

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD PIMIENTA CALIENTE) - BROWN- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD VINO CAUTIVANTE) - BROWN- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROSA VIVA) - PINK- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD CORAL ENSUENO) - RED- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROJO GLAM) - RED- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD CAFE HABANO) - BROWN- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD FUCSIA VIBRANTE) - PINK- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD MELON INTENSE) - PINK- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROSADO CHIC) - PINK- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD CIRUELA GLAM) - RED- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD FRAMBUESA ENCANTO) - PURPLE- octinoxate lipstick
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD MAGENTA SWEET) - PURPLE- octinoxate lipstick
ESIKA PRO HD COLOR 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.

ESIKA PRO HD COLOR 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, OCTYLDODECANOL, CAPRYLIC/CAPRIC TRIGLYCERIDE, POLYETHYLENE, TRIDECYL TRIMELLITATE, CASTOR ISOSTEARATE BEESWAX SUCCINATE, POLYGLYCERYL-3 DIISOSTEARATE, ISOPROPYL LANOLATE, COPERNICIA CERIFERA (CARNAUBA) WAX, MICA, MICROCRYSTALLINE WAX, DIISOSTEARYL MALATE, GLYCERYL ISOSTEARATE, ISOSTEARYL ALCOHOL, BUTYROSPERMUM PARKII (SHEA) BUTTER, PHENOXYETHANOL, BETA-SITOSTEROL, PHENYL TRIMETHICONE, SILICA, SILICA SILYLATE, EUPHORBIA CERIFERA (CANDELILLA) WAX, FRAGRANCE, CAPRYLYL GLYCOL, DIMETHICONE, CHLORPHENESIN, CERAMIDE 3, TOCOPHERYL ACETATE, OLEYL ALCOHOL, TRIMETHYLSILOXYSILICATE, BENZIMIDAZOLE DIAMOND AMIDOETHYL UREA CARBAMOYL PROPYL POLYMETHYLSILSESQUIOXANE, DIOLEYL TOCOPHERYL METHYLSILANOL. **May Contain:** TITANIUM DIOXIDE, MICA, IRON OXIDES, RED 30 LAKE, RED 7 LAKE, YELLOW 5 LAKE, RED 27 LAKE, TALC, CALCIUM ALUMINUM BOROSILICATE, CARMINE, TIN OXIDE.

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

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

HD COLOR

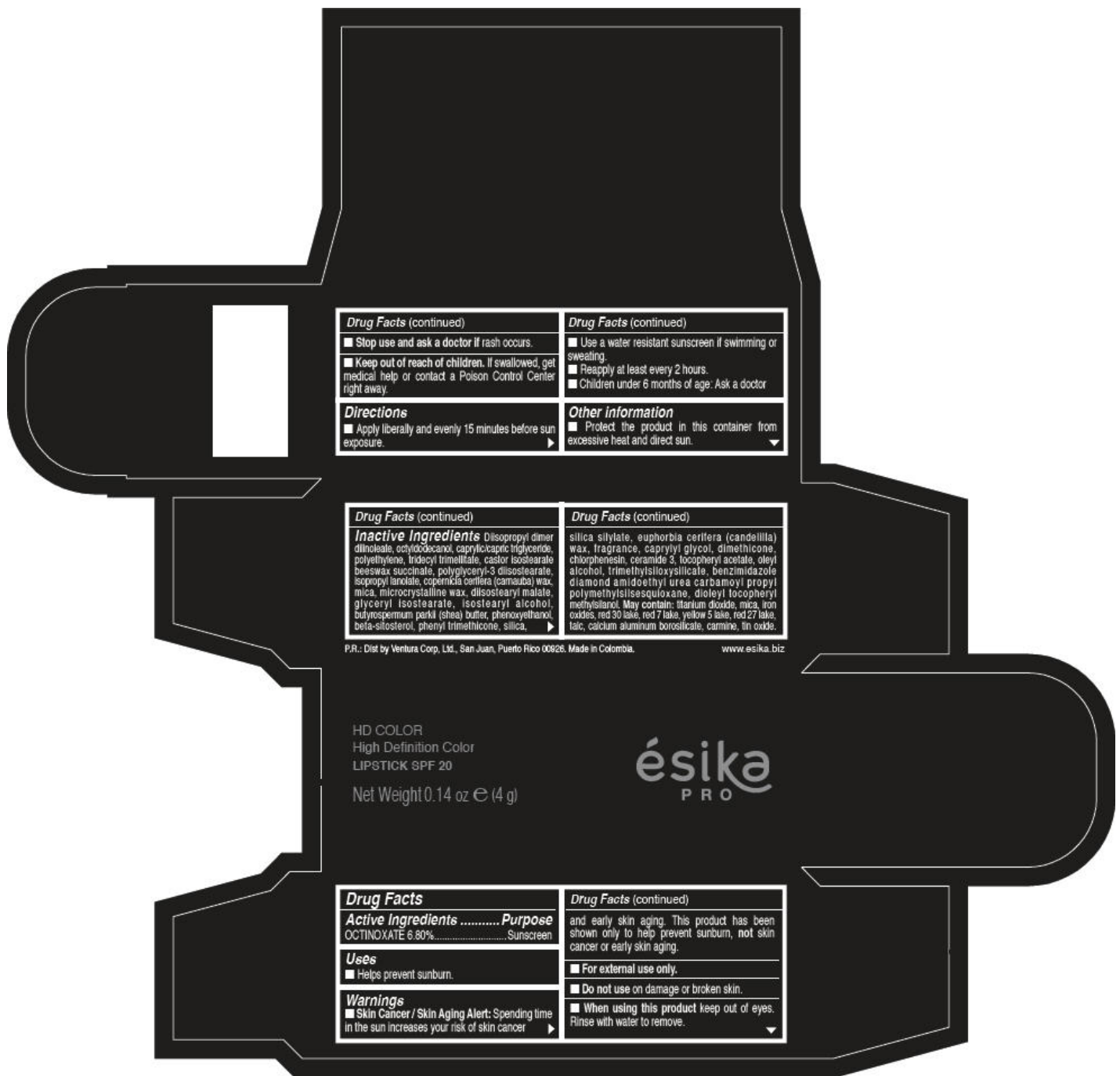
High Definition Color

LIPSTICK SPF 20

Net Weight 0.14 oz e (4 g)

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PRO



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)

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

Drug Facts (continued)

Inactive Ingredients Disopropyl dimar dilinolate, octyloctadecanoic caprylic/capric triglyceride, polyethylene, triethyl trimellitate, castor isostearate beeswax succinate, polyglyceryl-3 distostearate, isopropyl lanolate, copernicia cerifera (carnauba) wax, mica, microcrystalline wax, distostearyl malate, glyceryl isostearate, isostearyl alcohol, butyrospermium parkii (shea) butter, phenoxethylalcohol, beta-sitosterol, phenyl trimethylsiloxane, silica, ▶

Drug Facts (continued)

silica silylate, euphorbia cerifera (candelilla) wax, fragrance, caprylyl glycol, dimethicone, chlorphenesin, ceramide 3, tocopheryl acetate, oleyl alcohol, trimethylsilyloxy silicate, benzimidazole diamond amidoethyl urea carbamoyl propyl polymethylsilsesquioxane, dioleoyl tocopheryl methylsilanol. May contain: titanium dioxide, mica, iron oxides, red 30 lake, red 7 lake, yellow 5 lake, red 27 lake, lac, calcium aluminum borosilicate, carmine, tin oxide.

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HD COLOR
High Definition Color
LIPSTICK SPF 20
Net Weight 0.14 oz e (4 g)



Drug Facts

Active Ingredients **Purpose**
OCTINOXATE 6.80%..... 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.

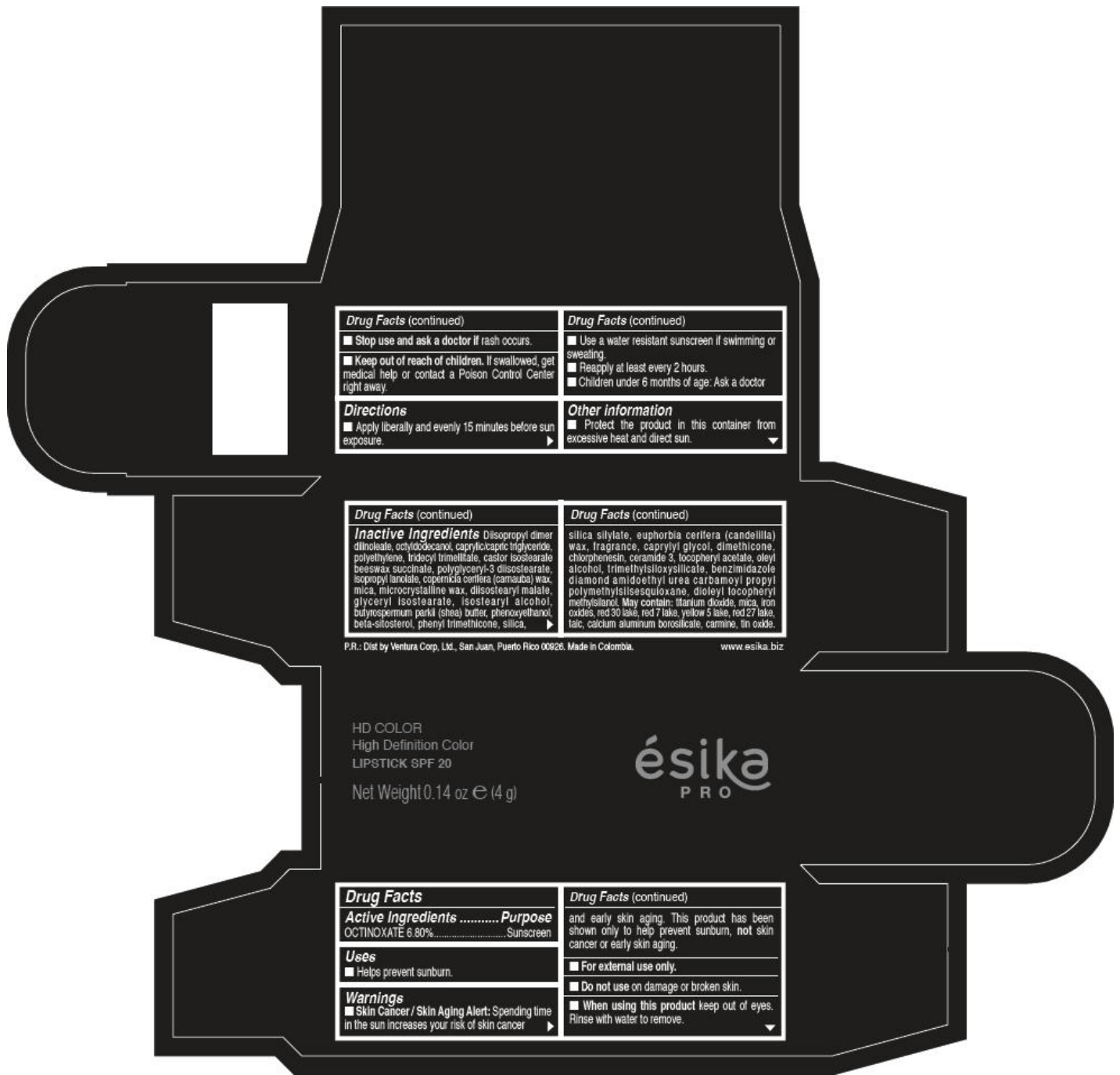
- For external use only.

