

Net Wt. 0.28 oz. **e**(8 g)



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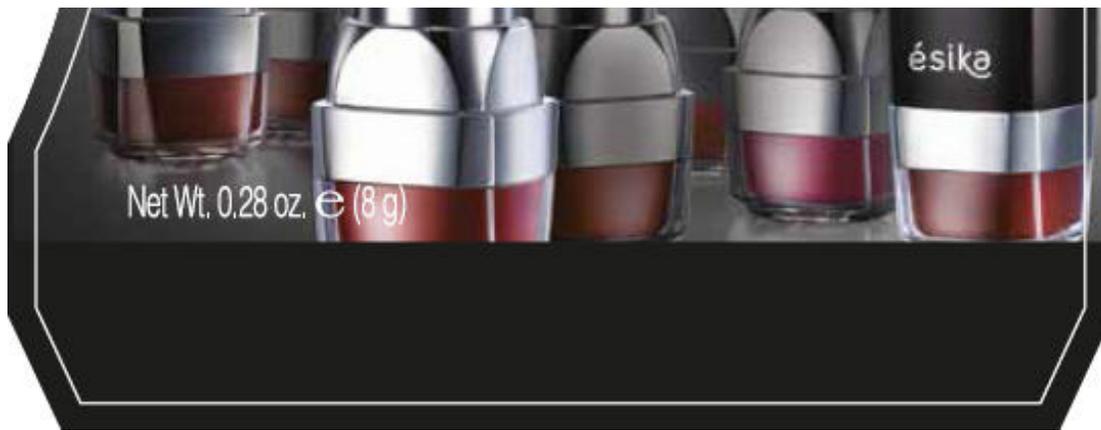
PUERTO RICO: Dist. by Ventura Corp, Ltd., San Juan, Puerto Rico 00926. Made in Colombia.

<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ■ Use a water resistant sunscreen if swimming or sweating. ■ Children under 6 months of age: Ask a doctor. <p>Other Information</p> <ul style="list-style-type: none"> ■ Protect this product in this container from excessive heat and direct sun. <p>Inactive Ingredients DIPENTAERYTHRITYL HEXACAPRYLATE/HEXADecAPRYLATE, ETHYLHEXYL PALMATE, OZOKERITE, WATER, POLYETHYLENE, TRIDECYL STEARATE, POLYGLYCERYL-3 DIISOSTEARATE, POLYMETHYL METHACRYLATE, COPERNICIA CERIFERA (CARNAUBA) WAX, GLYCERIN, NEOPENTYL GLYCOL DICAPRYLATE/DICAPRYLATE, FRAGRANCE, CAPRYLIC/CAPRIC ACETATE, PHENOXYETHANOL, COCOS NUCIFERA (COCONUT) OIL, ALOE BARBADENSIS LEAF EXTRACT, CAPRYLYL GLYCOL, CERAMIDE 3, CHLORPHENESIN, PROPYLENE GLYCOL, LIMONUM GERBERI EXTRACT, BUTYROSPERMIUM PAPII (SHEA) BUTTER, GLYCINE SOJA (SOYBEAN) OIL, TOCOPHEROL, MAGNESIUM CHLORIDE, POTASSIUM CHLORIDE, SILICA, SODIUM CHLORIDE, VITIS VINIFERA (GRAPE) FRUIT EXTRACT, MAY CONTAIN: MICA, TITANIUM DIOXIDE, RED 30 LAKE, IRON OXIDES, YELLOW 5 LAKE, RED 21 LAKE, RED 27 LAKE, RED 7 LAKE, TAUC, BLUE 1 LAKE, PEG-8 METHYL ETHER TRIETHOXYSLANE, CARMINE.</p>	<p>Drug Facts</p> <p>Active IngredientsSunscreen Octinoxate 6.64%,Sunscreen Oxybenzone 1.51%.....Sunscreen</p> <p>Uses</p> <ul style="list-style-type: none"> ■ Helps prevent sunburn. <p>Warnings</p> <ul style="list-style-type: none"> ■ 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. <p>Directions</p> <ul style="list-style-type: none"> ■ Apply liberally and evenly 15 minutes before sun exposure. ■ Reapply at least every 2 hours.
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HYDRACOLOR 2 IN 1
 Highly Moisturizing and Coloring
 Lipstick SPF 25

