

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 VINO CAUTIVANTE - PURPLE- octinoxate lipstick
ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 PIMIENTA CALIENTE - RED- octinoxate lipstick
ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 ROJO GLAM - RED- octinoxate lipstick
ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 ROJO PASION - RED- octinoxate lipstick
ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 VINO DESEO - PURPLE- octinoxate lipstick
ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 FUCSIA TENTACION - PINK- octinoxate lipstick
ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 FUCSIA DELIRIO - PINK- octinoxate lipstick
ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 FUCSIA VIBRANTE - PINK- octinoxate lipstick
ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 ROSA VIVA - PINK- octinoxate lipstick
ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 CORAL ENSUENO - RED- octinoxate lipstick
ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 MARRON BAMBU - BROWN- octinoxate lipstick
ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 ROSA FIORELLE - PINK- octinoxate lipstick
ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 NATURAL DUNE - BEIGE- octinoxate lipstick
ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 ROJO FIESTA - RED- octinoxate lipstick
ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 NUDE CREAM - BEIGE- octinoxate lipstick
ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 NUDE MOCCHA - BEIGE- octinoxate lipstick
ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 FUCSIA SUBLIME - PINK- octinoxate lipstick
ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 MARRON HAVANA - BROWN- octinoxate lipstick
ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 MARRON FANATIC - BROWN- octinoxate lipstick
ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 NUDE ROSE- BEIGE- octinoxate lipstick
ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20- octinoxate

Ventura Corporation LTD

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

Ésika PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR LIPSTICK SPF 20

Drug Facts

Active Ingredients

OCTINOXATE 6.8%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.

Warnings

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

Directions

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

Other information

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

Inactive ingredients

DIISOPROPYL DIMER DILINOLEATE, TRIDECYL TRIMELLITATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, POLYETHYLENE, OCTYLDODECANOL, CASTOR ISOSTEARATE BEESWAX SUCCINATE, ISOPROPYL LANOLATE, POLYGLYCERYL-3 DIISOSTEARATE, COPERNICIA CERIFERA (CARNAUBA) WAX, MICROCRYSTALLINE WAX, DIISOSTEARYL MALATE, MICA, ISODODECANE, POLYMETHYLSILSESQUIOXANE/TRIMETHYLSILOXYSILICATE, PHENOXYETHANOL, CETYL PEG/PPG-10/1 DIMETHICONE, POLYGLYCERYL-4 ISOSTEARATE, SILICA, SILICA Silylate, HEXYL LAURATE, METHYLPROPANEDIOL, FRAGRANCE, CAPRYLYL GLYCOL, CHLORPHENESIN, CERAMIDE 3, SILANEDIOL SALICYLATE, TOCOPHERYL ACETATE, OLEYL ALCOHOL, DIMETHICONE, TROMETHAMINE, BENZIMIDAZOLE DIAMOND AMIDOETHYL UREA CARBAMOYL PROPYL POLYMETHYLSILSESQUIOXANE, TRIMETHYLSILOXYSILICATE, DIOLEYL TOCOPHERYL METHYLSILANOL, ALPHA-ISOMETHYL IONONE, d-LIMONENE, LINALOOL, AMYL CINNAMAL, CITRONELLOL. **MAY CONTAIN:** IRON OXIDES (CI 77491), TITANIUM DIOXIDE (CI 77891), RED 30 LAKE (CI

73360), MICA (CI 77019), RED 27 LAKE (CI 45410), YELLOW 5 LAKE (CI 19140), RED 21 LAKE (CI 45380), RED 7 LAKE (CI 15850), IRON OXIDES (CI 77492), IRON OXIDES (CI 77499), TALC, BLUE 1 LAKE (CI 42090).

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

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - VINO CAUTIVANTE - PURPLE

ésika

PRO

HD LONGWEAR

Long-lasting
high-definition
color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

Drug Facts (continued)

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure. ▶

Drug Facts (continued)

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

Other Information

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

Drug Facts (continued)

Inactive Ingredients: Dilauropropyl dimer citriololate, triethyl trimellitate, caprylic/capric triglyceride, polyethylene, cyclohexanone, castor seed sterate beeswax succinate, isopropyl alcohol, polyglyceryl-3 distearate, copernicia cerifera (carnauba) wax, microcrystalline wax, bisisostearyl malate, isodecylate, polydimethylsiloxane, triethylcitrate, polypropylene glycol, sodium lauryl sulfate, glyceryl stearate, polypropylene glycol, chlorphenesin, carmellose, silandiol salicylate, tocopheryl acetate, glyceryl alcohol, dimethylsiloxane, tetramethylsiloxane, benzimidazole ▶

Drug Facts (continued)

diamond amidebutyl urea carbonyl propyl polymethyl methacrylate, trimethylsilylate, diethyl hexylenediol, ethyl hexyl dimethyl siloxane, 4-methylbenzyl, amylopalmitate, zinc octadecanoate (ci 7790), iron oxides (ci 7789), titanium dioxide (ci 7789), red 27 lake (ci 77490), red 21 lake (ci 77489), red 7 lake (ci 15525), iron oxides (ci 77489), iron oxides (ci 77489), lake blue 1 lake (ci 42050).

HD LONGWEAR
Long-lasting
high-definition
color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

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

ésika
PRO

Drug Facts

Active Ingredients Purpose

OCTINOXATE 6.8% Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin cancer ▶

Drug Facts (continued)

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. ▶

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - PIMIENTA CALIENTE - RED

ésika

PRO

HD LONGWEAR

Long-lasting

high-definition

color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - ROJO GLAM - RED

ésika
PRO

HD LONGWEAR

Long-lasting
high-definition
color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

Drug Facts (continued)

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure. ▶

Drug Facts (continued)

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

Other Information

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

Drug Facts (continued)

Inactive Ingredients: Diisopropyl dimethylolmaleate, triethyl trimellitate, caprylic/capric triglyceride, polyethylene, cyclohexaneol, castor sesquiterate beeswax succinate, isopropyl lanolate, polyglyceryl-3 distostearate, copermycin caprylate (ceramide) wax, microcrystalline wax, tisserney maleic anhydride, polyethylene glycol 1000, dimethylsiloxylmethoxy dimethyl siloxane crosspolymer, isopropyl laurate, caprylic/capric triglyceride, polyisobutyl methacrylate, chlorphenesin, carbonyl diethanolamine, tocopheryl acetate, oleyl alcohol, dimethylsiloxane, tetramethylammonium benzimidazole ▶