- Do not use on damage or broken skin.
- When using this product keep out of eyes. Rinse with water to remove. ▼

PRINCIPAL DISPLAY PANEL - 4 g Tube Box (HD VINO CAUTIVANTE) - BROWN

HD COLOR
High Definition Color
LIPSTICK SPF 20
Net Weight 0.14 oz e (4 g)

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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)

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

Drug Facts (continued)

Inactive Ingredients Disopropyl dimar dilinolate, octyloctadecanoic, caprylic/capric triglyceride, polyethylene, triethyl trimellitate, castor isostearate beeswax succinate, polyglyceryl-3 distostearate, isopropyl lanolate, copernicia cerifera (carnauba) wax, mica, microcrystalline wax, distostearyl malate, glyceryl isostearate, isostearyl alcohol, butyrospermium parkii (shea) butter, phenoxethylalcohol, beta-sitosterol, phenyl trimethylsiloxane, silica, ▶

Drug Facts (continued)

silica silylate, euphorbia cerifera (candelilla) wax, fragrance, caprylyl glycol, dimethicone, chlorphenesin, ceramide 3, tocopheryl acetate, oleyl alcohol, trimethylsiloxyethylsilicate, benzimidazole diamond amidoethyl urea carbamoyl propyl polymethylsilsesquioxane, dioleyl tocopheryl methylsilanol. May contain: titanium dioxide, mica, iron oxides, red 30 lake, red 7 lake, yellow 5 lake, red 27 lake, lake, calcium aluminum borosilicate, carmine, tin oxide.

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HD COLOR
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LIPSTICK SPF 20
Net Weight 0.14 oz e (4 g)



Drug Facts

Active Ingredients **Purpose**
OCTINOXATE 6.80%..... 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.

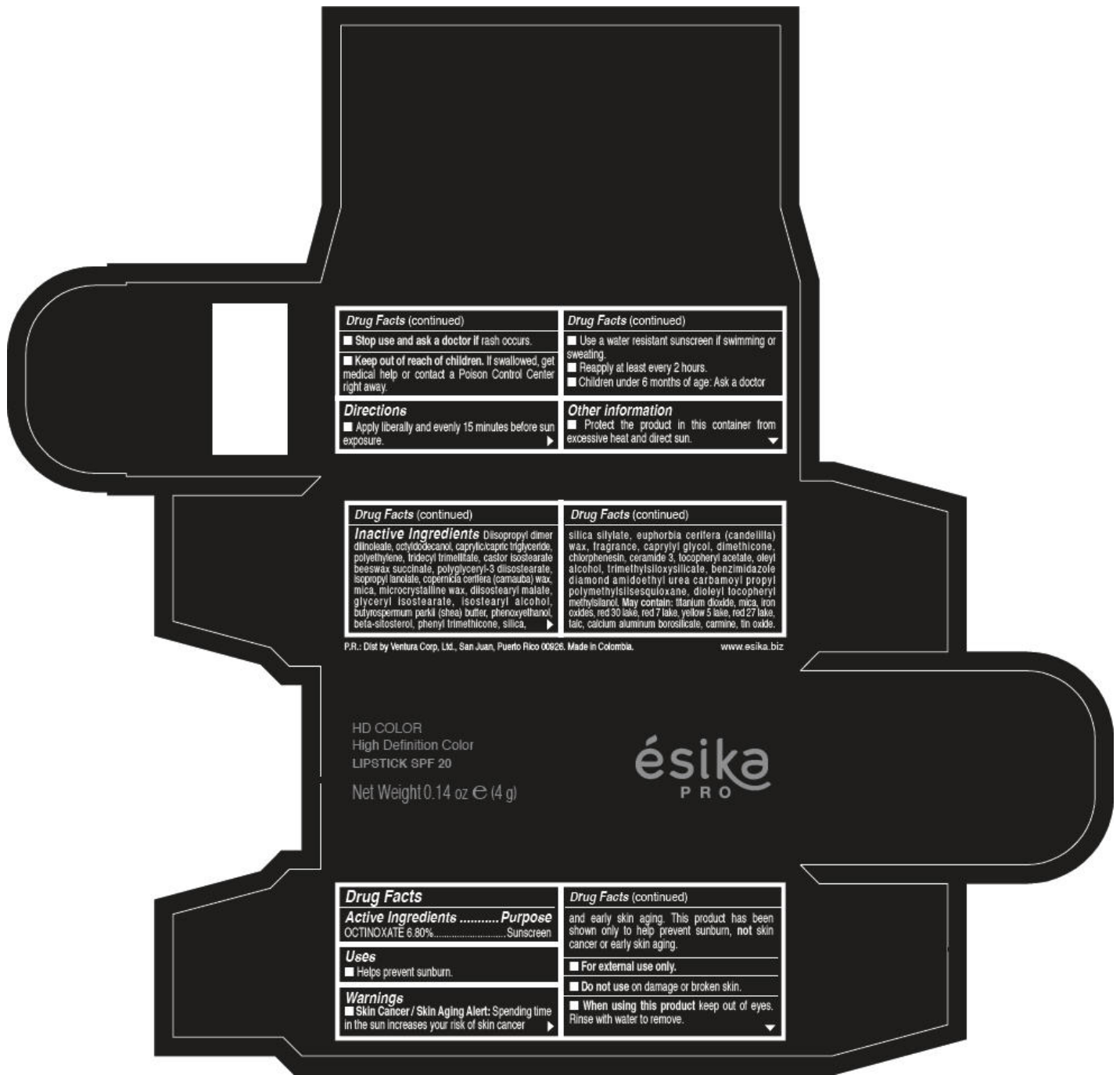
- Do not use on damage or broken skin.
- When using this product keep out of eyes. Rinse with water to remove. ▼

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

HD COLOR
High Definition Color
LIPSTICK SPF 20

Net Weight 0.14 oz e (4 g)

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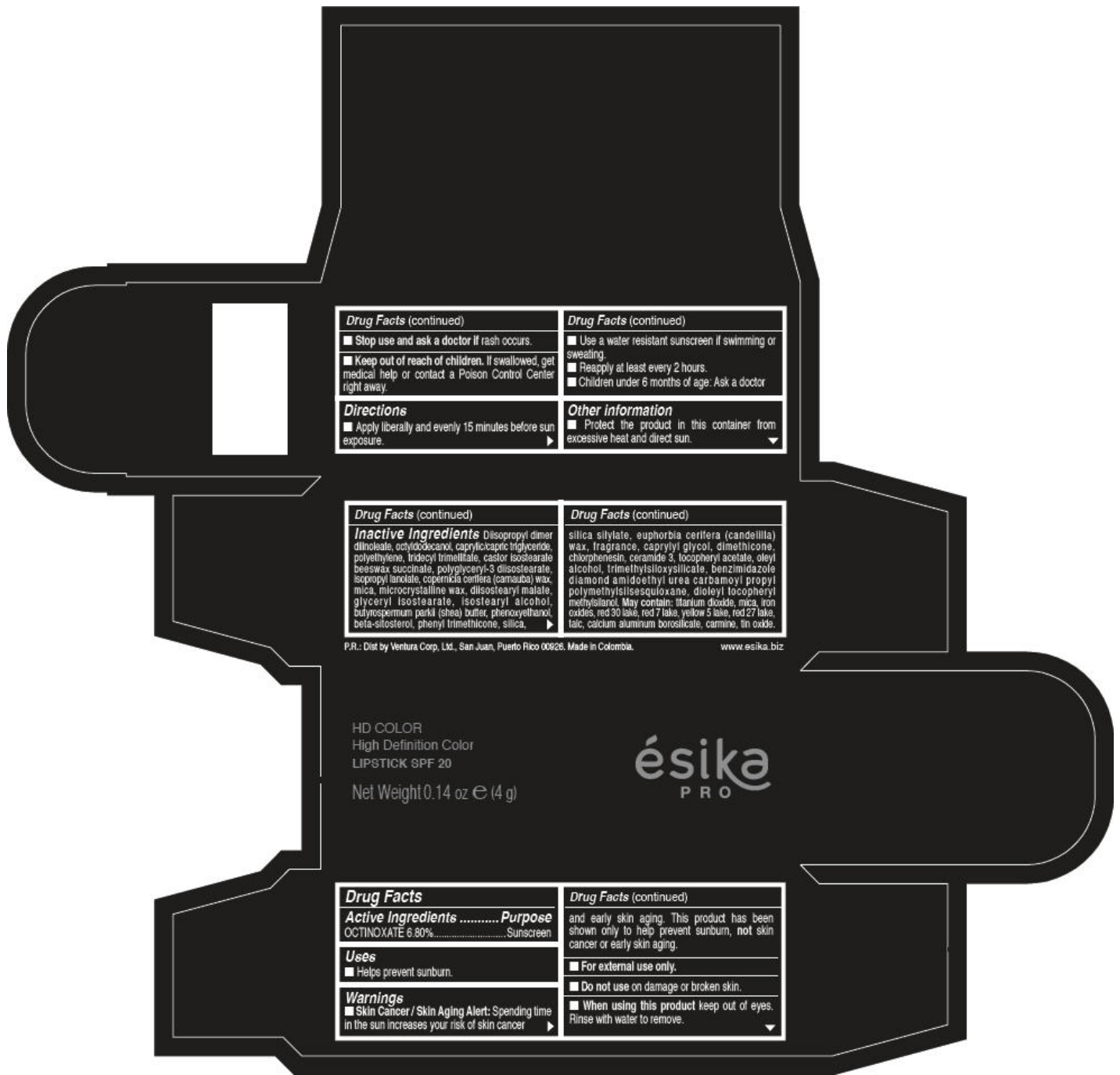