ésika





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<p>Drug Facts (continued) if swimming or sweating. ■ Children under 6 months of age: Ask a doctor.</p>	<p>Drug Facts (continued) Polyglyceryl-3 Diisostearate, Polymethyl Methacrylate, Copernicia Cerifera (Carnauba) Wax, Glycerin, Neopentyl Glycol Dicaprylate/dicaprate, Fragrance, Caprylic/capric Triglyceride, Sodium Starch Octenylsuccinate, Tocopheryl Acetate, Phenoxyethanol, Cocos Nucifera (Coconut) Oil, Aloe Barbadosis Leaf Extract, Caprylyl Glycol, Caramide 3, Chlorphenesin, Propylene Glycol, Limonium Gerberi Extract, Butyrospermum Parkii (Shea) Butter, Glycine Soja (Soybean) Oil, Tocopherol, Magnesium Chloride, Potassium Chloride.</p>
<p>Other Information ■ Protect the product in this container from excessive heat and direct sun.</p>	
<p>Inactive Ingredients Dipentaerythrityl Hexacaprylate/hexacaprate, Tridecyl Trimellitate, Ethylhexyl Palmitate, Ozokerite, Water, Polyethylene, Tridecyl Stearate.</p>	
<p>Drug Facts (continued) Silica, Sodium Chloride, Vitis Vinifera (Grape) Fruit Extract. May Contain: Mica, Titanium Dioxide, Red 30 Lake, Iron Oxides, Yellow 5 Lake, Red 21 Lake.</p>	<p>Drug Facts (continued) Red 27 Lake, Red 7 Lake, Taic, Blue 1 Lake, Pag-8 Methyl Ether Triethoxysilane, Carmine.</p>
<p>PUERTO RICO: Dist. by Ventura Corp, Ltd., San Juan, Puerto Rico 00926. Made in Colombia. www.esika.biz</p>	
<p>HYDRACOLOR 2 IN 1 Highly Moisturizing and Coloring Lipstick SPF 25 ésika Net Weight 0.14 oz. e (4 g)</p>	
<p>Drug Facts Active IngredientsPurpose OCTINOXATE 6.64%Sunscreen OXYBENZONE 1.51%Sunscreen</p>	<p>Drug Facts (continued) cancer or early skin aging. ■ For external use only. ■ Do not use on damage or broken skin. ■ When using this product keep out of eyes. Rinse with water to remove. ■ 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.</p>
<p>Uses ■ Helps prevent sunburn.</p>	
<p>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</p>	<p>Directions ■ Apply liberally and evenly 15 minutes before sun exposure. ■ Reapply at least every 2 hours. ■ Use a water resistant sunscreen.▲</p>

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Drug Facts (continued)

if swimming or sweating. ■ Children under 6 months of age: Ask a doctor.

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

Inactive Ingredients

Dipentaerythrityl Hexacaprylate/hexacaprate, Tridecyl Trimellitate, Ethylhexyl Palmitate, Ozokerite, Water, Polyethylene, Tridecyl Stearate. ▶

Drug Facts (continued)

Polyglyceryl-3 Diisostearate, Polymethyl Methacrylate, Copernicia Cerifera (Carnauba) Wax, Glycerin, Neopentyl Glycol Dicaprylate/dicaprate, Fragrance, Caprylic/capric Triglyceride, Sodium Starch Octenylsuccinate, Tocopheryl Acetate, Phenoxyethanol, Cocos Nucifera (Coconut) Oil, Aloe Barbadosis Leaf Extract, Caprylyl Glycol, Ceramide 3, Chlorphenesin, Propylene Glycol, Limonium Gerberi Extract, Butyrospermum Parkii (Shea) Butter, Glycine Soja (Soybean) Oil, Tocopherol, Magnesium Chloride, Potassium Chloride. ▼

Drug Facts (continued)

Silica, Sodium Chloride, Vitis Vinifera (Grape) Fruit Extract. May Contain: Mica, Titanium Dioxide, Red 30 Lake, Iron Oxides, Yellow 5 Lake, Red 21 Lake. ▶

Drug Facts (continued)

Red 27 Lake, Red 7 Lake, Talc, Blue 1 Lake, Peg-8 Methyl Ether Triethoxysilane, Carmine.

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

HYDRACOLOR 2 IN 1
Highly Moisturizing and Coloring
Lipstick SPF 25

Net Weight 0.14 oz. e (4 g)

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Drug Facts

Active Ingredients**Purpose**
OCTINOXATE 6.64%Sunscreen
OXYBENZONE 1.51%Sunscreen

Uses ■ Helps prevent sunburn.

Warnings ■ **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin ▶

Drug Facts (continued)

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Directions ■ Apply liberally and evenly 15 minutes before sun exposure. ■ Reapply at least every 2 hours. ■ Use a water resistant sunscreen. ▲

Drug Facts (continued)

if swimming or sweating. ■ Children under 6 months of age: Ask a doctor.

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

Inactive Ingredients

Dipentaerythrityl Hexacaprylate/hexacaprate, Tridecyl Trimellitate, Ethylhexyl Palmitate, Ozokerite, Water, Polyethylene, Tridecyl Stearate.

