**ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (MARRON HAVANA) - BROWN- octinoxate lipstick**
**ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (NATURAL DUNE) - PINK- octinoxate lipstick**
**ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (MARRON FANATIC) - RED- octinoxate lipstick**
**ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (ROJO FIESTA) - RED- octinoxate lipstick**
**ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (MARRON BAMBU) - BROWN- octinoxate lipstick**
**ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (FUCSIA DELIRIO) - PINK- octinoxate lipstick**
**ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (ROJO PASION) - RED- octinoxate lipstick**
**ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (FUCSIA SUBLIME) - PINK- octinoxate lipstick**
**ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (ROSA FIORELLE) - PINK- octinoxate lipstick**
**ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (NARANJA OBSESION) - ORANGE- octinoxate lipstick**
**ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (BORGONA SWEET) - PINK- octinoxate lipstick**
**ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (VINO DESEO) - PURPLE- octinoxate lipstick**
**ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (FUCSIA TENTACION) - PINK- octinoxate lipstick**
**ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT 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.*

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**ÉSIKA PRO ADVANCE LASTING LIPSTICK Long-lasting and comfort lipstick SPF 20**

***Drug Facts***

**Active Ingredients**

OCTINOXATE: 7.00%

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

**Other information**

- Protect this product in this container form excesive heat and direct sun.

**Inactive ingredients**

DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL TRIMELLITATE, ETHYLHEXYL PALMITATE, POLYETHYLENE, COPERNICIA CERIFERA (CARNAUBA) WAX, OZOKERITE, POLYMETHYL METHACRYLATE, TRIDECYL STEARATE, POLYGLYCERYL-3 DIISOSTEARATE, NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE, SYNTHETIC BEESWAX, TOCOPHERYL ACETATE, PHENOXYETHANOL, CERAMIDE 3, CAPRYLYL GLYCOL, CHLORPHENESIN, FRAGRANCE.

***MAY CONTAIN :***

MICA, MANGANESE VIOLET, TITANIUM DIOXIDE, BISMUTH OXYCHLORIDE, IRON OXIDES, RED 21 LAKE, RED 27 LAKE, YELLOW 5 LAKE, RED 7 LAKE, TALC, BLUE 1 LAKE.

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

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

**ésika**
**PRO**

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. e (4g)

ésika
PRO

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. ℮ (4g)

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

www.esika.biz

**Drug Facts** (continued)

GLYCOL DICAPRYLATE/DICAPRATE, SYNTHETIC BEESWAX, TOCOPHERYL ACETATE, PHENOXYETHANOL, CERAMIDE 3, CAPRYLYL GLYCOL, CHLORPHENESIN, FRAGRANCE. **MAY CONTAIN:** MICA, MANGANESE VIOLET, TITANIUM ▶

**Drug Facts** (continued)

DIOXIDE, BISMUTH OXYCHLORIDE, IRON OXIDES, RED 21 LAKE, RED 27 LAKE, YELLOW 5 LAKE, RED 7 LAKE, TALC, BLUE 1 LAKE.

**Drug Facts**

| Active Ingredients | Purpose |
|---|---|
| Octinoxate 7.00% | Sunscreen |

**Uses** ▶

**Drug Facts** (continued)

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

**Inactive ingredients** DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL ▶

**Drug Facts** (continued)

TRIMELLITATE, ETHYLHEXYL PALMITATE, POLYETHYLENE, COPERNICIA CERIFERA (CARNAUBA) WAX, OZOKERITE, POLYMETHYL METHACRYLATE, TRIDECYL STEARATE, POLYGLYCERYL-3 DIISOSTEARATE, NEOPENTYL ▶

**Drug Facts** (continued)

■ Helps prevent sunburn.

**Warnings**

■ **Skin Cancer / Skin Aging Alert:** Spending time in ▶

**Drug Facts** (continued)

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 ▶

**Drug Facts** (continued)

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 ▶

**Drug Facts** (continued)

contact a Poison Control Center right away.

**Directions**

■ Apply liberally and evenly 15 minutes before ▶

**Drug Facts** (continued)

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

**Other information** ▶

**PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (NATURAL DUNE) - PINK**

**ésika**
**PRO**

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. e (4g)

ésika
PRO

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. ℮ (4g)

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

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**Drug Facts** (continued)

GLYCOL DICAPRYLATE/DICAPRATE, SYNTHETIC BEESWAX, TOCOPHERYL ACETATE, PHENOXYETHANOL, CERAMIDE 3, CAPRYLYL GLYCOL, CHLORPHENESIN, FRAGRANCE. **MAY CONTAIN:** MICA, MANGANESE VIOLET, TITANIUM ▶

**Drug Facts** (continued)

DIOXIDE, BISMUTH OXYCHLORIDE, IRON OXIDES, RED 21 LAKE, RED 27 LAKE, YELLOW 5 LAKE, RED 7 LAKE, TALC, BLUE 1 LAKE.