PRINCIPAL DISPLAY PANEL - 4 g Tube Box (HD CORAL ENSUENO) - RED

HD COLOR
 High Definition Color
LIPSTICK SPF 20

Net Weight 0.14 oz e (4 g)

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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)

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

Drug Facts (continued)

Inactive Ingredients Disopropyl dimar dilinolate, octyloctadecanoic, caprylic/capric triglyceride, polyethylene, triethyl trimellitate, castor isostearate beeswax succinate, polyglyceryl-3 distostearate, isopropyl lanolate, copernicia cerifera (carnauba) wax, mica, microcrystalline wax, distostearyl malate, glyceryl isostearate, isostearyl alcohol, butyrospermium parkii (shea) butter, phenoxethyl alcohol, beta-sitosterol, phenyl trimethylsiloxane, silica, ▶

Drug Facts (continued)

silica silylate, euphorbia cerifera (candelilla) wax, fragrance, caprylyl glycol, dimethicone, chlorphenesin, ceramide 3, tocopheryl acetate, oleyl alcohol, trimethylsilyloxy silicate, benzimidazole diamond amidoethyl urea carbamoyl propyl polymethylsilsesquioxane, dioleyl tocopheryl methylsilanol. May contain: titanium dioxide, mica, iron oxides, red 30 lake, red 7 lake, yellow 5 lake, red 27 lake, lac, calcium aluminum borosilicate, carmine, tin oxide.

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HD COLOR
High Definition Color
LIPSTICK SPF 20
Net Weight 0.14 oz e (4 g)



Drug Facts

Active Ingredients **Purpose**
OCTINOXATE 6.80%..... 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.

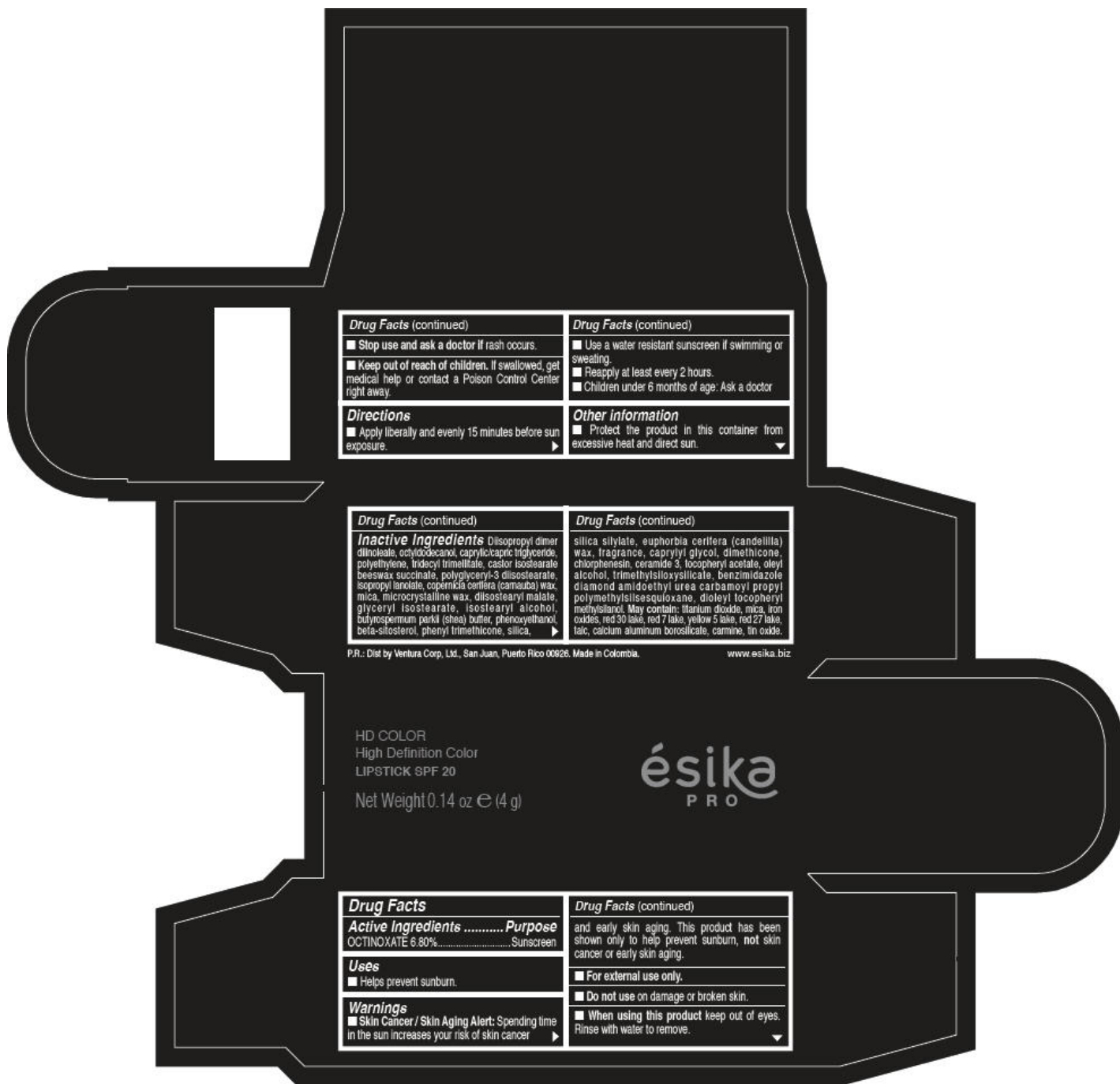
- Do not use on damage or broken skin.
- When using this product keep out of eyes. Rinse with water to remove.

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

HD COLOR
High Definition Color
LIPSTICK SPF 20

Net Weight 0.14 oz e (4 g)

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PRO



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)

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

Drug Facts (continued)

Inactive Ingredients Disopropyl dimar dilinoleate, octyloctadecanoic, caprylic/capric triglyceride, polyethylene, triethyl trimellitate, castor isostearate beeswax succinate, polyglyceryl-3 distostearate, isopropyl lanolate, copernicia cerifera (carnauba) wax, mica, microcrystalline wax, distostearyl malate, glyceryl isostearate, isostearyl alcohol, butyrospermium parkii (shea) butter, phenoxethylalcohol, beta-sitosterol, phenyl trimethylcone, silica, ▶

Drug Facts (continued)

silica silylate, euphorbia cerifera (candelilla) wax, fragrance, caprylyl glycol, dimethicone, chlorphenesin, ceramide 3, tocopheryl acetate, oleyl alcohol, trimethylsilyloxy silicate, benzimidazole diamond amidoethyl urea carbamoyl propyl polymethylsilsesquioxane, dioleyl tocopheryl methylsilanol. May contain: titanium dioxide, mica, iron oxides, red 30 lake, red 7 lake, yellow 5 lake, red 27 lake, lac, calcium aluminum borosilicate, carmine, tin oxide.

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HD COLOR
High Definition Color
LIPSTICK SPF 20
Net Weight 0.14 oz e (4 g)



Drug Facts

Active Ingredients **Purpose**
OCTINOXATE 6.80%.....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.