Drug Facts (continued)

Polyglyceryl-3 Diisostearate, Polymethyl Methacrylate, Copernicia Cerifera (Carnauba) Wax, Glycerin, Neopentyl Glycol Dicaprylate/dicaprate, Fragrance, Caprylic/capric Triglyceride, Sodium Starch Octenylsuccinate, Tocopheryl Acetate, Phenoxyethanol, Cocos Nucifera (Coconut) Oil, Aloe Barbadosis Leaf Extract, Caprylyl Glycol, Ceramide 3, Chlorphenesin, Propylene Glycol, Limonium Gerberi Extract, Butyrospermum Parkii (Shea) Butter, Glycine Soja (Soybean) Oil, Tocopherol, Magnesium Chloride, Potassium Chloride.

Drug Facts (continued)

Silica, Sodium Chloride, Vitis Vinifera (Grape) Fruit Extract. May Contain: Mica, Titanium Dioxide, Red 30 Lake, Iron Oxides, Yellow 5 Lake, Red 21 Lake.

Drug Facts (continued)

Red 27 Lake, Red 7 Lake, Talc, Blue 1 Lake, Peg-8 Methyl Ether Triethoxysilane, Carmine.

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HYDRACOLOR 2 IN 1
Highly Moisturizing and Coloring
Lipstick SPF 25

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Drug Facts (continued)

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Inactive Ingredients

Dipentaerythrityl Hexacaprylate/hexacaprate, Tridecyl Trimellitate, Ethylhexyl Palmitate, Ozokerite, Water, Polyethylene, Tridecyl Stearate. ▶

Drug Facts (continued)

Polyglyceryl-3 Diisostearate, Polymethyl Methacrylate, Copernicia Cerifera (Carnauba) Wax, Glycerin, Neopentyl Glycol Dicaprylate/dicaprate, Fragrance, Caprylic/capric Triglyceride, Sodium Starch Octenylsuccinate, Tocopheryl Acetate, Phenoxyethanol, Cocos Nucifera (Coconut) Oil, Aloe Barbadosis Leaf Extract, Caprylyl Glycol, Ceramide 3, Chlorphenesin, Propylene Glycol, Limonium Gerberi Extract, Butyrospermum Parkii (Shea) Butter, Glycine Soja (Soybean) Oil, Tocopherol, Magnesium Chloride, Potassium Chloride. ▼

Drug Facts (continued)

Silica, Sodium Chloride, Vitis Vinifera (Grape) Fruit Extract. May Contain: Mica, Titanium Dioxide, Red 30 Lake, Iron Oxides, Yellow 5 Lake, Red 21 Lake. ▶

Drug Facts (continued)

Red 27 Lake, Red 7 Lake, Talc, Blue 1 Lake, Peg-8 Methyl Ether Triethoxysilane, Carmine.

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Lipstick SPF 25

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Drug Facts (continued)

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Drug Facts (continued)

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Drug Facts (continued)

Silica, Sodium Chloride, Vitis Vinifera (Grape) Fruit Extract. **May Contain:** Mica, Titanium Dioxide, Red 30 Lake, Iron Oxides, Yellow 5 Lake, Red 21 Lake. ▶

Drug Facts (continued)

Red 27 Lake, Red 7 Lake, Talc, Blue 1 Lake, Peg-8 Methyl Ether Triethoxysilane, Carmine.

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Drug Facts (continued)

Silica, Sodium Chloride, Vitis Vinifera (Grape) Fruit Extract. May Contain: Mica, Titanium Dioxide, Red 30 Lake, Iron Oxides, Yellow 5 Lake, Red 21 Lake. ▶

Drug Facts (continued)

Red 27 Lake, Red 7 Lake, Talc, Blue 1 Lake, Peg-8 Methyl Ether Triethoxysilane, Carmine.

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Drug Facts (continued)

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Highly Moisturizing and Coloring
Lipstick SPF 25

Net Weight 0.14 oz. e (4 g)

ésika

Drug Facts

Active Ingredients**Purpose**
OCTINOXATE 6.64%Sunscreen
OXYBENZONE 1.51%Sunscreen

Uses ■ Helps prevent sunburn.

Warnings ■ **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin

Drug Facts (continued)

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

Drug Facts (continued)

if swimming or sweating. ■ Children under 6 months of age: Ask a doctor.

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

Inactive Ingredients

Dipentaerythrityl Hexacaprylate/hexacaprate, Tridecyl Trimellitate, Ethylhexyl Palmitate, Ozokerite, Water, Polyethylene, Tridecyl Stearate.

Drug Facts (continued)

Polyglyceryl-3 Diisostearate, Polymethyl Methacrylate, Copernicia Cerifera (Carnauba) Wax, Glycerin, Neopentyl Glycol Dicaprylate/dicaprate, Fragrance, Caprylic/capric Triglyceride, Sodium Starch Octenylsuccinate, Tocopheryl Acetate, Phenoxyethanol, Cocos Nucifera (Coconut) Oil, Aloe Barbadosis Leaf Extract, Caprylyl Glycol, Ceramide 3, Chlorphenesin, Propylene Glycol, Limonium Gerberi Extract, Butyrospermum Parkii (Shea) Butter, Glycine Soja (Soybean) Oil, Tocopherol, Magnesium Chloride, Potassium Chloride.