**Drug Facts**

| Active Ingredients | Purpose |
|---|---|
| Octinoxate 7.00% | Sunscreen |

**Uses** ▶

**Drug Facts** (continued)

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

**Inactive ingredients** DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL ▶

**Drug Facts** (continued)

TRIMELLITATE, ETHYLHEXYL PALMITATE, POLYETHYLENE, COPERNICIA CERIFERA (CARNAUBA) WAX, OZOKERITE, POLYMETHYL METHACRYLATE, TRIDECYL STEARATE, POLYGLYCERYL-3 DIISOSTEARATE, NEOPENTYL ▶

**Drug Facts** (continued)

■ Helps prevent sunburn.

**Warnings**

■ **Skin Cancer / Skin Aging Alert:** Spending time in ▶

**Drug Facts** (continued)

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 ▶

**Drug Facts** (continued)

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 ▶

**Drug Facts** (continued)

contact a Poison Control Center right away.

**Directions**

■ Apply liberally and evenly 15 minutes before ▶

**Drug Facts** (continued)

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

**Other information** ▶

**PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (MARRON FANATIC) - RED**

**ésika**
**PRO**

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. e (4g)

ésika
PRO

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. ℮ (4g)

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

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**Drug Facts** (continued)

GLYCOL DICAPRYLATE/DICAPRATE, SYNTHETIC BEESWAX, TOCOPHERYL ACETATE, PHENOXYETHANOL, CERAMIDE 3, CAPRYLYL GLYCOL, CHLORPHENESIN, FRAGRANCE. **MAY CONTAIN:** MICA, MANGANESE VIOLET, TITANIUM

**Drug Facts** (continued)

DIOXIDE, BISMUTH OXYCHLORIDE, IRON OXIDES, RED 21 LAKE, RED 27 LAKE, YELLOW 5 LAKE, RED 7 LAKE, TALC, BLUE 1 LAKE.

**Drug Facts**

| Active Ingredients | Purpose |
|---|---|
| Octinoxate 7.00% | Sunscreen |

**Uses**

**Drug Facts** (continued)

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

**Inactive ingredients** DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL

**Drug Facts** (continued)

TRIMELLITATE, ETHYLHEXYL PALMITATE, POLYETHYLENE, COPERNICIA CERIFERA (CARNAUBA) WAX, OZOKERITE, POLYMETHYL METHACRYLATE, TRIDECYL STEARATE, POLYGLYCERYL-3 DIISOSTEARATE, NEOPENTYL

**Drug Facts** (continued)

■ Helps prevent sunburn.

**Warnings**

■ **Skin Cancer / Skin Aging Alert:** Spending time in

**Drug Facts** (continued)

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

**Drug Facts** (continued)

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

**Drug Facts** (continued)

contact a Poison Control Center right away.

**Directions**

■ Apply liberally and evenly 15 minutes before

**Drug Facts** (continued)

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

**Other information**

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

**ésika**
**PRO**

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. e (4g)

ésika
PRO

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. ℮ (4g)

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**Drug Facts** (continued)

GLYCOL DICAPRYLATE/DICAPRATE, SYNTHETIC BEESWAX, TOCOPHERYL ACETATE, PHENOXYETHANOL, CERAMIDE 3, CAPRYLYL GLYCOL, CHLORPHENESIN, FRAGRANCE. **MAY CONTAIN:** MICA, MANGANESE VIOLET, TITANIUM ▶

**Drug Facts** (continued)

DIOXIDE, BISMUTH OXYCHLORIDE, IRON OXIDES, RED 21 LAKE, RED 27 LAKE, YELLOW 5 LAKE, RED 7 LAKE, TALC, BLUE 1 LAKE.

**Drug Facts**

| Active Ingredients | Purpose |
|---|---|
| Octinoxate 7.00% | Sunscreen |

**Uses** ▶

**Drug Facts** (continued)

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

**Inactive ingredients** DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL ▶

**Drug Facts** (continued)

TRIMELLITATE, ETHYLHEXYL PALMITATE, POLYETHYLENE, COPERNICIA CERIFERA (CARNAUBA) WAX, OZOKERITE, POLYMETHYL METHACRYLATE, TRIDECYL STEARATE, POLYGLYCERYL-3 DIISOSTEARATE, NEOPENTYL ▶

**Drug Facts** (continued)

■ Helps prevent sunburn.

**Warnings**

■ **Skin Cancer / Skin Aging Alert:** Spending time in ▶

**Drug Facts** (continued)

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 ▶

**Drug Facts** (continued)

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 ▶

**Drug Facts** (continued)

contact a Poison Control Center right away.