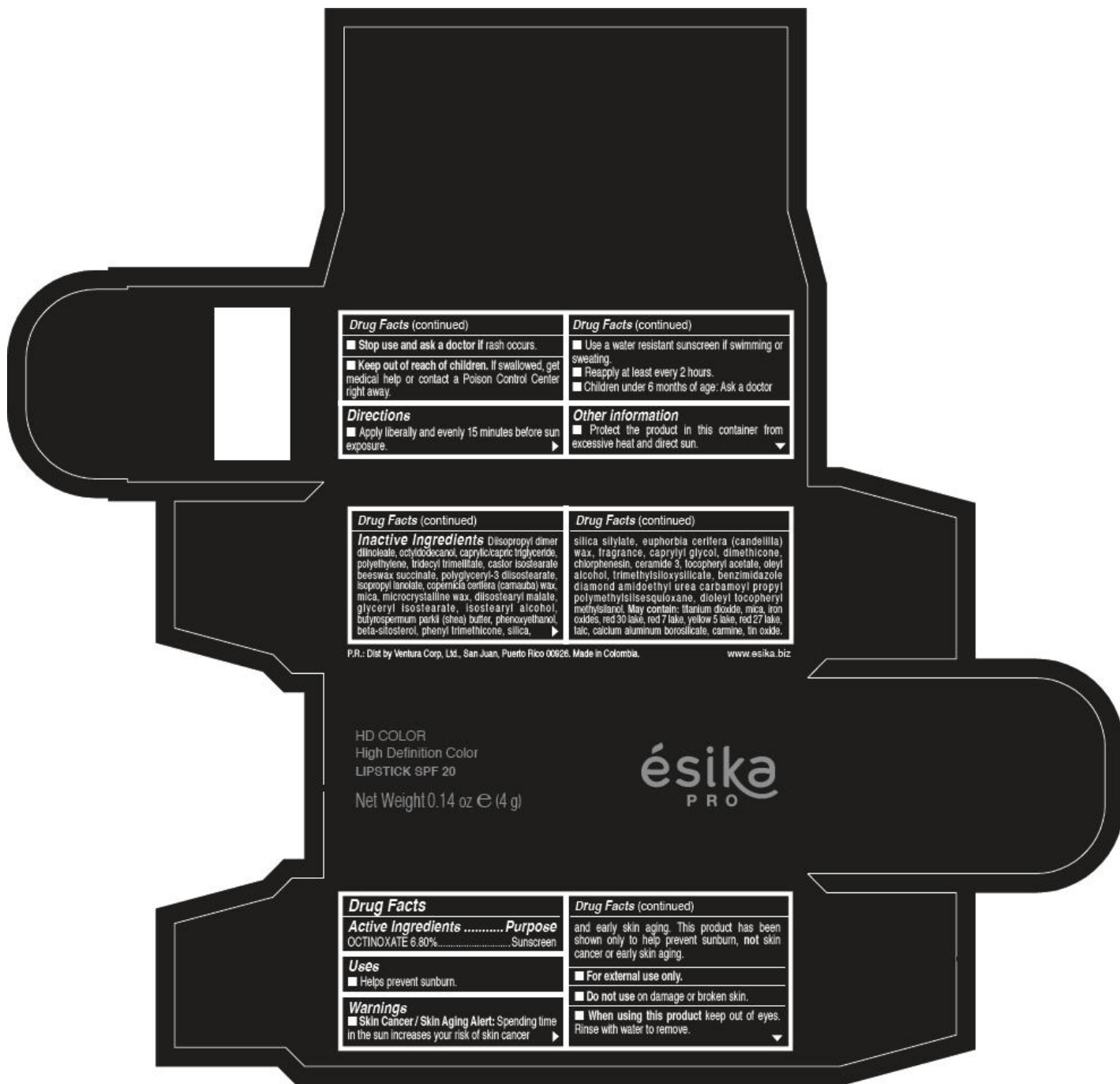
- For external use only.
- Do not use on damage or broken skin.
- When using this product keep out of eyes. Rinse with water to remove. ▼

PRINCIPAL DISPLAY PANEL - 4 g Tube Box (HD CAFE HABANO) - BROWN

HD COLOR
High Definition Color
LIPSTICK SPF 20

Net Weight 0.14 oz e (4 g)

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PRO

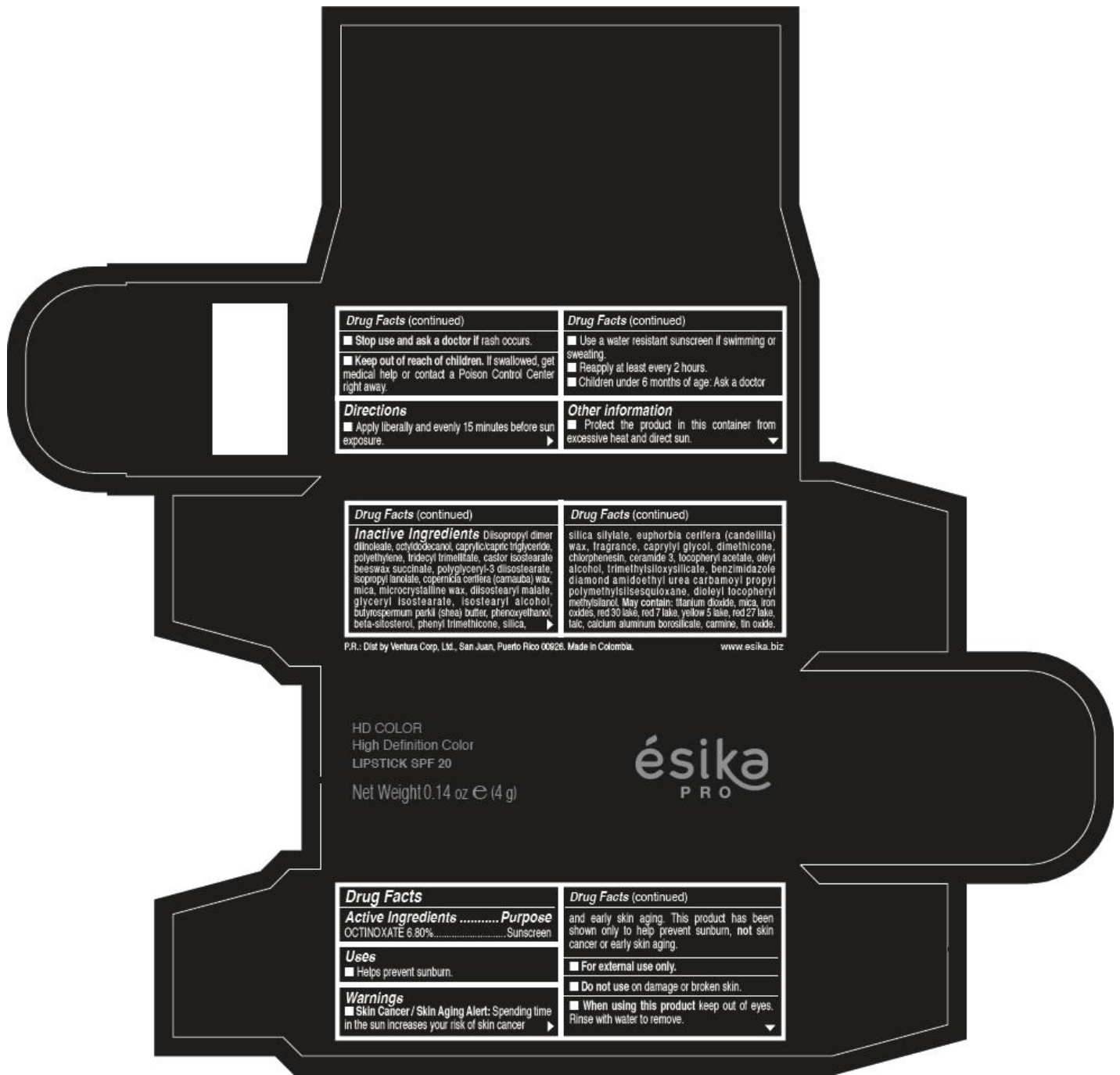


PRINCIPAL DISPLAY PANEL - 4 g Tube Box (HD FUCSIA VIBRANTE) - PINK

HD COLOR
 High Definition Color
LIPSTICK SPF 20

Net Weight 0.14 oz e (4 g)

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PRO



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)

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

Drug Facts (continued)

Inactive Ingredients Disopropyl dimar dilinolate, octyloctadecanoic, caprylic/capric triglyceride, polyethylene, triethyl trimellitate, castor isostearate beeswax succinate, polyglyceryl-3 distostearate, isopropyl lanolate, copernicia cerifera (carnauba) wax, mica, microcrystalline wax, distostearyl malate, glyceryl isostearate, isostearyl alcohol, butyrospermium parkii (shea) butter, phenoxethylalcohol, beta-sitosterol, phenyl trimethylsiloxane, silica.

Drug Facts (continued)

silica silylate, euphorbia cerifera (candelilla) wax, fragrance, caprylyl glycol, dimethicone, chlorphenesin, ceramide 3, tocopheryl acetate, oleyl alcohol, trimethylsilyloxy silicate, benzimidazole diamond amidoethyl urea carbamoyl propyl polymethylsilsesquioxane, dioleyl tocopheryl methylsilanol. May contain: titanium dioxide, mica, iron oxides, red 30 lake, red 7 lake, yellow 5 lake, red 27 lake, lac, calcium aluminum borosilicate, carmine, tin oxide.

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HD COLOR
High Definition Color
LIPSTICK SPF 20
Net Weight 0.14 oz e (4 g)



Drug Facts

Active Ingredients **Purpose**
OCTINOXATE 6.80%..... 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)