Drug Facts (continued)

Silica, Sodium Chloride, Vitis Vinifera (Grape) Fruit Extract. May Contain: Mica, Titanium Dioxide, Red 30 Lake, Iron Oxides, Yellow 5 Lake, Red 21 Lake.

Drug Facts (continued)

Red 27 Lake, Red 7 Lake, Talc, Blue 1 Lake, Peg-8 Methyl Ether Triethoxysilane, Carmine.

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Drug Facts (continued)

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Dipentaerythrityl Hexacaprylate/hexacaprate, Tridecyl Trimellitate, Ethylhexyl Palmitate, Ozokerite, Water, Polyethylene, Tridecyl Stearate. ▶

Drug Facts (continued)

Polyglyceryl-3 Diisostearate, Polymethyl Methacrylate, Copernicia Cerifera (Carnauba) Wax, Glycerin, Neopentyl Glycol Dicaprylate/dicaprate, Fragrance, Caprylic/capric Triglyceride, Sodium Starch Octenylsuccinate, Tocopheryl Acetate, Phenoxyethanol, Cocos Nucifera (Coconut) Oil, Aloe Barbadosis Leaf Extract, Caprylyl Glycol, Ceramide 3, Chlorphenesin, Propylene Glycol, Limonium Gerberi Extract, Butyrospermum Parkii (Shea) Butter, Glycine Soja (Soybean) Oil, Tocopherol, Magnesium Chloride, Potassium Chloride. ▼

Drug Facts (continued)

Silica, Sodium Chloride, Vitis Vinifera (Grape) Fruit Extract. May Contain: Mica, Titanium Dioxide, Red 30 Lake, Iron Oxides, Yellow 5 Lake, Red 21 Lake. ▶

Drug Facts (continued)

Red 27 Lake, Red 7 Lake, Talc, Blue 1 Lake, Peg-8 Methyl Ether Triethoxysilane, Carmine.

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

HYDRACOLOR 2 IN 1
Highly Moisturizing and Coloring
Lipstick SPF 25

Net Weight 0.14 oz. e (4 g)

ésika

Drug Facts

Active Ingredients**Purpose**
OCTINOXATE 6.64%Sunscreen
OXYBENZONE 1.51%Sunscreen

Uses ■ Helps prevent sunburn.

Warnings ■ **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin ▶

Drug Facts (continued)

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

Drug Facts (continued)

if swimming or sweating. ■ Children under 6 months of age: Ask a doctor.

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

Inactive Ingredients

Dipentaerythrityl Hexacaprylate/hexacaprate, Tridecyl Trimellitate, Ethylhexyl Palmitate, Ozokerite, Water, Polyethylene, Tridecyl Stearate. ▶

Drug Facts (continued)

Polyglyceryl-3 Diisostearate, Polymethyl Methacrylate, Copernicia Cerifera (Carnauba) Wax, Glycerin, Neopentyl Glycol Dicaprylate/dicaprate, Fragrance, Caprylic/capric Triglyceride, Sodium Starch Octenylsuccinate, Tocopheryl Acetate, Phenoxyethanol, Cocos Nucifera (Coconut) Oil, Aloe Barbadosis Leaf Extract, Caprylyl Glycol, Ceramide 3, Chlorphenesin, Propylene Glycol, Limonium Gerberi Extract, Butyrospermum Parkii (Shea) Butter, Glycine Soja (Soybean) Oil, Tocopherol, Magnesium Chloride, Potassium Chloride. ▼

Drug Facts (continued)

Silica, Sodium Chloride, Vitis Vinifera (Grape) Fruit Extract. May Contain: Mica, Titanium Dioxide, Red 30 Lake, Iron Oxides, Yellow 5 Lake, Red 21 Lake. ▶

Drug Facts (continued)

Red 27 Lake, Red 7 Lake, Talc, Blue 1 Lake, Peg-8 Methyl Ether Triethoxysilane, Carmine.

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Drug Facts (continued)

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Drug Facts (continued)

if swimming or sweating. ■ Children under 6 months of age: Ask a doctor.