**Directions**

■ Apply liberally and evenly 15 minutes before ▶

**Drug Facts** (continued)

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

**Other information** ▶

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

**ésika**
**PRO**

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. e (4g)

ésika
PRO

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. ℮ (4g)

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**Drug Facts** (continued)

GLYCOL DICAPRYLATE/DICAPRATE, SYNTHETIC BEESWAX, TOCOPHERYL ACETATE, PHENOXYETHANOL, CERAMIDE 3, CAPRYLYL GLYCOL, CHLORPHENESIN, FRAGRANCE. **MAY CONTAIN:** MICA, MANGANESE VIOLET, TITANIUM ▶

**Drug Facts** (continued)

DIOXIDE, BISMUTH OXYCHLORIDE, IRON OXIDES, RED 21 LAKE, RED 27 LAKE, YELLOW 5 LAKE, RED 7 LAKE, TALC, BLUE 1 LAKE.

**Drug Facts**

| Active Ingredients | Purpose |
|---|---|
| Octinoxate 7.00% | Sunscreen |

**Uses** ▶

**Drug Facts** (continued)

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

**Inactive ingredients** DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL ▶

**Drug Facts** (continued)

TRIMELLITATE, ETHYLHEXYL PALMITATE, POLYETHYLENE, COPERNICIA CERIFERA (CARNAUBA) WAX, OZOKERITE, POLYMETHYL METHACRYLATE, TRIDECYL STEARATE, POLYGLYCERYL-3 DIISOSTEARATE, NEOPENTYL ▶

**Drug Facts** (continued)

■ Helps prevent sunburn.

**Warnings**

■ **Skin Cancer / Skin Aging Alert:** Spending time in ▶

**Drug Facts** (continued)

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 ▶

**Drug Facts** (continued)

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 ▶

**Drug Facts** (continued)

contact a Poison Control Center right away.

**Directions**

■ Apply liberally and evenly 15 minutes before ▶

**Drug Facts** (continued)

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

**Other information** ▶

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

**ésika**
**PRO**

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. e (4g)

ésika
PRO

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. ℮ (4g)

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**Drug Facts** (continued)

GLYCOL DICAPRYLATE/DICAPRATE, SYNTHETIC BEESWAX, TOCOPHERYL ACETATE, PHENOXYETHANOL, CERAMIDE 3, CAPRYLYL GLYCOL, CHLORPHENESIN, FRAGRANCE. **MAY CONTAIN:** MICA, MANGANESE VIOLET, TITANIUM ▶

**Drug Facts** (continued)

DIOXIDE, BISMUTH OXYCHLORIDE, IRON OXIDES, RED 21 LAKE, RED 27 LAKE, YELLOW 5 LAKE, RED 7 LAKE, TALC, BLUE 1 LAKE.

**Drug Facts**

| Active Ingredients | Purpose |
|---|---|
| Octinoxate 7.00% | Sunscreen |

**Uses** ▶

**Drug Facts** (continued)

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

**Inactive ingredients** DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL ▶

**Drug Facts** (continued)

TRIMELLITATE, ETHYLHEXYL PALMITATE, POLYETHYLENE, COPERNICIA CERIFERA (CARNAUBA) WAX, OZOKERITE, POLYMETHYL METHACRYLATE, TRIDECYL STEARATE, POLYGLYCERYL-3 DIISOSTEARATE, NEOPENTYL ▶

**Drug Facts** (continued)

■ Helps prevent sunburn.

**Warnings**

■ **Skin Cancer / Skin Aging Alert:** Spending time in ▶

**Drug Facts** (continued)

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 ▶

**Drug Facts** (continued)

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 ▶

**Drug Facts** (continued)

contact a Poison Control Center right away.

**Directions**

■ Apply liberally and evenly 15 minutes before ▶

**Drug Facts** (continued)

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

**Other information** ▶

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

**ésika**
**PRO**

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. e (4g)

ésika
PRO

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. ℮ (4g)

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Made in Colombia

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**Drug Facts** (continued)

GLYCOL DICAPRYLATE/DICAPRATE, SYNTHETIC BEESWAX, TOCOPHERYL ACETATE, PHENOXYETHANOL, CERAMIDE 3, CAPRYLYL GLYCOL, CHLORPHENESIN, FRAGRANCE. **MAY CONTAIN:** MICA, MANGANESE VIOLET, TITANIUM

**Drug Facts** (continued)

DIOXIDE, BISMUTH OXYCHLORIDE, IRON OXIDES, RED 21 LAKE, RED 27 LAKE, YELLOW 5 LAKE, RED 7 LAKE, TALC, BLUE 1 LAKE.