Drug Facts (continued)

diamand ambodol, urea, carbamoyl propyl polymethylsiloxoxane, trimethylsilylsilicate, oleyl tocopheryl linoleyl succinate, alpha-squalene, 4-methylbenzyl alcohol, amyloamylose, caprylyl myristyl celastrol, polybutene-1, octyl tetrahydrofuran-3-yl methacrylate (C1751), iron oxides (C17719), titanium dioxide (C17720), iron oxides (C19140), red 27 lake (C15380), red 7 lake (C15381), iron oxides (C17182), iron oxides (C17183), blue 1 lake (C142950). ▶

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

ésika
PRO

HD LONGWEAR
Long-lasting
high-definition
color lipstick SPF 20

Net Wt. 0.14 oz. e (4g)

Drug Facts

Active Ingredients **Purpose**
OCTINOXATE 6.8% Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer ▶

Drug Facts (continued)

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. ▶

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - ROJO PASIÓN - RED

ésika
PRO

HD LONGWEAR

Long-lasting
high-definition
color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

Drug Facts (continued)

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure. ▶

Drug Facts (continued)

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

Other Information

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

Drug Facts (continued)

Inactive Ingredients: Diisopropyl dimethyl mallete, triethyl trimellitate, caprylyl capric triglyceride, polyethylene, cyclohexanone, castor isostearate beeswax succinate, isopropyl myristate, polyglyceryl-3 distostearate, copermidia cetilera (ceramide) wax, microcrystalline wax, bisisobutyl malate, isododecane, polymethylsqualene, diethylhexyl succinate, polybutene-1, dimethyl dimethylsiloxane, polyglyceryl-3 stearate, methyl methacrylate, chlorophenol, carbonyl diethanolamine, ethylhexyl glycol, chlorophenol, carbonyl diethanolamine, benzimidazole, ethyl alcohol, dimethylsiloxane, tetramethylammonium chloride. ▶

Drug Facts (continued)

diamant, amidoethyl urea, carbonyl propyl polymethylsiloxane, trimethylsilylate, octyl cocaprylyl myristate, ethyl hexyl palmitate, 4-methylbenzyl alcohol, amylic alcohol, cetyl alcohol, myristyl alcohol, methyl ethyl propyl siloxane (CI 77019), titanium dioxide (CI 77891), iron oxide (CI 77492), red 21 lake (CI 55080), red 7 lake (CI 55100), iron oxide (CI 77492), iron oxide (CI 77499), blue 1 lake (CI 42050), iron oxide (CI 77492).

Net Wt. 0.14 oz. e (4 g)

HD LONGWEAR
 Long-lasting
 high-definition
 color lipstick SPF 20

ésika
 PRO

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

Drug Facts

Active Ingredients **Purpose**
 OCTINOXATE 6.8% Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin cancer. ▶

Drug Facts (continued)

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. ▶

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - VINO DESEO - PURPLE

ésika

PRO

HD LONGWEAR

Long-lasting

high-definition

color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - FUCSIA TENTACIÓN - PINK

ésika

PRO

HD LONGWEAR

Long-lasting

high-definition

color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

Drug Facts (continued)

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure. ▶

Drug Facts (continued)

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

Other Information

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

Drug Facts (continued)

Inactive Ingredients: Ditetrapropyl dimer dilinolate, triethyl trimellitate, capryl/capric triglyceride, polyethylene, cyclohexanol, castor seed/leaves beeswax succinate, isopropyl palmitate, polyglyceryl-3 distearate, copermdia cetifera (cermuda) wax, microcrystalline wax, bissemyraldina, isodecane, polymethylsiloquosanol, trimethyl siloxy silicate, polybutene-1, diethyl piperonyl ether, polybutene-1, diethyl piperonyl ether, butyl laurate, cetyl alcohol, bisphenol A, acetyl ricinoleate, chlorophenol, cetyl palmitate, bisphenol A, acetyl ricinoleate, cetyl alcohol, dimethicone, tetraethylamine, benzimidazole ▶

Drug Facts (continued)

diamand, amidoethyl urea, carbamoyl propyl polymethyl silsequosana, trimethylsiloxylate, diethyl isopropyl trimethyl silsequosana, isone, 4-methyl-2-pyridyl, any (uniquid, dupesol, lity, celam; zinc oxides (ci 77967), titanium dioxide (ci 77891), iron 5 lake (ci 77490), red 21 lake (ci 45380), red 7 lake (ci 15352), iron oxides (ci 77489), iron oxides (ci 77489), lake 1 lake (ci 42939).

Net Wt. 0.14 oz. e (4 g)

HD LONGWEAR
Long-lasting
high-definition
color lipstick SPF 20

ésika
PRO

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

Drug Facts

Active Ingredients **Purpose**
OCTINOXATE 6.8% Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer ▶

Drug Facts (continued)

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. ▶

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - FUCSIA DELIRIO - PINK

ésika

PRO

HD LONGWEAR

Long-lasting

high-definition

color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

Drug Facts (continued)

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure. ▶

Drug Facts (continued)

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

Other Information

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

Drug Facts (continued)

Inactive Ingredients: Distearyl dimethyl dilinolate, triethyl trimellitate, caprylyl capric triglyceride, polyethylene, cyclohexanone, castor isostearate beeswax succinate, isopropyl lanolate, polyglyceryl-3 distostearate, copermycin caprylate (ceramide) wax, microcrystalline wax, bisisostearyl malate, isodecylate, polymethylsiloxane, dimethylsiloxane, polydimethylsiloxane, polypropylene glycol, hexyl laurate, ceramide 3, lanolin alcohol, stearic acid, myristyl alcohol, chlorphenesin, cinnamyl 3, silanediol salicylate, tocopheryl acetate, oleyl alcohol, dimethicone, tetramethylammonium benzimidazole ▶

Drug Facts (continued)

diamand amideethyl urea, carbomyl propyl polymethylsiloxane, trimethylsilylate, oleyl tocopheryl linoleate, ethyl-hexyl dimethyl siloxane, 4-methyl-2-ethyl-1-hexanol, myristyl alcohol, caprylyl myristyl dimethyl siloxane (C17-19), and 27 lakes (C15-17), lake 5 lake (C19-140), and 21 lakes (C15-380), red 7 lake (C15-352), iron oxides (C17-482), iron oxides (C17-489), lake blue 1 lake (C14-2630).