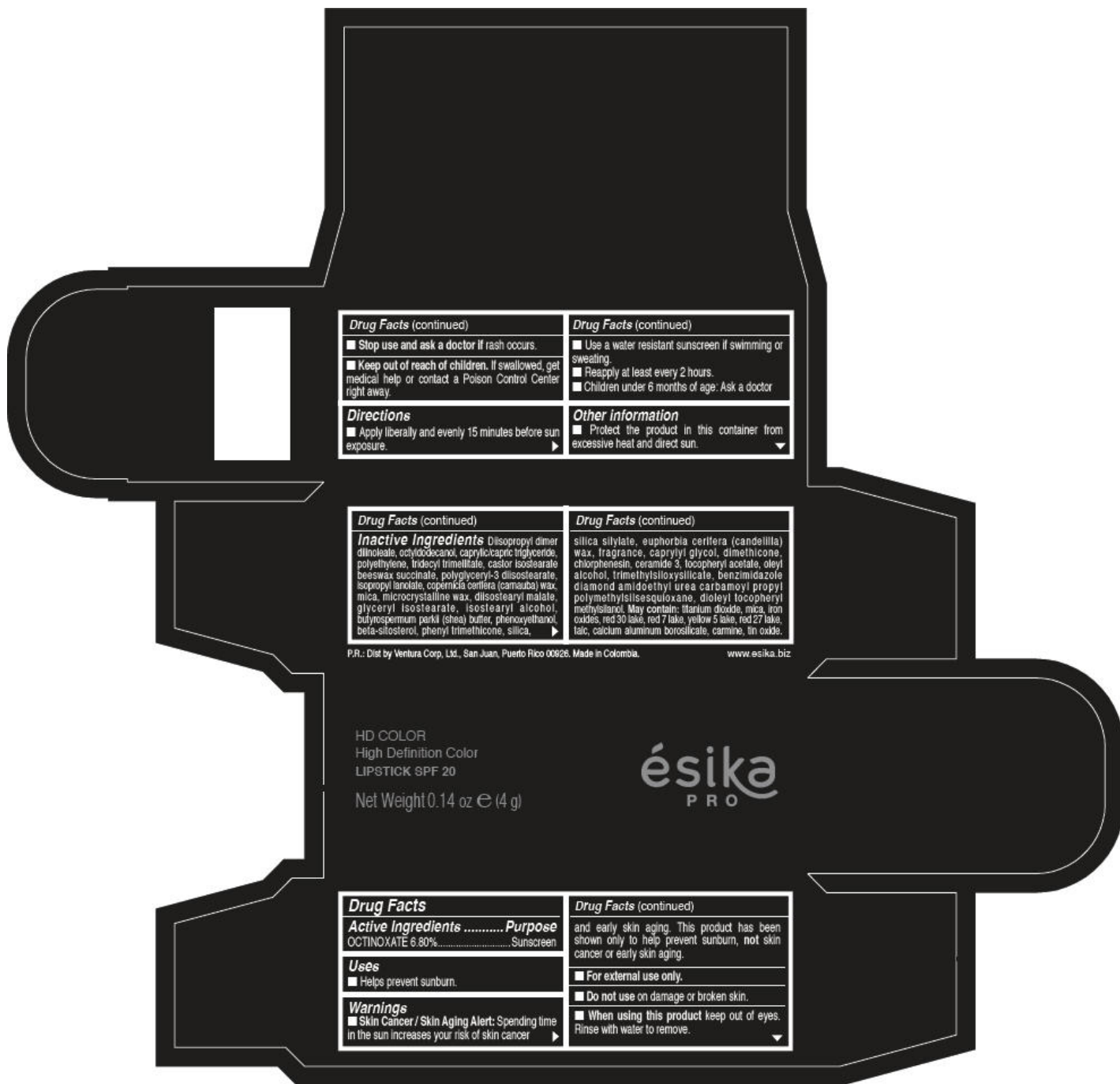
and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.

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

PRINCIPAL DISPLAY PANEL - 4 g Tube Box (HD MELON INTENSE) - PINK

HD COLOR
High Definition Color
LIPSTICK SPF 20
Net Weight 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)

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

Drug Facts (continued)

Inactive Ingredients Disopropyl dimethyl malate, octyldodecanol, caprylic/capric triglyceride, polyethylene, triethyl trimellitate, castor isostearate beeswax succinate, polyglyceryl-3 distostearate, isopropyl lanolate, copernicia cerifera (carnauba) wax, mica, microcrystalline wax, distostearyl malate, glyceryl isostearate, isostearyl alcohol, butyrospermium parkii (shea) butter, phenoxethyl alcohol, beta-sitosterol, phenyl trimethylsiloxane, silica.

Drug Facts (continued)

silica silylate, euphorbia cerifera (candelilla) wax, fragrance, caprylyl glycol, dimethicone, chlorphenesin, ceramide 3, tocopheryl acetate, oleyl alcohol, trimethylsilyloxy silicate, benzimidazole diamond amidoethyl urea carbamoyl propyl polymethylsilsesquioxane, dioleoyl tocopheryl methylsilanol. May contain: titanium dioxide, mica, iron oxides, red 30 lake, red 7 lake, yellow 5 lake, red 27 lake, lac, calcium aluminum borosilicate, carmine, tin oxide.

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HD COLOR
High Definition Color
LIPSTICK SPF 20
Net Weight 0.14 oz e (4 g)



Drug Facts

Active Ingredients **Purpose**
OCTINOXATE 6.80%..... 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.

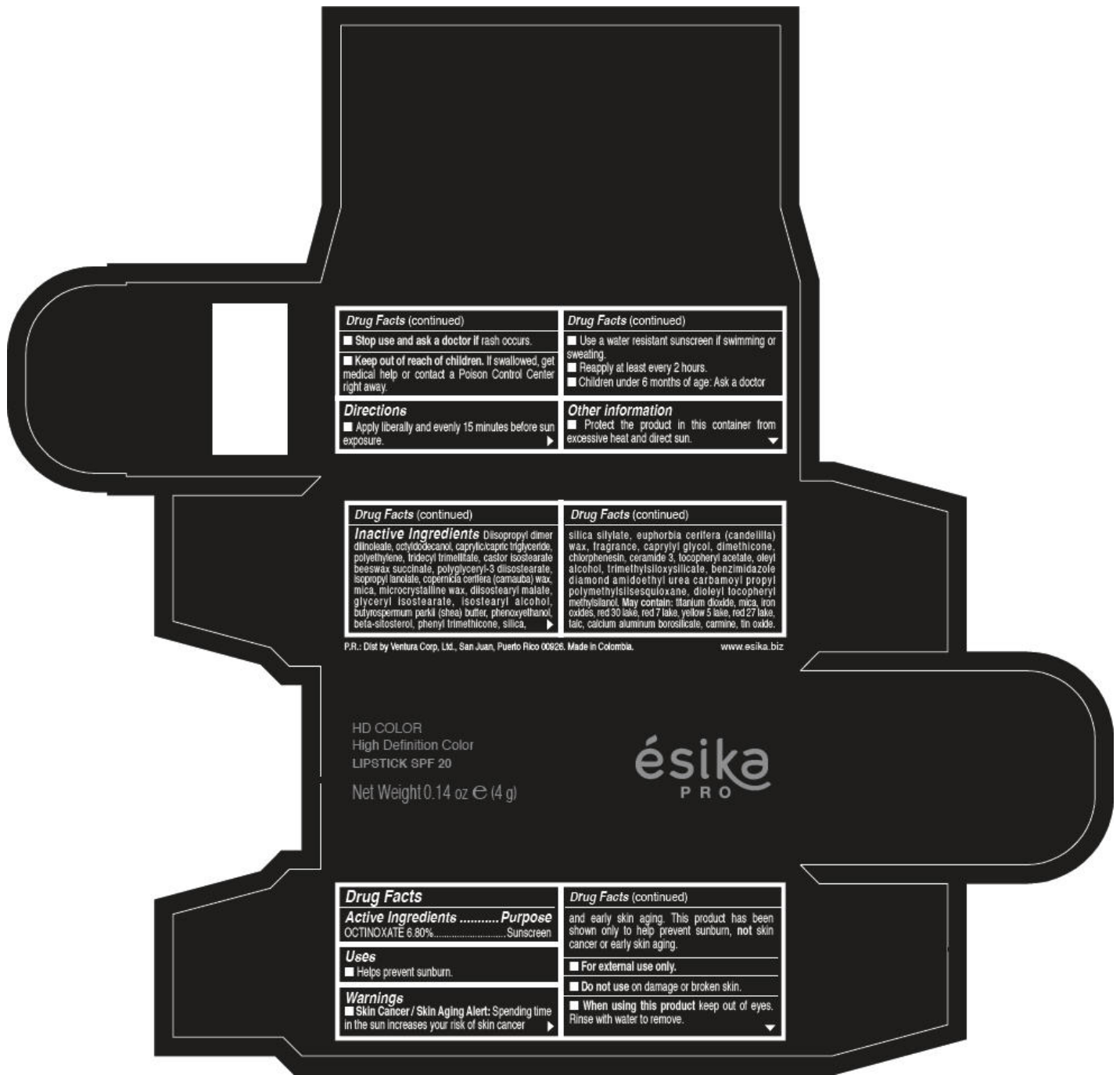
- Do not use on damage or broken skin.
- When using this product keep out of eyes. Rinse with water to remove.

PRINCIPAL DISPLAY PANEL - 4 g Tube Box (HD ROSADO CHIC) - PINK

HD COLOR
High Definition Color
LIPSTICK SPF 20

Net Weight 0.14 oz e (4 g)

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PRO



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)

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

Drug Facts (continued)

Inactive Ingredients Disopropyl dimar dilinolate, octyloctadecanoic, caprylic/capric triglyceride, polyethylene, triethyl trimellitate, castor isostearate beeswax succinate, polyglyceryl-3 distostearate, isopropyl lanolate, copernicia cerifera (carnauba) wax, mica, microcrystalline wax, distostearyl malate, glyceryl isostearate, isostearyl alcohol, butyrospermium parkii (shea) butter, phenoxethylalcohol, beta-sitosterol, phenyl trimethylsiloxane, silica, ▶

Drug Facts (continued)

silica silylate, euphorbia cerifera (candelilla) wax, fragrance, caprylyl glycol, dimethicone, chlorphenesin, ceramide 3, tocopheryl acetate, oleyl alcohol, trimethylsilyloxy silicate, benzimidazole diamond amidoethyl urea carbamoyl propyl polymethylsilsesquioxane, dioleyl tocopheryl methylsilanol. May contain: titanium dioxide, mica, iron oxides, red 30 lake, red 7 lake, yellow 5 lake, red 27 lake, lac, calcium aluminum borosilicate, carmine, tin oxide.

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HD COLOR
High Definition Color
LIPSTICK SPF 20
Net Weight 0.14 oz e (4 g)



Drug Facts

Active Ingredients **Purpose**
OCTINOXATE 6.80%..... 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.