**Drug Facts**

| Active Ingredients | Purpose |
|---|---|
| Octinoxate 7.00% | Sunscreen |

**Uses**

**Drug Facts** (continued)

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

**Inactive ingredients** DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL

**Drug Facts** (continued)

TRIMELLITATE, ETHYLHEXYL PALMITATE, POLYETHYLENE, COPERNICIA CERIFERA (CARNAUBA) WAX, OZOKERITE, POLYMETHYL METHACRYLATE, TRIDECYL STEARATE, POLYGLYCERYL-3 DIISOSTEARATE, NEOPENTYL

**Drug Facts** (continued)

■ Helps prevent sunburn.

**Warnings**

■ **Skin Cancer / Skin Aging Alert:** Spending time in

**Drug Facts** (continued)

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

**Drug Facts** (continued)

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

**Drug Facts** (continued)

contact a Poison Control Center right away.

**Directions**

■ Apply liberally and evenly 15 minutes before

**Drug Facts** (continued)

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

**Other information**

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

**ésika**
**PRO**

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. e (4g)

ésika
PRO

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. ℮ (4g)

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Ltd., San Juan, Puerto Rico 00926.
Made in Colombia

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**Drug Facts** (continued)

GLYCOL DICAPRYLATE/DICAPRATE, SYNTHETIC BEESWAX, TOCOPHERYL ACETATE, PHENOXYETHANOL, CERAMIDE 3, CAPRYLYL GLYCOL, CHLORPHENESIN, FRAGRANCE.
**MAY CONTAIN:** MICA, MANANESE VIOLET, TITANIUM ▶

**Drug Facts** (continued)

DIOXIDE, BISMUTH OXYCHLORIDE, IRON OXIDES, RED 21 LAKE, RED 27 LAKE, YELLOW 5 LAKE, RED 7 LAKE, TALC, BLUE 1 LAKE.

**Drug Facts**

| Active Ingredients | Purpose |
|---|---|
| Octinoxate 7.00% | Sunscreen |

**Uses** ▶

**Drug Facts** (continued)

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

**Inactive ingredients** DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL ▶

**Drug Facts** (continued)

TRIMELLITATE, ETHYLHEXYL PALMITATE, POLYETHYLENE, COPERNICIA CERIFERA (CARNAUBA) WAX, OZOKERITE, POLYMETHYL METHACRYLATE, TRIDECYL STEARATE, POLYGLYCERYL-3 DIISOSTEARATE, NEOPENTYL ▶

**Drug Facts** (continued)

■ Helps prevent sunburn.

**Warnings**

■ **Skin Cancer / Skin Aging Alert:** Spending time in ▶

**Drug Facts** (continued)

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 ▶

**Drug Facts** (continued)

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 ▶

**Drug Facts** (continued)

contact a Poison Control Center right away.

**Directions**

■ Apply liberally and evenly 15 minutes before ▶

**Drug Facts** (continued)

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

**Other information** ▶

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

**ésika**
**PRO**

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. e (4g)

ésika
PRO

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. ℮ (4g)

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

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**Drug Facts** (continued)

GLYCOL DICAPRYLATE/DICAPRATE, SYNTHETIC BEESWAX, TOCOPHERYL ACETATE, PHENOXYETHANOL, CERAMIDE 3, CAPRYLYL GLYCOL, CHLORPHENESIN, FRAGRANCE. **MAY CONTAIN:** MICA, MANANESE VIOLET, TITANIUM

**Drug Facts** (continued)

DIOXIDE, BISMUTH OXYCHLORIDE, IRON OXIDES, RED 21 LAKE, RED 27 LAKE, YELLOW 5 LAKE, RED 7 LAKE, TALC, BLUE 1 LAKE.

**Drug Facts**

| Active Ingredients | Purpose |
|---|---|
| Octinoxate 7.00% | Sunscreen |

**Uses**

**Drug Facts** (continued)

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

**Inactive ingredients** DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL

**Drug Facts** (continued)

TRIMELLITATE, ETHYLHEXYL PALMITATE, POLYETHYLENE, COPERNICIA CERIFERA (CARNAUBA) WAX, OZOKERITE, POLYMETHYL METHACRYLATE, TRIDECYL STEARATE, POLYGLYCERYL-3 DIISOSTEARATE, NEOPENTYL

**Drug Facts** (continued)

■ Helps prevent sunburn.

**Warnings**

■ **Skin Cancer / Skin Aging Alert:** Spending time in

**Drug Facts** (continued)

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

**Drug Facts** (continued)

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

**Drug Facts** (continued)

contact a Poison Control Center right away.