Net Wt. 0.14 oz. e (4 g)

HD LONGWEAR
Long-lasting
high-definition
color lipstick SPF 20



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

www.esika.biz

Drug Facts

Active Ingredients **Purpose**
OCTINOXATE 6.8% Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin cancer ▶

Drug Facts (continued)

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. ▶

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - FUCSIA VIBRANTE - PINK

ésika

PRO

HD LONGWEAR

Long-lasting

high-definition

color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

Drug Facts (continued)

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure. ▶

Drug Facts (continued)

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

Other Information

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

Drug Facts (continued)

Inactive Ingredients: Distearyl dimethyl malonate, triethyl trimellitate, caprylic/capric triglyceride, polyethylene, cyclohexanone, castor isostearate beeswax succinate, isopropyl alcohol, polyglyceryl-3 distostearate, caprylyl methyl ether, (cinnamyl) wax, microcrystalline wax, bisisostearyl malonate, isodecylate, polymethylsilyoxane, dimethylsiloxane, polyglyceryl-3 stearate, methyl methacrylate, polyglyceryl-3 laurate, acetyl stearate, chlorophenol, cinnamyl 5-phenyl salicylate, tocopheryl acetate, ethyl alcohol, dimethicone, tetramethylazole, benzimidazole ▶

Drug Facts (continued)

diamond ambodethy, urea, carbomyl, propyl polymethylsilyoxane, trimethylsilylate, diethyl hexylglycol dimethylsiloxane, terebinthene, 4-methylbenzyl, amyl dimethyl, caprylyl, methyl cetanate, zirconium dioxide (CI 77491), titanium dioxide (CI 77891), iron oxides (CI 77492, CI 77499, CI 77497), red 21 lake (CI 15850), red 7 lake (CI 15850), iron oxides (CI 77492), iron oxides (CI 77499), blue 1 lake (CI 42030).

HD LONGWEAR
Long-lasting
high-definition
color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

ésika
PRO

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

Drug Facts

Active Ingredients Purpose

OCTINOXATE 6.8% Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin cancer ▶

Drug Facts (continued)

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. ▶

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - ROSA VIVA - PINK

ésika

PRO

HD LONGWEAR

Long-lasting

high-definition

color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

Drug Facts (continued)

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure. ▶

Drug Facts (continued)

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

Other Information

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

Drug Facts (continued)

Inactive Ingredients: Distearyl dimethyl dilinolate, triethyl trimellitate, caprylyl capric triglyceride, polyethylene, cyclohexanone, castor isostearate beeswax succinate, isopropyl lanolate, polyglyceryl-3 distostearate, copermidia cetilera (ceramide) wax, microcrystalline wax, bisisostearyl malate, isodecylate, polydimethylsiloxane, dimethylsiloxane, polyglyceryl-3 stearate, caprylyl alcohol, hexyl laurate, cetyl alcohol, stearic acid, methyl alcohol, chlorphenesin, carbamide 5, silanediol salicylate, tocopheryl acetate, cetyl alcohol, dimethylsiloxane, tetramethylsiloxane, benzimidazole ▶

Drug Facts (continued)

diamand amidoethyl urea, carbamoyl propyl polymethylsiloxane, dimethylsiloxane, cetyl tocopheryl linoleyl laurate, ethylhexyl trioleate, 4-methylbenzyl alcohol, amylic alcohol, caprylyl alcohol, benzyl alcohol, octyl decanoate (CI 77169), titanium dioxide (CI 77891), iron oxides (CI 77491, CI 77492, CI 77499), red 27 lake (CI 45410), iron S lake (CI 41940), red 21 lake (CI 45380), red 7 lake (CI 15350), iron oxides (CI 77482), iron oxides (CI 77489), blue 1 lake (CI 42030). ▶

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



HD LONGWEAR
Long-lasting
high-definition
color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

Drug Facts

Active Ingredients **Purpose**
 OCTINOXATE 6.8% Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin cancer ▶

Drug Facts (continued)

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. ▶

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - CORAL ENSUEÑO - RED

ésika

PRO

HD LONGWEAR

Long-lasting

high-definition

color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - MARRÓN BAMBÚ - BROWN

ésika

PRO

HD LONGWEAR

Long-lasting

high-definition

color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - ROSA FIORELLE - PINK

ésika

PRO

HD LONGWEAR

Long-lasting

high-definition

color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

Drug Facts (continued)

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure.

Drug Facts (continued)

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

Other information

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

Drug Facts (continued)

Inactive Ingredients: Dilauryl dimethyl malonate, tridecyl trimellitate, capryloyl capric triglyceride, polyethylene, cyclohexanone, castor isostearate beeswax succinate, isopropyl palmitate, polyglyceryl-3 distostearate, copermide capfira (ceramide) wax, microlystal line wax, bisisostearyl malonate, isodecylate, polymethylsiloquosane-OT dimethicone, polybutene-1, dilauryl diglycidyl ether, hexyl laurate, copolymer of lanolin, isostearyl alcohol, chlorphenesin, ceramide 3, squalene, salicylic acid, isodecyl alcohol, dimethylsiloxane, tetraethylsiloxane, benzimidazole

Drug Facts (continued)

diamond amorphous silica, carbonyl poly (methyl silsesquioxane, trimethylsilylate), dibutyl cocopyrene trimethylsilane, ethyl hexylmethacrylate, amylic diurethane, dimethyl siloxane crosspolysiloxane (CI 77201), titanium dioxide (CI 77891), iron oxides (CI 77491) and 27 lake (CI 65710), iron S lake (CI 77492), red 21 lake (CI 65830), red 7 lake (CI 15850), iron oxides (CI 77492), iron oxides (CI 77499), black blue 1 lake (CI 42030).

ésika
PRO
HD LONGWEAR
Long-lasting
high-definition
color lipstick SPF 20

Net Wt. 0.14 oz. e (4g)

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

Drug Facts

Active Ingredients **Purpose**
OCTINOXATE 6.8% Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin cancer

Drug Facts (continued)

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.

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - NATURAL DUNE - BEIGE

ésika

PRO

HD LONGWEAR

Long-lasting

high-definition

color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - ROJO FIESTA - RED

ésika

PRO

HD LONGWEAR

Long-lasting

high-definition

color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - NUDE CREAM - BEIGE

ésika

PRO

HD LONGWEAR

Long-lasting

high-definition

color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

Drug Facts (continued)

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure.