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

Inactive Ingredients

Dipentaerythrityl Hexacaprylate/hexacaprate, Tridecyl Trimellitate, Ethylhexyl Palmitate, Ozokerite, Water, Polyethylene, Tridecyl Stearate. ▶

Drug Facts (continued)

Polyglyceryl-3 Diisostearate, Polymethyl Methacrylate, Copernicia Cerifera (Carnauba) Wax, Glycerin, Neopentyl Glycol Dicaprylate/dicaprate, Fragrance, Caprylic/capric Triglyceride, Sodium Starch Octenylsuccinate, Tocopheryl Acetate, Phenoxyethanol, Cocos Nucifera (Coconut) Oil, Aloe Barbadosis Leaf Extract, Caprylyl Glycol, Ceramide 3, Chlorphenesin, Propylene Glycol, Limonium Gerberi Extract, Butyrospermum Parkii (Shea) Butter, Glycine Soja (Soybean) Oil, Tocopherol, Magnesium Chloride, Potassium Chloride. ▼

Drug Facts (continued)

Silica, Sodium Chloride, Vitis Vinifera (Grape) Fruit Extract. **May Contain:** Mica, Titanium Dioxide, Red 30 Lake, Iron Oxides, Yellow 5 Lake, Red 21 Lake. ▶

Drug Facts (continued)

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Drug Facts (continued)

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Drug Facts (continued)

if swimming or sweating. ■ Children under 6 months of age: Ask a doctor.

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

Inactive Ingredients

Dipentaerythrityl Hexacaprylate/hexacaprate, Tridecyl Trimellitate, Ethylhexyl Palmitate, Ozokerite, Water, Polyethylene, Tridecyl Stearate.

Drug Facts (continued)

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Drug Facts (continued)

Silica, Sodium Chloride, Vitis Vinifera (Grape) Fruit Extract. May Contain: Mica, Titanium Dioxide, Red 30 Lake, Iron Oxides, Yellow 5 Lake, Red 21 Lake.

Drug Facts (continued)

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Inactive Ingredients

Dipentaerythrityl Hexacaprylate/hexacaprate, Tridecyl Trimellitate, Ethylhexyl Palmitate, Ozokerite, Water, Polyethylene, Tridecyl Stearate.

Drug Facts (continued)

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Drug Facts (continued)

Silica, Sodium Chloride, Vitis Vinifera (Grape) Fruit Extract. May Contain: Mica, Titanium Dioxide, Red 30 Lake, Iron Oxides, Yellow 5 Lake, Red 21 Lake.

Drug Facts (continued)

Red 27 Lake, Red 7 Lake, Talc, Blue 1 Lake, Peg-8 Methyl Ether Triethoxysilane, Carmine.

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Lipstick SPF 25

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Drug Facts (continued)

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Drug Facts (continued)

Silica, Sodium Chloride, Vitis Vinifera (Grape) Fruit Extract. May Contain: Mica, Titanium Dioxide, Red 30 Lake, Iron Oxides, Yellow 5 Lake, Red 21 Lake. ▶

Drug Facts (continued)

Red 27 Lake, Red 7 Lake, Talc, Blue 1 Lake, Peg-8 Methyl Ether Triethoxysilane, Carmine.

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Drug Facts (continued)

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Drug Facts (continued)

Silica, Sodium Chloride, Vitis Vinifera (Grape) Fruit Extract. May Contain: Mica, Titanium Dioxide, Red 30 Lake, Iron Oxides, Yellow 5 Lake, Red 21 Lake. ▶

Drug Facts (continued)

Red 27 Lake, Red 7 Lake, Talc, Blue 1 Lake, Peg-8 Methyl Ether Triethoxysilane, Carmine.

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Drug Facts (continued)

Silica, Sodium Chloride, Vitis Vinifera (Grape) Fruit Extract. May Contain: Mica, Titanium Dioxide, Red 30 Lake, Iron Oxides, Yellow 5 Lake, Red 21 Lake.

Drug Facts (continued)

Red 27 Lake, Red 7 Lake, Talc, Blue 1 Lake, Peg-8 Methyl Ether Triethoxysilane, Carmine.

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Drug Facts (continued)

Silica, Sodium Chloride, Vitis Vinifera (Grape) Fruit Extract. May Contain: Mica, Titanium Dioxide, Red 30 Lake, Iron Oxides, Yellow 5 Lake, Red 21 Lake. ▶

Drug Facts (continued)

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Drug Facts (continued)

Silica, Sodium Chloride, Vitis Vinifera (Grape) Fruit Extract. May Contain: Mica, Titanium Dioxide, Red 30 Lake, Iron Oxides, Yellow 5 Lake, Red 21 Lake.

Drug Facts (continued)

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Drug Facts (continued)

Silica, Sodium Chloride, Vitis Vinifera (Grape) Fruit Extract. **May Contain:** Mica, Titanium Dioxide, Red 30 Lake, Iron Oxides, Yellow 5 Lake, Red 21 Lake. ▶

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OXYBENZONE 1.51%Sunscreen

Uses ■ Helps prevent sunburn.

Warnings ■ **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin

Drug Facts (continued)

cancer or early skin aging. ■ **For external use only.** ■ **Do not use on damage or broken skin.** ■ **When using this product keep out of eyes.** ■ **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.** ▲

Drug Facts (continued)

if swimming or sweating. ■ Children under 6 months of age: Ask a doctor.