**Directions**

■ Apply liberally and evenly 15 minutes before

**Drug Facts** (continued)

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

**Other information**

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

**ésika**
**PRO**

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. e (4g)

ésika
PRO

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. ℮ (4g)

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

www.esika.biz

**Drug Facts** (continued)

GLYCOL DICAPRYLATE/DICAPRATE, SYNTHETIC BEESWAX, TOCOPHERYL ACETATE, PHENOXYETHANOL, CERAMIDE 3, CAPRYLYL GLYCOL, CHLORPHENESIN, FRAGRANCE. **MAY CONTAIN:** MICA, MANGANESE VIOLET, TITANIUM

**Drug Facts** (continued)

DIOXIDE, BISMUTH OXYCHLORIDE, IRON OXIDES, RED 21 LAKE, RED 27 LAKE, YELLOW 5 LAKE, RED 7 LAKE, TALC, BLUE 1 LAKE.

**Drug Facts**

| Active Ingredients | Purpose |
|---|---|
| Octinoxate 7.00% | Sunscreen |

**Uses**

**Drug Facts** (continued)

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

**Inactive ingredients** DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL

**Drug Facts** (continued)

TRIMELLITATE, ETHYLHEXYL PALMITATE, POLYETHYLENE, COPERNICIA CERIFERA (CARNAUBA) WAX, OZOKERITE, POLYMETHYL METHACRYLATE, TRIDECYL STEARATE, POLYGLYCERYL-3 DIISOSTEARATE, NEOPENTYL

**Drug Facts** (continued)

■ Helps prevent sunburn.

**Warnings**

■ **Skin Cancer / Skin Aging Alert:** Spending time in

**Drug Facts** (continued)

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

**Drug Facts** (continued)

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

**Drug Facts** (continued)

contact a Poison Control Center right away.

**Directions**

■ Apply liberally and evenly 15 minutes before

**Drug Facts** (continued)

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

**Other information**

**PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (BORGOÑA SWEET) - PINK**

**ésika**
**PRO**

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. e (4g)

ésika
PRO

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. ℮ (4g)

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

www.esika.biz

**Drug Facts** (continued)

GLYCOL DICAPRYLATE/DICAPRATE, SYNTHETIC BEESWAX, TOCOPHERYL ACETATE, PHENOXYETHANOL, CERAMIDE 3, CAPRYLYL GLYCOL, CHLORPHENESIN, FRAGRANCE. **MAY CONTAIN:** MICA, MANGANESE VIOLET, TITANIUM

**Drug Facts** (continued)

DIOXIDE, BISMUTH OXYCHLORIDE, IRON OXIDES, RED 21 LAKE, RED 27 LAKE, YELLOW 5 LAKE, RED 7 LAKE, TALC, BLUE 1 LAKE.

**Drug Facts**

| Active Ingredients | Purpose |
|---|---|
| Octinoxate 7.00% | Sunscreen |

**Uses**

**Drug Facts** (continued)

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

**Inactive ingredients** DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL

**Drug Facts** (continued)

TRIMELLITATE, ETHYLHEXYL PALMITATE, POLYETHYLENE, COPERNICIA CERIFERA (CARNAUBA) WAX, OZOKERITE, POLYMETHYL METHACRYLATE, TRIDECYL STEARATE, POLYGLYCERYL-3 DIISOSTEARATE, NEOPENTYL

**Drug Facts** (continued)

■ Helps prevent sunburn.

**Warnings**

■ **Skin Cancer / Skin Aging Alert:** Spending time in

**Drug Facts** (continued)

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

**Drug Facts** (continued)

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

**Drug Facts** (continued)

contact a Poison Control Center right away.

**Directions**

■ Apply liberally and evenly 15 minutes before

**Drug Facts** (continued)

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

**Other information**

**PRINCIPAL DISPLAY PANEL - 4 g Tube Box - (VINO DESEO) - PURPLE**

**ésika**
**PRO**

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. e (4g)

ésika
PRO

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. ℮ (4g)

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

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**Drug Facts** (continued)

GLYCOL DICAPRYLATE/DICAPRATE, SYNTHETIC BEESWAX, TOCOPHERYL ACETATE, PHENOXYETHANOL, CERAMIDE 3, CAPRYLYL GLYCOL, CHLORPHENESIN, FRAGRANCE. **MAY CONTAIN:** MICA, MANGANESE VIOLET, TITANIUM ▶

**Drug Facts** (continued)

DIOXIDE, BISMUTH OXYCHLORIDE, IRON OXIDES, RED 21 LAKE, RED 27 LAKE, YELLOW 5 LAKE, RED 7 LAKE, TALC, BLUE 1 LAKE.