Drug Facts (continued)

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

Other Information

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

Drug Facts (continued)

Inactive Ingredients: Distearyl dimethyl sebacate, triethyl trimellitate, caprylyl capric triglyceride, polyethylene, cyclohexanone, castor isostearate beeswax succinate, isopropyl lanolate, polyglyceryl-3 distostearate, cipermetol, cetilera (ceramide) wax, microcrystalline wax, bisisobutyl maleate, isodecylate, polymethylsiloxane, dimethylsiloxane, polydimethylsiloxane, dimethylmethacrylate, polyethylene glycol, polybutyl methacrylate, polypropylene glycol, triethyl laurate, ceramide 3, silandiol salicylate, isopropyl alcohol, chlorphenesin, carbamide 5, silandiol salicylate, isopropyl alcohol, diethyl alcohol, dimethylsiloxane, tetramethylsiloxane, benzimidazole

Drug Facts (continued)

diamand amidoethyl urea, carbamoyl propyl polymethylsiloxane, trimethylsilylate, diethyl isopropyl trimethyl siloxane, isononyl isononyl alcohol, amyloamine, caprylyl, cetilera, ceramide 3, ceramide 6, ceramide 12, ceramide 18, ceramide 30, ceramide 36, ceramide 48, ceramide 54, ceramide 60, ceramide 66, ceramide 72, ceramide 78, ceramide 84, ceramide 90, ceramide 96, ceramide 102, ceramide 108, ceramide 114, ceramide 120, ceramide 126, ceramide 132, ceramide 138, ceramide 144, ceramide 150, ceramide 156, ceramide 162, ceramide 168, ceramide 174, ceramide 180, ceramide 186, ceramide 192, ceramide 198, ceramide 204, ceramide 210, ceramide 216, ceramide 222, ceramide 228, ceramide 234, ceramide 240, ceramide 246, ceramide 252, ceramide 258, ceramide 264, ceramide 270, ceramide 276, ceramide 282, ceramide 288, ceramide 294, ceramide 300, ceramide 306, ceramide 312, ceramide 318, ceramide 324, ceramide 330, ceramide 336, ceramide 342, ceramide 348, ceramide 354, ceramide 360, ceramide 366, ceramide 372, ceramide 378, ceramide 384, ceramide 390, ceramide 396, ceramide 402, ceramide 408, ceramide 414, ceramide 420, ceramide 426, ceramide 432, ceramide 438, ceramide 444, ceramide 450, ceramide 456, ceramide 462, ceramide 468, ceramide 474, ceramide 480, ceramide 486, ceramide 492, ceramide 498, ceramide 504, ceramide 510, ceramide 516, ceramide 522, ceramide 528, ceramide 534, ceramide 540, ceramide 546, ceramide 552, ceramide 558, ceramide 564, ceramide 570, ceramide 576, ceramide 582, ceramide 588, ceramide 594, ceramide 600, ceramide 606, ceramide 612, ceramide 618, ceramide 624, ceramide 630, ceramide 636, ceramide 642, ceramide 648, ceramide 654, ceramide 660, ceramide 666, ceramide 672, ceramide 678, ceramide 684, ceramide 690, ceramide 696, ceramide 702, ceramide 708, ceramide 714, ceramide 720, ceramide 726, ceramide 732, ceramide 738, ceramide 744, ceramide 750, ceramide 756, ceramide 762, ceramide 768, ceramide 774, ceramide 780, ceramide 786, ceramide 792, ceramide 798, ceramide 804, ceramide 810, ceramide 816, ceramide 822, ceramide 828, ceramide 834, ceramide 840, ceramide 846, ceramide 852, ceramide 858, ceramide 864, ceramide 870, ceramide 876, ceramide 882, ceramide 888, ceramide 894, ceramide 900, ceramide 906, ceramide 912, ceramide 918, ceramide 924, ceramide 930, ceramide 936, ceramide 942, ceramide 948, ceramide 954, ceramide 960, ceramide 966, ceramide 972, ceramide 978, ceramide 984, ceramide 990, ceramide 996

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



HD LONGWEAR
Long-lasting
high-definition
color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

Drug Facts

Active Ingredients Purpose
OCTINOXATE 6.8% Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin cancer

Drug Facts (continued)

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.

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - NUDE MOCCHA - BEIGE

ésika

PRO

HD LONGWEAR

Long-lasting

high-definition

color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - FUCSIA SUBLIME - PINK

ésika

PRO

HD LONGWEAR

Long-lasting

high-definition

color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - MARRÓN HAVANA - BROWN

ésika

PRO

HD LONGWEAR

Long-lasting

high-definition

color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - MARRÓN FANATIC - BROWN

ésika

PRO

HD LONGWEAR

Long-lasting

high-definition

color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

PRINCIPAL DISPLAY PANEL - 4 g Tube Box - NUDE ROSE- BEIGE

ésika
PRO

HD LONGWEAR

Long-lasting
high-definition
color lipstick SPF 20

Net Wt. 0.14 oz. e (4 g)

PRINCIPAL DISPLAY PANEL - Kit Carton

HD LONGWEAR

LONG-LASTING HIGH-DEFINITION
COLOR LIPSTICK SPF 20

ésika

PRO

Net Wt. 0.24 oz. e (7 g)