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

Inactive Ingredients

Dipentaerythrityl Hexacaprylate/hexacaprate, Tridecyl Trimellitate, Ethylhexyl Palmitate, Ozokerite, Water, Polyethylene, Tridecyl Stearate.

Drug Facts (continued)

Polyglyceryl-3 Diisostearate, Polymethyl Methacrylate, Copernicia Cerifera (Carnauba) Wax, Glycerin, Neopentyl Glycol Dicaprylate/dicaprate, Fragrance, Caprylic/capric Triglyceride, Sodium Starch Octenylsuccinate, Tocopheryl Acetate, Phenoxyethanol, Cocos Nucifera (Coconut) Oil, Aloe Barbadosis Leaf Extract, Caprylyl Glycol, Ceramide 3, Chlorphenesin, Propylene Glycol, Limonium Gerberi Extract, Butyrospermum Parkii (Shea) Butter, Glycine Soja (Soybean) Oil, Tocopherol, Magnesium Chloride, Potassium Chloride.

Drug Facts (continued)

Silica, Sodium Chloride, Vitis Vinifera (Grape) Fruit Extract. May Contain: Mica, Titanium Dioxide, Red 30 Lake, Iron Oxides, Yellow 5 Lake, Red 21 Lake.

Drug Facts (continued)

Red 27 Lake, Red 7 Lake, Talc, Blue 1 Lake, Peg-8 Methyl Ether Triethoxysilane, Carmine.

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

HYDRACOLOR 2 IN 1
Highly Moisturizing and Coloring
Lipstick SPF 25

Net Weight 0.14 oz. e (4 g)

ésika

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ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MARRON GLAMOUR) - BROWN

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-590
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength

DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWW)
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
ETHYLHEXYL PALMITATE (UNII: 2865993309)
WATER (UNII: 059QF0KO0R)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: ROZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-590-02	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-590-01	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO DESEO) - RED

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-591
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	

MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-591-04	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-591-03	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO INTRIGANTE) - RED

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-592
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	

HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-592-06	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-592-05	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO LUJURIA) - RED

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-593
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

FERRIC OXIDE RED (UNII: 1K09F3G675)

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

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

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

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

TALC (UNII: 7SEV7J4R1U)

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-593-08	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-593-07	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL CHIC) - PINK

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-594
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

GLYCERIN (UNII: PDC6A3C00X)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: ROZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-594-10	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-594-09	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ENCANTO) - PINK

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-595
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

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

TALC (UNII: 7SEV7J4R1U)

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-595-12	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-595-11	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (BORGONA SEXY) - PURPLE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-596
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-596-14	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-596-13	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA CAUTIVANTE) - PINK

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-597
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KOOR)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-597-16	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-597-15	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (GRANATE SEDUCTOR) - PURPLE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-598
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: ROZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-598-18	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-598-17	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ROMANTICA) - PINK

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-599
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-599-20	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-599-19	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NARANJA PRIMAVERA) - ORANGE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-609
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	

CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: ROZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECWOLZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-609-22	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-609-21	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FRAMBUESA MANIA) - RED

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-610
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	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4S2)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:13537-610-24	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-610-23	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA DULZURA) - PINK

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-611
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KOOR)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	

SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-611-24	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-611-23	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (PIMIENTA CALIENTE) - BROWN

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-612
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-612-24	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-612-23	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CANELA NUDE) - ORANGE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-613
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-613-24	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-613-23	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MORA GLAM) - BROWN

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-614
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	

TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
ETHYLHEXYL PALMITATE (UNII: 2865993309)
WATER (UNII: 059QF0KO0R)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: ROZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-614-24	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-614-23	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL INTENSE) - RED

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-615
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-615-24	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-615-23	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FRESA COQUETA) - RED

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-616
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-616-24	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-616-23	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (PIMIENTA CALIENTE FEMME) - RED

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-617
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

FERRIC OXIDE RED (UNII: 1K09F3G675)

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

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

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

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

TALC (UNII: 7SEV7J4R1U)

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-617-24	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-617-23	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (GRANATE SEDUCTOR FEMME) - PURPLE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-618
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	

CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-618-24	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-618-23	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA CAUTIVANTE FEMME) -

PINK

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-619
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

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

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-619-24	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-619-23	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ROMANTICA FEMME) - PINK

octinoxate and oxybenzone lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-620
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-620-24	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-620-23	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO INTRIGANTE FEMME) - RED

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-621
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

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

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

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

TALC (UNII: 7SEV7J4R1U)

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-621-24	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-621-23	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ENCANTO FEMME) - PINK

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-622
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-622-24	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-622-23	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA GEOMETRIC) - PINK