**Drug Facts**

| Active Ingredients | Purpose |
|---|---|
| Octinoxate 7.00% | Sunscreen |

**Uses** ▶

**Drug Facts** (continued)

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

**Inactive ingredients** DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL ▶

**Drug Facts** (continued)

TRIMELLITATE, ETHYLHEXYL PALMITATE, POLYETHYLENE, COPERNICIA CERIFERA (CARNAUBA) WAX, OZOKERITE, POLYMETHYL METHACRYLATE, TRIDECYL STEARATE, POLYGLYCERYL-3 DIISOSTEARATE, NEOPENTYL ▶

**Drug Facts** (continued)

■ Helps prevent sunburn.

**Warnings**

■ **Skin Cancer / Skin Aging Alert:** Spending time in ▶

**Drug Facts** (continued)

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 ▶

**Drug Facts** (continued)

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 ▶

**Drug Facts** (continued)

contact a Poison Control Center right away.

**Directions**

■ Apply liberally and evenly 15 minutes before ▶

**Drug Facts** (continued)

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

**Other information** ▶

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

**ésika**
**PRO**

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. e (4g)

ésika
PRO

ADVANCE LASTING
LIPSTICK
Long-lasting and
comfort lipstick
SPF 20

Net Weigth
0.14 oz. ℮ (4g)

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

www.esika.biz

**Drug Facts** (continued)

GLYCOL DICAPRYLATE/DICAPRATE, SYNTHETIC BEESWAX, TOCOPHERYL ACETATE, PHENOXYETHANOL, CERAMIDE 3, CAPRYLYL GLYCOL, CHLORPHENESIN, FRAGRANCE. **MAY CONTAIN:** MICA, MANGANESE VIOLET, TITANIUM ▶

**Drug Facts** (continued)

DIOXIDE, BISMUTH OXYCHLORIDE, IRON OXIDES, RED 21 LAKE, RED 27 LAKE, YELLOW 5 LAKE, RED 7 LAKE, TALC, BLUE 1 LAKE.

**Drug Facts**

| Active Ingredients | Purpose |
|---|---|
| Octinoxate 7.00% | Sunscreen |

**Uses** ▶

**Drug Facts** (continued)

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

**Inactive ingredients** DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL ▶

**Drug Facts** (continued)

TRIMELLITATE, ETHYLHEXYL PALMITATE, POLYETHYLENE, COPERNICIA CERIFERA (CARNAUBA) WAX, OZOKERITE, POLYMETHYL METHACRYLATE, TRIDECYL STEARATE, POLYGLYCERYL-3 DIISOSTEARATE, NEOPENTYL ▶

**Drug Facts** (continued)

■ Helps prevent sunburn.

**Warnings**

■ **Skin Cancer / Skin Aging Alert:** Spending time in ▶

**Drug Facts** (continued)

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 ▶

**Drug Facts** (continued)

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 ▶

**Drug Facts** (continued)

contact a Poison Control Center right away.

**Directions**

■ Apply liberally and evenly 15 minutes before ▶

**Drug Facts** (continued)

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

**Other information** ▶

**PRINCIPAL DISPLAY PANEL - Kit Carton**

**ADVANCE**
**LASTING LIPSTICK**
LONG-LASTING AND COMFORT **LIPSTICK** SPF 20

**ésika**
**PRO**

Net Weight 0.24 oz. **e** (6.8 g.)

## Drug Facts

**Active Ingredients** ..... **Purpose**

OCTINOXATE 7.00% ..... 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.

### Drug Facts (continued)

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

### Other information

- Protect this product in this container form excesive heat and direct sun.

### Inactive Ingredients

DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL TRIMELLITATE, ETHYLHEXYL PALMITATE, POLYETHYLENE, COPERNICIA CERIFERA (CARNAUBA) WAX, OZOKERITE, POLYMETHYL METHACRYLATE, TRIDECYL STEARATE, POLYGLYCERYL-3 DIISOSTEARATE, NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE, SYNTHETIC BEESWAX, TOCOPHERYL ACETATE, PHENOXYETHANOL, CERAMIDE 3, CAPRYLYL GLYCOL, CHLORPHENESIN, FRAGRANCE. **MAY CONTAIN:** MICA, MANGANESE VIOLET, TITANIUM DIOXIDE, BISMUTH OXYCHLORIDE, IRON OXIDES, RED 21 LAKE, RED 27 LAKE, YELLOW 5 LAKE, RED 7 LAKE, TALC, BLUE 1 LAKE.