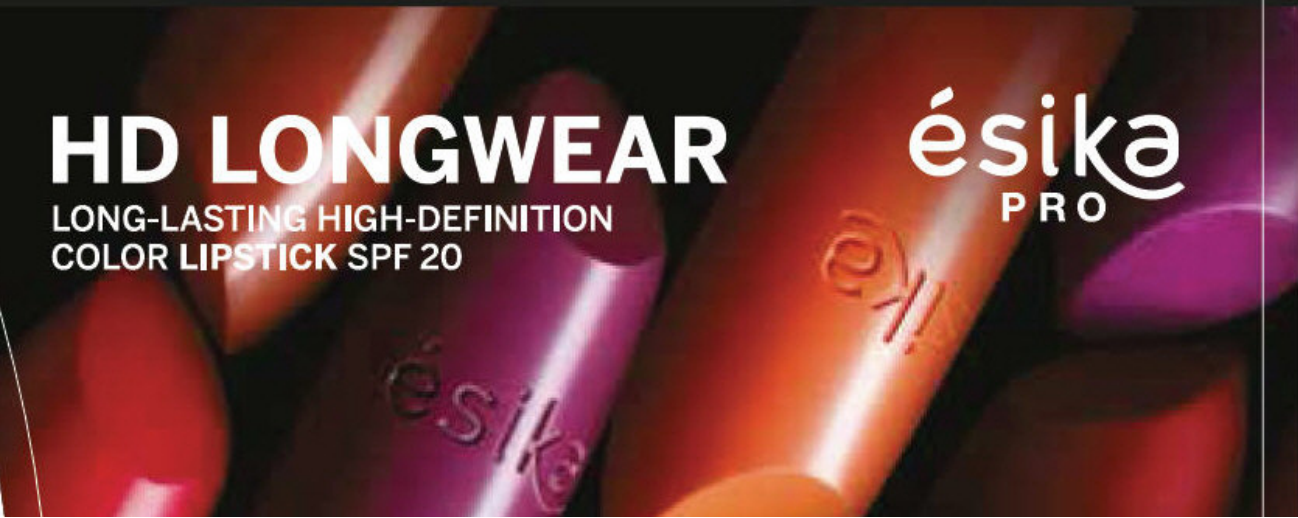
www.esika.biz

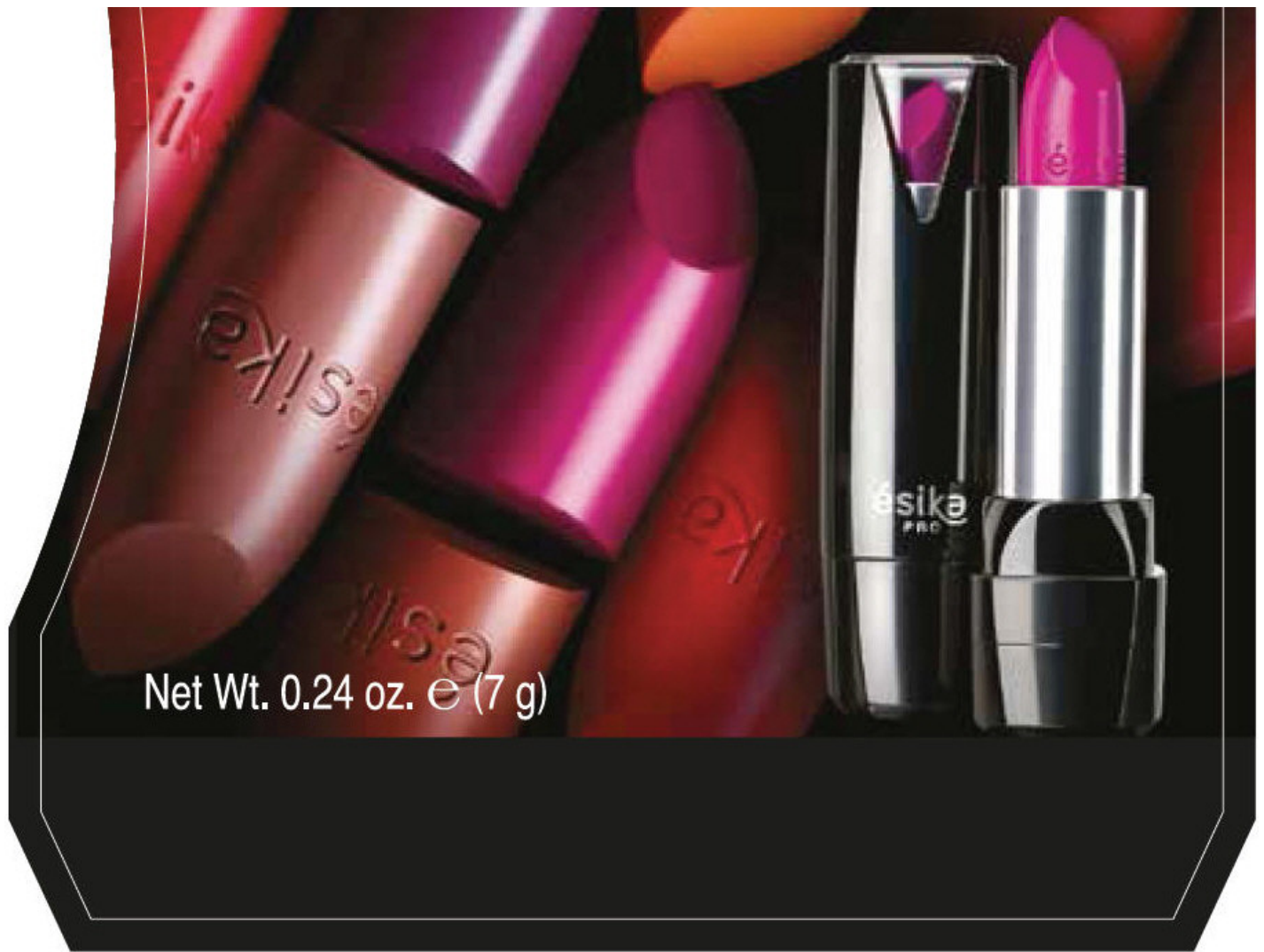
PUERTO RICO: Dist. by Ventura Corp., Ltd., San Juan, Puerto Rico 00926. Made in Colombia.

<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> Children under 6 months of age: Ask a doctor. <p>Other information</p> <ul style="list-style-type: none"> Protect the product in this container from excessive heat and direct sun. <p>Inactive ingredients DIISOPROPYL DIMER DILINOLEATE, TRIDECYL TRIMELLITATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, POLYETHYLENE OCTYLDODECANOL, CASTOR ISOSTEARATE BEESWAX SUCCINATE, ISOPROPYL LANOLATE, POLYGLYCERYL-3 DIISOSTEARATE, COPERNICIA CERIFERA (CARNAUVA) WAX, MICROCRYSTALLINE WAX, DIISOSTEARYL MALATE, MICA, ISODODECANE, POLYMETHYLSILSESQUOXANE/TRIMETHYLSILOXYSILICATE, PHENOXYETHANOL, CETYL PEG-10/1 DIMETHICONE, POLYGLYCERYL-4 ISOSTEARATE, SILICA, SILICA SILYLATE, HEXYL LAURATE, METHYLPROPANEDIOL, FRAGRANCE, CAPRYLYL TOCOPHERYL ACETATE, OLEYL ALCOHOL, DIMETHICONE, TROMETHAMINE, BENZIMIDAZOLE DIAMOND AMIDOETHYL UREA, CARBAMOYL PROPYL POLYMETHYLSILSESQUOXANE, TRIMETHYLSILOXYSSILICATE, DIOLEYL TOCOPHERYL METHYLSILANOL, ALPHA-ISOMETHYL IONONE, d-LIMONENE, LINALOOL, AMYL CINNAMAL, CITRONELEOL. MAY CONTAIN: IRON OXIDES (CI 77491), TITANIUM DIOXIDE (CI 77891), RED 30 LAKE (CI 73360), MICA (CI 77019), RED 27 LAKE (CI 45410), YELLOW 5 LAKE (CI 19140), RED 21 LAKE (CI 45380), RED 7 LAKE (CI 15850), IRON OXIDES (CI 77492), IRON OXIDES (CI 77499), TALC, BLUE 1 LAKE (CI 42090).</p>	<p>Drug Facts</p> <p>Active Ingredients Sunscreen Octinoxate 6.8 %</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. Use a water resistant sunscreen if swimming or sweating.
--	--