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-623
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KOOR)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-623-24	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-623-23	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA PRISMA) - RED

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-624
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H90)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-624-24	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-624-23	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NARANJA ESFERA) - ORANGE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-664
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-664-24	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-664-23	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NUDE INFINITO) - BROWN

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-665
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	

CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-665-24	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-665-23	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO ESIKA) - ORANGE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-666
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	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC: 12527-666			

1	NDC:13537-666-24	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-666-23	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MARRON TOPACIO) - BROWN

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-667
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KOOR)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	

SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-667-24	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-667-23	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA AMATISTA) - RED

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-668
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-668-24	1 in 1 BOX	11/23/2015	12/31/2021
1	NDC:13537-668-23	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 Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL QUARZO) - ORANGE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-691
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-691-24	1 in 1 BOX	12/18/2015	12/31/2021
1	NDC:13537-691-23	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 Drug	M020	12/18/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NUDE PRISMA) - BEIGE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-692
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	

TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
ETHYLHEXYL PALMITATE (UNII: 2865993309)
WATER (UNII: 059QF0KO0R)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: ROZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-692-24	1 in 1 BOX	12/18/2015	12/31/2021
1	NDC:13537-692-23	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC Monograph Drug	M020	12/18/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (DORADO ESENCIAL) - YELLOW

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-693
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-693-24	1 in 1 BOX	12/18/2015	12/31/2021
1	NDC:13537-693-23	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 Drug	M020	12/18/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (PIMIENTA CALIENTE EXOTIC) - BROWN

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-694
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	

HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-694-24	1 in 1 BOX	12/18/2015	12/31/2021
1	NDC:13537-694-23	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 Drug	M020	12/18/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ENCANTO EXOTIC) - PINK

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-695
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

FERRIC OXIDE RED (UNII: 1K09F3G675)

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

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

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

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

TALC (UNII: 7SEV7J4R1U)

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-695-24	1 in 1 BOX	12/18/2015	12/31/2021
1	NDC:13537-695-23	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 Drug	M020	12/18/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL CHIC EXOTIC) - PINK

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-696
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-696-24	1 in 1 BOX	12/18/2015	12/31/2021
1	NDC:13537-696-23	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 Drug	M020	12/18/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA CAUTIVANTE EXOTIC) - PINK

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-697
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

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

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

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

TALC (UNII: 7SEV7J4R1U)

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-697-24	1 in 1 BOX	12/18/2015	12/31/2021
1	NDC:13537-697-23	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 Drug	M020	12/18/2015	

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO DESEO EXOTIC) - BROWN

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-698
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-698-24	1 in 1 BOX	12/18/2015	12/31/2021
1	NDC:13537-698-23	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 Drug	M020	12/18/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FRAMBUESA MANIA EXOTIC) - RED

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-699
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	

TALC (UNII: 7SEV7J4R1U)

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-699-24	1 in 1 BOX	12/18/2015	12/31/2021
1	NDC:13537-699-23	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 Drug	M020	12/18/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (BORGONA SEXY EXOTIC) - PURPLE

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-700
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: ROZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-700-24	1 in 1 BOX	12/18/2015	12/31/2021
1	NDC:13537-700-23	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 Drug	M020	12/18/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MARRON GLAMOR EXOTIC) - BROWN

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-701
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-701-24	1 in 1 BOX	12/18/2015	12/31/2021
1	NDC:13537-701-23	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 Drug	M020	12/18/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25

octinoxate and oxybenzone kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-669
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-669-28	2 in 1 BOX	08/25/2015	12/31/2021
1	NDC:13537-669-27	1 in 1 TUBE; Type 0: Not a Combination Product		

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

Part 1 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NARANJA ESFERA) - ORANGE

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KOOR)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

Part 2 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NUDE INFINITO) - BROWN

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

Part 3 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO ESIKA) - ORANGE

octinoxate and oxybenzone lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	

TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
ETHYLHEXYL PALMITATE (UNII: 2865993309)
WATER (UNII: 059QF0KO0R)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

Part 4 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MARRON TOPACIO) - BROWN

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECWOLZ41X8)	
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 Drug	M020	11/23/2015	12/31/2021

Part 5 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA AMATISTA) - RED

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	

HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

Part 6 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL QUARZO) - ORANGE

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)

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 Drug	M020	12/18/2015	12/31/2021

Part 7 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NUDE PRISMA) - BEIGE

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	

POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49I55WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/18/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (DORADO ESENCIAL) - YELLOW

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLV429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

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

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/18/2015	12/31/2021

Part 9 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (PIMIENTA CALIENTE EXOTIC) - BROWN

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	

CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: ROZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/18/2015	12/31/2021

Part 10 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ENCANTO EXOTIC) -

PINK

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

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

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

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/18/2015	12/31/2021

Part 11 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL CHIC EXOTIC) - PINK
 octinoxate and oxybenzone lipstick