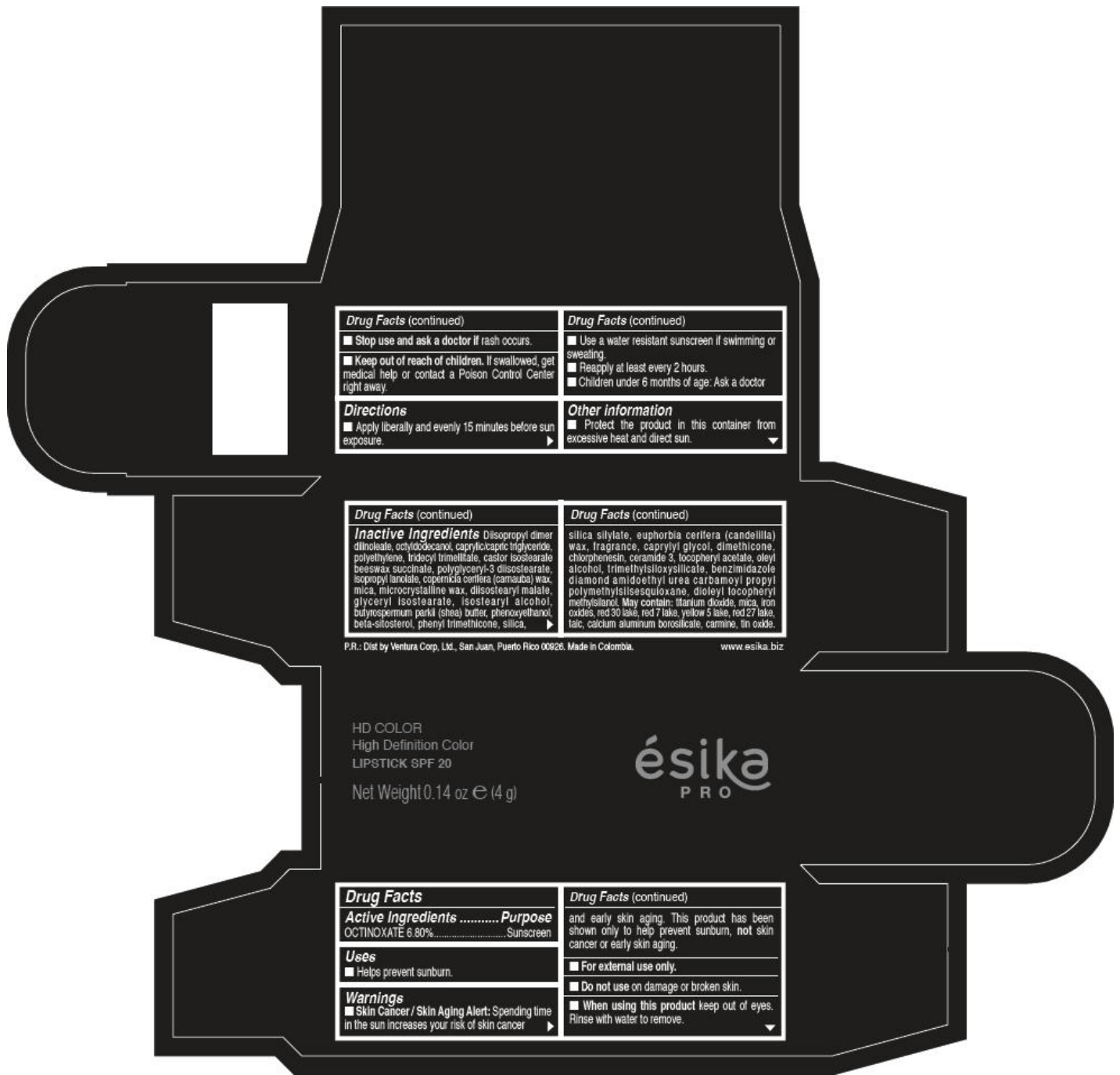
- Do not use on damage or broken skin.
- When using this product keep out of eyes. Rinse with water to remove. ▼

PRINCIPAL DISPLAY PANEL - 4 g Tube Box (HD CIRUELA GLAM) - RED

HD COLOR
High Definition Color
LIPSTICK SPF 20

Net Weight 0.14 oz e (4 g)

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PRO



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)

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

Drug Facts (continued)

Inactive Ingredients Disopropyl dimar dilinolate, octyloctadecanoic, caprylic/capric triglyceride, polyethylene, triethyl trimellitate, castor isostearate beeswax succinate, polyglyceryl-3 distostearate, isopropyl lanolate, copernicia cerifera (carnauba) wax, mica, microcrystalline wax, distostearyl malate, glyceryl isostearate, isostearyl alcohol, butyrospermium parkii (shea) butter, phenoxethylalcohol, beta-sitosterol, phenyl trimethylcone, silica, ▶

Drug Facts (continued)

silica silylate, euphorbia cerifera (candelilla) wax, fragrance, caprylyl glycol, dimethicone, chlorphenesin, ceramide 3, tocopheryl acetate, oleyl alcohol, trimethylsilyloxy silicate, benzimidazole diamond amidoethyl urea carbamoyl propyl polymethylsilsesquioxane, dioleoyl tocopheryl methylsilanol. May contain: titanium dioxide, mica, iron oxides, red 30 lake, red 7 lake, yellow 5 lake, red 27 lake, lac, calcium aluminum borosilicate, carmine, tin oxide.

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HD COLOR
High Definition Color
LIPSTICK SPF 20
Net Weight 0.14 oz e (4 g)



Drug Facts

Active Ingredients	Purpose
OCTINOXATE 6.80%	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)

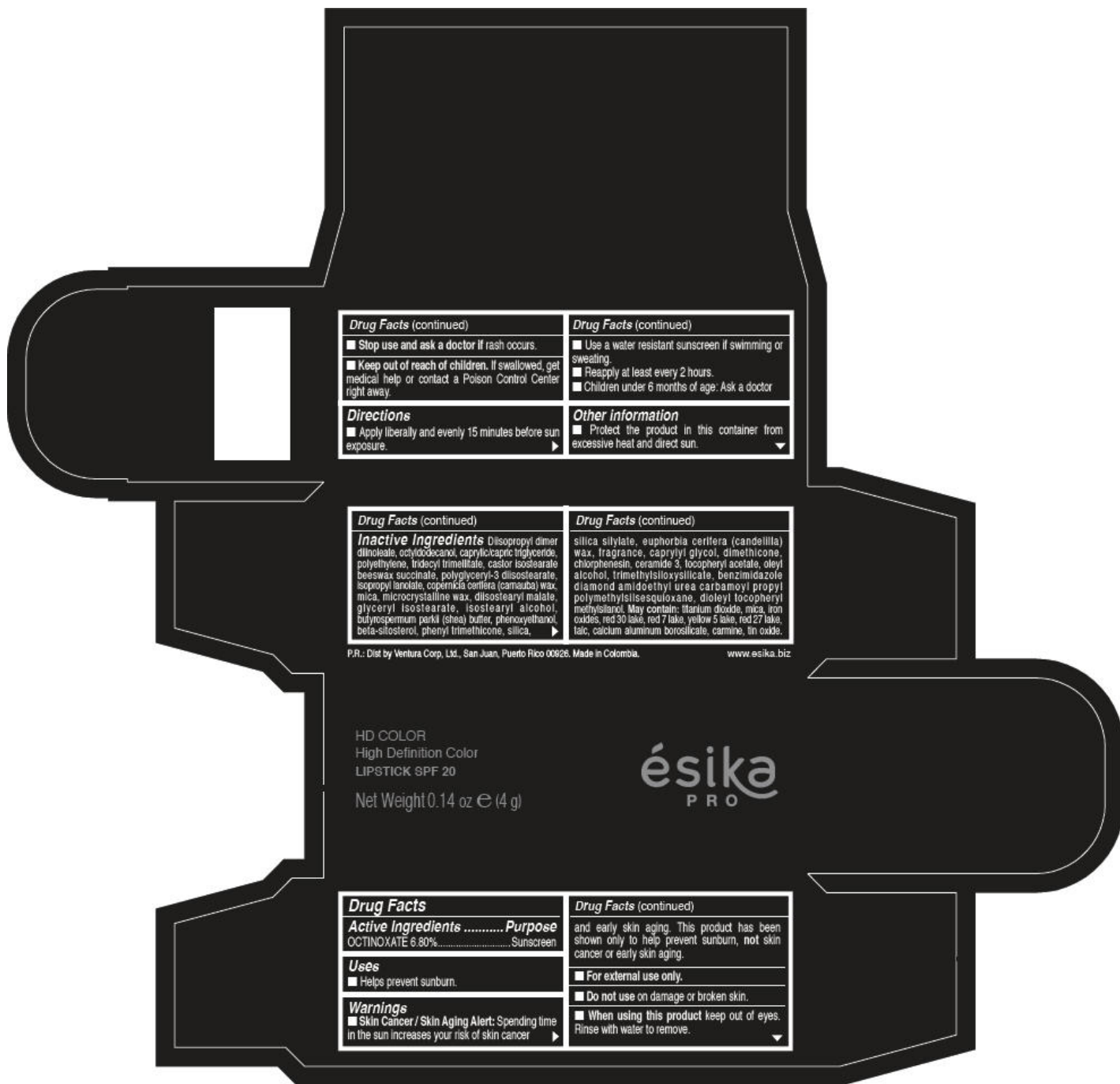
and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.

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

PRINCIPAL DISPLAY PANEL - 4 g Tube Box (HD FRAMBUESA ENCANTO) - PURPLE

HD COLOR
High Definition Color
LIPSTICK SPF 20
Net Weight 0.14 oz e (4 g)

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PRO**



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)

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

Drug Facts (continued)

Inactive Ingredients Disopropyl dimar dilinolate, octyloctadecanoic, caprylic/capric triglyceride, polyethylene, triethyl trimellitate, castor isostearate beeswax succinate, polyglyceryl-3 distostearate, isopropyl lanolate, copernicia cerifera (carnauba) wax, mica, microcrystalline wax, distostearyl malate, glyceryl isostearate, isostearyl alcohol, butyrospermium parkii (shea) butter, phenoxethylalcohol, beta-sitosterol, phenyl trimethylsiloxane, silica, ▶

Drug Facts (continued)

silica silylate, euphorbia cerifera (candelilla) wax, fragrance, caprylyl glycol, dimethicone, chlorphenesin, ceramide 3, tocopheryl acetate, oleyl alcohol, trimethylsilyloxy silicate, benzimidazole diamond amidoethyl urea carbamoyl propyl polymethylsilsesquioxane, dioleyl tocopheryl methylsilanol. May contain: titanium dioxide, mica, iron oxides, red 30 lake, red 7 lake, yellow 5 lake, red 27 lake, lac, calcium aluminum borosilicate, carmine, tin oxide.