HD LONGWEAR
 LONG-LASTING HIGH-DEFINITION
 COLOR LIPSTICK SPF 20

ésika
 PRO





ESIKA PRO HD LONG WEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 VINO CAUTIVANTE - PURPLE

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0023
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
OCTYLDODECANOL (UNII: 461N1O614Y)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)
MICA (UNII: V8A1AW0880)
ISODODECANE (UNII: A8289P68Y2)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
METHYLPROPANEDIOL (UNII: N8F53B3R4R)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
SILANEDIOL SALICYLATE (UNII: C054DF30K0)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
DIMETHICONE (UNII: 92RU3N3Y1O)
TROMETHAMINE (UNII: 023C2WHX2V)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ACID RED 87 (UNII: TDQ283MPCW)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0023-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0023-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 PIMIENTA CALIENTE - RED

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0024
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
MICA (UNII: V8A1AW0880)	
ISODODECANE (UNII: A8289P68Y2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROMETHAMINE (UNII: 023C2WHX2V)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ACID RED 87 (UNII: TDQ283MPCW)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0024-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0024-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 ROJO GLAM - RED

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0025
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)
MICA (UNII: V8A1AW0880)
ISODODECANE (UNII: A8289P68Y2)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
METHYLPROPANEDIOL (UNII: N8F53B3R4R)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
SILANEDIOL SALICYLATE (UNII: C054DF30K0)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
DIMETHICONE (UNII: 92RU3N3Y1O)
TROMETHAMINE (UNII: 023C2WHX2V)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ACID RED 87 (UNII: TDQ283MPCW)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0025-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0025-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF

20 ROJO PASION - RED

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0026
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISO STEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISO STEARYL MALATE (UNII: QBS8A3XZGQ)	
MICA (UNII: V8A1AW0880)	
ISODODECANE (UNII: A8289P68Y2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISO STEARATE (UNII: 820DPX33S7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROMETHAMINE (UNII: 023C2WHX2V)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	

D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ACID RED 87 (UNII: TDQ283MPCW)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0026-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0026-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 VINO DESEO - PURPLE

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0027
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
MICA (UNII: V8A1AW0880)	

ISODODECANE (UNII: A8289P68Y2)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
METHYLPROPANEDIOL (UNII: N8F53B3R4R)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
SILANEDIOL SALICYLATE (UNII: C054DF30K0)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
DIMETHICONE (UNII: 92RU3N3Y1O)
TROMETHAMINE (UNII: 023C2WHX2V)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ACID RED 87 (UNII: TDQ283MPCW)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0027-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0027-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 FUCSIA TENTACION - PINK

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0028
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
MICA (UNII: V8A1AW0880)	
ISODODECANE (UNII: A8289P68Y2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROMETHAMINE (UNII: 023C2WHX2V)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ACID RED 87 (UNII: TDQ283MPCW)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	

FERRIC OXIDE YELLOW (UNII: EX438O2MRT)

FERROSO FERRIC OXIDE (UNII: XM0M87F357)

TALC (UNII: 7SEV7J4R1U)

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0028-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0028-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 FUCSIA DELIRIO - PINK

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0029
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
MICA (UNII: V8A1AW0880)	
ISODODECANE (UNII: A8289P68Y2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISO STEARATE (UNII: 820DPX33S7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

HEXYL LAURATE (UNII: 4CG9F9W01Q)
METHYLPROPANEDIOL (UNII: N8F53B3R4R)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
SILANEDIOL SALICYLATE (UNII: C054DF30K0)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
DIMETHICONE (UNII: 92RU3N3Y1O)
TROMETHAMINE (UNII: 023C2WHX2V)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ACID RED 87 (UNII: TDQ283MPCW)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0029-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0029-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 FUCSIA VIBRANTE - PINK

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
MICA (UNII: V8A1AW0880)	
ISODODECANE (UNII: A8289P68Y2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROMETHAMINE (UNII: 023C2WHX2V)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ACID RED 87 (UNII: TDQ283MPCW)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0030-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0030-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 ROSA VIVA - PINK

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0031
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
MICA (UNII: V8A1AW0880)	
ISODODECANE (UNII: A8289P68Y2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
SILANEDIOL SALICYLATE (UNII: C054DF30K0)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
DIMETHICONE (UNII: 92RU3N3Y1O)
TROMETHAMINE (UNII: 023C2WHX2V)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ACID RED 87 (UNII: TDQ283MPCW)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0031-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0031-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 CORAL ENSUENO - RED

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0032
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1g
Inactive Ingredients		
Ingredient Name	Strength	
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)		
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)		
OCTYLDODECANOL (UNII: 461N1O614Y)		
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)		
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)		
MICA (UNII: V8A1AW0880)		
ISODODECANE (UNII: A8289P68Y2)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
HEXYL LAURATE (UNII: 4CG9F9W01Q)		
METHYLPROPANEDIOL (UNII: N8F53B3R4R)		
CAPRYLYL GLYCOL (UNII: 00YIU5438U)		
CHLORPHENESIN (UNII: I670DAL4SZ)		
CERAMIDE NP (UNII: 4370DF050B)		
SILANEDIOL SALICYLATE (UNII: C054DF30K0)		
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
OLEYL ALCOHOL (UNII: 172F2WN8DV)		
DIMETHICONE (UNII: 92RU3N3Y1O)		
TROMETHAMINE (UNII: 023C2WHX2V)		
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)		
LIMONENE, (+)- (UNII: GFD7C86Q1W)		
LINALOOL, (+/-)- (UNII: D81QY6I88E)		
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)		
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
D&C RED NO. 30 (UNII: 2S42T2808B)		
ALUMINUM OXIDE (UNII: LM26O6933)		
D&C RED NO. 27 (UNII: 2LRS185U6K)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		
ACID RED 87 (UNII: TDQ283MPCW)		
D&C RED NO. 7 (UNII: ECW0LZ41X8)		
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)		
FERROSFERRIC OXIDE (UNII: XM0M87F357)		
TALC (UNII: 7SEV7J4R1U)		
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0032-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0032-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