Product Information	
Route of Administration	TOPICAL

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

Inactive Ingredients	
Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/18/2015	12/31/2021

Part 12 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA CAUTIVANTE EXOTIC) - PINK

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49I55WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

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

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

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

TALC (UNII: 7SEV7J4R1U)

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

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/18/2015	12/31/2021

Part 13 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO DESEO EXOTIC) - BROWN

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/18/2015	12/31/2021

Part 14 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FRAMBUESA MANIA EXOTIC) - RED

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49I55WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

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

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

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

TALC (UNII: 7SEV7J4R1U)

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

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/18/2015	12/31/2021

Part 15 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (BORGONA SEXY EXOTIC) - PURPLE

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/18/2015	12/31/2021

Part 16 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MARRON GLAMOR EXOTIC) - BROWN

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49I55WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

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

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

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

TALC (UNII: 7SEV7J4R1U)

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

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/18/2015	12/31/2021

Part 17 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MARRON GLAMOUR) - BROWN

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWW)
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
ETHYLHEXYL PALMITATE (UNII: 2865993309)

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 Drug	M020	11/23/2015	12/31/2021

Part 18 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO DESEO) - RED

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: ROZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	

TALC (UNII: 7SEV7J4R1U)

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

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

Part 19 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO INTRIGANTE) - RED

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

Part 20 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO LUJURIA) - RED

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KOOR)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

Part 21 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL CHIC) - PINK

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

Part 22 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ENCANTO) - PINK

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: ROZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

Part 23 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (BORGONA SEXY) - PURPLE

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4S2)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: ROZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

Part 24 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCCIA CAUTIVANTE) - PINK

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

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

OXYBENZONE

0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2025

Part 25 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (GRANATE SEDUCTOR) - PURPLE

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	

SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

Part 26 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ROMANTICA) - PINK

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

Part 27 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (NARANJA PRIMAVERA) - ORANGE

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: ROZB2556P8)	

MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

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ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FRAMBUESA MANIA) - RED

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49I55WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

Part 29 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA DULZURA) - PINK

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

Part 30 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (PIMIENTA CALIENTE) - BROWN
 octinoxate and oxybenzone lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	

TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
ETHYLHEXYL PALMITATE (UNII: 2865993309)
WATER (UNII: 059QF0KO0R)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

Part 31 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CANELA NUDE) - ORANGE

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

Part 32 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (MORA GLAM) - BROWN

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	

HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
TRIDECYL STEARATE (UNII: A8OE252M6L)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

Part 33 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (CORAL INTENSE) - RED

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLV429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

Part 34 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FRESA COQUETA) - RED

octinoxate and oxybenzone lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	

POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (PIMIENTA CALIENTE FEMME) - RED

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

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

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

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ESIKA HYDRACOLOR 2 IN 1 SPF 25 (GRANATE SEDUCTOR FEMME) - PURPLE

octinoxate and oxybenzone lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	

POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA CAUTIVANTE FEMME) - PINK

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

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

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

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ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ROMANTICA FEMME) - PINK

octinoxate and oxybenzone lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	

POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROJO INTRIGANTE FEMME) - RED

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

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

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

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ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA ENCANTO FEMME) - PINK

octinoxate and oxybenzone lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	

POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
WINE GRAPE (UNII: 3GOV20705G)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (ROSA GEOMETRIC) - PINK

octinoxate and oxybenzone lipstick

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLV429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WINE GRAPE (UNII: 3GOV20705G)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

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

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

Part 42 of 42

ESIKA HYDRACOLOR 2 IN 1 SPF 25 (FUCSIA PRISMA) - RED

octinoxate and oxybenzone lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
WATER (UNII: 059QF0KO0R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
COCONUT OIL (UNII: Q9L0O73W7L)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CERAMIDE 3 (UNII: 4370DF050B)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHEA BUTTER (UNII: K49155WL9Y)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
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D&C RED NO. 21 (UNII: 08744Z6JNY)
D&C RED NO. 27 (UNII: 2LRS185U6K)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/23/2015	12/31/2021

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/25/2015	12/31/2021

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	manufacture(13537-590, 13537-591, 13537-592, 13537-593, 13537-594, 13537-595, 13537-596, 13537-597, 13537-598, 13537-599, 13537-609, 13537-610, 13537-611, 13537-612, 13537-613, 13537-614, 13537-615, 13537-616, 13537-617, 13537-618, 13537-619, 13537-620, 13537-621, 13537-622, 13537-623, 13537-624, 13537-664, 13537-665, 13537-666, 13537-667, 13537-668, 13537-669, 13537-691, 13537-692, 13537-693, 13537-694, 13537-695, 13537-696, 13537-697, 13537-698, 13537-699, 13537-700, 13537-701)

Revised: 11/2025

Ventura Corporation LTD