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

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# ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (MARRON HAVANA) - BROWN

octinoxate lipstick

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:13537-638 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **Octinoxate** (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51) | Octinoxate | 0.07 g in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |

| | |
|---|---|
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:13537-638-02 | 1 in 1 BOX | | |
| **1** | NDC:13537-638-01 | 4 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

# ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (NATURAL DUNE) - PINK

octinoxate lipstick

### Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:13537-639 |
| **Route of Administration** | TOPICAL | | |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **Octinoxate** (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51) | Octinoxate | 0.07 g in 1 g |

### Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |

| | |
|---|---|
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:13537-639-04 | 1 in 1 BOX | | |
| **1** | NDC:13537-639-03 | 4 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

# ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (MARRON FANATIC) - RED

octinoxate lipstick

### Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:13537-640 |
| **Route of Administration** | TOPICAL | | |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **Octinoxate** (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51) | Octinoxate | 0.07 g in 1 g |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:13537-640-06 | 1 in 1 BOX | | |
| **1** | NDC:13537-640-05 | 4 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

# ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (ROJO FIESTA) - RED

octinoxate lipstick

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:13537-642 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **Octinoxate** (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51) | Octinoxate | 0.07 g in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:13537-642-08 | 1 in 1 BOX | | |
| **1** | NDC:13537-642-07 | 4 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

# ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20

# (MARRON BAMBU) - BROWN

octinoxate lipstick

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:13537-643 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **Octinoxate** (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51) | Octinoxate | 0.07 g in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:13537-643-10 | 1 in 1 BOX | | |
| **1** | NDC:13537-643-09 | 4 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

# ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (FUCSIA DELIRIO) - PINK

octinoxate lipstick

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:13537-644 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **Octinoxate** (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51) | Octinoxate | 0.07 g in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:13537-644-12 | 1 in 1 BOX | | |
| **1** | NDC:13537-644-11 | 4 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

# ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (ROJO PASION) - RED

octinoxate lipstick

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:13537-645 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **Octinoxate** (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51) | Octinoxate | 0.07 g in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |

| | |
|---|---|
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:13537-645-14 | 1 in 1 BOX | | |
| **1** | NDC:13537-645-13 | 4 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

# ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (FUCSIA SUBLIME) - PINK

octinoxate lipstick

### Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:13537-646 |
| **Route of Administration** | TOPICAL | | |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **Octinoxate** (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51) | Octinoxate | 0.07 g in 1 g |

### Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |

| | |
|---|---|
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:13537-646-16 | 1 in 1 BOX | | |
| **1** | NDC:13537-646-15 | 4 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

# ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (ROSA FIORELLE) - PINK

octinoxate lipstick

### Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:13537-647 |
| **Route of Administration** | TOPICAL | | |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **Octinoxate** (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51) | Octinoxate | 0.07 g in 1 g |

### Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |

| | |
|---|---|
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:13537-647-18 | 1 in 1 BOX | | |
| **1** | NDC:13537-647-17 | 4 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

# ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (NARANJA OBSESION) - ORANGE

octinoxate lipstick

### Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:13537-648 |
| **Route of Administration** | TOPICAL | | |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **Octinoxate** (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51) | Octinoxate | 0.07 g in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:13537-648-20 | 1 in 1 BOX | | |
| **1** | NDC:13537-648-19 | 4 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

# ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (BORGONA SWEET) - PINK

octinoxate lipstick

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:13537-649 |

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

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **Octinoxate** (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51) | Octinoxate | 0.07 g in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:13537-649-22 | 1 in 1 BOX | | |
| **1** | NDC:13537-649-21 | 4 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

# ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (VINO DESEO) - PURPLE

octinoxate lipstick

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:13537-650 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **Octinoxate** (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51) | Octinoxate | 0.07 g in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:13537-650-24 | 1 in 1 BOX | | |
| **1** | NDC:13537-650-23 | 4 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

# ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (FUCSIA TENTACION) - PINK

octinoxate lipstick

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:13537-651 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **Octinoxate** (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51) | Octinoxate | 0.07 g in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:13537-651-26 | 1 in 1 BOX | | |
| **1** | NDC:13537-651-25 | 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 | 04/17/2015 | |

# ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20

octinoxate kit

### Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:13537-688 |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:13537-688-28 | 2 in 1 CARTON | | |
| **1** | NDC:13537-688-27 | 1 in 1 TUBE | | |

### Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|---|---|---|
| **Part 1** | 1 TUBE | 6.8 g |
| **Part 2** | 1 TUBE | 6.8 g |
| **Part 3** | 1 TUBE | 6.8 g |
| **Part 4** | 1 TUBE | 6.8 g |
| **Part 5** | 1 TUBE | 6.8 g |
| **Part 6** | 1 TUBE | 6.8 g |
| **Part 7** | 1 TUBE | 6.8 g |
| **Part 8** | 1 TUBE | 6.8 g |
| **Part 9** | 1 TUBE | 6.8 g |
| **Part 10** | 1 TUBE | 6.8 g |
| **Part 11** | 1 TUBE | 6.8 g |
| **Part 12** | 1 TUBE | 6.8 g |