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

HD COLOR
High Definition Color
LIPSTICK SPF 20
Net Weight 0.14 oz e (4 g)



Drug Facts

Active Ingredients **Purpose**
OCTINOXATE 6.80%..... 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)

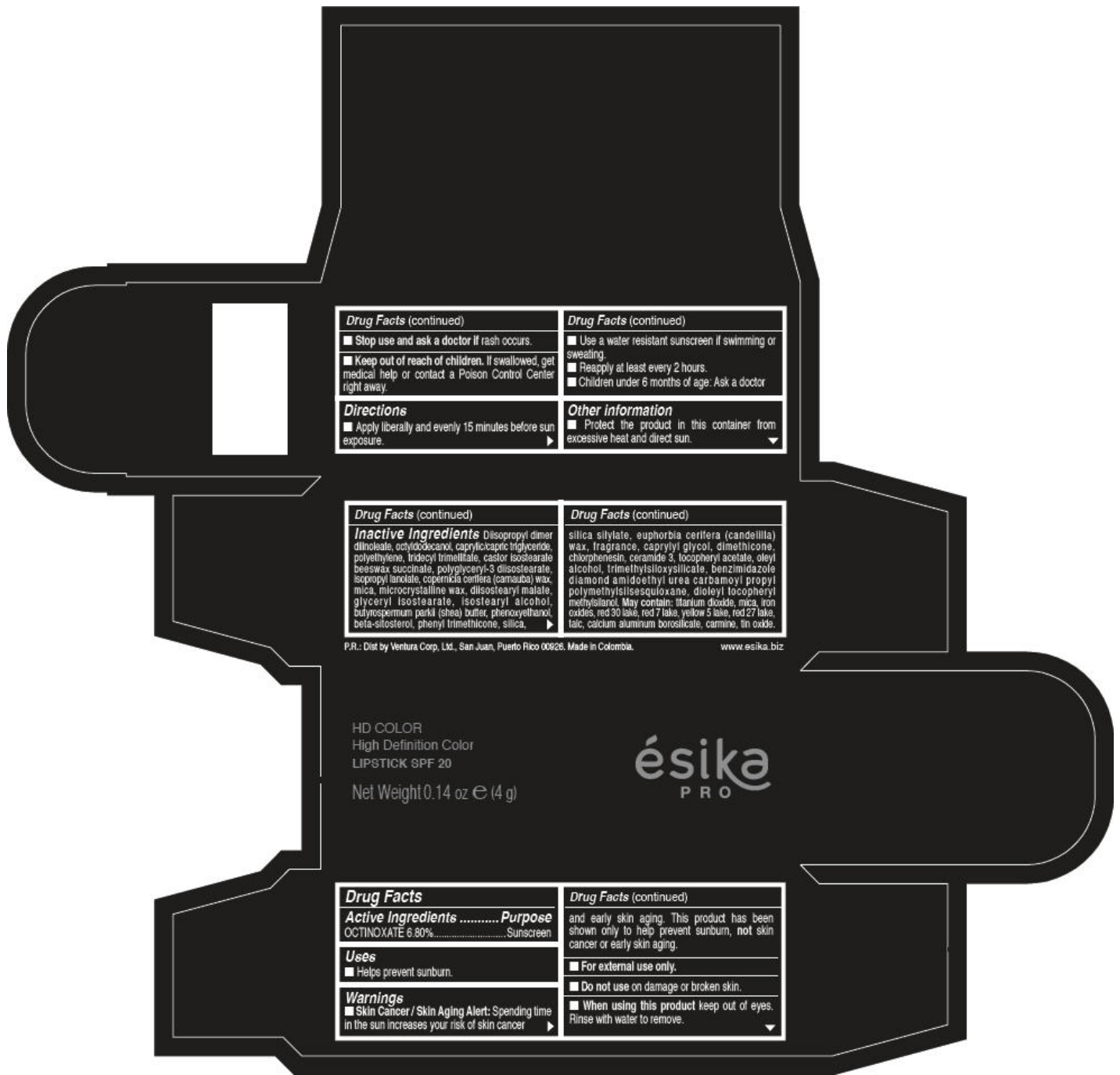
and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.

- For external use only.
- Do not use on damage or broken skin.
- When using this product keep out of eyes. Rinse with water to remove. ▼

PRINCIPAL DISPLAY PANEL - 4 g Tube Box (HD MAGENTA SWEET) - PURPLE

HD COLOR
High Definition Color
LIPSTICK SPF 20
Net Weight 0.14 oz e (4 g)

ésika
PRO



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)

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

Drug Facts (continued)

Inactive Ingredients Disopropyl dimar dilinolate, octyloctadecanoic, caprylic/capric triglyceride, polyethylene, triethyl trimellitate, castor isostearate beeswax succinate, polyglyceryl-3 distostearate, isopropyl lanolate, copernicia cerifera (carnauba) wax, mica, microcrystalline wax, distostearyl malate, glyceryl isostearate, isostearyl alcohol, butyrospermium parkii (shea) butter, phenoxethylalcohol, beta-sitosterol, phenyl trimethylsiloxane, silica, >

Drug Facts (continued)

silica silylate, euphorbia cerifera (candelilla) wax, fragrance, caprylyl glycol, dimethicone, chlorphenesin, ceramide 3, tocopheryl acetate, oleyl alcohol, trimethylsilyloxy silicate, benzimidazole diamond amidoethyl urea carbamoyl propyl polymethylsilsesquioxane, dioleoyl tocopheryl methylsilanol. May contain: titanium dioxide, mica, iron oxides, red 30 lake, red 7 lake, yellow 5 lake, red 27 lake, lake, calcium aluminum borosilicate, carmine, tin oxide.

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

HD COLOR
High Definition Color
LIPSTICK SPF 20
Net Weight 0.14 oz e (4 g)



Drug Facts

Active Ingredients **Purpose**
OCTINOXATE 6.80%..... 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 damage or broken skin.
- When using this product keep out of eyes. Rinse with water to remove.

PRINCIPAL DISPLAY PANEL - Kit Carton

HD COLOR
HIGH DEFINITION COLOR LIPSTICK
SPF 20

ésika
PRO

Net Weight
0.275 oz. e (7.8 g)



www.esika.biz

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

<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ■ Reapply at least every 2 hours. ■ Children under 6 months of age: Ask a doctor. <p>Other Information</p> <ul style="list-style-type: none"> ■ Protect this product in this container from excessive heat and direct sun. <p>Inactive Ingredients DIISOPROPYL DIMER DILINOLEATE, OCTYLDODECANOL, CAPRYLIC/CAPRIC TRIGLYCERIDE, POLYETHYLENE TRIDECYL TRIMELLITATE, CASTOR (SOSTERATE) BEESWAX SUCCINATE, POLYGLYCERYL-4 DIISOSTEARATE, ISOPROPYL LAURYLATE, COPERNICIA CERIFERA (CARNAUVA) WAX, MICA, MICROCRYSTALLINE WAX, CERIFERA (CARNAUVA) WAX, MICA, MICROCRYSTALLINE WAX, DIISOSTEARYL MALATE, GLYCERYL ISOSTEARATE, ISOSTEARYL ALCOHOL, BUTYROSPERMUM PARAKI (SHEA) BUTTER, PHENOXYETHANOL, BETA-STOSTEROL, PHENYL TRIMETHICONE, SILICA, SILICA SILYLATE, EUPHORBIA CERIFERA (CANDELLILA) WAX, FRAGRANCE, CAPRYLYL GLYCOL, DIMETHICONE, CHLORPHENESIN, CERAMIDE 3, TOCOPHERYL ACETATE, OLEYL ALCOHOL, TRIMETHYLSILOXYSILICATE, BENZYLDAZOLE DIAMOND AMIDOETHYL UREA CARBAZOYL PROPYL POLYMETHYLSILSESQUOXANE, DIOLEYL TOCOPHERYL METHYLSILOXOL, POLYETHYLSILSESQUOXANE, MICA, IRON OXIDES, RED 30 LAKE, RED 7 LAKE, YELLOW 5 LAKE, RED 27 LAKE, TALC, CALCIUM ALUMINUM BORSILICATE, CARMINI, TIN OXIDE.</p>	<p>Drug Facts</p> <p>Active Ingredients Sunscreen OCTINOXATE 6.80%</p> <p>Uses</p> <ul style="list-style-type: none"> ■ Helps prevent sunburn. <p>Warnings</p> <ul style="list-style-type: none"> ■ 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 every 15 minutes before sun exposure. ■ Use a water resistant sunscreen if swimming or sweating.
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HD COLOR
HIGH DEFINITION COLOR LIPSTICK
SPF 20

ésika
PRO

Net Weight
0.275 oz. e (7.8 g)

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD PIMIENTA CALIENTE) - BROWN

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-577
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)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

DIMETHICONE (UNII: 92RU3N3Y1O)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW No. 5 (UNII: I753WB2F1M)
D&C RED No. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BORSILICATE (UNII: 3JRB8A35M0)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-577-02	1 in 1 BOX		
1	NDC:13537-577-01	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 HD COLOR HIGH DEFINITION COLOR SPF 20 (HD VINO CAUTIVANTE) - BROWN