ESIKA PRO HD LONG WEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 MARRON BAMBU - BROWN

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0033
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
MICA (UNII: V8A1AW0880)	
ISODODECANE (UNII: A8289P68Y2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
DIMETHICONE (UNII: 92RU3N3Y1O)
TROMETHAMINE (UNII: 023C2WHX2V)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ACID RED 87 (UNII: TDQ283MPCW)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0033-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0033-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 ROSA FIORELLE - PINK

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0034
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
MICA (UNII: V8A1AW0880)	
ISODODECANE (UNII: A8289P68Y2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROMETHAMINE (UNII: 023C2WHX2V)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ACID RED 87 (UNII: TDQ283MPCW)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0034-2	1 in 1 BOX	01/27/2017	

1	NDC:43596-0034-1	4 g in 1 TUBE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part352	01/27/2017		

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 NATURAL DUNE - BEIGE

octinoxate lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0035
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g
Inactive Ingredients			
	Ingredient Name	Strength	
	DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)		
	TRIDECYL TRIMELLITATE (UNII: FY36J270ES)		
	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
	HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)		
	OCTYLDODECANOL (UNII: 461N1O614Y)		
	POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)		
	CARNAUBA WAX (UNII: R12CBM0EIZ)		
	MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)		
	DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)		
	MICA (UNII: V8A1AW0880)		
	ISODODECANE (UNII: A8289P68Y2)		
	PHENOXYETHANOL (UNII: HIE492ZZ3T)		
	POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)		
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
	HEXYL LAURATE (UNII: 4CG9F9W01Q)		
	METHYLPROPANEDIOL (UNII: N8F53B3R4R)		
	CAPRYLYL GLYCOL (UNII: 00YIU5438U)		
	CHLORPHENESIN (UNII: I670DAL4SZ)		
	CERAMIDE NP (UNII: 4370DF050B)		
	SILANEDIOL SALICYLATE (UNII: C054DF30K0)		
	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
	OLEYL ALCOHOL (UNII: 172F2WN8DV)		
	DIMETHICONE (UNII: 92RU3N3Y1O)		

TROMETHAMINE (UNII: 023C2WHX2V)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ACID RED 87 (UNII: TDQ283MPCW)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0035-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0035-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 ROJO FIESTA - RED

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0036
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
-----------------	----------

DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
OCTYLDODECANOL (UNII: 461N1O614Y)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)
MICA (UNII: V8A1AW0880)
ISODODECANE (UNII: A8289P68Y2)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
METHYLPROPANEDIOL (UNII: N8F53B3R4R)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
SILANEDIOL SALICYLATE (UNII: C054DF30K0)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
DIMETHICONE (UNII: 92RU3N3Y1O)
TROMETHAMINE (UNII: 023C2WHX2V)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ACID RED 87 (UNII: TDQ283MPCW)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0036-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0036-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 NUDE CREAM - BEIGE

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0037
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
MICA (UNII: V8A1AW0880)	
ISODODECANE (UNII: A8289P68Y2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROMETHAMINE (UNII: 023C2WHX2V)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	

.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ACID RED 87 (UNII: TDQ283MPCW)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0037-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0037-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

ESIKA PRO HD LONG WEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 NUDE MOCCHA - BEIGE

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0048
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
OCTYLDODECANOL (UNII: 461N1O614Y)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)
MICA (UNII: V8A1AW0880)
ISODODECANE (UNII: A8289P68Y2)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
METHYLPROPANEDIOL (UNII: N8F53B3R4R)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
SILANEDIOL SALICYLATE (UNII: C054DF30K0)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
DIMETHICONE (UNII: 92RU3N3Y1O)
TROMETHAMINE (UNII: 023C2WHX2V)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ACID RED 87 (UNII: TDQ283MPCW)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0048-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0048-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 FUCSIA SUBLIME - PINK

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0049
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
MICA (UNII: V8A1AW0880)	
ISODODECANE (UNII: A8289P68Y2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROMETHAMINE (UNII: 023C2WHX2V)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ACID RED 87 (UNII: TDQ283MPCW)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0049-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0049-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 MARRON HAVANA - BROWN

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)
MICA (UNII: V8A1AW0880)
ISODODECANE (UNII: A8289P68Y2)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
METHYLPROPANEDIOL (UNII: N8F53B3R4R)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
SILANEDIOL SALICYLATE (UNII: C054DF30K0)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
DIMETHICONE (UNII: 92RU3N3Y1O)
TROMETHAMINE (UNII: 023C2WHX2V)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ACID RED 87 (UNII: TDQ283MPCW)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0050-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0050-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF

20 MARRON FANATIC - BROWN

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0051
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
MICA (UNII: V8A1AW0880)	
ISODODECANE (UNII: A8289P68Y2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROMETHAMINE (UNII: 023C2WHX2V)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	

D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ACID RED 87 (UNII: TDQ283MPCW)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0051-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0051-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 NUDE ROSE- BEIGE

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0052
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
MICA (UNII: V8A1AW0880)	

ISODODECANE (UNII: A8289P68Y2)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
METHYLPROPANEDIOL (UNII: N8F53B3R4R)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
SILANEDIOL SALICYLATE (UNII: C054DF30K0)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
DIMETHICONE (UNII: 92RU3N3Y10)
TROMETHAMINE (UNII: 023C2WHX2V)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ACID RED 87 (UNII: TDQ283MPCW)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0052-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0052-1	4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20

octinoxate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0053
---------------------	----------------	---------------------------	----------------