## Part 1 of 12

## ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20

# (MARRON HAVANA) - BROWN

octinoxate lipstick

## Product Information

| | |
|---|---|
| **Route of Administration** | TOPICAL |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **OCTINOXATE** (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 0.07 g in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | | 6.8 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

## Part 2 of 12

# ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (NATURAL DUNE) - PINK

octinoxate lipstick

## Product Information

| | |
|---|---|
| **Route of Administration** | TOPICAL |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **OCTINOXATE** (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 0.07 g in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| 1 | | 6.8 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

## Part 3 of 12

# ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (MARRON FANATIC) - RED

octinoxate lipstick

## Product Information

| | |
|---|---|
| **Route of Administration** | TOPICAL |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **OCTINOXATE** (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 0.07 g in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |

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

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | | 6.8 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

## Part 4 of 12

# ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (ROJO FIESTA) - RED

octinoxate lipstick

## Product Information

| | |
|---|---|
| **Route of Administration** | TOPICAL |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **OCTINOXATE** (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 0.07 g in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |

| | |
|---|---|
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | | 6.8 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

## Part 5 of 12

## ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (MARRON BAMBU) - BROWN

octinoxate lipstick

### Product Information

| | |
|---|---|
| **Route of Administration** | TOPICAL |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **OCTINOXATE** (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 0.07 g in 1 g |

### Inactive Ingredients

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

| | |
|---|---|
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | | 6.8 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

## Part 6 of 12

## ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (FUCSIA DELIRIO) - PINK

octinoxate lipstick

## Product Information

| | |
|---|---|
| **Route of Administration** | TOPICAL |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **OCTINOXATE** (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 0.07 g in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | | 6.8 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

## Part 7 of 12

## ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (ROJO PASION) - RED

octinoxate lipstick

## Product Information

| | |
|---|---|
| **Route of Administration** | TOPICAL |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **OCTINOXATE** (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 0.07 g in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | | 6.8 g in 1 TUBE; Type 0: Not a Combination Product | | |

# Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

## Part 8 of 12

# ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (FUCSIA SUBLIME) - PINK

octinoxate lipstick

### Product Information

| | |
|---|---|
| **Route of Administration** | TOPICAL |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **OCTINOXATE** (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 0.07 g in 1 g |

### Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| 1 | | 6.8 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

## Part 9 of 12

# ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (ROSA FIORELLE) - PINK

octinoxate lipstick

## Product Information

| | |
|---|---|
| **Route of Administration** | TOPICAL |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **OCTINOXATE** (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 0.07 g in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |

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

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | | 6.8 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

## Part 10 of 12

## ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (BORGONA SWEET) - PINK

octinoxate lipstick

### Product Information

| | |
|---|---|
| **Route of Administration** | TOPICAL |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **OCTINOXATE** (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 0.07 g in 1 g |

### Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |

| | |
|---|---|
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | | 6.8 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

## Part 11 of 12

# ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (VINO DESEO) - PURPLE

octinoxate lipstick

## Product Information

| | |
|---|---|
| **Route of Administration** | TOPICAL |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **OCTINOXATE** (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 0.07 g in 1 g |

## Inactive Ingredients

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

| | |
|---|---|
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | | 6.8 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

## Part 12 of 12

## ESIKA PRO ADVANCE LASTING LONG-LASTING AND COMFORT SPF 20 (FUCSIA TENTACION) - PINK

octinoxate lipstick

### Product Information

| | |
|---|---|
| **Route of Administration** | TOPICAL |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **OCTINOXATE** (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 0.07 g in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE** (UNII: 554N82UWVW) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **HIGH DENSITY POLYETHYLENE** (UNII: UG00KM4WR7) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **POLYGLYCERYL-3 DIISOSTEARATE** (UNII: 46P231IQV8) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CERAMIDE 3** (UNII: 4370DF050B) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **MICA** (UNII: V8A1AW0880) | |
| **MANGANESE VIOLET** (UNII: 72M48QQV8Q) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **BISMUTH OXYCHLORIDE** (UNII: 4ZR792I587) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **D&C RED NO. 21** (UNII: 08744Z6JNY) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **D&C RED NO. 7** (UNII: ECW0LZ41X8) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | | 6.8 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |


## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part352 | 04/17/2015 | |

## Labeler - Ventura Corporation LTD (602751344)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Bel Star S.A. (Colombia) | | 880160197 | MANUFACTURE(13537-638, 13537-639, 13537-640, 13537-642, 13537-643, 13537-644, 13537-645, 13537-646, 13537-647, 13537-648, 13537-649, 13537-650, 13537-651, 13537-688) |