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-578
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)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
MICA (UNII: V8A1AW0880)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)
SHEA BUTTER (UNII: K49155WL9Y)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
.BETA.-SITOSTEROL (UNII: S347WMO6M4)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
CANDELILLA WAX (UNII: WL0328HX19)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
DIMETHICONE (UNII: 92RU3N3Y1O)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW No. 5 (UNII: I753WB2F1M)
D&C RED No. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-578-04	1 in 1 BOX		
1	NDC:13537-578-03	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 HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROSA VIVA) - PINK

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-579
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)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW No. 5 (UNII: I753WB2F1M)	
D&C RED No. 27 (UNII: 2LRS185U6K)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BORSILICATE (UNII: 3JRB8A35M0)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-579-06	1 in 1 BOX		
1	NDC:13537-579-05	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 HD COLOR HIGH DEFINITION COLOR SPF 20 (HD CORAL ENSUENO) - RED

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-580
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)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW No. 5 (UNII: I753WB2F1M)
D&C RED No. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-580-08	1 in 1 BOX		
1	NDC:13537-580-07	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 HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROJO GLAM) - RED

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-581
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)	
OCTYLDODECANOL (UNII: 461N10614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
MICA (UNII: V8A1AW0880)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)
SHEA BUTTER (UNII: K49155WL9Y)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
.BETA.-SITOSTEROL (UNII: S347WMO6M4)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
CANDELILLA WAX (UNII: WL0328HX19)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
DIMETHICONE (UNII: 92RU3N3Y1O)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW No. 5 (UNII: I753WB2F1M)
D&C RED No. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BORSILICATE (UNII: 3JRB8A35M0)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-581-10	1 in 1 BOX		
1	NDC:13537-581-09	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 HD COLOR HIGH DEFINITION COLOR SPF 20 (HD CAFE HABANO) - BROWN

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-582
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)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW No. 5 (UNII: I753WB2F1M)	
D&C RED No. 27 (UNII: 2LRS185U6K)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-582-12	1 in 1 BOX		
1	NDC:13537-582-11	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 HD COLOR HIGH DEFINITION COLOR SPF 20 (HD FUCSIA VIBRANTE) - PINK
octinoxate lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-583
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)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	

CERAMIDE 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW No. 5 (UNII: I753WB2F1M)
D&C RED No. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BORSILICATE (UNII: 3JRB8A35M0)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-583-14	1 in 1 BOX		
1	NDC:13537-583-13	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 HD COLOR HIGH DEFINITION COLOR SPF 20 (HD MELON INTENSE) - PINK
 octinoxate lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-584
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)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	

POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
MICA (UNII: V8A1AW0880)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)
SHEA BUTTER (UNII: K49155WL9Y)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
.BETA.-SITOSTEROL (UNII: S347WMO6M4)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
CANDELILLA WAX (UNII: WL0328HX19)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
DIMETHICONE (UNII: 92RU3N3Y1O)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW No. 5 (UNII: I753WB2F1M)
D&C RED No. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-584-16	1 in 1 BOX		
1	NDC:13537-584-15	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 HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROSADO CHIC) - PINK

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-585
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)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q6130CQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW No. 5 (UNII: I753WB2F1M)	
D&C RED No. 27 (UNII: 2LRS185U6K)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:13537-585-18	1 in 1 BOX		
1	NDC:13537-585-17	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 HD COLOR HIGH DEFINITION COLOR SPF 20 (HD CIRUELA GLAM) - RED
 octinoxate lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-586
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)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE 3 (UNII: 4370DF050B)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW No. 5 (UNII: I753WB2F1M)	
D&C RED No. 27 (UNII: 2LRS185U6K)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-586-20	1 in 1 BOX		
1	NDC:13537-586-19	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 HD COLOR HIGH DEFINITION COLOR SPF 20 (HD FRAMBUESA ENCANTO) - PURPLE

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-587
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)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	

CARNAUBA WAX (UNII: R12CBM0EIZ)
MICA (UNII: V8A1AW0880)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)
SHEA BUTTER (UNII: K49155WL9Y)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
.BETA.-SITOSTEROL (UNII: S347WMO6M4)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
CANDELILLA WAX (UNII: WL0328HX19)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
DIMETHICONE (UNII: 92RU3N3Y1O)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW No. 5 (UNII: I753WB2F1M)
D&C RED No. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-587-22	1 in 1 BOX		
1	NDC:13537-587-21	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 HD COLOR HIGH DEFINITION COLOR SPF 20 (HD MAGENTA SWEET) - PURPLE

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-588
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Route of Administration

TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW No. 5 (UNII: I753WB2F1M)	
D&C RED No. 27 (UNII: 2LRS185U6K)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-588-24	1 in 1 BOX		

1	NDC:13537-588-23	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 HD COLOR HIGH DEFINITION COLOR SPF 20
octinoxate kit

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-589

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-589-28	2 in 1 BOX		
1	NDC:13537-589-27	1 in 1 TUBE		

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	4 g
Part 2	1 TUBE	4 g
Part 3	1 TUBE	4 g
Part 4	1 TUBE	4 g
Part 5	1 TUBE	4 g
Part 6	1 TUBE	4 g
Part 7	1 TUBE	4 g
Part 8	1 TUBE	4 g
Part 9	1 TUBE	4 g
Part 10	1 TUBE	4 g
Part 11	1 TUBE	4 g
Part 12	1 TUBE	4 g

Part 1 of 12
ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD PIMIENTA CALIENTE) - 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	0.068 g in 1g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW No. 5 (UNII: I753WB2F1M)	
D&C RED No. 27 (UNII: 2LRS185U6K)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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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	04/17/2015	

Part 2 of 12

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD VINO CAUTIVANTE) - 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	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE 3 (UNII: 4370DF050B)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW No. 5 (UNII: I753WB2F1M)
D&C RED No. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	04/17/2015	

Part 3 of 12

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROSA VIVA) - PINK

octinoxate lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

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

Inactive Ingredients

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

POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
MICA (UNII: V8A1AW0880)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)
SHEA BUTTER (UNII: K49155WL9Y)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
.BETA.-SITOSTEROL (UNII: S347WMO6M4)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
CANDELILLA WAX (UNII: WL0328HX19)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
DIMETHICONE (UNII: 92RU3N3Y1O)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW No. 5 (UNII: I753WB2F1M)
D&C RED No. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	04/17/2015	

Part 4 of 12

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD CORAL ENSUENO) - 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	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW No. 5 (UNII: I753WB2F1M)	
D&C RED No. 27 (UNII: 2LRS185U6K)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	04/17/2015	

Part 5 of 12

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROJO GLAM) - RED

octinoxate lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW No. 5 (UNII: I753WB2F1M)
D&C RED No. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	04/17/2015	

Part 6 of 12

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD CAFE HABANO) - BROWN

octinoxate lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N10614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW No. 5 (UNII: I753WB2F1M)	
D&C RED No. 27 (UNII: 2LRS185U6K)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	04/17/2015	

Part 7 of 12

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD FUCSIA VIBRANTE) - 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	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW No. 5 (UNII: I753WB2F1M)	
D&C RED No. 27 (UNII: 2LRS185U6K)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	04/17/2015	

Part 8 of 12**ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD MELON INTENSE) - PINK**

octinoxate lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

DIMETHICONE (UNII: 92RU3N3Y1O)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW No. 5 (UNII: I753WB2F1M)
D&C RED No. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	04/17/2015	

Part 9 of 12

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD ROSADO CHIC) - PINK

octinoxate lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
MICA (UNII: V8A1AW0880)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)
SHEA BUTTER (UNII: K49155WL9Y)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
.BETA.-SITOSTEROL (UNII: S347WMO6M4)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
CANDELILLA WAX (UNII: WL0328HX19)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
DIMETHICONE (UNII: 92RU3N3Y1O)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW No. 5 (UNII: I753WB2F1M)
D&C RED No. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BORSILICATE (UNII: 3JRB8A35M0)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	04/17/2015	

Part 10 of 12

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD CIRUELA GLAM) - 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	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE 3 (UNII: 4370DF050B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ALUMINUM OXIDE (UNII: LM26O6933)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C YELLOW No. 5 (UNII: I753WB2F1M)	
D&C RED No. 27 (UNII: 2LRS185U6K)	
TALC (UNII: 7SEV7J4R1U)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	04/17/2015	

Part 11 of 12

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD FRAMBUESA ENCANTO) - 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	0.068 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

CANDELILLA WAX (UNII: WL0328HX19)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
DIMETHICONE (UNII: 92RU3N3Y1O)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW No. 5 (UNII: I753WB2F1M)
D&C RED No. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	04/17/2015	

Part 12 of 12

ESIKA PRO HD COLOR HIGH DEFINITION COLOR SPF 20 (HD MAGENTA SWEET) - PURPLE

octinoxate lipstick

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
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DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)
OCTYLDODECANOL (UNII: 461N1O614Y)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
CARNAUBA WAX (UNII: R12CBM0EIZ)
MICA (UNII: V8A1AW0880)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)
SHEA BUTTER (UNII: K49155WL9Y)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
.BETA.-SITOSTEROL (UNII: S347WMO6M4)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
CANDELILLA WAX (UNII: WL0328HX19)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
DIMETHICONE (UNII: 92RU3N3Y1O)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE 3 (UNII: 4370DF050B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 30 (UNII: 2S42T2808B)
ALUMINUM OXIDE (UNII: LM26O6933)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
FD&C YELLOW No. 5 (UNII: I753WB2F1M)
D&C RED No. 27 (UNII: 2LRS185U6K)
TALC (UNII: 7SEV7J4R1U)
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	04/17/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-577, 13537-578, 13537-579, 13537-580, 13537-581, 13537-582, 13537-583, 13537-584, 13537-585, 13537-586, 13537-587, 13537-588, 13537-589)

Revised: 8/2015

Ventura Corporation LTD