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0053-3	1 in 1 BOX	01/27/2017	
1	NDC:43596-0053-2	12 in 1 TRAY		
1	NDC:43596-0053-1	1 in 1 CONTAINER		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 CONTAINER	0.5833 g
Part 2	1 CONTAINER	0.5833 g
Part 3	1 CONTAINER	0.5833 g
Part 4	1 CONTAINER	0.5833 g
Part 5	1 CONTAINER	0.5833 g
Part 6	1 CONTAINER	0.5833 g
Part 7	1 CONTAINER	0.5833 g
Part 8	1 CONTAINER	0.5833 g
Part 9	1 CONTAINER	0.5833 g
Part 10	1 CONTAINER	0.5833 g
Part 11	1 CONTAINER	0.5833 g
Part 12	1 CONTAINER	0.5833 g

Part 1 of 12**ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 VINO CAUTIVANTE - PURPLE**

octinoxate paste

Product Information

Route of Administration	TOPICAL
--------------------------------	---------

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
-----------------	----------

DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
OCTYLDODECANOL (UNII: 461N1O614Y)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)
MICA (UNII: V8A1AW0880)
ISODODECANE (UNII: A8289P68Y2)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
METHYLPROPANEDIOL (UNII: N8F53B3R4R)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
SILANEDIOL SALICYLATE (UNII: C054DF30K0)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
DIMETHICONE (UNII: 92RU3N3Y1O)
TROMETHAMINE (UNII: 023C2WHX2V)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ACID RED 87 (UNII: TDQ283MPCW)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.5833 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

Part 2 of 12

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 VINO DESEO - PURPLE

octinoxate paste

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
MICA (UNII: V8A1AW0880)	
ISODODECANE (UNII: A8289P68Y2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROMETHAMINE (UNII: 023C2WHX2V)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	

LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ACID RED 87 (UNII: TDQ283MPCW)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.5833 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

Part 3 of 12

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 MARRON BAMBU - BROWN

octinoxate paste

Product Information

Route of Administration	TOPICAL
-------------------------	---------

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
MICA (UNII: V8A1AW0880)	
ISODODECANE (UNII: A8289P68Y2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROMETHAMINE (UNII: 023C2WHX2V)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ACID RED 87 (UNII: TDQ283MPCW)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.5833 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

Part 4 of 12

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 NUDE MOCCHA - BEIGE

octinoxate paste

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
MICA (UNII: V8A1AW0880)	
ISODODECANE (UNII: A8289P68Y2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROMETHAMINE (UNII: 023C2WHX2V)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	

.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ACID RED 87 (UNII: TDQ283MPCW)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.5833 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

Part 5 of 12

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 PIMIENTA CALIENTE - RED

octinoxate paste

Product Information	
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
MICA (UNII: V8A1AW0880)	
ISODODECANE (UNII: A8289P68Y2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROMETHAMINE (UNII: 023C2WHX2V)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ACID RED 87 (UNII: TDQ283MPCW)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.5833 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

Part 6 of 12

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 ROJO FIESTA - RED

octinoxate paste

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
MICA (UNII: V8A1AW0880)	
ISODODECANE (UNII: A8289P68Y2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROMETHAMINE (UNII: 023C2WHX2V)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ACID RED 87 (UNII: TDQ283MPCW)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.5833 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

Part 7 of 12

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 ROJO PASION - RED

octinoxate paste

Product Information

Route of Administration	TOPICAL
-------------------------	---------

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	

CARNAUBA WAX (UNII: R12CBM0EIZ)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)
MICA (UNII: V8A1AW0880)
ISODODECANE (UNII: A8289P68Y2)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
METHYLPROPANEDIOL (UNII: N8F53B3R4R)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
SILANEDIOL SALICYLATE (UNII: C054DF30K0)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
DIMETHICONE (UNII: 92RU3N3Y1O)
TROMETHAMINE (UNII: 023C2WHX2V)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ACID RED 87 (UNII: TDQ283MPCW)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.5833 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 CORAL ENSUENO - RED

octinoxate paste

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
MICA (UNII: V8A1AW0880)	
ISODODECANE (UNII: A8289P68Y2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROMETHAMINE (UNII: 023C2WHX2V)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ACID RED 87 (UNII: TDQ283MPCW)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.5833 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

Part 9 of 12

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 FUCSIA TENTACION - PINK

octinoxate paste

Product Information

Route of Administration	TOPICAL
-------------------------	---------

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	

DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)
MICA (UNII: V8A1AW0880)
ISODODECANE (UNII: A8289P68Y2)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
METHYLPROPANEDIOL (UNII: N8F53B3R4R)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
SILANEDIOL SALICYLATE (UNII: C054DF30K0)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
DIMETHICONE (UNII: 92RU3N3Y1O)
TROMETHAMINE (UNII: 023C2WHX2V)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
ACID RED 87 (UNII: TDQ283MPCW)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.5833 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

Part 10 of 12

**ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR
SPF 20 FUCSIA DELIRIO - PINK**

octinoxate paste

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
MICA (UNII: V8A1AW0880)	
ISODODECANE (UNII: A8289P68Y2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
DIMETHICONE (UNII: 92RU3N3Y10)	
TROMETHAMINE (UNII: 023C2WHX2V)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ACID RED 87 (UNII: TDQ283MPCW)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.5833 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

Part 11 of 12

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 NUDE ROSE- BEIGE

octinoxate paste

Product Information

Route of Administration	TOPICAL
-------------------------	---------

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
MICA (UNII: V8A1AW0880)	

ISODODECANE (UNII: A8289P68Y2)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROMETHAMINE (UNII: 023C2WHX2V)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ACID RED 87 (UNII: TDQ283MPCW)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.5833 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

Part 12 of 12

ESIKA PRO HD LONGWEAR LONG-LASTING HIGH-DEFINITION COLOR SPF 20 ROSA FIORELLE - PINK

octinoxate paste

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
MICA (UNII: V8A1AW0880)	
ISODODECANE (UNII: A8289P68Y2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROMETHAMINE (UNII: 023C2WHX2V)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ACID RED 87 (UNII: TDQ283MPCW)	

D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.5833 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2017	

Labeler - Ventura Corporation LTD (602751344)

Establishment			
Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(43596-0023, 43596-0024, 43596-0025, 43596-0026, 43596-0027, 43596-0028, 43596-0029, 43596-0030, 43596-0031, 43596-0032, 43596-0033, 43596-0034, 43596-0035, 43596-0036, 43596-0037, 43596-0048, 43596-0049, 43596-0050, 43596-0051, 43596-0052, 43596-0053)